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March 15, 2010

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attn: CMS-0033-P
7500 Social Security Blvd
Baltimore, MD 21244-1850

Re: *CMS-0033-P, Medicare & Medicaid Programs: Electronic Health Record Initiative Program; Proposed Rule (Vol 75, No.98), January 13, 2010*

Trinity Health appreciates the opportunity to comment on the Notice of Proposed Rule Making (NPRM) titled "*Medicare and Medicaid Programs; Electronic Health Record (EHR) Incentive Program,*" published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on January 13, 2010 [CMS-0033-P]. In this letter, we will identify four critical success factors in implementing EHRs across a system and highlight recommendations for improving the Meaningful Use regulation.

Trinity Health is the fourth-largest Catholic health care system in the country. Headquartered in Novi, Mich. Trinity Health operates 44 acute-care hospitals, 379 outpatient facilities, 33 long-term care facilities, and numerous home health offices and hospice programs in eight states – California, Idaho, Indiana, Iowa, Maryland, Michigan, Nebraska, Ohio. Our hospitals and clinics employ nearly 1,000 physicians, and we work with another 7,000 physicians through our open medical staff model.

Trinity Health hospitals are very appreciative of the opportunity presented by the EHR incentive program established by the HITECH Act, which was part of the American Recovery and Reinvestment Act of 2009 or ARRA. We agree with the vision that widespread use of interoperable EHRs supports improved clinical care, better coordination of care, more informed and engaged patients and improved public health. Trinity Health also appreciates – and shares – the goals that CMS is working to achieve: motivating hospitals and physicians to move further and faster in using EHRs to improve all aspects of health care, while facilitating the flow of EHRs incentive funds in a responsible and appropriate manner that fosters continued and timely advancements in health information technology (HIT).

In fact, our journey to use EHRs to deliver better and more efficient care began nearly a decade ago. Trinity Health has deployed one of the nation's most advanced Electronic Health Record (EHR) systems among community hospital systems, which is where the vast majority of Americans receive their care. Extensive use of HIT helped Trinity Health become one of the top 10 hospitals for clinical performance, as recognized in 2009 by the Thomson Reuters' 100 Top Hospitals: Health Systems Quality/Efficiency Study.

Trinity Health has already made strategic investments exceeding \$400 million to connect 25 community hospitals with an integrated HIT platform, including a common EHR, and clinical

support tools – and will be bringing our other owned hospitals “on line” during the next two years. During peak hours, more than 1,200 clinicians and staff in the Trinity Health system simultaneously use the Cerner Millennium(R) healthcare computing platform to electronically manage medication administration, to provide clinicians with access to evidence-based clinical data and to identify opportunities for clinical, operational, financial and regulatory improvement. Each day, more than 600,000 orders transactions are managed in our system including order entry and processing. Trinity Health’s EHR contains more than 7.4 million patient records, making it one of the largest comprehensive EHRs based data repositories in the United States.

Speaking from the perspective of a health system that has spent nearly a decade working on EHR implementations, we have some general recommendations for your consideration. And, beyond these recommendations we would like to offer our support and assistance in helping CMS/HHS drive more clarity into Meaningful Use and broader HIT policy. Trinity Health has a long history of working collaboratively with policy makers, including the Agency for Health Research and Quality (AHRQ), to leverage our learnings into better health policy for the entire nation. In summary, we have learned that to optimize the use of EHRs to improve the quality and efficiency of care delivery we should:

1. Anticipate and allow for decrease in short-term productivity that will accompany an EHR implementation;
2. Encourage simplicity and usability in the meaningful use measures and certification standards;
3. Consider the challenges of the open medical staff model used in most communities to care for the vast majority of patients in America, and
4. Provide effective communication tools and other support mechanisms to hospitals and physicians to advance adoption.

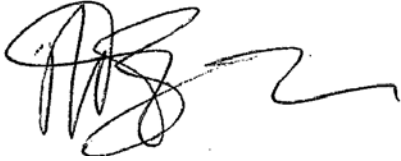
Overall, **Trinity Health supports the concepts of meaningful use for hospitals and eligible providers.** However, we have some specific recommendations that we believe would improve the regulation. We have organized our key concerns and recommendations into the following broad topical areas with more specific commentary provided in the respective sections:

- I. Modify the NPRM language on objectives and measures for meaningful use for hospitals to:
 - A. **Accept the HIT Policy Committee (HITPC) recommendations** from February 17, 2010, in particular **as it pertains to the flexibility in the “all-or-nothing” approach** to earning meaningful use incentives
 - B. **Advance EHR adoption that achieves meaningful use in a community hospital setting with open medical staff models using certain criteria changes.**
 - C. See other detailed recommendations provided in attached letter.
- II. Modify the NPRM language on objectives and measures for meaningful use for eligible providers to simplify the language in the rule in order to reduce the burden of private physician practices in meeting the measures (see detailed recommendations provided in attached letter).
- III. **Consider the impact and provide clarity on** following areas of the *“Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Interim Final Rule (IFR)”* and how it pertains to **hospitals and eligible providers achieving meaningful use:**
 - A. **Define the way that certification criteria for vendors will be applied when users make modifications to certified EHRs to address limitations or incomplete functionality.**
 - B. Clarify how the security capabilities required of vendors may affect future meaningful use measures, recognizing the significant changes required by the IFR.

- IV. Define a hospital-based eligible professional more narrowly to exclude physicians practicing in outpatient centers and clinics.
- V. Refine language to ensure that each hospital within a system with a single CMS certification number is evaluated for eligibility for incentive payments.
- VI. Other matters

Trinity Health would like to help our nation move toward an e-enabled health care system where all hospitals and physicians use EHRs to improve patient care and safety, ultimately improving health and reducing cost. We support the goals of Meaningful Use and we are ready, willing and able to help CMS/HHS formulate the best possible policy by providing our expertise through advisory roles or other capacities. We believe our perspective as an early adopter and advanced user of EHRs in a community setting is particularly relevant as this is the setting where the vast majority of Americans are treated. We believe the suggestions made in our comment letter advance the regulations toward the goals of the ARRA legislation. We urge you to accept our recommendations and include them in the final rule.

Sincerely,



Paul Browne
Senior Vice President and CIO

I. RECOMMENDATIONS ON OBJECTIVES AND MEASURES FOR MEANINGFUL USE FOR HOSPITALS

A. We recommend that you accept the HIT Policy Committee (HITPC) recommendations from February 17, 2010.

In particular, we strongly encourage you to follow their suggestions as it pertains to the flexibility in the “all-or-nothing” approach to earning meaningful use incentives. We believe that allowing facilities to defer a certain number of measures is the right approach. Trinity Health is an early adopter of technology but has not fully implemented the breadth of technologies required to meet meaningful use. It will take several years and substantial investment to meet these fully even with an already fully implemented EMR.

We recommend the removal of core measures beyond the recommendations of the HITPC. The NPRM lists 34 distinct quality of care measures that require the collection of 97 data elements. Successful automation of these measures depends on fully integrated Surgical, Emergency Department, Inpatient, and Cardiology systems that are a substantial high bar for any single vendor system. Alternatively hospitals and practices can achieve the performance in these measures by building complex interfaces or through manual abstraction. For example, we have yet to find a cardiology vendor that can send data elements required for cardiology measures. In order to report them we would be required to do 100% manual abstraction and duplication of documentation. This is not an efficient use of hospital resources and does not improve care. Quality measure reporting should be deferred until 2013 when these data elements can be better understood and specialty systems can be integrated with the primary hospital EMR.

B. We recommend that you advance EHR adoption that achieves meaningful use in a community hospital setting with open medical staff models using certain criteria changes.

Trinity Health is a national organization with inpatient facilities in 40 different communities. Our medical staff is nearly 90% voluntary. This means that our physicians are independent practitioners with an average 2-4 partners in each group. Moreover, this model of practice is the predominant model outside of academic facilities in the United States. These providers primarily manage outpatient practices and will practice in the inpatient setting when their private patients need hospital services. These practitioners are primarily concerned about the ease of practice and are infrequent users of an inpatient electronic medical record.

In order for hospitals to achieve meaningful use, there are substantial changes in the manner of ordering, documentation, and use of inpatient EMR's that requires intuitive user interfaces or a high learning curve and time investment. Unfortunately it appears that there is nothing available for us to incentivize our voluntary medical staff to comply with meaningful use criteria when they are practicing in the hospital setting. Most community based practices and voluntary medical staff do not feel compelled to participate in helping hospitals achieve meaningful use.

To encourage and incentivize our physician partners to participate with their hospitals, we recommend that eligible outpatient providers attest that they are meeting meaningful use

criteria in their office practice AND inpatient practice in 2011 in order to receive their respective incentives.

We agree that direct use of the EHR system by providers is important to achieving the highest level of care. However, we believe that many of our practitioners are achieving quality measures but are often documenting in a manner that does not provide discrete reportable data. We believe quality measure reviewers should be able to document and report this discrete data so long as they reference the primary source of the quality measure data in Stage 1. The final rules should state the acceptability of scribes and proxy reporting specifically. We should defer the direct physician documentation of discrete quality documentation until Stage 3.

C. We have the following specific recommendations listed below that pertain to Objectives and Measure for Meaningful Use for Hospitals

1. Drug Formulary Checking

The NPRM delineates a 2011 objective to implement drug formulary checks. In reviewing the rule, Trinity Health has identified two possible interpretations:

- a. Compare inpatient medications against the hospital negotiated formulary, OR
- b. Compare prescribed drugs versus the formulary requirements of the patient's payer

We recommend that you revise the rule to specify the hospital's standard formulary as the source for comparison (choice (a) as listed above) and remove the requirement that "checks" are performed. We recommend the rule should require hospitals to use formulary medications in a reliable fashion and set a target no greater than 70% through retrospective reporting and attestation.

Trinity Health has negotiated significant multi-million dollar annual cost savings by providing generic and discounted drugs in specific classes. We can influence ordering practice using preferential lists, order sets, and protocol-based substitutions. We believe that we already are providing our payers with substantial value by existing means. It is not necessary to apply active alerting mechanisms.

If the intention of the rule is to compare prescribed drugs versus the formulary requirements of the patient's payer (choice (b) from above), we have serious concerns about the future monopoly power of Surescripts, the only vendor that currently has this capability. Currently Surescripts charges \$2 per transaction when used within the hospital facility to compare prescribed drugs versus the formulary requirements of the patient's payer. Trinity Health would need to spend an additional \$1 million per year in fees to Surescripts if required to validate formulary requirements of the patient's payer.

In addition to the cost implications described above, we have concerns about current policies in place at Surescripts to restrict patient access to their data. We strongly discourage a meaningful use requirement that would force hospital-based providers, including Emergency Departments, to compare prescribed drugs versus the formulary requirements of the patient's payer thus supporting the monopoly provider of Surescripts.

If this interpretation is chosen and there will be a requirement for hospital-based providers to compare prescribed drugs versus the formulary requirements of the patient's payer, we

recommend that this requirement be deferred until 2013 and that HHS review the costs that are placed on inpatient facilities for this service.

We also think it is important that CMS is aware of and considers the implications of the weaknesses that exist currently in the payor systems. Our experience with such payor systems has shown them to be often incorrect with poor reliability on eligibility and drug formularies. Even if hospitals are able to do such checks, malfunction in the payor systems, will generate a poor and possibly unsafe result. Such a result does not advance the safety and efficiency of health care delivery for the patient.

2. Record demographics: preferred language, insurance type, gender, race, ethnicity, date of birth, date and cause of death in the event of mortality

Trinity Health supports the idea of collecting the variety of information (preferred language, race, ethnicity, etc) all of which help in developing a better understanding of the individuals we serve, which is an underlying principle of Trinity Health's mission.

Our recommendation is to include a minimum requirement that each health information system be able to have demographics recorded as structured data. These data elements would include preferred language, insurance type, gender, race, ethnicity and date of birth. We agree with the recommendations of the College of Healthcare Information Management Executives (CHIME) to eliminate the requirement to report date and cause of death.

Clarifying Comments:

- We understand the importance of capturing this important information and suggest that the proposed measure be re-evaluated to reflect the percentage of the data captured with the numerator being the number of data fields captured with the denominator reflective of the total number of data fields required to be captured. This may be more reflective of the providers' efforts rather than reporting based on the count of unique patients.
- All fields may not be complete for all patients, specifically patients unwilling to provide information such as race and ethnicity; providers should not be penalized for their inability to capture this data.

3. Incorporate clinical lab-test results

We recommend that you defer the structured data requirement for lab test results until HHS has provided 3rd party laboratory vendors certification requirements. As an alternative, we recommend the development of a staged, multi-year plan outlining requirements for reporting lab results via a standard (eg, LOINC, order id management, etc). At this juncture there are too many sources for storing lab results and any long intent to perform comparative effectiveness research would be hampered by the lack of standardization and would require significant data normalization.

4. Implement 5 clinical decision rules

Trinity Health strongly agrees with the requirement to implement 5 clinical decision rules. During the February 17th HIT Policy Commission meeting, there was a consideration to require (for Stage 1) at least one clinical decision rule to "address efficient diagnostic test ordering". In reviewing this language, several options surfaced:

- a. Selection based on price
- b. Selection based on extent of care previously provided
- c. Selection based on best practice guidelines used in the hospital

We recommend that you clarify the definition using a selection based on best practice guidelines used in the hospital. We recommend that you consider American College of Radiology diagnostic criteria.

However, we request that you defer this requirement until 2013.

5. Provide patients with electronic copy of health information

This objective for engaging patients and families presents the same challenges to Eligible Providers as to the hospital. The objective to provide patients and families with timely access to data creates several challenges to health care providers. The major concerns evolve around:

- a. The certification criteria to create an electronic copy of a patient's clinical information
- b. The measurement of progress based on the request being completed within 48 hours.

Trinity Health recommends that CMS defer this objective and develop a more specific approach to clearly define standards on the media and the format. The rationale is that the flexibility that is currently proposed in both the media type and the document format provide a wide range of variation and possibilities that the hospital would need to support. In addition, the electronic exchange of information opens a new element of risk regarding privacy. A more prescriptive approach would add clarity for hospital organizations as well as consistency as a consumer interacts with hospitals.

Trinity Health recommends that CMS defer the 48 hour time limit and provide a description regarding the 48 hour time frame to 7 calendar days. The rationale is that there are conditions (weekends, holidays, etc.) that make complying with the turnaround requirements problematic. Further clarification of the patient exchange would provide helpful guidance.

6. Provide patients with an electronic copy of discharge instructions

Trinity Health supports the transparency of providing patients with their discharge information. The lack of clarity and specificity is cause for concern regarding consistently meeting the objective and patients' expectations.

Recommendation: Defer the generation of electronic copy in Stage I and define specifically a limited set of options for hospitals to meet compliance. Guidelines should:

- Require measure calculation as part of EHR certification process.
- Specify time period health information must be available if providing on secure web site.
- Allow for the patient to patient to "opt in" or "out" and exclude these from measure calculation.

7. Check insurance eligibility electronically from public and private payers

Trinity Health agrees with the recommendations of the College of Healthcare Information Management Executives (CHiME) and the American Hospital Association (AHA) on this

measure. Trinity Health recommends removing this from the listing of HIT functionality measures due to the fact that they are currently covered within HIPAA regulations.

We also think it is important that CMS is aware of and considers the implications of the weaknesses that exist currently in the private payor systems. Our experience with such payor systems has shown them to be often incorrect on eligibility. Even if hospitals are able to do such checks, malfunction in the payor systems, will generate a poor and possibly unsafe result. Such result does not advance the safety and efficiency of health care delivery for the patient.

8. Submit claims electronically to public and private payers

Trinity Health agrees with the recommendations of the College of Healthcare Information Management Executives (CHIME) and the American Hospital Association (AHA) on this measure. Trinity Health recommends removing this from the listing of HIT functionality measures due to the fact that they are currently covered within HIPAA's regulations.

9. 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.

Trinity Health continues to be engaged with health information exchange activities that are underway in the 8 states where we practice. We are very aware of the complexity and the political implications for organizations participating in regional exchanges. While Trinity Health supports this objective, we lack the resources to implement EHRs in our physician's practices while simultaneously working on regional exchanges.

Trinity Health recommends that CMS defer exchange requirement until the EHR implementation is completed and a regional interoperable, secure health IT network has been established. The rationale is that the exchange structure is not in place today and significant efforts are required to successfully implement (EHR use, programming, testing, training and information exchange with external organizations).

Trinity Health recommends the following alternatives be considered as the regulations as written require more than most hospitals are going to be able to achieve:

- Phase in percentage requirements to allow for provider adoption of electronic exchange
- Providers will need to provide implementation education and on-going training support
- Structured CCD and management of HIE or EMPI is too much for 2011-2014.

10. Provide summary care record for each transition of care and referral

Trinity Health recommends that providers be allowed to implement release of information technology that supports publishing the summary and pertinent documents to a secure web-site or electronic drop box with the option of notifying provider access to unstructured printed electronic health record is available to be retrieved via e-mail or phone notification.

Trinity Health recommends the following alternatives be considered as the regulations as written require more than most hospitals are going to be able to achieve:

- Meet 25% in 2011/2012 period; meet 50% in 2013/2014 period; Meet 75% in 2015/2016 period and 100% in 2017 period
- 2011 - 2015 could be provided in unstructured PDF format via secure web-site with e-mail notification to provider.
- 2015 - 2017 would be provided through on-line electronic methods in structured format.

II. RECOMMENDATIONS ON OBJECTIVES AND MEASURES FOR MEANINGFUL USE FOR ELIGIBLE PROVIDERS

A. Use CPOE for all orders

The care goal to provide access to comprehensive patient health data is driven by CPOE for at least 80% of all orders. Trinity Health has identified several possibilities for interpreting the intended approach:

- a. All orders initiated in the physician office are captured in the eligible provider's EHR and transmitted to external entities, if necessary.
- b. All orders initiated in the physician office are captured in the eligible provider's EHR. If the patient needs to secure additional services, a paper requisition is printed

Trinity Health recommends that CMS clarify the eligible provider approach to solely capture orders in the EHR for at least 80% of all orders. The rationale for this focused action is to promote strong initial adoption of EHR within the office along with the work process changes that will be necessary. In addition, the physician office environment currently presents a large number of external contacts communicated via paper today and in which electronic interaction would be required with the proposed NPRM. The physician office span includes referrals to specialists, orders for lab work, orders for diagnostic testing, and consult follow up documents. The measurement goal also includes medication orders, which in many cases would need to be paper based on the capabilities of the targeted pharmacy. Adoption by eligible providers would be more likely to succeed with an incremental compliance percentage as well as "break-in" period for other points in the chain (pharmacies, patients, etc) modify approaches and processes.

B. Generate & transmit permissible Rx electronically

The health outcomes policy to improve quality, safety and efficiency calls out the generation and transmission of permissible prescriptions electronically for at least 75% of prescriptions generated. Trinity Health acknowledges the efficiencies that can be achieved with this objective. Several pragmatic concerns have been identified:

- a. Hand written scripts are requested by the patient or required by law
- b. Patient's pharmacy of choice does not handle electronic orders
- c. Prescription renewals should be included in the calculation explicitly.

Trinity Health recommends that the final rule provide clarification on identified circumstances described above and revise the measurement target in a staggered model over Stage I and Stage II. The rationale is that a high bar for electronic submission is not achievable due to a lack of standards, requirements for pharmacies to participate in electronic exchange, and generally accepted processes that factor into current ordering processes by providers.

C. Incorporate clinical lab-test results

Similar to the Hospital requirements, the Eligible Provider environment currently comprised of a wide array of labs that can provide services. The lack of a standard (eg., LOINC and

bidirectional order interfaces) in the proposed rule hampers the ability of the eligible providers and their IT support team to effectively plan for structured data. The lack of consistency for reporting lab results is problematic to receiving and subsequently storing lab values in a standard manner.

Trinity Health recommends that the final rule defer the structured data requirement for lab test results. We suggest that a staged, multi-year plan outlining requirements for laboratory vendors including lab results via a standard (eg, LOINC and bidirectional order interfaces) be developed. The rationale is that there are too many sources for performing and reporting lab results and any long-term intent to perform comparative effectiveness research would be hampered by the lack of standardization and would require significant data normalization. The requirement to electronically exchange lab results without standards will drive the need to extensive, expensive point-to-point interfaces. Without bidirectional interfaces and order identifiers, key aspects of the Patient Centered Medical Home cannot be achieved. A more organized, and broader approach considering hospital, practice, and 3rd party lab vendors will benefit all parties involved.

D. Report ambulatory quality measures

Trinity Health supports the goal of reporting ambulatory clinical measures to monitor and improve the quality of health care provided and patient outcomes.

Recommendation: In Stage one, require Eligible Providers to report on three measures, and provide clear definition of all measures in a fashion that considers the electronic medical record.

The list of 90 measures for Primary Care providers and 14 specialty provider designations is too large and unwieldy. Assessing the impact of systems and processes used to create the quality measures (including patient participant selection, data entry, data calculation and results reporting) on the validity and reliability of the data output should be the primary focus in stage one. This would be aided by shortening the list of measures available and requiring each Eligible Provider to report fewer measures in stage one.

From the Federal Register, Volume 75, No. 8, 1/13/2010, Medicare and Medicaid Programs; Electronic Health Record Incentive Program Proposed Rule – “We anticipate that EPs will report on at least five clinical quality measures.”

Trinity Health recommends that for Stage I, eligible providers should be required to report no more than three measures with the following characteristics:

1. The measures aid in the practice of evidence based medicine.
2. The measures represent a large proportion of the patient population treated by the EP and preferably, a large proportion of the patient population at risk for death or disability if their care is not managed well.
3. The measures for specialists should have been validated by specialty associations.

E. Implement 5 clinical decision rules

Trinity Health appreciates the requirement for implementing 5 clinical decision rules in the physician office environment and is aware of the value that can be achieved based on its hospital experience. In assessing the requirements for the Eligible Provider environment, the application of clinical decision rules is a relatively new concept and lacks significant structure in a consistent way

Trinity Health recommends that CMS clarify definition of decision rules for Eligible Providers environment (type of condition from nationally accepted guidelines, appropriate clinical actions based previous care, etc.) and defer the requirement for a rule to address “efficient diagnostic test ordering” until a standard has been established. A peer-accepted guidance in care delivery is not currently available, yet necessary to develop a standard.

F. Provide patients with electronic copy of health information

This objective for engaging patients and families presents the same challenges to Eligible Providers as to the hospital. The objective to provide patients and families with timely access to data creates several challenges to health care providers. The major concerns evolve around:

- c. The certification criteria to create an electronic copy of a patient’s clinical information
- d. The measurement of progress based on the request being completed within 48 hours.

Trinity Health recommends that CMS defer objective and develop a more specific approach to clearly define standards on the media and the format. The rationale is that the flexibility that is currently proposed in both the media type and the document format provide a wide range of variation and possibilities that the hospital would need to support. In addition, the electronic exchange of information opens a new element of risk regarding privacy. A more prescriptive approach would add clarity for hospital organizations as well as consistency as a consumer interacts with hospitals.

Recommendation: Defer the 48 hour time limit and provide a description regarding the 48 hour time frame to 7 calendar days. The rationale is that there are conditions (weekends, holidays, etc.) that make complying with the turnaround requirements problematic. Further clarification of the patient exchange would provide helpful guidance.

G. Provide patients with timely access to health information

Trinity Health is embarking on initiatives to provide patients with electronic access to information. The challenges associated with the deployment of this functionality within a physician office environment are significant. The costs associated with the acquisition of the technology are high and the types of resources necessary for the training and marketing are not readily available to most providers. In addition, the 10% compliance rate is too high because it assumes that patients are interested and able to participate. Providers that care for populations in certain age and socio-economic classes are likely to have challenges in meeting this objective.

Trinity Health recommends that CMS clarify the key attributes that are exhibited with “timely electronic access” and identify a limited set of methods for achieving electronic access. The rationale for this recommendation is that the 96 hour target suggests a high degree of sophistication in tracking various pieces of clinical information which may be coming from different sources outside the physician practices (lab results, procedure completed, etc.). Specific descriptions regarding electronic access would provide clear direction for a wide variety of players in the information delivery arena.

Trinity Health recommends that CMS defer any requirement that would need a patient personal health record to accomplish this objective. The rationale is that the

- 1) patients may prefer their own PHR over one supplied by the hospital or specialty practice.

- 2) The transmission standards to current national PHR providers OR EMR based provider PHR's are widely varying in such a fashion that no practice or hospital could accommodate.
- 3) This requirement likely assumes the existence of PHR standard documentation and exchange technology, which are unlikely in the next 3 years.

H. Capability to exchange key clinical information among providers and patient authorized entities

Trinity Health continues to be engaged with health information exchange activities that are underway in the 8 states where we practice. We are very aware of the complexity and the political implications for organizations participating in regional exchanges. While Trinity Health supports this objective, we lack the resources to implement EHRs in our physician's practices while simultaneously working on regional exchanges.

Trinity Health recommends that CMS defer exchange requirement until the EHR implementation is completed and a regional interoperable, secure health IT network has been established. The rationale is that the exchange structure is not in place today and significant efforts are required to successfully implement (EHR use, programming, testing, training and information exchange with external organizations).

I. Perform medication reconciliation at transitions of care

The delivery of health care in a multitude of settings occurs in Trinity Health communities and reinforces the need for medication reconciliation at transition points. Trinity Health believes this function is critical for providing quality patient care and ensuring patient safety. The challenge with respect to this requirement is the identification and documentation of discrete medications between care providers, since no data standards exist. We believe that there is an under-appreciation of the variety of medication sources and that the technology does not yet exist to safely reconcile multiple medication sources such as 1) primary care, 2) specialty care, 3) hospital, and 4) multiple pharmacy data sources.

Trinity Health recommends that CMS refine this requirement to accommodate a phased approach for medication reconciliation structured in the following way:

- a. Stage I – capture and review of medications at each office visit
- b. Stage II – enhance reconciliation with medications from 1 other source system (via electronic exchange)
- c. Stage III – enhance reconciliation with medications distributed by multiple sources (via electronic exchange)

The rationale for this approach is to allow the Eligible Provider and EMR industry to develop familiarity and competency regarding the automated reconciliation process within the office environment and then progressively with other sources. This phased approach is designed to increase the likelihood of adoption for every patient visit.

III. IMPACTS OF CERTIFICATION REQUIREMENTS ON MEANINGFUL USE

A. Define the way that certification criteria for vendors will be applied when users make modifications to certified EHRs to address limitations or incomplete functionality.

The first requirement of meaningful use is to use certified EHR technology. In the NPRM, CMS accepts the definition of certified EHR technology put forth by ONC. ONC lays out a multi-stage definition of "certified EHR technology" to mean: "A Complete EHR or a

combination of EHR Modules.” ONC specifies that a complete EHR has been developed to meet all of the applicable certification criteria adopted by the Secretary of the Department of Health and Human Services, 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 states that providers who 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.

However, hospitals generally do not use a single EHR system. Hospitals routinely bring together many different HIT systems from numerous vendors to create an EHR system. Even those that install a main enterprise system routinely supplement with other products meant to achieve specific needs, such as department-specific systems for the operating room or radiology department. Thus, ensuring that the hospital’s system is certified against all of the meaningful use objectives will be a challenging exercise.

A specific example of this at Trinity Health is a solution that we developed when the Cerner system functionality for med reconciliation did not meet our needs. We developed a safer alternative to their “out of the box” meds rec program that using the tools provided in their software. We suspect that there are other early adopters of EHRs that have developed entire systems or components of systems to meet their needs. There is not yet a proposed process to certify EHRs according to this definition. We are extremely concerned that the current lack of a process will severely limit our hospital’s ability to meet the meaningful use requirements in a timely manner. In addition, Trinity Health suggests that CMS’ Meaningful Use regulations are intended to promote best practice use and should provide flexibility to allow innovative, incremental approaches to improving care delivery.

Given the limited vendor capacity, existing workforce shortages, and the timelines required to upgrade existing EHR systems, we recommend that CMS:

1. Consider existing but not yet certified EHR systems compliant for a period of three years, as long as the hospital can meet specific **meaningful use** objectives.
2. Require that all upgrades to existing systems be certified.
As the meaningful use requirements change, provide a transition time of at least 24 months from when products certified to meet new requirements are available to when certification is required for incentive payments.
3. Define “core certified system” as that which contains the primary source of workflow, clinical data, and decision support. If such a system is certified, support systems may feed data to this core system without themselves being certified. By these means, surgical and specialty systems would not need to be certified but can contribute to achievement of meaningful use.

B. Clarify how the security capabilities required of vendors may affect future meaningful use measures, recognizing the significant changes required by the IFR.

We have a general concern that the security capabilities required of the vendors will become future measures for Meaningful Use for eligible professionals and hospitals. Many of the

technical capabilities included in the Interim Rule represent significant changes to how information is currently secured and managed across the health care industry.

Trinity Health recommends that CMS take the following concerns into consideration as they determine how eligible hospitals and professionals will be impacted by the *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule*.

- Encrypt and decrypt electronic health information according to user-defined preferences (in accordance with Table 2B, row 1). Currently, data is protected at the “data level” in a trusted, secured environment that meets or exceeds the HIPAA security provisions. If data at rest is stored in a trusted and secured environment (e.g., secured data center, compliance with HIPAA security requirements) additional encryption is not necessary. Could have negative impact on patient care.
- Encrypt and decrypt electronic health information when exchanged (in accordance with Table 2B, row 2). When data is exchanged between trusted, secured environments, additional encryption is not necessary. Implementation by professionals and hospitals would require significant work flow changes and adequate time to develop best practice procedures.
- Record actions (e.g., deletion, printing, etc.) related to electronic health information (in accordance with Table 2B, row 3); Our concern is related primarily to printing of documents. Currently, logs are not created when printing occurs in the publishing application. Additionally, the use of the “print screen” desktop function is used frequently during patient care. We are not aware of the ability to track when print screen functionality has been used nor are we currently aware of the ability to disable the screen print function (which could negatively impact patient care).
- Verify that the electronic health information has not been altered in transit and detect the alteration and deletion of electronic health information. (in accordance with Table 2B, row 4). This provision appears to address the security of data during transmission rather than a technical capability of the EHR technology. Implementation by professionals and hospitals would require significant work flow changes and adequate time to develop best practice procedures
- Verify that a person or entity seeking access to electronic health information access a network is the one claimed to be authorized (in accordance with Table 2B, row 5). Each party (e.g., receiving and sending) must have implemented Cross-Enterprise Authentication (e.g., we are not able to control the receiving party’s technology).
- Accounting of disclosure related to treatment, payment and operations (e.g., print screens are an issue as discussed in item #6 above, tracking, etc.) (in accordance with Table 2B, row 6). Depending upon the technical capabilities of the electronic health record, implementation by professionals and hospitals could require significant (potentially costly) workflow changes and adequate time to develop best practice procedures.

IV. DEFINE A HOSPITAL-BASED ELIGIBLE PROFESSIONAL MORE NARROWLY TO EXCLUDE PHYSICIANS PRACTICING IN OUTPATIENT CENTERS AND CLINICS.

Ambulatory-care EHRs are very different from inpatient EHRs because of the inherent differences between the types of care provided. In addition, implementing an EHR in an ambulatory setting requires a significant cost above and beyond the cost of implementing the inpatient EHR.

Excluding physicians practicing in hospital ambulatory-care settings from eligibility for the HIT incentive payments would limit the benefit of EHR adoption in all communities, and especially in inner-city and rural settings. These inner-city and rural practice sites, which utilize an ambulatory EHR that is comparable or equivalent to the EHR platform used in traditional private practice settings, provide anchors to community-based services in their markets. In many cases, they are, in fact, the only available source of ambulatory care to thousands of people.

Trinity Health agrees with AHA recommendations on the definition of a hospital-based eligible professional: a pathologist, anesthesiologist, emergency physician, hospitalist or intensivist for whom at least 90 percent of his/her billed claim lines have a site of service of the inpatient, outpatient or emergency department and for whom at least 90 percent of his/her claims do not contain an ambulatory-care setting code (as set forth in the e-prescribing policy) and for whom the hospital alone funded the EHRs in the hospital inpatient and outpatient departments.

V. REFINE LANGUAGE TO ENSURE THAT EACH HOSPITAL WITHIN A SYSTEM WITH A SINGLE CMS CERTIFICATION NUMBER IS EVALUATED FOR ELIGIBILITY FOR INCENTIVE PAYMENTS

CMS proposes to identify hospitals eligible for EHR incentive payments by the CMS certification number (CCN) on the cost report.

Defining hospitals and CAHs solely by CCN could, contrary to the intent of the ARRA, create a barrier to widespread EHR adoption and use. There is no standard policy that defines the specific types of hospital and CAH facilities to which a CCN applies; a single CCN could, for example, encompass multiple hospitals or CAHs within a system. Because the Medicare and Medicaid payment incentives in the ARRA are calculated using a per-hospital base amount, plus a capped per-discharge amount per hospital, using only a CCN to define a hospital would result in ARRA incentives being distributed in a manner that does not foster widespread EHR adoption and use. Specifically, a health care system with multiple hospitals but a single CCN would be disadvantaged because the system would be eligible for only one base amount and much more likely to reach the discharge cap. In addition, such a health care system would be subject to HIT penalties at the system level, even if, for example, only one of the system's multiple hospitals was not found to be a meaningful user.

Linking HIT incentive payments only to a single CCN would not accurately reflect the deployment costs of all EHR systems across all hospitals in a system. The total cost of EHR implementation far exceeds the purchase cost of the actual application or software. Even hospitals that are part of the same system often require significant variations in their EHRs, as local policies and processes must be incorporated in EHR utilization. For example,

installations must accommodate the differing network infrastructures of legacy software, physician preferences, clinical protocols, expert rules protocols, workflows and ancillary system integration. In addition, a hospital system may encompass both a children's hospital and an adult acute-care hospital, each of which requires a different interface and clinical system. Further, hospitals incur additional administrative costs for necessities such as workstation installation, servers, staff training and differences in clinical services among each of the hospitals, resulting in additional variation among facilities.

For HIT incentive payment purposes, we urge CMS not to use a CCN as the sole criterion to define a hospital or CAH. Instead, we ask CMS to use a multi-pronged approach that allows a "hospital" or "CAH" to be defined in ways that acknowledge the varied organizational structure of multi-hospital systems, including by a distinct CCN, a distinct emergency department or a distinct state hospital license. Under this multi-pronged definition, each distinct hospital or CAH would be eligible to qualify separately for the HIT incentives.

VI. OTHER MATTERS

A. Appeals Process

Trinity Health agrees with the AHA recommendation that CMS implement 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, to ensure that the program is implemented fairly, providers must have a process to appeal and provide documentation to support the appeal of:

- (1) Incentive payments
- (2) Incentive payment amounts
- (3) Provider eligibility determinations

Given that this is a new and highly complex program, we also urge CMS to provide vigorous and well-planned contractor and provider education, so as to maximize the likelihood of success.

B. Common Definition of Meaningful Use for Medicare and Medicaid

Trinity Health has operations in numerous states and has implemented common EHR technology to provide efficient and consistent use of EHR across our system. Required compliance with additional unique state Medicaid criteria would be burdensome. Trinity Health supports AHA recommendations:

In implementing the common definition of meaningful use, we request that CMS NOT approve any additional state criteria. The requirements under the proposed rule are complex and will be extremely challenging for hospitals to meet, particularly under the suggested timelines. In addition, both CMS and the states will be establishing a new application, reporting and payment processes, which hospitals will need to master quickly in order to demonstrate meaningful use. The potential for states to layer on additional meaningful use requirements would significantly complicate matters for all hospitals, and particularly for hospitals that serve patients in multiple states.

CMS further proposes to “deem” hospitals that are meaningful users under Medicare as meaningful users under Medicaid, with no obligation to meet any additional or different, state-specific meaningful use requirements approved by the Secretary. We ask that CMS adopt and affirm the deeming approach in its final rule and ensure that the regulatory language reflects this approach.

C. Medicaid Incentive Payment Calculation for Hospitals

Trinity Health supports AHA recommendations:

The ARRA provides for Medicaid incentive payments to eligible hospitals that are meaningful users of certified EHR technology. At their option, state Medicaid agencies are fully responsible for administering and disbursing these Medicaid incentive payments and may receive 100 percent federal financial participation for these payments. It is critical that these incentive payments be made in a timely manner and not be delayed or otherwise affected by any state budget problems or changes to state Medicaid program payments or eligibility, especially given that the federal government is bearing 100 percent of the cost of the EHR incentive payments. Additionally, these incentive payments should not be included in any calculation of total Medicaid payments for the purpose of determining Medicaid shortfalls, disproportionate share payments, upper payment limits, or any general Medicaid program service. To ensure that this occurs, we ask CMS to consider Medicaid incentives as separate and apart from other Medicaid program payments for patient care.

D. Eligibility of Critical Access Hospitals for Medicaid Incentive Program

Trinity Health supports AHA recommendations:

For purposes of the Medicaid EHR incentive payment program, the ARRA defines an eligible hospital as an acute care hospital or a children’s hospital. CMS proposes to define an acute-care hospital as a health care facility where the average length of patient stay is 25 days or fewer, and that has a Medicare CCN that has the last four digits in the series 0001 through 0879.

These CCN numbers encompass short-term general hospitals and the 11 cancer hospitals in the United States, but not CAHs because all CAHs have a Medicare CCN with the last four digits in the series 1300 through 1399. However, under the *Social Security Act*, CAHs are, by definition, general, acute-care hospitals with an average length of patient stay of 25 days or fewer. Thus, CAHs meet both the ARRA definition of being acute-care hospitals, as well as CMS’s proposed definition of being short-term general hospitals. Accordingly, we urge CMS to revise its definition of hospitals that are eligible for Medicaid payment incentives so as to also include hospitals with a Medicare CCN that has the last four digits in the series 1300 through 1399.

E. Cost Report Data used to Calculate Medicare and Medicaid Incentive Payments

CMS proposes to use Medicare cost reports for the source of data used to calculate Medicare incentive payments and allows States to use other auditable sources of data to calculate Medicaid incentive payments. Trinity Health recommends that the Medicare Cost reports be the source of data for both Medicare and Medicaid incentive payments and other auditable state sources only be used where Medicare cost report do not include state required data.

The formula to calculate Medicare incentive payments uses a Medicare utilization component based on Medicare Part A and Part C days. Medicare Part C days are billed as informational to the Medicare program and are commonly referred to as zero balance or shadow bills. These Part C days impact the calculation of graduate medical education program payments. Historically, non-teaching hospitals may not have submitted bills for Part C patients and in some cases fiscal intermediaries are rejecting these bills from non-teaching hospitals. Trinity Health recommends that Part C bills be accepted by all fiscal intermediaries. In addition where Part C bills may not have been billed or accepted by the fiscal intermediary in a timely manner to be incorporated into Medicare cost reports, alternative reporting of Part C days be allowed.