December 14, 2015

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3321–NC and CMS-3321-NC2
Submitted electronically at: www.regulations.gov

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017.

Dear Mr. Slavitt:

The College of Healthcare Information Management Executives (CHIME) is pleased to submit recommendations on the final rules with comment, Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017. CHIME thanks the Centers for Medicare and Medicaid Services (CMS) for this additional opportunity to comment on the Stage 3 rules.

CHIME is an executive organization serving more than 1,700 chief information officers (CIOs) and other senior health information technology leaders at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business technology systems that are facilitating healthcare transformation. CHIME members are among the nation's foremost health IT experts and strongly support the administration's stated goals to:

- align national health care quality improvement efforts,
- promote interoperability and health information exchange, and
- focus on ways to reduce costs, promote access to care, and improve quality.

Since enactment of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), the healthcare industry has made a significant shift in the way technology is used to treat and engage with patients. Our members represent some of the earliest and most prolific adopters of electronic health records (EHRs) and other health IT resources for clinicians and patients. However, CHIME remains increasingly concerned that our commonly shared goals will not be met if the administration moves forward with the current plan to finalize the Stage 3 Meaningful Use requirements. We are also concerned that key issues not addressed by Meaningful Use will continue to hamper interoperability, such as the lack of way to uniquely identify patients, a problem that will only continue to grow as more health information is digitalized.

It is from this perspective and an unwavering commitment to the aforementioned goals that we reiterate our concerns about the trajectory of the program and offer recommendations necessary to provide greater stability for our members as they navigate transitions to new payment models and the drive toward high-value care. We recommend CMS:

1. **Require providers start Stage 3 no earlier than 2019 and only after 75 percent of all eligible providers have met Stage 2.**
2. **Remove the 2017 transitional year for meeting Meaningful Use Stage 3 and require 2015 Edition Certified Electronic Health Record Technology (CEHRT) no earlier than 2018.**
3. **Create the option of a 90-day reporting period for all future years of the program to include, at the very least, the first year at Stage 3 and any other years where a provider deems it necessary for implementing upgrades, planned downtime, fixes related to technology or optimizing the use of new technology within workflows.**
4. **Create parity for both eligible providers (EPs) and eligible hospitals (EHs) by removing the existing pass/fail approach for Meaningful Use.**
5. **Continue to work to reduce the burden for providers by streamlining reporting redundancies and refrain from requiring data collection and submission on measures that do not advance patient care.**

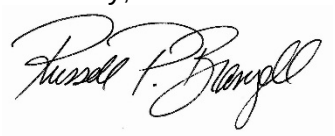
Appended to this letter are more detailed comments, including our recommendations and feedback on specific objectives and measures. Listed immediately below is a table highlighting our recommendations around measure thresholds. CHIME continues to have significant concerns with measures that require action on the part of those other than the eligible provider and which hold providers accountable for measures outside their control. While we also support the move to the use of Application Programming Interfaces (APIs) and use of patient-generated data (PGD), we believe it is premature to include such mandates in the Meaningful Use program given the lack of mature standards. Providers are, however, working to incorporate these functions into their systems and the delivery of care. We fear that a federal mandate will hamper progress that is being made. We believe the focus now should rest largely on ensuring standards are in place to support interoperability, and that an intense focus is placed on ensuring infrastructure issues like security and successful patient matching are in place to facilitate the digital health care system to so that we can get to our shared goals of reduced costs, better quality, and improved access.

OBJECTIVE	THRESHOLD	CHIME RECOMMENDATIONS
1. Protect Patient Info	Perform risk analysis and security updates 1x per reporting period	Remove as it duplicates HIPAA mandates
2. ePrescribing	EH: 25%	EH: 10%
3. CDS	Implement 5 rules	Implement 5 rules
4. CPOE	Measure 1 - meds: 60% Measure 2 – labs: 60% Measure 3 – imaging: 60%	60% meds 60% labs 60% imaging
5. Patient electronic access	Measure 1: 80% given access in: 24 hours; and Via API Measure 2: 35% identified patient resources thru CEHRT and given access to them	Measure 1: For EHs the threshold should be 72 hours and for EPs it should be 4 days. We opposed API mandates. Measure 2: 10%
6. Coordination of care through patient engagement	Measure 1: 10% patients access info via VDT or API or both Measure 2: 25% patients get or respond to secure message from provider Measure 3: 5% of patient's PGD from non-clinical setting incorporated into EHR	Measure 1: 5% and remove API mandate Measure 2: Remove EH mandate; 5% for EPs Measure 3: Remove Only mandate providers meet one of the three measures
7. Health Information Exchange	Measure 1: Sending provider creates SoC using CEHRT and sends electronically for 50% of patients Measure 2: Receiving provider incorporates SoC for 40% spatients never seen Measure 3: Receiving provider does med rec for 80% patients never seen	Measure 1: 20% Measure 2: 10% Measure 3: 50%
8. Public health reporting	EH: Meet 4 of 6 EP: Meet 3 of 5	EH: 3 EP: 2

Conclusion

CHIME appreciates the added opportunity to offer our feedback and recommendations around Stage 3 and we look forward to continuing to be a constructive stakeholder in shaping federal digital health policy. If you have any questions concerning our comments please contact Mari Savickis, Vice President of Federal Affairs at msavickis@chimecentral.org.

Sincerely,



Russell P. Branzell, FCHIME, CHCIO – CHIME President and CEO

Charles Christian, FCHIME, LCHIME, CHCIO, FHIMSS - CHIME Board of Trustees Chair; Vice President of Technology and Engagement, Indiana Health Information Exchange

High-Level Recommendations

1. **Begin Stage 3 no earlier than 2019 and only after 75 percent of all eligible professionals have met Stage 2.**

CHIME is deeply committed to the policy goals outlined by CMS. However, we do not believe the course laid out by CMS for Stage 3 will deliver the intended results. We shared these thoughts in our May comment letter on Stage 3 and since the requirements were finalized in October, our members' concerns have only deepened. CHIME continues to assert that the best path forward is one focused on a clear set of standards, a laser focus on interoperability, and a commitment to ensuring American patients' health information is secure from cyber threats and other possible breaches.

To the degree that CMS continues to adhere to the current construct of the Meaningful Use program, CHIME is concerned that 2018 does not represent a reasonable start date for the vast majority of providers. The timeframe would only give providers and their vendor partners two years under Stage 2 before having to try and meet Stage 3 requirements, a timeframe which we know from the past is inadequate. Beginning Stage 3 in 2019 offers providers more time to focus on many of the beneficial changes CMS recently made under Stage 2. Additionally, providers and patients benefit when there is certainty around the rules. There is precedent for Meaningful Use regulations to be amended on a routine basis, often leaving limited time for providers and vendors to make the necessary adjustments to meet the new demands. Pushing the Stage 3 start time to no sooner than 2019 would give the industry more time to learn what worked well under Modified Stage 2 and properly re-orient Stage 3 to best position providers for success under new payment and delivery models of care. Starting Stage 3 no earlier than 2019 provides greater certainty and creates a breeding ground for evaluation.

In addition to providing ample time to learn from Modified Stage 2, waiting until 2019 will allow stakeholders to address other critical challenges being raised by CHIME members. There is growing concern that some of the program's measures continue to advance a check-the-box mentality rather than promote innovations aimed at accelerating delivery system transformation. For example, many CHIME members have set up Direct addresses to share summaries of care (SoC), however, our CIOs report that their clinicians find the SoC of little value and ask instead to have the relevant clinical information faxed to them. With no way to import the data contained in a SoC in a meaningful way, the clinical value is deemed useless. There is also a recognition among our members that the regulations do not take into account key organizational and resource differences between provider institutions. As a result, there is a growing gap among providers that are poised to successfully meet the Modified Stage 2 rules, while others will lag behind. That gulf would only widen under the Stage 3 thresholds being advanced by CMS. Finally, the dramatic changes occurring within healthcare require that providers make substantial investments not just in EHR systems, but bolster IT across the organization — new financial systems, improved data analytics capabilities, new and improved medical devices and more. The accelerated Stage 3 timeline could force organizations to pull valuable resources away from those important

priorities. **With these concerns in mind CHIME urges CMS to require providers start Stage 3 no earlier than 2019 and only after 75 percent of all eligible providers have met Stage 2.**

2. **Remove the 2017 transitional year for meeting Stage 3 and require 2015 Edition CEHRT no earlier than 2018**

We are concerned that not only is 2018 an unrealistic timeframe for the vast majority of providers to meet Meaningful Use, but that 2017 also represents an unreasonable timeframe to require vendors to deliver 2015 Edition CEHRT to the marketplace. Under current rules, vendors will need adequate time to develop software that can be tested and safely deployed. To date, many vendors have been unable to deliver updated certified products to the market due to late and shifting federal policies. We worry about their ability to deliver 2015 Edition certified EHRs by 2017 given these previous challenges.

Furthermore, vendors themselves have noted through the Electronic Health Record Association (EHRA) Merit-Based Incentive Payment System (MIPS) Request for Information comment letter that, "The transition from fee-for-service to value-based care and other delivery reform models has accelerated the need for a more consistent and streamlined approach to measuring performance and quality. Health IT can substantially advance quality measurement and reporting by providing access to information not previously available and by automating data collection – all necessary to evolving alternative payment models (APMs)… we caution against over- reliance on the use of EHRs and health IT for collecting data that is outside the scope of EHRs, or is not currently defined and implemented today. For items that may be appropriate to add to an EHR for measuring or reporting, both vendors and providers need sufficient time to develop and implement new functionality or reporting capabilities, which may not be possible in time for the 2017 performance year."

3. Create the option of a 90-day reporting period

CHIME appreciates the added flexibility CMS has indicated they will give around hardships, such as when a provider switches vendors. Since all providers will need to upgrade their systems at some point, it's unclear how CMS plans to address these scenarios in future years. We also understand that this is only one of several scenarios intended by CMS and that other scenarios such as upgrading to a new version with the same vendor would also qualify. Despite the addition of hardship exemption categories, concerns remain that a shorter reporting period is needed for all future years including the first year at Stage 3, particularly in the absence of CMS removing the pass/fail construct for the program. We would also note that upgrading systems can take several months and the length of future reporting periods should take this into account. While not every provider upgrades every year, the pace of change is increasing the frequency of the upgrades for many and this would mitigate the potential chaos that would come with administrative management of a large number of exceptions. **We urge CMS to create the option of a 90-day reporting period for all future years of the**

program to include at the very least the first year at Stage 3 and any other years where a provider deems it necessary for implementing upgrades, planned downtime, fixes related to technology or optimizing the use of new technology within workflows.

4. **Creating parity for both eligible professionals (EPs) and eligible hospitals (EHs) by removing the existing pass/fail approach for MU.**

CHIME continues to believe that the pass/fail approach does more harm than good. It jeopardizes the hard work and investments that well-intended providers have made to meet the program's requirements and risks them incurring a financial penalty, even after making a good faith effort to be successful in the program.

CHIME appreciates CMS' willingness to explore removing the pass/fail approach as discussed in the recent MIPS RFI. We are concerned, however, that CMS is taking one approach for EPs and a separate one for EHs. Based on our understanding of CMS' interpretation of the laws governing Meaningful Use, the agency does not believe it has the ability under HITECH to completely remove the pass/fail methodology, though, Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provides some relief for physicians. CHIME believes that CMS should continue to pursue policy decisions that bring EPs and EHs under a single set of requirements. For instance, the agency moved all providers to a calendar year reporting. We strongly support the agency's consideration of removing the pass/fail construct for EPs, however, leaving it in place for hospitals will introduce a level of complexity that will be very difficult for providers and CMS to manage. This is especially important as payment models evolve to necessitate greater coordination between hospitals and physician offices. Having a different set of standards for different providers could jeopardize attempts to connect organizations under ACO or bundled payment models. **We strongly urge CMS to create parity for hospitals and to remove the pass/fail construct for all providers.**

5. **Align and streamline quality reporting by eliminating duplicative and burdensome measures, which often take time away from direct patient care**

CHIME appreciates CMS' intention to further harmonize measures across the various reporting programs. Providers continue to be incredibly challenged in meeting quality reporting requirements, as detailed in our recent MIPS comment letter. Efforts have been underway since before passage of HITECH to devise quality indicators that can be electronically captured in normal clinical workflow, yet organizations still must deploy sizable staffs for manual abstracting. Since the future of value-based reimbursement is contingent upon the ability to measure performance and outcomes, we believe a unified strategy for capturing and communicating quality in healthcare is needed.

Currently, providers are required to report clinical quality measures (CQMs) to several public and private entities. Many CHIME members submit more than 20 reports across federal, state and private sector programs

for various CQMs each month. Hours of work and expertise are required to comply with these reporting demands and such burdens are exacerbated by a lack of technical harmonization. In other words, even when the same CQMs are used among different programs, they tend to require different technical specifications or values to be reported. The goal should be to eliminate duplicative quality measures and reporting requirements. Doing so would help to reduce healthcare costs and allow clinicians to focus more attention on patient care. **CHIME recommends CMS continue to work to reduce the burden for providers by streamlining reporting redundancies and refrain from requiring data collection and submission on measures that do not advance patient care. CMS should also provide access to real-time and actionable data, both which will be critical for success under MIPS.**

Stage 3 Objectives and Measures

Objective 1: Protect Patient Health Information

Objective 1 focuses on protecting patient health information through technical, administrative and physical safeguards. The related measure requires providers to conduct or review a security risk analysis and implement security updates as necessary, with the timing or review of such analysis to occur upon installation of CEHRT or upon upgrade to a new Edition of CEHRT, and subsequently at least once per EHR reporting period.

Safeguarding protected patient information (PHI) is paramount, however, we believe this objective is redundant given the fact that the Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements already apply to providers. We see no need to impose additional requirements through the EHR Meaningful Use program since providers are already held accountable for privacy and security under HIPAA and other federal laws and regulations. The measure itself requires that the security risk analysis be conducted or reviewed consistent with the HIPAA requirements under 45 CFR 164.308(a)(1).

As we noted in our previous comment letter on the Stage 3 proposed rule, this provision could cause confusion around the timing of required assessments or reviews. CMS should articulate in the regulatory text of the measure a precise statement of the requisite frequency and timing of security risk analyses. We had suggested the following language and we ask that CMS reconsider its decision to address these issues in the context of Frequently Asked Questions and modify the regulation text at §495.24(d)(1)(i) and (ii), respectively, as follows:

The timing or review of the security risk analysis to satisfy this measure shall be as follows:

EPs, EHs, and critical access hospitals (CAHs) must conduct the security risk analysis upon initial installation of CEHRT or upon upgrade to a new Edition of certified EHR Technology (CEHRT). The initial security risk analysis and testing may occur prior to the beginning of the first EHR reporting period using that CEHRT.

In subsequent years, a provider must review the security risk analysis of the CEHRT and the administrative, physical, and technical safeguards implemented, and review the security analysis as necessary, but at least once per EHR reporting period.

This clarification will help providers understand their responsibilities vis-à-vis this objective and avoid any possible misunderstanding that reviews be required every time a provider receives a patch or other update to their CEHRT from a vendor.

Objective 2: Electronic Prescribing

Objective 2 focuses on electronic prescribing. As finalized, the hospital measure requires that more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) be queried for a drug formulary and transmitted electronically using CEHRT. **We urge CMS to set the threshold for hospitals under the measure to 10 percent.**

While we support the goals and see benefits of electronic prescribing, especially in the case of EPs, this objective and measure was a menu objective for hospitals in Stage 2. The Modified Stage 2 objective and measure for hospitals sets a 10 percent threshold and also acknowledges the difficulty many hospitals will face in meeting this measure by providing for alternative exclusions for 2015 and 2016. Hospitals will face substantial challenges to reorganize their workflows to meet this measure under the Modified Stage 2 threshold of 10 percent in 2017. To expect the same hospitals to meet a significantly increased threshold (more than double) for 2018 is unrealistic. The outcome will be that hospitals seeking to meet the objective but fail due to the substantial changes required of them over a short period of time will be penalized for trying to incorporate electronic prescribing.

CMS finalizes exclusions to the measure for EPs and hospitals if both their organizations' internal pharmacies do not accept electronic prescriptions and no pharmacies within a 10-mile radius of the EP or hospital accept electronic prescriptions. CHIME is concerned about the appropriateness of the uniform 10-mile requirement for hospitals and pharmacies across the country as well as the number of pharmacies that still do not accept electronic prescriptions in some areas of the country. We are also concerned by the unintended consequence that the 10-mile radius test could result in limiting patient choice of their pharmacies. For example, in an area where there is only one pharmacy within the 10-mile radius that accept electronic prescriptions, this requirement could result in steering patients toward that one pharmacy where charges for the prescriptions may be higher than other pharmacies. Additionally, many patients have established relationships with their

pharmacists. If this requirement forces patients to other pharmacies, the benefits of existing pharmacist-patient relationships would be jeopardized, especially in small or rural communities.

Additionally, some states already mandate the use of e-prescribing and at least one state is requiring scripts be sent electronically for controlled substances, with more states are considering this type of requirement. We recommend that CMS provide for an exclusion from this measure for an EP or hospital in a state that meets the state mandated electronic prescribing reporting requirements. This would help alleviate burden on providers by eliminating duplicative reporting requirements, which is one of the goals of the current administrations.

With respect to the issue of controlled substances, CHIME interprets the language of the regulation text and in the preamble to mean that the inclusion of controlled substances within a permissible prescription for purposes of this objective and measure is optional. We request CMS clarify that our understanding is correct. We believe that it should remain optional to give adequate time to EPs and hospitals to register and implement the necessary changes to comply. We believe that additional time should be no less than two years.

CHIME commends CMS for its decisions to continue to allow refill prescriptions (not only new and changed prescriptions) to count in the definition of permissible prescriptions and to continue to exclude over the counter medicines from that definition.

Objective 4: Computerized Provider Order Entry

Objective 4 focuses on computerized provider order entry (CPOE) with separate measures for medication, laboratory and diagnostic imaging orders.

CHIME commends CMS for finalizing a 60 percent threshold for medication orders, which we believe reflects a realistic goal for all providers. We also find there is great value in having the same percentage threshold apply to all three types of orders.

Objective 5: Patient Electronic Access to Health Information

Objective 5 addresses patient electronic access to their health information and the use of clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to them. Measure 1 focuses on the first issue and Measure 2 focuses on the second.

Measure 1 calls for providers to provide for 80 percent of patients both timely access (within 24 hours) to view, download or transmit their information; and, to provide such access via an application programming interface (API). While not stated specifically in the measure, we presume CMS intended this timeframe to be the proposed 24-hour timeframe. **CHIME strongly opposes the Measure 1 requirement that patient access to**

health information must be provided within 24 hours of its availability to the provider. We note that comparable Modified Stage 2 measure allows hospitals to make information accessible within 36 hours of patient discharge. The 24-hour timeframe for providers is unreasonable and does not, for example, provide time for a hospital to give the patient's attending physician time to review the information about to be made accessible or account for possible system downtime or other technical impediments to information posting. **For EHs, a 72-hour timeframe is more appropriate and will enable a patient's care team to review the record. We also believe that the 48-hour timeframe in Stage 3 for EPs is too onerous and that CMS should retain the Modified Stage 2 objective of four business days for EPs.** CHIME appreciates the clarification in the final rule that the specified timeframe for providers applies no earlier than after the patient has been discharged from the hospital.

CHIME believes that use of APIs holds promise for helping access and contextualizing patient information. However, we reiterate that there is tremendous uncertainty regarding mandating the use of APIs, including potential security and authentication issues, and even whether they will be readily available in vendor products by 2018. Thus, CHIME continues to adamantly oppose proposals requiring EPs and hospitals to make the API function available to patients. To our knowledge, APIs do not yet exist for most EHRs, which makes the decision to mandate their use premature. Given that there are no standards for APIs, it is unclear how CMS envisions this requirement to work and how interoperability would be fully supported. For example, we do not understand how an API would address the situation where patient information is maintained in multiple portals that do not necessarily aggregate all the health information for the patient; the inability to do so raises concerns about the utility of the API technology. Additionally some patients are still hesitant to share health information electronically. CHIME members report extremely low usage of patient portals, especially in rural areas and among older patients. In one case, only 10 percent of patients in a rural area that were offered the choice to log onto a portal did so. Other CHIME members report that clinics in rural areas face similar challenges encouraging patients to use portals, especially given the experience that they may be required to log on to multiple portals, depending how many providers they visit. CHIME urges CMS to let natural market forces encourage providers and patients to move to the use of APIs. A mandate at this point in time is premature and does nothing to advance the Triple Aim policy goal. CHIME remains concerned by the lack of unique patient identifiers which is essential to safe and efficient accessibility to, and exchange of, electronic health information. These experiences underscore that it is inappropriate to mandate the use of APIs at this time, and it is certainly inappropriate to penalize EPs and hospitals for the reticence of their current patient populations to embrace technology.

CHIME continues to have very strong reservations regarding Measure 2, and the final rule not only increases the percentage threshold to 35 percent, but also precludes counting in the numerator in those instances where patients have been given access to educational materials in a non-electronic format. While CHIME agrees that electronic access to such educational materials may have important advantages, it is premature to require such electronic access for a specified percentage of unique patients, especially a percentage considerably higher than the current one finalized under Modified Stage 2. We believe such an electronic access will impose significant additional costs on providers stemming from content vendor-related charges, and would also

necessitate significant workflow changes. CHIME urges CMS to maintain the percentage thresholds for Measure 2 to the threshold that applies to hospitals in 2017 under the Modified Stage 2 measure which is 10 percent until there is more experience with electronic access to educational resources.

To our knowledge, there has not been any analysis or measurement of the value or efficacy of these measures. We believe that any increase to thresholds under these measures is premature until it has been demonstrated that the requirements on providers and their patients (over which providers have little control with respect to patient use of technology) have resulted in greater efficiency and better patient outcomes in the delivery of health care. Given the significant impact of these requirements on provider workflow, we urge CMS to ensure its measures are actually leading to the intended policy goals before increasing thresholds under the measures.

Objective 6: Coordination of Care Through Patient Engagement

Objective 6 focuses on the use of the communication functions of CEHRT to engage patients or their authorized representatives about patients' care. Measure 1 addresses patients actively taking advantage of available options for accessing their health information. Measure 2 addresses the sending of secure messages containing health information to patients or their representatives by providers. Measure 3 requires the incorporation into CEHRT of patient-generated health data or data from what the proposed rule labels "non-clinical settings." Providers must attest to the numerator and denominator for all three measures and successfully meet the threshold for two of the three measures.

CHIME members continue to see relatively low usage of patient portals, a necessary step to gaining access to their health information. In other cases, it is simply unreasonable to expect patients being treated by multiple providers to access the portals of all of these providers. **CHIME remains deeply concerned about objectives and measures that leave providers vulnerable for patient unwillingness or inability to complete certain actions.** Further, to the extent that policymakers wish patients to take specific actions, they need to provide sufficient incentives for them to do so, and not simply hold providers accountable for behavior over which they have essentially no control. **Therefore, CHIME has significant concerns regarding Measure 1 and recommends that CMS maintain the 5 percent threshold, which will be mandatory beginning in 2017, rather than a 10 percent threshold for this measure.** We also reiterate the concerns we expressed above about the use of APIs under this measure. Since there aren't currently adopted standards for APIs, we have a number of concerns around the secure operation of APIs with hospital EHR systems. We also note that a hospital is not the logical healthcare provider upon which to impose a duty to incorporate patient health information from several different portals and to update that data on those portals; the appropriate provider for this function is the primary care physician.

With respect to Measure 2, CHIME believes that secure messaging is not an appropriate requirement for most patients discharged from the inpatient or emergency department settings. A secure messaging measure is

much more relevant to the EP setting, especially where there is an ongoing relationship between the EP and the patient. CHIME has the same concerns regarding Measure 3. Once patients have left the hospital, their primary point of contact for incorporating patient-generated data or data from "non-clinical settings" should be an EP practice. While we understand CMS' desire to adopt a set of meaningful use objectives and measures involving minimal differences between EPs and hospitals, we do not consider Measure 3 to be appropriate for hospitals, even as an option. **We recommend removing the secure messaging requirement for EPs and maintaining the 2017 requirement for EPs of 5 percent for them in Stage 3. As far as Measure 3 is concerned, while we believe PGD will become an important part of medical care, we believe it is premature to mandate any PGD requirement.** We do not believe most providers are ready for this and the technology is still under development.

In sum, CHIME recommends that hospitals be required to meet only Measure 1, assuming a more reasonable threshold is adopted. We also believe it would be more reasonable to require EPs to meet only one of the three measures associated with this objective.

Objective 7: Health Information Exchange

Objective 7 focuses on health information exchange. CMS finalized three measures, one focusing on the creation and electronic exchange of summary of care records, one on the incorporation of summary of care records by providers on the receiving end of a transition of care or referral, and one on clinical information reconciliation by a receiving provider. Providers must attest to the numerator and denominator for all three measures and successfully meet the threshold for two of the three.

CHIME continues to believe that the thresholds for the three measures are unrealistic. In the case of Measure 1, many receiving providers are not currently able to accept electronic summary of care records and many are unlikely to be capable of doing so even in 2018, such as post-acute care providers, who have not been eligible for EHR incentive payments. This again represents a scenario where an eligible provider is being held accountable for actions outside their control.

With respect to Measures 2 and 3, CHIME believes it is unreasonable to focus not only on transitions of care and referrals, but also on patients never before seen by the provider. For example, emergency department workflows are simply incompatible with requirements to try to identify outside sources of summary of care records for walk-in patients. The infrastructure for doing this does not exist in most areas and is not likely to exist for many years to come.

The thresholds for all 3 measures must be significantly reduced:

- **For Measure 1, we again suggest a 20 percent threshold instead of the 50 percent threshold.** This would be double the threshold CMS finalized for the comparable Modified Stage 2 measure.
- **For Measure 2, which is new, we recommend a threshold of 10 percent.** The finalized 40 percent threshold is far too onerous.
- For Measure 3, clinical information reconciliation, we recognize that the comparable Modified Stage 2 medication reconciliation measure has a 50 percent threshold. However, given the very limited experience with medication reconciliation and given the expanded requirement to reconcile medication allergies and problems (not just medications), we believe it is inappropriate to raise the clinical information reconciliation threshold for Measure 3 to 80 percent. We note that providers may not have access to all the relevant data for meaningful medication reconciliation and that performing this function is particularly complex where there are multiple sources of data as well as differences in various health IT systems. These complexities reduce certainty that the list of drugs that are actually reconciled is entirely accurate. **We recommend retaining the Modified Stage 2 threshold of 50 percent.**

CHIME does not agree with the mandate that providers attest to all three measures even though they are not required to meet all three measures. **Providers should only be required to attest to the numerators and denominators of the measures they actively attempt to meet. We recommend providers only need to meet one of the three measures.**

CHIME members have also expressed confusion around how they are supposed to define the denominators of these measures. For example, does the provider count an electronic transition of care for health care providers who cannot accept an electronic transition of care? Additionally, it is unclear how a hospital is supposed to access a SoC from a walk-in patient. There is also confusion around what electronic exchange means especially in the context where the transmitting provider does not get confirmation that a Consolidated Clinical Document Architecture (C-CDA) was received. Is the test whether the document is sent electronically without regard to receipt? CHIME requests better clarification on these issues.

Further, CHIME urges CMS to clarify that the denominator is limited to providers covered by the EHR Incentive Program (i.e., EPs and EHs and CAHs). **Because providers have no control over the ability of other parties to receive, we recommend that CMS modify the measure to focus only on the ability of the eligible provider to send and receive a transition of care document rather than assessing whether the document was sent and actually received.**

CHIME is also concerned about the purpose of the measures and their utility in improving care. Our experience shows that physicians have asked hospitals to stop sending transition of care documents since they are of little value to their follow-up care plans; rather, physicians need the discharge summary and the relevant portions of the patient's medical record which are often faxed to physician office. Thus, while CMS intends that the requirements under these measures advance use of health IT, the practical experience of hospitals and physicians is that the measures do not contribute to care quality because physicians do not find the information

in the transition of care documents helpful. Thus the requirement under the objective and measure appear to add to the costs of care through impacts on workflow as well as software acquisition and implementation costs without any demonstrable improvement to efficiency or care quality. Additionally, CHIME members do not understand why it is incumbent on them to encourage other health care providers to take advantage of health information exchanges. We are also very concerned that there is insufficient infrastructure to support HIEs and we are not convinced that HIEs will be sustainable over the long-term.

Objective 8: Public Health and Clinical Data Registry Reporting

Objective 8 focuses on public health (PHA) and clinical data registry (CDR) reporting. EPs must choose from among five measures and successfully attest to any combination of three measures, and hospitals must choose from among six measures and successfully attest to any combination of four measures.

This objective fails to recognize the limited capabilities of many PHAs and CDRs. For example, in the arena of immunization reporting, bidirectional communication is far from an established capability. State PHA capability for bidirectional communication varies widely. We do not believe the industry will make significant progress between now and 2018. This is especially problematic for a hospital system that reports to multiple states. **Therefore, we urge CMS to delay the mandate for bidirectional communication until such time as it can be shown that all States have implemented the capability, after testing and validation. CHIME believes that developing a clearinghouse for multistate reporting would be ideal.**

We also note the challenges that states face in reporting back to providers. It is unclear how a state will be able to identify the data that they should report to the provider given patient matching issues as well as the data in their own systems. The experience of member hospitals that report to PHAs has shown that the inability to match data reported to a specific patient is the most significant issue.

Additionally, CHIME members are concerned with the complexity around capturing and reporting other registry data. While most providers currently capture a significant amount of data in a discrete manner, registry reporting still relies heavily on manually abstracted data. Given the extreme complexity involved, CHIME experts believe it will take significantly longer than three years before this process can be automated on a wide scale. What is needed to make this a reality is:

1. Registry data definitions need to be validated and standardized across registry organizations and states;
2. Vendors need to create the forms and workflows for discrete data capture and build the reports in a future release of their software —given the extent of the changes, this is likely to require a major version upgrade;
3. Registries will need to build the ability to receive such reports (currently most registries still rely on manual data submission through a web user interface);

4. Because much of the information required for the registries is captured at the referring hospital, in the event of regional hospital services (neonatal intensive care units, trauma, etc.), the HIEs will have to develop a way to pair additional information to the current C-CDA, not just for the patient at hand but others, further increasing the identity matching challenge (e.g. For a neonatology registry, like VON, in the event of a newborn transfer from a community hospital labor and delivery to a regional NICU, mother information is needed in the registry, but the mother is never a patient in the admitting NICU, and her data would need to be sent through the HIE and the receiving hospital's EHR would need a receptacle for that data and a way to know it is paired to that of the baby);
5. Providers will then need to:
    a. Upgrade their software,
    b. Modify their existing workflows, and
    c. Train clinicians and other support personnel so that these changes are adopted in day to day work.

Even though providers realize the desirability of achieving the efficiencies of registry automation both for improved patient care and for cost savings, and are committed to moving in this direction, the technical and process change challenges facing them are vast, and 3 years will not suffice to tackle them.

In meeting this objective CHIME also seeks a point of clarification. We have been made aware of some commercial products that offer to take the relevant data from providers; add manually abstracted data; reformat it for submission; and submit the data to a PHA or CDR. We seek guidance from CMS on whether data reported to PHAs or CDRs through a certified registry reporting module that allows manual abstraction would constitute compliance with the reporting requirements of this objective as we are unclear whether CMS plans to allow abstracted data to be used in Certified Registry reporting modules/systems outside the EHR.

Last, we recognize that available exclusions for Objective 8 measures include those relating to PHA and CDR capacity to accept the specific standards required to meet the CEHRT definition and their readiness to receive data, but we also note that an exclusion for a measure does not count toward the total of three or four measures that must be met by an EP or hospital, respectively. **In light of the current state of readiness of PHAs and CDRs, we believe that EPs and hospitals should be expected to meet a combination of two or three measures in Stage 3, respectively.** We also note that the measures for specialized registries are not necessarily helpful to providers for purposes of the meaningful use program. Because they are specialized, providers must either manually enter the data or purchase specific software which may not work with the providers EHR software.