

February 26, 2010

Charlene Frizerra
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-0033-P
7500 Social Security Blvd
Baltimore, MD21244-1850

[Submitted electronically]

Ref: CMS-0033-P

Dear Ms. Frizerra:

The College of Healthcare Information Management Executives (CHIME) appreciates the opportunity to comment on the Notice of Proposed Rule Making (NPRM) entitled Medicare and Medicaid Programs; Electronic Health Record Incentive Program, published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on January 13, 2010 [CMS-0033-P].

CHIME's 1,400 members represent chief information officers (CIOs) and other top information technology executives at many of the nation's largest hospitals. CHIME members have front-line experience in implementing clinical systems, and have learned by trial and error what works and what doesn't in implementing such electronic systems and optimizing the value derived from them. Healthcare CIOs share the vision of an e-enabled healthcare system as laid out by the HIT Policy Committee, the Office of the National Coordinator for Health Information Technology, and the Centers for Medicare & Medicaid Services.

One of CHIME's primary objectives is to provide educational and other resources to further the adoption of EHR systems across the healthcare continuum. To that end, we have offered numerous educational sessions in past years at our semi-annual meetings, enabling members to share their successes and lessons learned. We plan to re-double our educational efforts in the coming years to support accelerated adoption under the EHR incentive programs through venues such as our successful CIO Boot Camps and LEAD Forums, which facilitate information sharing among our members.

The NPRM provides the regulatory framework for the Electronic Health Record Incentive Programs established in the American Recovery and Reinvestment Act of 2009 (ARRA). The effort to stimulate the use of EHR systems through financial incentives represents a rare opportunity for the nation’s healthcare providers, the government, American citizens and the country as a whole. We appreciate and relish the opportunity to build a crucial piece of the infrastructure needed to support better health for our nation.

The definition of meaningful use described in the NPRM builds on a framework of using certified EHR systems to improve clinical care, promote coordination of care, better engage patients, and improve public health, while ensuring adequate privacy and security for personal health information.

The objectives laid out in the proposed rule provide essential – and ultimately achievable – goals for our nation. Healthcare CIOs share the vision of an e-enabled healthcare system. Indeed, the proposed rule brings closer to reality a dream that some of our members have labored toward for years – the implementation of EHR systems within healthcare organizations and the sharing of data across providers to best support the health and healthcare of Americans.

Implemented effectively, EHR systems will improve healthcare delivery, increase safety for patients, optimize efficiency and reduce expenses in the current paper-based records system. However, if healthcare organizations rush to implement these systems, or can’t customize the approach to fit their individual circumstances, potential benefits to the country could be limited, resulting in physician frustration, suboptimal deployments, and perhaps unintended consequences, such as patient harm from incomplete data or providers leaving the federal payment programs.

It is in the spirit of seeking to share our members’ years of experience in the deployment of these EHR systems and knowledge of the current marketplace that we offer the following observations, comments and recommendations.

Our comments are organized into two areas: Critical Concerns, which we feel are foundationally important for the regulations and overall effort to succeed; and areas where we feel clarification is needed. Our comments, which align with several other large hospital and physician organizations, seek an incremental approach for providers, rewarding them for overall efforts to install electronic health records systems, and which relieves the time pressure and helps all participants reap the full benefit of these systems within healthcare environments.

I. Critical Concerns

A. The proposed “all-or-nothing” approach to defining meaningful use is too ambitious and will limit the program’s impact on the economy.

[The section provides comment on Section II.A of the NPRM.]

Premise:

The Medicare and Medicaid EHR Incentive Programs were included in the stimulus bill, and we believe that the definition of meaningful use needs to be harmonized with the original intent of stimulus legislation, which was to promote the adoption and use of EHR systems by providing federal payments that would simultaneously have the effect of stimulating the economy as quickly as possible.

Several aspects of the proposed approach will limit the program's impact on the economy. First, the 23 proposed objectives for defining meaningful use set a "high bar" for adoption that is not achievable by most hospitals in the U.S. by 2011. Under the current structure, facilities can get stimulus payments only after buying, installing and "meaningfully using" clinical applications – a process that historically has taken years, not months. Second, the requirement that all hospitals must meet all of the objectives and successfully report all of the HIT functionality and quality measures to receive incentive payments is inflexible and does not reward incremental progress. Third, the specificity of the objectives is prescriptive, and takes away the flexibility needed to meet individual organizations' starting points and needs. Finally, the combination of a high bar and tight timeframes increases the likelihood that organizations with limited resources (critical access hospitals, rural facilities, and urban facilities serving indigent populations) will have little chance of qualifying for stimulus payments.

Discussion:

Meaningful use criteria were established to accomplish five goals: to improve quality, safety and efficiency, and reduce health disparities; engage patients and families in their healthcare; improve population and public health; improve care coordination; and ensure adequate privacy and security of health information. The framework of using certified EHRs to improve clinical care, promote coordination of care, better engage patients, and improve public health puts forth important, and ultimately achievable goals.

The proposed meaningful use definition represents a comprehensive vision of fully optimized electronic health records; as such, it describes the desired end-state achieved after a methodical adoption process. We share that long-term vision, but prefer a regulatory structure that gives support to hospitals that can show evidence they are committed to making progress over time.

The list of meaningful use requirements for 2011 and 2012 includes many advanced clinical applications, such as computerized provider order entry (CPOE) and clinical decision support (CDS) that usually are installed atop a foundation of other clinical and background IT systems. At the same time, the definition of meaningful use leaves out many crucial foundational systems, such as documentation of nursing assessments and electronic capture of medication administration records, that are required for the more advanced applications to

work. Our members' experience has shown that installation of advanced clinical functionality generally comes at the end of a 5- to 7-year incremental adoption process that involves significant redesign of clinical care processes and steep learning curves for clinicians. Implementation of a CPOE system on top of already established core clinical functionality by itself requires 12 to 18 months. Rushing these processes can result in failed implementations and, potentially, compromised care. A growing body of literature has documented the potential safety issues that can arise from CPOE and other automated systems and reinforces the need for careful, systematic implementations with ongoing monitoring.¹

Under the proposed rule, healthcare providers must do ALL of the following to be considered to have achieved the meaningful use of electronic health records:

- Use certified EHR technology.
- Meet all objectives of meaningful use (23 for hospitals, 25 for physicians).
- Report on specific healthcare IT functionality measures for each objective.
- Report on new quality measures with data generated from EHRs (35 such measures for hospitals, varying numbers for physicians).

According to the proposed regulations, failing to achieve any one aspect of the above would disqualify a provider from receiving stimulus payments, setting up a daunting “all or nothing” gauntlet to qualify for payments. Rushing to install advanced clinical systems in time to receive incentive payments will introduce risk and the potential for patient harm.

An incremental approach is needed

To achieve success with the EHR Incentive Program, and ultimately achieve the widest adoption of life-saving technology, an incremental path is needed to achieve the meaningful use end-state. Our members' experience in implementing EHRs suggests that an incremental approach is most effective; it enables essential changes in both work processes and cultures of care, both of which are absolutely necessary to achieve lasting improvements in outcomes. Many factors affect the successful implementation of these complex systems, and historically, the chances for success are substantially improved when sufficient time is allowed for installing systems, changing work processes and training users.

Hard-wiring change in the healthcare system will involve more than just the simple implementation of technology. It involves increasing the use of IT applications within real-world healthcare settings, staffed by medical professionals whose specialty is providing hands-on care for patients. IT adoption in healthcare facilities requires attention to matters such as change management, workflow adaptation and cultural changes. These are significant issues at hospitals, which are currently ramping up their use of technology on a variety of fronts, as well as complying with additional regulatory requirements.

¹ DF Sittig; DC Classen. Safe electronic health record use requires a comprehensive monitoring and evaluation framework. *JAMA*. 2010;303(5):450-451.

All healthcare organizations are limited in terms of their capacity to successfully adapt to change, particularly when facing the wide range of regulatory challenges that will happen at the same time as they plan to adopt healthcare information technology. The federal government is asking healthcare organizations to pursue additional, significant initiatives that will have an impact on IT operations, such as a conversion to ICD-10 by 2013 and the move to X12 Version 5010 for HIPAA transactions, scheduled for compliance by Jan. 1, 2012. Significant work also must be done in support of these standards transitions, and this will affect all IT implementations. Additional modifications will be needed to comply with HIPAA breach notification and accounting for disclosures requirements.

Current adoption levels are low

The meaningful use definition must be grounded in current reality – which is that many providers will be starting from low levels of adoption, from which they will have to significantly advance to achieve compliance with meaningful use definitions. According to a recent study by Jha, et al, only 1.5 percent of hospitals have the kind of comprehensive EHR described by the meaningful use objectives.

Further analysis of hospital survey data indicates that almost no hospitals can currently meet all of the proposed MU objectives – even those that are currently acknowledged to be world leaders in health IT use. Many of the nation’s leading institutions have finished their gap analyses and have concluded that they will not be able to meet the proposed Phase I objectives until 2012 or 2013.

At the other end of the spectrum, many American hospitals have just begun the journey to install EHRs. Furthermore, smaller and rural hospitals generally lag behind in adoption of clinical systems, and for them, meeting the proposed Phase I of meaningful use objectives on the timeline outline in ARRA will be nearly impossible.

The proposed objectives are unrealistic because of the tight timelines

Given the adoption process awaiting most healthcare organizations, the proposed definition of meaningful use is unrealistic in light of the timelines included in ARRA. Market conditions exacerbate the timing issues. While the prospect of additional funding for EHRs has increased demand from providers, current vendor capacity is not likely to match that demand in the timeframes proposed by the regulations.

Thus, hospitals that are just starting an EHR implementation process will find it very difficult to receive incentive payments in time to have a significant impact on the economy. Beginning EHR implementation today is difficult, however, because vendor queues are lengthening and software delivery dates currently are extending well into 2011 and even 2012. For example, some hospitals signing contracts and making upfront deposits in early 2010 are being told by vendors that their installations will begin in mid-2011. A five-year implementation path to install base systems and build on them to achieve advanced clinical applications like CPOE would result in these hospitals first achieving Phase I meaningful use in mid-2016 – too late to receive an incentive payment and after penalties have begun.

Timing constraints also affect the most advanced hospitals. For example, one Midwestern hospital has already achieved HIMSS Level 5 using a version of a vendor product that will not be certified for meaningful use. This hospital currently has CPOE installed and in use. The hospital will not qualify for meaningful use in 2011, however, because their vendor does not plan to certify prior versions of their product for meaningful use.

The hospital is in negotiations with the vendor to upgrade to the next version that will be certified. The vendor has said that if a contract is signed by the end of March 2010, the vendor will put the hospital in the queue to begin the upgrade of their core clinical system sometime in the first quarter of 2011 – 9 to 12 months after the contract is signed.

That upgrade will take 6 to 9 months, and affect only the currently installed applications, infrastructure and database. Additional modules, such as alerts and reminders, nursing care plans and physician progress notes, will be needed on top of that upgrade. Thus, a hospital that is now within the top six percent of performance in use of EHRs will not likely be eligible to receive an incentive payment until fiscal 2012, at the earliest.²

The core clinical system vendors do not have enough experienced staff to support numerous simultaneous new installations. Federal efforts to train additional HIT staff for providers and vendors are greatly needed and appreciated, but it will be months, and perhaps years, before training programs' students can make an impact. Nursing shortages further challenge providers' ability to recruit and train staff that can serve to bring together clinical and technical knowledge in practice.

The need for EHR products to be certified, as specified in the regulation, also represents a time constraint over which providers have no control. As of late February, a notice of proposed rule-making on the regulation covering certification of electronic health records has not yet been released. This rule will set up the process by which electronic health records will be certified, an essential requirement of qualifying for the meaningful use of electronic health records. This conundrum is discussed further below, along with our associated recommendations. For now, suffice it to say that many providers are waiting for assurances that any EHR system they acquire will be certified or that the system that they install from a vendor will be an upgraded version that will meet certification requirements.

In sum, all these factors create an environment in which few providers will be able to successfully meet the proposed objectives in time to receive incentive payments that then could have a significant stimulative impact on the economy. The lack of incentive payments in early years of the proposed plan also means that one of the key barriers to adoption – lack of capital – will still remain an issue for providers. The current digital divide between larger

² According to HIMSS Analytics, only 3.8 percent of U.S. hospitals had reached Stage 5 in 2009. About 2 percent of hospitals have reached higher stages.
http://www.himssanalytics.org/hc_providers/emr_adoption.asp.

hospitals that have more successfully pursued IT adoption, and smaller and rural facilities could widen. The EHR Incentive Program is part of the nation's effort to stimulate the economy. We are concerned that, if the proposed rules are implemented as is, the process to qualify for stimulus funding would appear so difficult that it would discourage organizations that have a long way to go before achieving a fully optimized EHR by the end of the program. In that scenario, the ultimate goal of better, more efficient services, improved care coordination, and greater flow of health information would not be achieved.

The current combination of a high bar and short timeline will limit the payout of incentives and increase the likelihood of penalties being imposed, even for providers making good-faith efforts to implement EHR systems. If the proposed rules are implemented, the EHR incentive program will not likely provide significant economic stimulus.

Recommendations

Taken together, the following recommendations comprise an alternative approach to defining meaningful use over time that will increase the payout of incentives in the short term and result in almost all hospitals achieving the ultimate goal of meaningful use of EHR systems over time. The American Hospital Association also will recommend this alternative approach, and CHIME fully endorses it.

1. CMS should take a building block approach to defining meaningful use.

By this, we mean that CMS should allow providers to receive incentive payments by meeting fewer requirements in the early years of the program, building toward achieving the full set of meaningful use objectives over time. An increasing number of requirements could be expected over time, and incremental improvements should be required to sustain incentive payments and avoid penalties. As real information exchange capacity and use of structured data grows, these elements also could be strengthened. This approach would enable facilities to engage in the program early on and build toward the shared, final vision together. In short, it enables them to “get on the escalator” with a reasonable first step.

2. Lengthen the timeframe for achieving the ultimate vision for meaningful use.

To support incremental adoption, the goal line for meeting full meaningful use should be extended to 2017 and encompass four phases of increased functionality and use (2011/2012, 2013/2014, 2015/2016 and 2017). By law, 2017 is the first year in which no incentive payments are made. Under ARRA, providers that first become eligible for incentives in 2013 or later will receive payments through 2016. In addition, 2017 is the year when penalties are expected to be completely phased in – although they start in 2015, the penalties increase in size through 2017. Therefore, the statute suggests 2017 as the year in which providers should finish their adoption process.

This proposal would not change the payment structures set in law, but would provide a more realistic timeframe for meeting the ultimate goal of using technology to support high-quality, well-coordinated, efficient healthcare. It would replace the proposed “adoption-year” approach with a phased transition for all hospitals. Although the adoption-year approach

provides some cushion for those first meeting meaningful use in a later timeframe, it also locks latecomers into an accelerated adoption curve that would be challenging, if not impossible, to meet. For instance, under the current proposed structure, a hospital that first becomes eligible for meaningful use in 2013 would be expected to meet the Phase 2 objectives in 2014 and the Phase 3 objectives in 2015.

3. Establish the full scope of Meaningful Use objectives upfront so providers know what will be expected as the end-state vision of a fully optimized EHR system.

The NPRM addresses only the first two years of the EHR Incentive Program. We recommend that the final vision for 2017 be laid out now to provide a longer, more certain roadmap.

The NPRM includes objectives for Phase I that leave out many key applications to support safe, high-quality inpatient care, such as nursing and physician documentation, electronic medication administration records, and availability of X-rays and other images at the point of care. Many of those functions were, however, recommended by the HIT Policy Committee for 2013 and 2015, and many are also necessary precursors to more advanced clinical applications, such as CPOE, as well as key sources of information to support care coordination.

Therefore, we recommend establishing a broader set of hospital meaningful use objectives that includes a modified set of the proposed 2011/2012 objectives (described later) plus relevant objectives proposed by the HIT policy committee for 2013 and 2015. At the end of our comments, we include Table 1, “Alternative Framework of Hospital Meaningful Use Objectives Over Time,” which includes a proposed list of 34 meaningful use objectives drawn from both the NPRM and recommendations from the HIT policy committee.

We recommend that the list of hospital meaningful use objectives remain essentially the same until 2017, while the scope of their use accelerates, so that:

- Levels of use increase over time (such as increased use of CPOE);
- Use of structured data increases over time; and
- Information exchange increases over time.

Although laid out in advance, the full set of hospital objectives and expected levels of use, structured data, and information exchange would be reviewed periodically through rulemaking. The regulatory requirements would represent a minimum level of achievement to be deemed a meaningful user of electronic health records; many hospitals would likely achieve a higher number of objectives and greater levels of use to meet competitive pressures. Forward momentum would continue as the penalties provide a very strong incentive to complete the EHR adoption process. In addition, hospitals make multi-year contractual commitments to install full systems.

Electronic health records systems are complicated applications, with many interconnected and interrelated pieces; they affect all aspects of how care is delivered in a facility. They require planning, staging and constant maintenance. For most facilities, such systems could be the largest single capital investment they make outside of their own buildings. They are multi-million-dollar, multi-year investments. As such, it's important for facilities to make wise choices based on a clear view and understanding of the end state.

One of CHIME's veteran members compared the EHR implementation effort to building a house; providers need to see and understand the entire blueprint to achieve successful construction. The current approach to mapping meaningful use objectives to deadline years is akin to viewing separate elevations with no sense of context for how those pieces fit into the whole. CHIME recommends that more thought be given to the entire scope of meaningful use objectives envisioned over the next seven years, with an end-goal deadline of 2017.

4. Allow flexibility in making progress toward meaningful use.

Progress toward full implementation and meaningful use is, of necessity, specific to the staffing, strategy and community of each institution. Hospitals often begin their implementations in departments that have strong technology champions. They also tailor technology installations to their specific quality improvement challenges and strategies. For some hospitals, this may mean that systems to support safe medication administration come first. For others, specific forms of clinical decision support may be their first priority.

In the areas of engaging patients, improving care coordination, and supporting public health, which comprise many of the proposed meaningful use objectives, hospitals operate in a local context. Their approaches to these tasks depend on the extent to which existing health information exchanges and public health efforts have been developed, and the specific objectives being pursued by their communities. For example, the states of Wisconsin and Minnesota have made tremendous progress in establishing vaccine registries. In other states, such as North Carolina and parts of Texas, efforts to install automated biosurveillance systems have taken precedence.

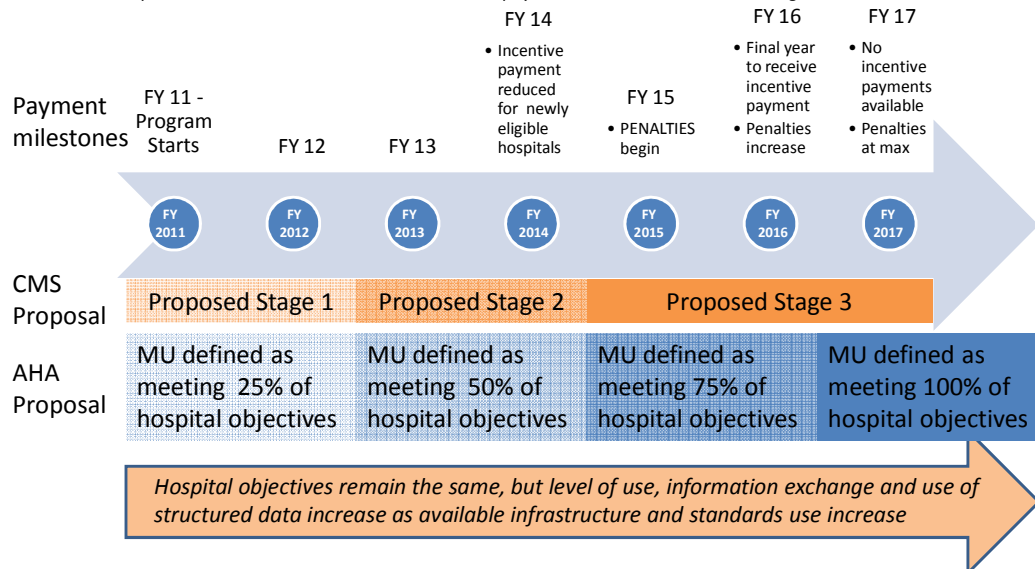
Given the incremental, context-specific nature of the adoption process, we recommend that CMS promulgate a flexible, incremental approach that would enable hospitals to choose a subset of the hospital meaningful use objectives that matches their adoption path and strategic plan (See Figure 1, "Alternative Approach to Defining Meaningful Use.")

With this flexible approach, the share of objectives that must be met would increase over time:

- 2011/2012 – Meet at least 25 percent (8 objectives);
- 2013/2014 – Meet at least 50 percent (17 objectives);
- 2015/2016 – Meet at least 75 percent (24 objectives);
- 2017 – Meet substantially all of the objectives.

Figure 1. Alternative Approach to Defining Meaningful Use

Recommendation: CMS should identify a single, expanded set of meaningful use objectives to be achieved between 2011 and 2017. Hospitals would be considered meaningful EHR users and qualify for the full EHR incentive payment if they meet a specified share of the hospital objectives in a given fiscal year. The required share would increase over time. The payment schedule would not change.



5. Require a core set of the hospital objectives.

We recognize, however, that policy priorities place greater emphasis on certain objectives over others. Additionally, advancing toward increased sharing of health information requires developing a common set of tools. Therefore, we recommend that CMS require a core set of hospital objectives in each time period. For 2011/2012, we recommend that the following objectives from the proposed rule be required:

- Drug-drug/drug-allergy checks
- Structured medication list
- Protection of electronic health information

This alternative approach provides the roadmap needed for hospitals to plan for and meet the long-term goal of high-quality, well-coordinated care that engages patients and promotes public health. Along the way, it will reward progress and enable hospitals to use their incentive payments to fund further adoption, addressing the need for capital funding, which has been a key barrier to adoption. In the short run, it will allow more incentive payments to be made, thereby adding needed stimulus dollars to the economy.

B. Uncertainty over the EHR certification process complicates progress

[This section provides comment on Section II.A. of the NPRM]

Premise:

To receive stimulus payments under the EHR Incentive Program, providers must use systems that are certified by an approved organization. As of late February 2010, however, the Office of the National Coordinator for Health Information Technology (ONC) has yet to issue a proposed rule governing how products will be certified. Many steps must be taken before certified systems are in use, including promulgation of final rules, establishment of a federal accrediting agency, creation and accreditation of certification bodies, and actual certification of vendor products. We are concerned, therefore, that uncertainty over certification will delay providers' progress and prevent them from receiving incentive payments in the near term. We also are concerned that the absolute certification requirement will result in heightened market pressure as all hospitals seek to upgrade or install new systems simultaneously. Temporarily relaxing this component of the regulation is essential to move the acquisition and implementation of EHRs forward in a timely manner, thus enabling stimulus payments for providers to achieve the intent of Congress and the EHR Incentive Program.

Discussion:

The requirement for use of EHR systems that have received federally recognized certification is beneficial and will bring long-term accountability and transparency to the vendor market. It also will provide assurance that federal funds are being well spent and that steps toward greater interoperability are taken over time. In the short-term, however, conflicting timelines between certification and achieving meaningful use could further limit providers' ability to meet the meaningful use targets in a timely manner and result in negative market impacts.

Conflicting timelines

The final rule governing EHR product certification is not likely to go into effect until late this year. As of the writing of this comment, an NPRM has yet to be issued for certification. Even after an NPRM is issued, there will need to be a comment period (typically 60 days); time to incorporate those comments into a final rule; issuance of a final rule; and the setting of an effective date for the rule. These regulatory steps must happen before certifying bodies can be recognized and products approved.

Vendors must also adapt their products in order for them to be certified. Many current products do not have the ability to meet all requirements of the proposed rule, so additional products and reporting tools will have to be developed, a process that takes time to complete. These new products also must be tested for performance, compatibility and accuracy. The ONC rule estimates that "it will generally take 6 to 18 months for commercial vendors and open source developers...to prepare for testing and certification."³

In our estimation, it seems unlikely that these processes will be completed until well after the start of the Medicare and Medicaid EHR incentive programs.

Even if federally certified products were available in the summer of 2010, a requirement for

³ Federal Register Vol. 75, No. 8, p. 2041.

certification in 2011 and 2012 still would conflict with efforts to meet the meaningful use objectives in a timely manner and could actually set back the goal of using EHR systems to improve patient care.

Under the proposed rule, institutions that have already implemented EHRs will need to upgrade their systems to meet the certification requirements even if their current systems can perform the meaningful use functions. The certification requirement in the proposed regulations then would force these institutions to make new investments and undertake installation work solely to meet the certification requirements. For those companies whose vendors cannot meet certification requirements, there is the challenging prospect of switching to a new vendor, with all the associated transitional work that accompanies such change.

Already, some organizations that are at advanced stages of clinical system implementation are receiving quotes from vendors for “add-ons” that will be needed to achieve certification for anticipated Phase 1 requirements. Although a healthcare organization may buy a certified system, vendors typically charge separate fees for implementing interfaces, new reports and features. If an organization decides not to purchase these additional modules immediately, there’s uncertainty about whether existing applications could be considered certified.

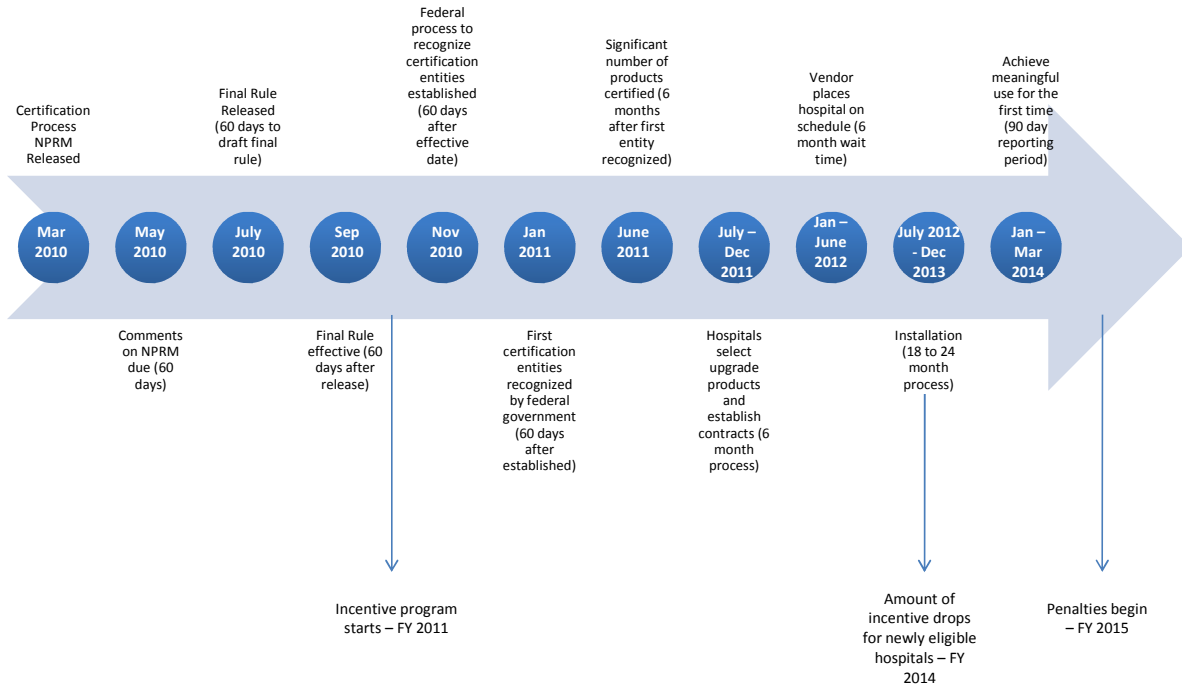
Selection and implementation timelines for new inpatient EHR systems involve sequential steps that typically span years, as was described previously. Upgrading existing systems also takes significant planning and execution. While the experience of individual hospitals varies tremendously and depends on the current level of EHR deployment, a general timeline for upgrading a basic system to be certified and meet proposed Phase I meaningful use would involve:

1. Needs assessment – 6 months
2. Vendor selection and contracting – 2 to 6 months
3. Vendor scheduling for installation (contract and deposit generally required for an organization to be placed in the queue) – traditionally 6 months, but current reports are as long as 18 months, particularly for smaller facilities
4. Installation – 9 to 24 months.

As illustrated in Figure 2 on the next page, adding these steps onto the point at which a significant number of certified products are available results in achieving meaningful use in early 2014, when only partial incentive payments are possible, even if all goes according to plan.

Although some of these steps can be undertaken while the certification process is being established, and most hospitals are moving forward with planning and contracting today, doing so carries tremendous risk for the provider. If a contracted vendor does not receive certification in a timely manner, incentive payments could be delayed or missed entirely, and upfront capital investments are at risk. In addition, with the probable delays of certification until mid-summer to late 2010, many vendors are currently delaying software releases or functionality improvements because they are waiting to ensure their products are compliant with meaningful use provisions. This further limits providers’ ability to move forward now.

Figure 2. Uncertain certification process limits hospitals' ability to upgrade existing systems to achieve meaningful use in a timely manner



To illustrate with an actual case, a forward-thinking, risk-taking CHIME member who is a CIO at an East Coast hospital reported the following timeline to purchase an EHR system to add the advanced clinical systems required by the proposed Phase I objectives.

- March 2009: Begin EHR/EMR vendor selection process.
- November 2009: Select vendor and get in queue for an April 2010 implementation start.
- Ongoing: Needs assessment to evaluate additional modules needed to meet meaningful use.
- April 2010: Start installation.
- November 2011: Planned go-live of replacement basic EHR functions.
- May 2012: Planned go-live of more advanced clinical functionality, including CPOE.

This planned timeline does not account for any delays that may come from difficulties in getting products certified or acquiring trained resources. In addition, the CIO for this facility notes that, “The best scoped plans and deadlines can be derailed due to competing priorities, such as operational, scheduling issues and emergencies. While we are increasing our staff

due to this project, it still will be difficult managing the implementation of a new EHR together with the day-to-day infrastructure projects and other hospital projects.”

Impact on the market

The absolute certification requirement essentially means that all providers must simultaneously upgrade existing and install new EHR systems. Institutions that have already implemented EHRs will need to upgrade their systems to meet the certification requirements, even if their current systems already are capable of performing meaningful use objectives. At the same time, providers beginning their adoption curve will be seeking to install certified products. Few markets can accommodate that level of simultaneous activity.

The combined demand from providers seeking both to upgrade and install new systems will likely outstrip the market’s capacity, specifically regarding vendor capacity, the HIT workforce, and organizational workforce. As recently noted by ONC, the shortage of workers in HIT has been estimated at 50,000 to 60,000. Workforce shortages and limited vendor capacity will likely delay many upgrades and installations.

We are concerned about how the EHR Incentive Program will affect healthcare staffing at our facilities. We already are detecting a trend of hospital operations staff seeking training in IT. We fear that gearing up for the implementation of clinical systems will have a major impact on our staffing models; that’s because front-line caregivers are typically deeply involved with IT implementations, and that creates staffing pressures in departments such as Nursing, the Emergency Department, Surgery and Pharmacy, which often are difficult to staff.

The training program grants that have been awarded by the federal government are crucial to ameliorating this situation and greatly appreciated. However, it will take time for those resources to make an impact for providers. These workforce training programs may not solve the short-term workforce needs of vendors, which typically need employees with at least one year, if not many years, of experience with products in order to effectively install them.

The pressure on the market also may have disproportionate impacts across types of facilities. As vendors make choices about where to focus their limited resources amidst widespread demand for implementations, we are concerned that they are likely to favor existing clients and larger institutions over smaller rural and community hospitals. Rural hospitals and small practice physicians have few choices of products that can be simply and inexpensively deployed, and this lack of choice puts them in competition for existing complex applications with larger, more experienced organizations that represent existing clients and easier deployments for vendors.

Recommendation:

1. Grandfather existing applications for two years.

We recommend that CMS adopt a “grandfathering provision” under which existing systems that hospitals use to meet meaningful use objectives could be accepted as “certified” for a

period of two years. All upgrades to existing systems or deployment of new systems after that period of two years, however, would be required to be certified under the new federal process.

Given the mismatched timing of the availability of products certified through the new federal process and the statutory start of the EHR incentive programs, we believe that current systems capable of performing the meaningful use functions should be recognized as certified on an interim basis. This approach would avoid wholesale replacement of existing EHR systems and ease the difficulties presented by the short timelines and vast market demand for both upgrades and new installations.

C. Quality Reporting Requirements

[This section provides comment on Section II.A.3 of the NPRM]

Premise:

CMS proposes that hospitals begin reporting 35 new quality measures directly from their EHRs to be considered meaningful EHR users. Automated quality reporting directly from EHRs is a shared goal. However, most of the proposed measures have not yet been specified for collection through EHRs, and EHR systems have not yet been programmed to report these measures. Furthermore, many of these measures would be required in addition to the existing Medicare quality-reporting program for hospitals, Report Hospital Quality Data for the Annual Payment Update (RHQDAPU), leading to an even greater reporting burden.

Discussion:

Automated quality reporting is a critically important part of the meaningful use of electronic health records that will further improvements in the healthcare system. However, development of “e-measures” is ongoing, and no EHR system in common use today is capable of automated reporting of the full set of proposed measures; in fact, most of these measures have not yet been specified for automated reporting. Therefore, the following proposed requirement is premature: “Specifically, for 2011, we propose to require that Medicare EPs and hospitals attest to the use of a certified EHR system to capture the data elements and calculate the results for the applicable clinical quality measures.” (p. 1901 FR)

The process of developing and testing measures for automated reporting takes time. For example, under contract from CMS and ONC, HITSP began a process of retooling 16 inpatient measures in September 2008; a final set of specifications was just released in January 2010. In its report, the HITSP team noted that development of e-measures takes time and must be done carefully to maintain the scientific integrity of the output. If automated reporting is not valid, reliable, and clinically relevant, it is not useful.⁴

⁴ In its report, the HITSP team noted that: “Retooling is not translation; eMeasurement necessarily broadens the set of essential stakeholders needed for performance measure development, refinement and maintenance. The task of associating the concepts incorporated in a performance measure with terms found in one or more

In the FY2010 IPPS final rule, CMS indicated that pilot testing of these 16 measures would begin as soon as July 1, 2010. The purpose of the pilot was to test “the components required for the submission of clinical quality data extracted from EHRs for these measures, and ... (explore) different mechanisms and formats that will aid the submission process, as well as ensure that the summary measure results extracted from the EHRs are reliable.”⁵ CMS was still accepting applications to test submission in February 2010. The notice does not indicate how long the pilot will last, but given that the specifications for three of the 16 measures are more than 400 pages in length, it seems unlikely to be finished quickly.⁶ If it begins in July 1, 2010, and takes three months, CMS will have concluded its pilot as the EHR Incentive Program begins.

After the pilot test has been conducted, the following steps will be required before routine reporting from EHRs, for these 16 measures, would be possible:

- Revise specifications based on pilot test;
- Conduct additional testing of revisions;
- Embed revised specifications into vendor products;
- Secure certification for vendor products;
- Install certified systems in hospitals (12 months to reach majority of hospitals);
- Accumulate sufficient data with adequate specificity to calculate measures.

Even when e-specifications are widely available, gathering this expanded set of quality information will not be simple and is likely to involve additional costs to providers. CMS must clarify the benefits of the additional reporting requirements and balance them against the likely costs. Vendors whose systems don’t have these reporting capabilities may choose to provide them through add-on modules, at added cost to their customers. Adding these system capabilities to certification requirements will slow down the development of technology and/or its ability to be certified.

Vendors need time to create and test these capabilities as part of an EHR, and providers must feel comfortable that the vendor products are producing valid and reliable data. It is currently uncertain whether additional programming or work from vendors for quality reporting will be absorbed by the vendors, although some providers have clauses in current contracts requiring

vocabularies requires the active collaboration of the measure developers and their clinical experts, terminologists and the vendor community to assure that the clinical and data collection pathways and objectives, and their underlying bases in evidence, are meaningfully preserved even as they are transformed. The complexity of the retooling process and resulting e-specifications raises new challenges for the public review and consensus process of the National Quality Forum and others in order to assure that the resulting eMeasures continue to be consistent with the needs of the broader community.” (**HITSP Quality Measures Technical Note ED, VTE, and Stroke Examples for Implementation of the HITSP Quality Interoperability Specification, HITSP TN906, Jan 25, 2010**).

⁵ See 74 FR 43893.

⁶ Available at: http://www.hitsp.org/constructset_details.aspx?&prefixalpha=5&prefixnumeric=906.

vendors to absorb costs related to achieving compliance with government mandates. Even after vendors have incorporated these measures, some, including those currently being pilot tested, are mapped to standards, such as LOINC and SNOMED, which are not currently supported by installed systems. Moving to those standards is part of the incremental adoption process.

In the broader context of hospital quality reporting, the proposed approach conflicts with the current RHQDAPU hospital quality reporting initiative. Hospitals will find it difficult to manage dual reporting processes – the current approach and new, automated reporting. CMS has been very successful in establishing a predictable approach to setting measures for reporting, establishing clinical priorities, providing for a consultative process, and publishing a timeline that gives notice of likely future requirements. This process has taken time to establish, and should not be disrupted just because new technology is available to calculate measures.

Recommendation:

1. Delay quality reporting until 2012.

The proposed rule requested comment on whether quality reporting should happen in 2011 or be postponed until 2012. We would support the latter: CMS itself will not be ready to receive electronic data until 2012, meaning attestation will have to be used to verify compliance in 2011. Additionally, tested electronic measure specifications will not be available in 2011. No widespread testing of installed, certified EHRs will be possible in such a short timeframe, either.

We further recommend that:

2. Hospitals continue to report measures through the RHQDAPU process.

3. Future reporting requirements continue to be made through the established RHQDAPU process.

4. Automated reporting begin with the measures currently being piloted by CMS, after successful completion of that pilot.

5. Moving forward, increase the number of measures to be reported through EHRs incrementally, and only after sufficient testing of e-measures.

D. Comments on Specific Objectives and HIT Functionality Measures

[This section provides comment on Section II.A. and Section III. of the NPRM.]

Premise:

As stated earlier in these comments, the NPRM includes 23 specific objectives of meaningful use with associated HIT functionality measures. Changes are needed in some of those measures to make them more relevant to the inpatient environment or to decrease the reporting burden. We are also concerned about the overall burden of reporting the HIT functionality measures and believe that the proposed regulation vastly underestimates the burden that providers will face. Our specific comments address this issue and suggest

alternative measures that would be less burdensome. We also recommend that ONC require certified EHRs to produce all HIT functionality measures that can be generated directly from the EHR and will make separate comment to that effect.

Discussion:

The proposed rule includes 23 functions of meaningful use for the inpatient environment. Each of these objectives and supporting HIT functionality measures are described in the rule. CHIME members carefully reviewed each of these objectives and measures. Below, we address a subset on which we have strong concerns. Our recommendation for changes also are included in the attached Table 2, “Detailed Comments on the Proposed Stage 1 Objectives and Measures of Meaningful Use for Eligible Hospitals,” which recommend specific changes to some of the objectives from the proposed rule and associated measures, that should be incorporated in the final meaningful use requirements.

1. Administrative measures.

The NPRM includes two administrative measures that must be performed using the EHR. These administrative activities are already addressed under the HIPAA Administrative Procedures regulations and are overseen by CMS. Hospitals already face a financial penalty for submitting paper claims. These electronic activities are undertaken through existing claims processing systems, which almost always are integrated with clinical EHR systems, although they are rarely part of the EHR installation.

Including billing activities in the meaningful use objectives would result in a requirement that hospitals upgrade existing, functional billing systems to new products that have been certified through the federal EHR certification process. Such a requirement would create unnecessary work and expense and take hospital IT staff away from implementation of the clinical systems that are at the heart of meaningful use. There is no apparent benefit to this requirement.

In addition, there are measurement concerns with these objectives. Electronic eligibility verification requires a connection with the insurer. Hospitals routinely see patients with dozens, if not hundreds, of different insurers, and cannot be expected to have connections with all of them. This is particularly difficult for hospitals in areas with large part-year populations, such as Florida and Arizona. In addition, the value of electronic eligibility verification is often minimal, as insurers only provide information on whether the individual is enrolled, without providing more granular details needed to inform patients of their financial obligations. Finally, hospitals cannot check the eligibility of patients that present without their insurance information or who are uninsured.

Recommendation

We recommend that CMS remove the following objectives:

- **Check insurance eligibility electronically from public and private payers (measure: 80 percent of unique patients)**

- **Submit claims electronically to public and private payers (measure: 80 percent of unique patients)**

2. CPOE

CPOE, when implemented appropriately, can be very effective in improving the quality and efficiency of care. It is, however, a challenging application to install and train clinicians to use appropriately. Under our proposed alternative approach, which supports incremental adoption, we are certain that successful CPOE is possible. We are concerned, however, about the proposed HIT functionality measure that states, “CPOE is used for at least 10 percent of all orders” (any type).

First, the CPOE measure in the NPRM excludes the use of CPOE within a hospital’s emergency department. This should be reconfigured to include the use of CPOE within a hospital’s emergency department for patients that are subsequently admitted. CPOE use within an emergency department is important because the majority of ED patients at most hospitals are eventually admitted as inpatients, and CPOE within the ED helps with care handoffs. Also, the ED is a logical place for most healthcare organizations to begin implementing CPOE.

Second, to calculate the percentage of all orders placed through CPOE, hospitals will need to define the denominator of all orders – placed via CPOE, in writing, or through other means. The only way to accomplish this would be through manual chart review. Hospitals routinely conduct chart review for purposes of quality reporting, and experienced abstracters doing this work generally take 20 minutes per chart. For quality reporting, this chart review is done for only a subset of patients; as currently proposed, the CPOE measure would require 100 percent chart review. Thus, a hospital with 15,000 discharges would need to invest 5,000 hours in chart review to calculate this measure.

Recommendations

We recommend that:

- **CMS adopt a different measure for use of CPOE that would be less burdensome to report. Our preferred measure is Hospital has CPOE activated.**
- **If CMS does not accept this as a preferred measure, we recommend either 1) at least 10 percent of unique patients have had at least one order placed through CPOE, or 2) at least 10 percent of medication orders placed through CPOE, which can be calculated from a hospital’s pharmacy information system.**
- **If either of the secondary options are chosen, ONC should require this measure calculation as part of the EHR certification process.**

3. Medication reconciliation

The NPRM includes the following objective: Perform medication reconciliation at relevant encounters and each transition of care (measure: Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care).

CMS rightly notes in the NPRM that the medical community lacks a clear, shared understanding of medication reconciliation and the use of EHR systems to support this process. In fact, the Joint Commission is currently revising its National Patient Safety Goal on medication reconciliation. CMS should not attempt to define medication reconciliation processes and requirements separately and differently from The Joint Commission. Doing so will cause confusion and could actually slow efforts to build and spread best practice models of medication reconciliation.

At its core, however, medication reconciliation is a tool to prevent medication errors. It involves clinicians consulting with patients and other providers making informed judgments about current and new medications. Medication reconciliation is not an automated EHR process; it is a human workflow process that is supported by the EHR.

In the NPRM, the term “transitions of care” includes an array of transfers across the continuum of care that is not currently supported by information exchange among providers. Consequently, medication reconciliation as defined is not possible. Medication reconciliation across settings (for example, hospital to long-term care facility or hospital to physician office) is not possible given current levels of information exchange. If CMS keeps medication reconciliation as an objective, we recommend defining it to include only medication reconciliation processes within an institution, not across settings of care.

The calculation for achieving this measure across all admissions would be overly burdensome to report. Inclusion of the emergency department in these measurements is important because many patients enter a hospital via the ED and first discuss current medications in that setting. Electronic medication reconciliation tools in use today do not generally include a flag or other measure to indicate that medication reconciliation was done accurately or done at all, so this measure is not currently easy to calculate. If CMS retains medication reconciliation as an objective, we recommend the following alternative measure: Hospital is using EHR to support medication reconciliation during admission, discharge and transition within the facility.

If CMS determines that a percentage measure is required, a sampling methodology must be developed to reduce the reporting burden. In addition, if a percentage measure is included, CMS and ONC should require measure calculation as part of the EHR certification process.

Recommendations

We recommend that

- **For the foreseeable future, the meaningful use objective is defined to include only medication reconciliation processes during admission, discharge and within an institution, not across settings of care.**
- **We recommend that CMS change the medication reconciliation measure to be “hospital is using EHR to support medication reconciliation.”**

4. Electronic information for patients

The NPRM includes 2 measures related to providing data to patients:

- Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request.
- Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

The use of portable media, such as a USB device, presents security problems for hospitals. Securing PHI on the portable media could require the patient to have advanced computing capabilities to access the information at home. In addition, introducing portable media can compromise the security of the hospital's IS systems.

Recommendation

Clarification is needed to determine what electronic data are to be given to patients and their families, and in what format. If in electronic format, we support movement over time to the use of records in the CCD (Continuity of Care Document) standard, which provides the best opportunity for interoperability between providers' records. The CCD will not, however, be used widely in the near term.

5. Submitting data to public health organizations

The NPRM includes 3 measures related to public health reporting:

- Capability to submit electronic data to immunization registries and actual submission where required and accepted.
- Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received.
- Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

The proposed objectives raise many questions – for example, who decides when actual submission is necessary? Should providers be required to electronically submit data if a Department of Health is not ready to receive it electronically in a standard format? States such as Nebraska have web-based immunization registries that work effectively but cannot accept data from EHRs. Hospitals are actively participating in this registry, which achieves the goal of the objective, but using different means.

In addition, while we support transmission of data to public health agencies, it is important that there be a standard set of information requested by the public agencies, in order to provide optimum interoperability and ease the flow of data. Uniformity is needed across public health agencies in the form of data requests that can be fulfilled through the use of standards, to ease the burden on providers and limit the amount of customization required of vendors' systems. A lack of standardization is particularly a burden for provider organizations that offer services to patients in more than one state. As an alternative, we recommend that the requirement be recast so that providers have achieved it if they can

demonstrate that they have submitted data as requested to one public health agency of their choice.

Recommendation

Further clarification is needed regarding the exchange of health information for public health, such as for immunization registries, reportable lab results and syndromic surveillance.

6. Generation of measures from EHRs

CMS states in the proposed rule (p. 1903), that the agency does “not believe that demonstration of meaningful use should require use of certified EHR technology beyond the capabilities certified” through the federal certification process. The IFR released by ONC, however, does NOT include generation of the HIT functionality measures as a certification requirement.

Laborious, manual process to report on the use of automated technologies detracts from the very efficiencies the EHR incentive program seeks to realize.

Recommendation

CHIME will separately comment to ONC on inclusion of certification criteria for specific HIT functionality measures in the IFR. However, we feel strongly that CMS should not require submission of HIT functionality measure data that cannot be derived easily from the EHR, and that the EHR has not been certified to produce.

II. Needed Clarifications

A. Hospital-based professionals

[This section provides comment on Section II.A.6. of the NPRM]

The NPRM proposes an exclusive definition of hospital-based professionals that will prevent approximately 30 percent of physicians from receiving stimulus payments under the EHR Incentive Program. We believe that the intent of withholding payments from hospital-based professionals was to exclude potential “double dipping” by physicians who work in hospitals but actually use the inpatient EHR system.

The proposed regulation has the effect of excluding too many physicians, and the exclusion will have unintended consequences for care coordination and continuity of care. The current approach excludes many hospital-based ambulatory clinics, including teaching programs, solely because of which entity owns the EMR system. As hospitals seek to prioritize implementations of EHR systems, they are likely to make decisions based on what will have the biggest impact in receiving stimulus funding, and the regulations as defined will have the unintended consequence of slowing down EMR adoption in these ambulatory settings.

Ownership of the EMR system should not be the criteria for determining if members of a group practice or an individual professional is eligible for stimulus funds. The criteria should be based on whether a true ambulatory EMR module/system was purchased and installed. If hospitals are the purchasers of systems for these groups now defined as non-eligible by the proposed regulations, physicians can simply assign back their stimulus payments to the hospital, which is a common arrangement for these groups in reconciling reimbursement issues.

We support the concept of rewarding physicians only once, but we want to make sure that the regulations encourage active participation by the largest number of physicians.

Recommendation

We recommend a thoughtful review and revision of the definition of “eligible professional” to include all physicians practicing in ambulatory clinics, whether owned by physicians or hospitals. We endorse the AHA’s proposed change to the definition of Eligible Professional, which is based on specialty, types of services provides and contribution to the EHR system.

B. Definition of Eligible Hospital for Medicare

[This section provides comment on Section II.B.2a of the NPRM]

CMS proposes to use the CMS Certification Number (CCN) as the criteria for determining a hospital's eligibility and incentives. In many facilities, a single provider number can include multiple campuses of a hospital system. If the Medicare provider number is used to define a hospital, a healthcare system with multiple hospital sites (but a single Medicare provider number) would receive one incentive payment for the entire healthcare system. This penalizes hospital systems with only one provider number relative to hospital systems with multiple provider numbers. For EHR incentive payment purposes, we ask CMS to identify hospitals as discrete facilities of service so that individual sites of hospitals are eligible to separately qualify for the incentives.

Recommendation.

For EHR incentive payments, we recommend identification of hospitals as discrete facilities.

C. Demonstrating use of a certified EHR system

[This section provides comment on Section II.A.4. of the NPRM.]

To be eligible for incentive payments, providers must use certified EHR technology. In the NPRM, CMS accepts the definition of certified EHR technology put forth by ONC in its Interim Final Rule entitled Health Information Technology: Initial Set of Standards,

Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, also published in the Federal Register on January 13, 2010.

ONC lays out a multi-stage definition of “certified EHR technology” to mean: “A Complete EHR or a combination of EHR Modules, each of which 1) meets the requirements included in the [statutory] definition of a Qualified EHR and 2) has been tested and certified in accordance with the certification program established by the National Coordinator as having met all application certification criteria adopted by the Secretary.”

ONC specifies that a “Complete EHR” has been developed to meet all of the applicable certification criteria adopted by the HHS Secretary, while a combination of “EHR Modules” can be “any service, component, or combination thereof that can meet the requirements of at least one” of the certification criteria adopted by the Secretary.

ONC further states that providers that choose to combine multiple EHR modules must ensure that the modules work together and that, together, they meet all of the certification criteria. Taken together, the two regulations require that hospitals demonstrate to CMS that the EHR system they are using has been certified for all 23 meaningful use objectives through a federal process that is yet to be established.

Few hospitals use a single vendor to provide their EHR. Instead, they generally integrate different systems from a variety of vendors. Even those hospitals that install a main enterprise system routinely supplement it with dozens of other products meant to achieve specific needs, such as department systems for Surgery or Radiology. They also may have a clinical data repository, infection control or oncology systems. On top of all these vendor products, many hospitals also write custom programs to generate specific reports or provide specific decision support functions, including, for instance, evidence-based order sets derived by clinical staff. For example, during testimony in front of the HIT Standards Committee Implementation Workgroup on October 29, 2009, Allegiance Health in Michigan noted that its EHR incorporates 200 IT systems that involve 75 to 80 vendors.

Given the array of programs that comprise a hospital’s EHR system, ensuring that the hospital’s system is certified against all of the meaningful use objectives will be a challenging exercise, particularly during the next two or three years, where EHR vendors will be attaining product certification and working with their customers to upgrade existing and install new systems.

Practical questions have arisen, such as: Does my data repository need to be certified? If I report lab data to public health entities via my EHR, does my lab system also need to be certified? Can I generate quality reports using modules that are not certified if I report the data to CMS via a system that is? Am I supposed to get all 50 products I use certified?

The guidance in the NPRM states only the following: “We propose that an EP or eligible hospital would through a one-time attestation following the completion of the EHR reporting

period for a given payment year identify the certified EHR technology they are utilizing and the results of their performance on all the measures associated with the objectives of meaningful use.”

Recommendation

Additional clarity is needed as to what is involved to demonstrate use of a certified EHR system.

D. Operational issues

[This section provides comment on Section II.B. of the NPRM.]

The NPRM provided few details of how program operations will work. We are anxious to hear more details about how the program will be operated and particularly what the requirements will be for attestation. We look forward to the final rule and for complete details on how the attestation process will work. We urge CMS and its contractors to provide ample opportunities for providers to test all data submission processes. CMS and its contractors also must give prompt feedback on missing or incomplete data, giving providers an opportunity to correct and re-submit their attestation.

Recommendations

- **We recommend that CMS include for the Medicare program all of the appeals processes it proposes to require of state Medicaid programs in 495.370 (Appeals process for a Medicaid provider receiving electronic health record incentive payments.) Specifically, a process to appeal and provide documentation to support the appeal of incentive payments; incentive payment amounts; and provider eligibility determinations.**
- **Given that this is a new program, we also urge CMS to provide vigorous and well-planned contractor and provider education, so as to maximize the opportunity for success.**
- **Finally, we are troubled by the requirement in 495.8(c)(2) that “EPs, eligible hospitals, and CAHs must keep documentation supporting their demonstration of meaningful use for 10 years.” We recommend a shorter record retention period of five years, given the rapid changes in EHR technology that will occur in the next decade.**

E. Health information exchange

We agree with the limited requirements for health information exchange in the proposed regulation. Rural and community hospitals often lack the basic infrastructure to participate in regional exchanges. Even large urban areas have struggled to achieve integration. Through grants and cooperative agreements with the states, ONC has encouraged development of

regional HIEs. Many of our members are participating in those efforts. Still, most HIEs are in early stages of development, especially in achieving a sustainable financial model. Regulations must recognize the fact that HIE is in its infancy with many technical, organizational and financial hurdles yet to be surmounted. In addition, successful HIEs in larger communities will require competitors to come together in order to be successful. The governance of such is not something that is easy to legislate. Adequate time must be provided for HIEs to mature.

Many of these efforts have been challenged by the task of accurately matching patients to their records in the absence of a national patient identifier (NPI). The federal health agencies that are furthest along in building true information exchange – the armed forces and the Veterans Health Administration – benefit from having a unique identifier for their shared population. Without concerted, coordinated effort to solve this problem, health information exchange will continue to face serious challenges in the future. Current approaches to matching records, using software that has at best a 99 percent probabilistic matching accuracy rate, still involves a large administrative and cost burden for organizations attempting to exchange information. We are aware that many consumers see the creation of an NPI as a significant privacy concern, but as patient information is increasingly exchanged in the next few years, patient safety will be exponentially compromised as patient record mismatches rise in frequency.

Even though there is statistically high reliability with probabilistic matching algorithms, the number of people who could be affected is huge. Even if the accuracy of algorithms is 99.99 percent, an error rate of only 0.01 percent would mean 300,000 mistakes in matching patients to records would occur, assuming all U.S. citizens sought medical care once annually. Even if it's assumed that only 10 percent of U.S. citizens would seek medical care once a year, 30,000 mismatches would occur every year.

Recommendation

To eliminate chances for mistakes in matching patients to records, we continue to strongly recommend the development and widespread use of a national patient identifier.

F. Impact analysis

[This section comments on Section V of the NPRM.]

The impact analysis in the NPRM seriously underestimates the total cost of ownership for these systems and overstates the amount of incentive payments that will be paid if the proposed rules are implemented without modification.

Acquisition of software licenses is just one part of the total cost of implementing systems. In our experience, other implementation costs and ongoing expenses that are essential to system implementation over the first five years typically are at least six times the cost of acquiring

the software license from a vendor. Additional costs include internal and external resources, most commonly vendor support and hiring dozens of consultants to help an organization successfully implement the application.

The cost impact also will be significant for physician practices, where implementation of electronic health records systems significantly disrupt workflow and the speed with which they work during the early stages of the learning curve. Literature has indicated that physician practices see a 20 percent decline in their revenue streams during the early stages of adoption, a hit to income that is not factored into the estimated cost of implementing systems.

Also in terms of costs, healthcare organizations will be paying a premium to retain services from consultants who have experience with implementing electronic health records systems, because there is a shortage of such highly specialized professionals. In the last month, we've noted instances where costs for future consulting services have risen by more than 50 percent, and timelines already are being extended for implementation by vendors and consultants.

Recommendation

We recommend that the estimates for EMR acquisition and ongoing expenses be modified. We further recommend that the rules make allowances for the fact that the speed of spend on releasing stimulus funds is likely to be slower than anticipated because of the delays in certified systems becoming available and the time needed by healthcare providers to implement them to become meaningful users.

G. Miscellaneous concerns

1. Privacy and security [Section II.A. of the NPRM]

Privacy and security provisions are mandated through the HIPAA regulations, which are overseen and enforced by the Office of Civil Rights (OCR). We applaud CMS for making the decision to remove the requirement for privacy and security compliance from the Meaningful Use measures, leaving HIPAA penalties and enforcement in the hands of OCR.

2. Support for federal grant programs.

The creation of Regional Extension Centers is appreciated, and required to help support IT rollouts by healthcare organizations. However, this represents more of a long-term solution rather than an immediate fix for support needs, which will be acute over the next 18 months. The reality is that it will take many months to adequately train a workforce to support these centers; indeed, funding for these extension centers was just announced on February 12, 2010. Much more needs to be done before these centers are ready to have an impact on healthcare IT rollouts in provider settings. An extension of the deadlines for the creation of these Centers and a continued commitment to support them is recommended.

3. Medicaid EHR incentive programs [Section II.A.b. and Section II.D. of the NPRM.]

We are concerned over the Medicaid incentive portion of the program and the implied ability for states to add requirements or meaningful use objectives or have alternate reporting means. For the purpose of the stimulus incentive, we ask that states not be allowed to add to the criteria or metrics. State and national metrics should be reported the same way through the same means. Providers should only have to prove that they are meaningful users of electronic health records once, not twice for widely varying standards adopted by the federal government in addition to their state's Medicaid program. Lack of harmonization would be especially challenging for organizations that have hospitals in more than one state.

4. Use of Standards [Section II.A. of the NPRM.]

The proposed regulations assume a high degree of industry readiness to adopt standards that will undergird EHR applications to enable the exchange of clinical information. However, many of the standards suggested for use with healthcare clinical systems are relatively new; a survey of CHIME members released in December 2009 found that a majority of respondents said the standards were not in use at their facilities, nor were the standards incorporated into their vendors' products. The survey also found that, to varying degrees, members were relatively unfamiliar with the standards they would be required to use. We appreciate that CMS limited its requirements for use of standards in the early years of meaningful use.

Recommendation

We recommend that timelines for adopting these standards into EHR products be carefully calibrated to give providers and vendors time to implement solutions that use them and test interoperability.

5. Medicare Advantage plans [Section II.C. of the NPRM.]

A substantial percentage of our senior citizens receive their care from Eligible Professionals providing services by way of Medicare Advantage plans. Current proposed rules provide incentive payment only to EPs in whose practices 80 percent or more of total services are to Medicare Advantage patients. This would exclude many EPs treating our most vulnerable citizens from the opportunity to meaningfully adopt EHRs in their practices.

Recommendation

The 80 percent practice requirement should be eliminated.

III. Additional Recommendation

Recommendation on the creation of a Technical Expert Industry Panel

We recommend that CMS establish a Technical Expert Industry Panel with significant representation from a variety of hospitals and eligible professionals at various stages of implementation. The Technical Expert Industry Panel would provide input on the challenges and opportunities associated with achieving meaningful use objectives, with attention to technological advances and the growth of regional exchanges. The Panel may also continue to serve in an advisory capacity to CMS on other matters related to the adoption of

technologies to improve outcomes and reduce costs. CHIME members have tremendous operational experience that could prove invaluable to CMS. CHIME would be pleased to recommend experts for the Panel and serve as a resource to CMS.

Closing

In closing, we reiterate our support for the deployment of EHR systems. We are grateful to participate in activities that can facilitate needed improvements in healthcare quality and efficiency, patient engagement, and the public health. As those with leadership roles during this promising transformation of information systems, we take this challenge very seriously and plan to work tirelessly to achieve our collective vision. To borrow a phrase from our physician partners, it is our duty to ensure that we do no harm by rushing installations of advanced clinical systems. We believe that the most effective EHR incentive program will create the opportunity for and encourage all healthcare institutions and professionals – not just those on the leading edge or those with sufficient access to capital – to benefit from the stimulus funds.

If you have questions on any of these comments or need more information, please contact Sharon Canner at scanner@cio-chime.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Correll', with a long horizontal flourish extending to the right.

Richard A. Correll, President & CEO

Table 1: Alternative Framework of Hospital Meaningful Use Objectives Over Time

2011/2012 Meet 25% (8) of:^{a,b}	2013/2014 Meet 50% (17) of:^a	2015/2016 Meet 75% (24) of:^a	2017 Meet substantially all of:^a
<ol style="list-style-type: none"> 1. CPOE (10% or more) 2. Drug-drug/drug-allergy checks 3. Drug-formulary checks 4. Structured problem list 5. Structured medication list 6. Structured medication allergy list 7. Record demographics 8. Record vital signs 9. Record smoking status 10. Incorporate structured clinical-lab data (50%) 11. Patient lists by condition 12. 5 clinical decision support rules 13. Electronic copy of health information to patients on request 14. Electronic copy of discharge instructions and procedures at discharge, upon request 15. Exchange key clinical information 16. Summary care record 17. Immunization registries (capability) 18. Reportable lab results (capability) 19. Syndromic surveillance data 	<ol style="list-style-type: none"> 1. CPOE (10% or more) 2. Drug-drug/drug-allergy checks 3. Drug-formulary checks 4. Structured problem list 5. Structured medication list 6. Structured medication allergy list 7. Record demographics 8. Record vital signs 9. Record smoking status 10. Incorporate structured clinical-lab data (50%) 11. Patient lists by condition 12. 5 clinical decision support rules 13. Electronic copy of health information to patients on request 14. Electronic copy of discharge instructions and procedures at discharge, upon request 15. Exchange key clinical information 16. Summary care record 17. Immunization registries (capability) 18. Reportable lab results (capability) 19. Syndromic surveillance data 	<ol style="list-style-type: none"> 1. CPOE (50% or more) 2. Drug-drug/drug-allergy checks 3. Drug-formulary checks 4. Structured problem list 5. Structured medication list 6. Structured medication allergy list 7. Record demographics 8. Record vital signs 9. Record smoking status 10. Incorporate structured clinical-lab data (75%) 11. Patient lists by condition 12. 25 clinical decision support rules 13. Electronic copy of health information to patients on request (CCD) 14. Electronic copy of discharge instructions and procedures at discharge, upon request 15. Exchange key clinical information (CCD) 16. Summary care record 17. Immunization registries (submit data if possible) 18. Reportable lab results (submit data if possible) 19. Syndromic surveillance data 	<ol style="list-style-type: none"> 1. CPOE (substantially all) 2. Drug-drug/drug-allergy checks 3. Drug-formulary checks 4. Structured problem list 5. Structured medication list 6. Structured medication allergy list 7. Record demographics 8. Record vital signs 9. Record smoking status 10. Incorporate structured clinical-lab data (subst. all) 11. Patient lists by condition 12. 25 clinical decision support rules 13. Electronic copy of health information to patients on request (CCD) 14. Electronic copy of discharge instructions and procedures at discharge, upon request 15. Exchange key clinical information (CCD) 16. Summary care record 17. Immunization registries (submit data if possible) 18. Reportable lab results (submit data if possible) 19. Syndromic surveillance data

Table 1: Alternative Framework of Hospital Meaningful Use Objectives Over Time

2011/2012 Meet 25% (8) of:^{a,b}	2013/2014 Meet 50% (17) of:^a	2015/2016 Meet 75% (24) of:^a	2017 Meet substantially all of:^a
<p>(capability)</p> <p>20. Security protections</p> <p>21. <i>Use of evidence-based order sets (1 department)</i></p> <p>22. <i>Electronic medication administration record (eMAR) (1 department)</i></p> <p>23. <i>Bedside medication administration support (barcode/RFID) (1 department)</i></p> <p>24. <i>Record nursing assessment in EHR (1 department)</i></p> <p>25. <i>Record nursing plan of care in EHR (1 department)</i></p> <p>26. <i>Record physician assessment in EHR (1 department)</i></p> <p>27. <i>Record physician notes in EHR (1 department)</i></p> <p>28. <i>Multimedia/Imaging integration (e.g., X-Ray viewing)</i></p> <p>29. <i>Generate permissible discharge prescriptions electronically</i></p> <p>30. <i>Contribute data to a PHR</i></p> <p>31. <i>Record patient preferences (language, etc.)</i></p> <p>32. <i>Provide electronic access to patient-specific educational resources</i></p>	<p>(capability)</p> <p>20. Security protections</p> <p>21. <i>Use of evidence-based order sets (3 departments)</i></p> <p>22. <i>Electronic medication administration record (eMAR) (3 departments)</i></p> <p>23. <i>Bedside medication administration support (barcode/RFID) (3 departments)</i></p> <p>24. <i>Record nursing assessment in EHR (3 departments)</i></p> <p>25. <i>Record nursing plan of care in EHR (3 departments)</i></p> <p>26. <i>Record physician assessment in EHR (3 departments)</i></p> <p>27. <i>Record physician notes in EHR (3 departments)</i></p> <p>28. <i>Multimedia/imaging integration (e.g., X-Ray viewing)</i></p> <p>29. <i>Generate permissible discharge prescriptions electronically</i></p> <p>30. <i>Contribute data to a PHR</i></p> <p>31. <i>Record patient preferences (language, etc.)</i></p> <p>32. <i>Provide electronic access to patient-specific educational resources</i></p>	<p>(submit data if possible)</p> <p>20. Security protections</p> <p>21. <i>Use of evidence-based order sets (5 departments)</i></p> <p>22. <i>Electronic medication administration record (eMAR) (5 departments)</i></p> <p>23. <i>Bedside medication administration support (barcode/RFID) (5 departments)</i></p> <p>24. <i>Record nursing assessment in EHR (5 departments)</i></p> <p>25. <i>Record nursing plan of care in EHR (5 departments)</i></p> <p>26. <i>Record physician assessment in EHR (5 departments)</i></p> <p>27. <i>Record physician notes in EHR (5 departments)</i></p> <p>28. <i>Multimedia/imaging integration (e.g., X-Ray viewing)</i></p> <p>29. <i>Generate and transmit permissible discharge prescriptions electronically</i></p> <p>30. <i>Contribute data to a PHR</i></p> <p>31. <i>Provide electronic access to patient-specific educational resources</i></p> <p>32. <i>Record patient preferences (language, etc.)</i></p>	<p>(submit data if possible)</p> <p>20. Security protections</p> <p>21. <i>Use of evidence-based order sets (substantially all dept)</i></p> <p>22. <i>Electronic medication administration record (eMAR) (substantially all dept)</i></p> <p>23. <i>Bedside medication administration support (barcode/RFID) (substantially all dept)</i></p> <p>24. <i>Record nursing assessment in EHR (substantially all departments)</i></p> <p>25. <i>Record nursing plan of care in EHR (substantially all departments)</i></p> <p>26. <i>Record physician assessment in EHR (substantially all departments)</i></p> <p>27. <i>Record physician notes in EHR (substantially all departments)</i></p> <p>28. <i>Multimedia/imaging integration (e.g., X-Ray viewing)</i></p> <p>29. <i>Generate and transmit permissible discharge prescriptions electronically</i></p> <p>30. <i>Contribute data to a PHR</i></p> <p>31. <i>Provide electronic access to patient-specific educational resources</i></p>

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2011/2012 Meet 25% (8) of:^{a,b}	2013/2014 Meet 50% (17) of:^a	2015/2016 Meet 75% (24) of:^a	2017 Meet substantially all of:^a
33. Medication reconciliation within hospital 34. Quality reporting through RHQDAPU	33. Medication reconciliation across settings of care (pilot) 34. Reporting of some RHQDAPU measures through EHR	33. Medication reconciliation across settings of care (if possible) 34. Reporting of some RHQDAPU measures through EHR	resources 32. Record patient preferences (language, etc.) 33. Medication reconciliation across settings of care 34. Reporting of RHQDAPU measures through EHR

Notes:

- a. *Italicized* objectives are from HIT PC recommendations for 2013 and 2015 (with exception of measure 34 on quality reporting)
- b. **BOLD** objectives would be required in 2011/2012. Required objectives for future years would be decided through annual rule-making.

Table 2: Detailed Comments on Proposed Stage 1 Objectives and Measures of Meaningful Use for Eligible Hospitals

Proposed Objective	Proposed Measure	Clarifying Comments	Recommendation
<p>1. Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)</p>	<p>1. For eligible hospitals, CPOE is used for 10% of all orders</p>	<ul style="list-style-type: none"> • Need definition of denominator – what is included in orders of “any type”? ONC IFR lists 11 types. • As currently specified, the denominator combines paper and electronic processes. Measurement would require manual review of 100 percent of paper charts to count all orders and distinguish those placed through verbal/paper means from orders placed through CPOE. Efficient chart review for quality reporting takes approximately 20 minutes per chart, resulting in tremendous burden. A hospital with 15,000 discharges would spend 5,000 hours per year reviewing charts. • There are times when scribes are necessary and their use should be counted (such as during surgery or when an on-call physician places a verbal order to address an emergent problem). • Order sets should be “unpacked” to count individual orders • Orders placed in the ED for patients that are subsequently admitted should be included in the measure calculation. 	<ul style="list-style-type: none"> • Do NOT use a measure with a denominator that requires review of paper charts. • Replace the proposed measure with one of the following alternatives: • Hospital has CPOE activated (preferred) • At least 10% of unique patients have had at least one order placed through CPOE • At least 10% of medication orders placed through CPOE (can be calculated from pharmacy information system) • If option 2 or 3 is chosen, require measure calculation as part of EHR certification process

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2. Implement drug-drug, drug-allergy, drug-formulary checks	2. The eligible hospital has enabled this functionality	<ul style="list-style-type: none"> • This measure combines two clinical alerts with an efficiency alert. We recommend separating them. • Drug-drug and drug-allergy checks happen in both pharmacy information systems and as part of CPOE. Both approaches contribute significantly to medication safety. • For inpatient settings, the drug-formulary check is generally defined as checking against the hospital's formulary, not external insurer formularies. 	<p>Create two measures:</p> <ul style="list-style-type: none"> • Hospital has implemented drug-drug and drug-allergy checks (clinical) • Hospital has implemented drug-formulary checks (efficiency)
3. Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT [®]	3. At least 80% of all unique patients seen admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data	<ul style="list-style-type: none"> • Currently installed EHRs generally use text or proprietary coding today, so there will be an adjustment process. Physician-facing screens will likely continue to be in more "accessible" language than structured codesets, with mapping to standards. Mapping systems must be built and deployed. During transitions, mapping to ICD-9 may happen at the end of a stay. • The HIPAA transactions standards require a move to ICD-10-CM in 2013. The measure should be updated over time to harmonize with this change. 	<ul style="list-style-type: none"> • Require measure calculation as part of EHR certification process

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4. Maintain active medication list	4. At least 80% of all unique patients admitted to the eligible hospital have at least one entry (or an indication of “none” if the patient is not currently prescribed any medication) recorded as structured data	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • Require measure calculation as part of EHR certification process
5. Maintain active medication allergy list	5. At least 80% of all unique patients admitted to the eligible hospital have at least one entry or (an indication of “none” if the patient has no medication allergies) recorded as structured data	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • Require measure calculation as part of EHR certification process
6. Record demographics: <ul style="list-style-type: none"> • preferred language • insurance type • gender • race • ethnicity • date of birth • date and cause of death in the event of mortality 	6. At least 80% of all unique patients admitted to the eligible hospital have demographics recorded as structured data	<ul style="list-style-type: none"> • All fields may not be complete for all patients. For instance, some patients may not be willing to report race and ethnicity. Insisting that this data be provided could interfere with care delivery process. Therefore, missing data in two or three of the 7 fields should not disqualify a record from counting toward the numerator. • In Massachusetts, field experience with reporting race and ethnicity according to specific standards (such as OMB definitions) found that significant training across many different staff members is required to achieve 	<ul style="list-style-type: none"> • Require measure calculation as part of EHR certification process • Allow records with two to three missing fields to count toward the numerator • Remove cause of death

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		<p>uniformity. While clearly important for evaluating and addressing disparities in care, the time and resources required to achieve uniform recording of race and ethnicity data should not be underestimated.</p> <ul style="list-style-type: none"> • Cause of death is determined by the coroner and is not generally available to the hospital at the time of death. Considerable coordination with coroner is required to obtain this data and timely receipt may be beyond the hospital's control. • Date of death is known only when the death occurs at the reporting hospital. 	
<p>7. Record and chart changes in vital signs:</p> <ul style="list-style-type: none"> • height • weight • blood pressure • Calculate and display: BMI • Plot and display growth charts for children 2-20 years, including BMI. 	<p>7. For at least 80% of all unique patients age 2 and over admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2-20</p>	<ul style="list-style-type: none"> • General acute care inpatient setting not appropriate for plotting growth charts, and most children are admitted infrequently, so no trend data are available. Growth chart is useful in children's hospitals. • Patients admitted to the hospital are not necessarily routinely measured for height. Including this measure would change the requirements for nursing assessments. If maintained as a vital sign for inpatient care, estimated or reported height may be recorded. • Other vital signs are more appropriate to the inpatient setting, such as temperature, blood oxygen levels, heart rate, and glucose levels. EHRs should be capable of showing trend for these values (hourly to daily). • As currently specified, this is a test of 3 	<ul style="list-style-type: none"> • Remove growth charts for children for general hospitals. Add temperature, blood oxygen levels, heart rate, and glucose levels, with capacity to trend values • Allow records missing two or three of the bundled fields and processes to be included in the numerator. • Require measure

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		<p>measurements being taken, 2 calculations being performed, and two displays viewed. Not all fields may be complete for all patients. Missing two or three of these steps should not disqualify a patient from the numerator.</p> <ul style="list-style-type: none"> Do EHRs provide tag that calculations have been performed and displays viewed? 	<p>calculation as part of EHR certification process, including tags that indicate when BMI calculation has been performed and plot has been displayed.</p>
8. Record smoking status for patients 13 years old or older	8. At least 80% of all unique patients 13 years old or older seen admitted to the eligible hospital have "smoking status" recorded	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> Require measure calculation as part of EHR certification process
9. Incorporate clinical lab-test results into EHR as structured data	9. At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data	<ul style="list-style-type: none"> This measure is poorly specified. Requires specific definitions of tests that are positive/negative and in numeric format. Automated measurement would require flags in EHR for when a result is in positive/negative or numerical form. Very challenging to calculate. Unless limited to tests in the EHR, would require looking across electronic and paper processes. ONC IFR specified LOINC codes, which CHIME survey data indicates is used by 40.5 percent of its members' institutions. 	<ul style="list-style-type: none"> Revise objective to read: At least 50 percent of all clinical lab tests incorporated into the EHR whose results are in a positive/negative or numerical format are incorporated into certified EHR technology as structured data Require measure calculation as part of EHR certification process

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10. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	10. Generate at least one report listing patients of the eligible hospital with a specific condition.	<ul style="list-style-type: none"> In the hospital setting, analysis of patient data often drives off of post-discharge coding of diagnoses and procedures, rather than problem lists. 	
11. Report hospital quality measures to CMS or the States	<p>11. For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of the proposed rule</p> <p>For 2012, electronically submit the measures as discussed in section II(A)(3) of the proposed rule</p>	<ul style="list-style-type: none"> Many concerns, addressed separately 	<ul style="list-style-type: none"> Multiple, addressed separately
12. Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules	12. Implement 5 clinical decision support rules relevant to the clinical quality metrics the eligible hospital is responsible for as described further in section II(A)(3) of the proposed rule.	<ul style="list-style-type: none"> The medication alert measures are also clinical decisions support rules. Use of order-sets is a form of clinical decision support. Tracking compliance can be challenging, as specific clinical scenarios warrant different responses. For instance, patients in an intensive care unit may receive combinations and doses of medications that would be inappropriate in other departments. Hospitals sometimes implement rules that cannot be over-ridden, so that there is no measure of compliance (clinician has not made an accept/over-ride choice). 	

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13. Check insurance eligibility electronically from public and private payers	13. Insurance eligibility checked electronically for at least 80% of all unique patients admitted to the eligible hospital	<ul style="list-style-type: none"> • Billing systems are not generally part of the hospital EHR system, although they are almost always integrated. • Covered under HIPAA administrative simplification regulations • Major concern that if this is maintained, will require these systems to be certified, which is unnecessary and wasteful 	<ul style="list-style-type: none"> • Remove this objective and measure.
14. Submit claims electronically to public and private payers.	14. At least 80% of all claims filed electronically by the eligible hospital	<ul style="list-style-type: none"> • Billing systems are not generally part of the hospital EHR system, although they are almost always integrated. • Covered under HIPAA administrative simplification regulations • Major concern that if this is maintained, will require these systems to be certified, which is unnecessary and wasteful 	<ul style="list-style-type: none"> • Remove this objective and measure.
15. Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request	15. At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours	<ul style="list-style-type: none"> • Requires separate tracking of who requests copy and when (date stamp) • Use of portable media such as USB presents security problems for the hospital (both security of PHI on the portable media and security of the hospital's IT systems when portable media are introduced). • Use of structured data for this purpose (such as CCD) will be valuable in the future, but not possible for most providers in the near term. • To ensure patients can read the information without needing special software, most likely format in near term is a PDF of electronic/scanned chart. The time period 	<ul style="list-style-type: none"> • Require measure calculation as part of EHR certification process • Revise to be electronic copy of health information "maintained in electronic form" (rationale: consistent with ARRA privacy provision) • Drop the time requirement in favor

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		(48 hours) is too short and more proscriptive than HIPAA requirements. Clinicians must review information and ensure that they have received all test results and discussed sensitive results with the patient before release, per CLIA and state laws. Staff must be available to receive and fulfill requests, and required workforce may not be available on weekends and holidays.	of existing HIPAA policies on providing patients with copies of medical records.
16. Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request	16. At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it	<ul style="list-style-type: none"> • Requires separate tracking of who requests copy and when (date stamp); such tracking is not currently part of EHR systems • Use of portable media such as USB presents security problems for hospitals (both security of PHI on the portable media and security of the hospital's IS systems when portable media are introduced) • Formats likely to include pdf and Word documents 	<ul style="list-style-type: none"> • Require measure calculation as part of EHR certification process
17. Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	17. Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information	<ul style="list-style-type: none"> • Specificity? Does this need to be a "live" test? • The definition of "key clinical information" should be expanded to include test results and dictated documents (H&P, operative report, diagnostic report, etc.), which are the most in demand by physicians. • The test should involve the specific subset of key clinical information that is most appropriate to meet current local needs and HIE infrastructure (for example, in the context of a local HIE, a collaboration with local 	<ul style="list-style-type: none"> • Require providers to perform this test only for the subset of clinical information that is most appropriate to meet current local needs and HIE infrastructure, not all listed clinical information.

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		ambulatory physician groups, or a pilot to provide data to long-term care facilities).	
<p>18. Perform medication reconciliation at relevant encounters and each transition of care</p> <p>Medication reconciliation = the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider.</p> <p>Transition of care = transfer of a patient from one clinical setting (inpatient, outpatient, physician office, home health, rehab, long-term care facility, etc.) to another or from one EP or eligible hospital (as</p>	<p>18. Perform medication reconciliation for at least 80% of relevant encounters and transitions of care</p> <p>The numerator for this objective is the number of relevant encounters and transitions of care for which the EP or an inpatient facility/department (POS21) that falls under the eligible hospital's CCN was a participant during the EHR reporting period where medication reconciliation was performed. The denominator for this</p>	<ul style="list-style-type: none"> • The proposed definition does not match current hospital medication reconciliation processes. • Medication reconciliation is not an automated EHR process. It is a human workflow process that is supported by the EHR. • Availability of a single medication list in the EHR that is available to all clinicians at the point of care makes medication reconciliation within the institution unnecessary. • The term “transitions of care” includes an array of transfers across the continuum of care that are not currently supported by information exchange among providers. Consequently, medication reconciliation as defined is not possible. Med rec across settings (hospital to LTC or hospital to physician office, etc) not possible given current levels of information exchange • Calculation of this measure across all admissions would be overly burdensome to 	<ul style="list-style-type: none"> • Measures on medication reconciliation should be limited to appropriate transfer points internal to hospital, such as ED to ICU, ICU to general med/surg unit, etc. (including on admission and discharge) • Recommended alternative measure: Hospital is using EHR to support medication reconciliation • If a percentage measure is included, a sampling

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<p>defined by CCN) to another.</p> <p>Relevant encounter = any encounter that the EP or eligible hospital judges performs a medication reconciliation due to new medication or long gaps in time between patient encounters or other reasons determined by the EP or eligible hospital.</p> <p>We encourage comments on whether our descriptions of ‘transition of care’ and ‘relevant encounter’ are sufficiently clear and medically relevant.</p>	<p>objective is the number of relevant encounters and transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital’s CCN was a participant during the EHR reporting period.</p>	<p>report. Inclusion of ED in measurement is important as many patients enter hospital via ED and first discuss current medications in that setting.</p> <ul style="list-style-type: none"> • Electronic med rec tools in use today do not generally include a flag or other measure to indicate that med rec was done or done accurately, so not currently easy to calculate. • The Joint Commission is currently revising its National Patient Safety Goal on medication reconciliation. CMS should not attempt to define medication reconciliation processes and requirements separately and differently from The Joint Commission. Doing so will cause confusion and could actually slow efforts to build and spread best practice models of medication reconciliation. 	<p>methodology should be developed to reduce reporting burden.</p> <ul style="list-style-type: none"> • If a percentage measure is included, require measure calculation as part of EHR certification process
<p>19. Provide summary care record for each transition of care and referral</p> <p>Transition of care = transfer of a patient from one clinical setting (inpatient, outpatient, physician office, home health, rehab, long-term care facility, etc.) to another or from one EP or eligible hospital (as defined by CCN) to another.</p> <p>Referral is not defined.</p>	<p>19. Provide summary of care record for at least 80% of transitions of care and referrals</p> <p>The numerator for this objective is the number of transitions of care and referrals for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital’s CCN was</p>	<ul style="list-style-type: none"> • How does this measure relate to the inpatient setting? How is transition of care different from discharge? Would discharge instructions and summary care record both be required when a patient leaves the hospital? • What is a referral in context of an inpatient stay? Would specialty consult during a stay require provision of a summary care record? For referrals post-discharge, it is unclear how hospital could do this before a patient has a visit scheduled or even has selected a specific provider selected from a short list of referrals. • Who does the summary care record go to? The patient or the next provider to care for the 	<ul style="list-style-type: none"> • The concept behind this measure and its measurement must be clarified, particularly in the context of inpatient care. If something other than discharge is intended, require provision of summary care record on request only • Require measure calculation as part of

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	<p>the transferring or referring provider during the EHR reporting period where a summary of care record was provided. The summary of care record can be provided through an electronic exchange, accessed through a secure portal, secure e-mail, electronic media such as CD or USB fob, or printed copy.</p> <p>The denominator for this objective is the number of transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was the transferring or referring provider during the EHR reporting period.</p>	<p>patient?</p> <ul style="list-style-type: none"> • How do you count transitions of care and referrals? • Use of portable media such as USB presents security problems for the hospital (both security of PHI on the portable media and security of the hospital's IS systems) • Use of structured data for this purpose (such as CCD) will be valuable in the future, but not possible for most providers in the near term. 	<p>EHR certification process?</p>

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20. Capability to submit electronic data to immunization registries and actual submission where required and accepted	20. Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries	<ul style="list-style-type: none"> • Does this need to be a “live” test? • Who decides when actual submission is required and accepted? 	
21. Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received	21. Performed at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically)	<ul style="list-style-type: none"> • Does this need to be a “live” test? • Who decides when actual submission is required and accepted? 	

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22. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	22. Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an eligible hospital submits such information have the capacity to receive the information electronically)	<ul style="list-style-type: none"> • Does this need to be a “live” test? • Who decides when actual submission is required and accepted? • Public health departments at local, state and national levels must move toward standard data elements, formats, and information exchange protocols. Hospitals currently submitting electronic data to public health are overwhelmed by overlapping and conflicting requests from multiple agencies, resulting in significant burden. For instance, some syndromic surveillance systems rely on demographic and limited symptom data, while other systems want real time lab and pharmacy feeds. 	<ul style="list-style-type: none"> • Require test for submission to a single public health agency only • Require actual submission of only demographic information and key lab findings.
23. Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	23. Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary		