Greater New York Hospital Association
555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

March
Fifteen
2 0 1 0

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

RE: GNYHA Comments on CMS-00330P, Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule (Vol. 75, No. 98), January 13, 2010

Dear Administrator Frizzera:

On behalf of the Greater New York Hospital Association (GNYHA), I am grateful for the opportunity to provide comments on the Notice of Proposed Rule Making (NPRM) for the Medicare and Medicaid Programs; Electronic Health Record Incentive Program, published in the *Federal Register* on January 13, 2010, by the Centers for Medicare & Medicaid Services (CMS).

GNYHA is a not-for-profit trade association that represents nearly 250 hospitals and continuing care facilities, all of which are not-for-profit, charitable organizations, or publicly sponsored organizations located in New York, New Jersey, Connecticut, Rhode Island, and Pennsylvania.

GNYHA member hospitals firmly believe that accelerated adoption of EHRs and their use to improve care should be a national priority. However, GNYHA is deeply concerned about many of the provisions in the NPRM. We believe the proposed framework for implementing the program materially undermines the potential success of the program and could stymie the nation's current efforts to reform the health care system, which are premised on providers' ability to improve safety, reduce costs, and enhance efficiency. Both the Administration and the Congress recognize that successful, broad-based implementation of HIT is the linchpin for achieving these goals. We fear, however, that the regulation as proposed will impede the Administration's and the Congress's vision for our nation's health care system, one in which providers have electronic access to comprehensive medical information to help ensure quality, safety, efficiency, and access to care.

GNYHA is particularly alarmed by the breadth and scope of the proposed meaningful use criteria in the regulations and fear that these criteria will limit the number of hospitals that adopt HIT, or worse, will compromise the thoughtful planning and implementation that is necessary to achieve the intended goals.

Our attached comments address the following key issues:

- Definition and timeframes associated with "meaningful use"
- Meaningful use objectives and reporting
- Collection, calculation, and reporting of clinical quality measures
- The Medicaid Incentive Program
- Definition of a hospital-based "eligible professional"
- Definition of a "hospital"
- Technical issues with payment methods
- Privacy and security

The adoption and widespread use of HIT holds tremendous potential for patients and health care providers alike. Without workable requirements, however, we risk hindering the achievement of this potential. GNYHA looks forward to continuing to work with HHS on more practical solutions to the issues we have raised and thanks you in advance for the consideration of these comments and recommendations.

If you have any questions about our comments and recommendations, please contact Zeynep Sumer, Vice President, Regulatory and Professional Affairs (212-258-5315; zsumer@gnyha.org) or Elisabeth Wynn, Vice President, Health Finance & Reimbursement (212-259-0719; wynn@gnyha.org).

Sincerely,

Kenneth E. Raske
President

GNYHA Comments on the CMS Proposed Medicare and Medicaid Electronic Health Record Incentive Program

Table of Contents

EXECUTIVE SUMMARY

GNYHA is pleased to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed structure and timeframe for the Medicare and Medicaid electronic health record (EHR) incentive programs and to offer recommendations for alternative approaches in key areas.

GNYHA and its member hospitals are fully committed to the goal of rapid and widespread health information technology adoption to provide timely and accurate information to health care providers, so that they may deliver high-quality health care to their patients. However, GNYHA is very concerned that the criteria and timeline set forth by CMS will limit the number of hospitals that will qualify for incentive funds. Furthermore, we fear that the program, as it is structured in the NPRM, would discourage those hospitals that are furthest behind in adopting EHRs, as the adoption challenges may be insurmountable under the NPRM requirements.

Our comments are based on the feedback we have received from our member hospitals, including guidance from our Hospital HIT Steering Committee, which comprises more than 40 hospitals across our multi-state membership. In addition, GNYHA has partnered with the Health Information Technology Evaluation Collaborative (HITEC), which is charged by the State of New York to assess levels of HIT adoption in New York hospitals. Our assessment of current levels of adoption, access to capital for HIT, and vendor capabilities was based on the statewide assessment that resulted from our partnership with HITEC. GNYHA also worked closely with the American Hospital Association (AHA) on our comments and are in full support of their proposed alternative approach to defining meaningful use.

In the detailed letter that follows, GNYHA outlines its concerns about the framework for meaningful use; specific objectives and measures; quality measures and reporting; the burden of reporting requirements for demonstrating meaningful use; technical issues with the proposed payment methods; the Medicaid incentive program; and privacy and security policies.

Specific areas of concern include:

Definition and Timeframe of Meaningful Use: Although the criteria for achieving "meaningful use" of EHRs laid out in the CMS proposal are worthy goals in the long term, they exceed the limit that hospitals and the EHR market can achieve at the outset of the EHR incentive program. GNYHA is specifically concerned about the requirement to meet a lengthy list of functionality objectives and the electronic collection, calculation, and submission of quality measures. GNYHA proposes the AHA's alternative definition and timeframe for meaningful use. This approach includes:

- Modifying the proposed meaningful use objectives and adding 12 additional objectives;
- Replacing CMS' proposed adoption year concept with an approach that allows hospitals to satisfy the meaningful use definition if they meet 25% of the objectives in 2011 or 2012, and increasing the percentages in future years;
- Expanding required levels of use and data sharing requirements over time;
- Changing many of the measures of meaningful use to decrease the reporting burden;

- Allowing hospitals to meet the meaningful use objectives by grandfathering currently installed and functioning hospital EHR systems as certified; and
- Relying on existing quality reporting structures until EHR quality measures and products for quality reporting are ready for broad use.

Definition of a Hospital-Based Eligible Professional: GNYHA is concerned that CMS's proposed criteria for defining providers eligible for the EHR incentive program will inappropriately exclude many physicians from qualifying for incentive payments. GNYHA proposes a more limited exclusion of hospital-based physicians from the incentive payment program.

Definition of a Hospital: GNYHA is concerned about how hospitals are identified for the EHR incentive programs. We ask that each hospital within a system that shares a Medicare Provider Number be evaluated individually for meeting the meaningful use definition and be eligible individually for incentive payments.

GNYHA urges CMS to consider these concerns and adopt the proposed recommendations offered herein.

MEANINGFUL USE FRAMEWORK AND TIMELINE

The NPRM outlines a phased approach to meaningful use with increasingly more stringent requirements being introduced over time. In its proposal, CMS introduces 23 EHR functionality objectives, including the collection, calculation, and reporting of 35 clinical quality measures, all of which hospitals must meet in order to qualify for incentive funds in Stage 1. Stages 2 and 3 are planned to be defined as part of subsequent rulemaking, and CMS intends to build on the Stage 1 requirements by adding additional objectives. Although CMS allows hospitals some time for transitioning among Stages 1-3, all hospitals will need to meet Stage 3 requirements by FY 2015 to avoid payment penalties.

GNYHA Concerns

The meaningful use framework and timeline require too much, too soon.

The 23 objectives proposed by CMS in the NPRM certainly constitute what a comprehensive EHR system should comprise. GNYHA is in agreement that an EHR system with all of the functionalities proposed to be required in Stage 1 would assist providers in being more efficient and providing better quality of care to their patients. However, an EHR system that is capable of functioning in this capacity does not currently exist. The EHR marketplace and the hospital community must have a realistic timeframe, in addition to the momentum that the EHR incentive program will provide, to develop and implement these functions.

According to a recent AHA survey, fewer than 1% of the 795 hospital–respondents reported that their EHR systems are capable of performing all of the 23 meaningful use functions and 55% said that they did not anticipate being able to perform these functions by 2015, when the payment penalties are introduced.[1] A survey conducted in New York State prior to the release of meaningful use criteria suggested similar results. The New York State survey, like AHA's survey, shows that while many hospitals have adopted subsets of the technologies required by the meaningful use criteria, none of the 148 responding hospitals met all meaningful use objectives.[2]

CMS's proposal for an "all-or-nothing" approach to achieving meaningful use sets an inflexible and likely unachievable goal for many hospitals in the GNYHA membership. GNYHA is concerned that this approach does not take into account the multi-year investment that EHR implementation realistically requires. Based on the experience of many of the most advanced hospitals in New York, the timelines expected by the CMS approach do not coincide with the actual pace at which complex EHR systems and health information exchange can be realized. These hospitals attest to years of workflow redesign, staff training, customization of systems, and multiple and significant financial investments, all before clinicians are able to use the system for patient care. Despite their efforts, none of these hospitals is able to meet the meaningful use criteria today. Given these realities, a hospital that is just beginning the journey of implementing an EHR will find it challenging, if not impossible, to receive any Medicare EHR incentive payments under the proposed definition and timeframe of meaningful use.

[1] American Hospital Association Survey of Hospitals' Current EHR Systems: January 2010.
[2] McGinnis S, Moore J, and R Kaushal. (Unpublished Draft) Health Information Technology Adoption in New York Hospitals. Rensselaer, NY: CHWS; 2010.

With respect to health information exchange, the State of New York has made significant investments statewide. Since 2006, a total of $400 million has been invested in the New York State health information infrastructure. A majority of that investment has been made to support health information exchange initiatives and the development of the Statewide Health Information Network for New York (SHIN-NY), with $160 million in funding through the Health Care Efficiency and Affordability Law for New Yorkers (HEAL–NY) Capital Grant Program, $200 million in private sector (including hospitals) matching funds and $40 million in other State and Federal programs.[3] Despite a multi-year, statewide effort to establish health information exchange governance, standards, and specifications, as well as the significant amount of financial investment, New York providers are not regularly exchanging data today. In fact, although a small majority of New York hospitals (59%) report that they participate in a regional data exchange, most (77%) are not exchanging data of any kind.[4]

Furthermore, New York State hospitals have the added step of going through a State-regulated certificate of need (CON) process before they can purchase EHR systems, extending the already abbreviated timeline in which they can put systems in place. Further delay is anticipated once the NPRM becomes final and the number of New York hospitals applying for CON review and approval increases.

Hospitals also face an anticipated shortage of HIT professionals to assist with implementation and the ability for EHR vendors to respond to the increased demand for their products and support. This will place smaller and safety net providers at a particular disadvantage, as they will be competing with large institutions for vendor interest and timely support. We are also especially concerned about hospitals that, in most cases, are just beginning the EHR adoption process. Small hospitals and safety-net hospitals, in particular, face greater capital constraints, as well as other challenges in implementing EHRs. Adopting the approach proposed by CMS could cause a widening of the existing gap between hospitals that have been fortunate enough to have sufficient resources to make EHR investments, and those that have not.

The structure of the CMS EHR Incentive Program and the meaningful use criteria are inflexible and do not consider organization-specific HIT implementation plans.

Many hospitals have included implementation of EHR systems in their institutional strategic plans and their operational budgets for a number of years. These strategic plans, which were at various stages when Congress first introduced the concept of "meaningful use," were the result of hospitals conducting needs assessments, determining staff readiness to adopt HIT, and developing phased implementation plans that take into account the change-management and technical requirements needed to meet their goals, as well as their existing workforce and capital resources. For these reasons, not all hospitals follow the same path to full EHR implementation and adoption of advanced clinical systems, but rather local and institutional priorities and conditions may drive hospital timing and choice of HIT systems and functionalities. Disrupting existing plans in order to meet a prescriptive definition of meaningful use will be costly, and may result in unnecessary changes to a work plan that is equally valuable.

[3] New York State Department of Health, Office of Health Information Technology Transformation Web site: http://www.health.state.ny.us/technology/

[4] McGinnis S, Moore J., et al.

Proposal for an Alternative Approach to Meaningful Use

The ARRA gives the Secretary authority to define meaningful use. Therefore, CMS has the authority to adopt alternative timeframes and requirements that more closely match a realistic implementation timeline for EHR implementation. Although GNYHA hospitals are motivated by the ambitious charge of the EHR incentive program, most are concerned that they may not achieve the criteria to be deemed meaningful users in time and miss out on the incentive payments or, worse, incur payment penalties.

GNYHA and its members have provided significant input in to the development of an American Hospital Association's proposed approach to defining the meaningful use structure and timeframe. We are supportive of their recommendations to modify the meaningful use criteria and eligibility for EHR incentive payments and ***we strongly urge CMS to adopt the AHA's approach.***

We believe that Congress intended to phase-in meaningful use criteria over time to support providers through an incremental adoption curve with increasingly stringent requirements. This support should allow for both hospitals and the EHR market to progress at a reasonable pace, while still challenging providers to make significant changes in the way they care for patients over a relatively short period of time. CMS's proposal could serve the opposite purpose of what Congress intended and, instead, discourage providers from undertaking challenging adoption efforts.

GNYHA recommends that CMS identify a single, expanded set of meaningful use objectives to be achieved between 2011 and 2017. In addition, we propose that hospitals should be considered meaningful EHR users and qualify for the full EHR incentive payment if they meet a specified percentage of the hospital objectives in a given fiscal year. The required percentage would increase over time.

The details of the alternative approach are as follows:

Establish the full recommended scope of meaningful use objectives up-front.
Although, many of the Stage 1 objectives that CMS proposes are advanced functions—such as CPOE, clinical decision support, and automated medication reconciliation—that generally are implemented at the end of a multi-year transition to an EHR, the list leaves out several additional key EHR functions that some GNYHA members have already implemented and are benefiting from. Additionally, since the objectives for Stages 2 and 3 have not been defined in the NPRM, it is difficult for hospitals to plan their HIT adoption activities. The final vision and criteria for meaningful use of EHRs should be specified now to provide hospitals the certainty needed to plan capital needs and implementation plans over the next several years.

The complete list of hospital meaningful use objectives should include those in the proposed rule (with modifications, as discussed below and in **Appendix A**) and should be expanded to include 12 additional objectives that have been discussed and proposed by the HIT Policy Committee for FYs 2013 and 2015.

Although specified in advance, the full set of hospital objectives should be reviewed periodically through rule-making. The regulatory requirements would represent the minimum necessary to achieve meaningful use, and certainly many hospitals would likely achieve a higher number of objectives and greater level of use to meet competitive pressures.

While the list of objectives required would remain relatively unchanged over the coming years, the scope of their use by hospitals should accelerate, so that:

- Levels of use increase over time;
- Use of structured data increases over time; and
- Information exchange increases over time.

A final set of 34 recommended objectives, which include the additional 12 proposed objectives, along with the changing requirements over time, is listed in **Appendix A**. GNYHA's comments on recommended key changes to CMS's 23 proposed objectives are provided in the section that follows.

Lengthen the timeframe for achieving the ultimate vision for meaningful use.
GNYHA recommends that the timeframe for meeting all of the 34 specified meaningful use criteria in full be extended to 2017. This would acknowledge and support the time needed to go through incremental adoption over four phases with increasing functionality and use of technology. The four phases and the objectives with increasing functionality requirements are outlined in Appendix A and would be as follows: 2011/2012, 2013/2014, 2015/2016, and 2017.

The extended timeframe that we recommend is supported by the ARRA statute, in which Congress sets 2017 as the first year when no incentive payments can be made. Under the ARRA, providers that first become eligible for EHR incentives in 2013 or later will receive payments through 2016. In addition, 2017 is the year in which the penalties will be completely phased-in. Although they start in 2015, the penalties increase in size through 2017. Therefore, the statute suggests 2017 as the year when providers should have finished their adoption process.

Take a phased, flexible approach to defining meaningful use.
CMS should take a phased approach in which hospitals can be considered meaningful users by meeting fewer requirements in the early years of the program, but building toward achieving the full set of meaningful use objectives over time. To be successful in achieving meaningful use, hospitals must have some choice and flexibility in meeting the objectives. Therefore, we recommend that CMS allow hospitals to choose the subset of the meaningful use objectives that match their adoption path and strategic plan. We propose that CMS phase in the increased requirements in the following manner:

- FYs 2011/2012 – Meet at least 25% of the objectives;
- FYs 2013/2014 – Meet at least 50% of the objectives;
- FYs 2015/2016 – Meet at least 75% of the objectives; and
- FY 2017 and beyond – Meet substantially all of the objectives.

MEANINGFUL USE OBJECTIVES AND MEASURES

In addition to the proposed approach described above, GNYHA requests clarification and offers recommendations for modifications to certain meaningful use objectives and their associated measures. GNYHA provides key comments with respect to several meaningful use objectives below.

Key Recommendations on Meaningful Use Objectives

GNYHA urges CMS to eliminate the two objectives related to administrative claims, specifically the requirements to submit claims electronically to public and private payers and to check insurance eligibility electronically from public and private payers. Hospitals currently submit claims electronically and, in fact, face a financial penalty for submitting paper claims. Although, according to a NYS HIT survey, most (95.4%) electronic systems that are used to submit claims are integrated with clinical systems, they are not packaged and installed that way and therefore are not part of systems that will likely become certified through the EHR certification process. However, by including these administrative activities as part of the meaningful use objectives, CMS would force hospitals to upgrade existing and well-functioning systems to new products that have been certified. This would impose an unnecessary financial and operational burden on hospitals, with no apparent benefit.

Additionally, the measure associated with the objective to check insurance eligibility electronically requires hospitals to meet a threshold of 80% of their unique patients being verified in this way. In order to meet the requirement, hospitals would need to have unique connections with all of the different insurers in their markets and their ability to do so is dependent in large part on cooperation from these payers.

Moreover, hospitals state that the value of the electronic eligibility verification is often minimal, as the information that is electronically available from insurers is often incomplete. This requires hospitals to follow up an electronic verification of eligibility with a phone call, which defeats the ultimate purpose of the electronic process to spur efficiencies.

Lastly, hospitals cannot check the eligibility of patients who present without their insurance information or who are uninsured. If a hospital's uninsured patient mix is greater than 20% of all patients, by default it would not meet the objective because of the threshold of 80% that CMS has proposed.

Drug-drug interaction alerts and drug-allergy alerts should be considered one objective, and drug-formulary alert should be considered a second, separate objective.
Drug-drug interaction alerts and drug-allergy alerts serve to prevent medication errors and are clinical in nature. These alerts require a connection with systems that include drug safety information and could occur within pharmacy systems in the early stages of adoption, prior to implementation of CPOE. However, even at that level, these functions are invaluable and should be prioritized. Inclusion of these alerts in the pharmacy system should count toward meeting these objectives, even if they are not met at the bedside.

The requirement to perform medication reconciliation at relevant encounters should be deferred until there is clear guidance from entities like The Joint Commission on its implementation.

GNYHA recognizes the importance of medication reconciliation as a critical process to better coordinate care across providers. However, once again, the technical infrastructure to perform medication reconciliation electronically does not exist. Furthermore, there is a lack of consensus and understanding among the medical community on how medication reconciliation should be supported by technology. The Joint Commission (TJC) is in the process of evaluating and revising its National Patient Safety Goal on medication reconciliation. GNYHA strongly urges CMS to defer implementation of this objective until TJC revises its priorities.

Quality Reporting should be deferred until there is a clear process for reporting measures that are valid, reliable, and field-tested.

GNYHA strongly believes that CMS compromises the value of its existing pay-for-reporting program (RHQDAPU) if it does not incorporate the EHR Incentive Program reporting requirements into its structure. GNYHA provides more detailed comments on this issue in the section on quality reporting.

DEMONSTRATING MEANINGFUL USE

Each of the CMS proposed meaningful use objectives has an associated measure for hospitals to demonstrate that they have implemented and are using the specified EHR functionality. To be deemed a meaningful user of EHR technology, a hospital must determine whether it is performing to the level specified in the measure and then it must attest to doing so. Of the 22 proposed HIT functionality measures (not including quality reporting), eight require a declarative response from hospitals and 14 require a calculation of meeting a CMS-specified performance level.

Definition of EHR Reporting Period

GNYHA appreciates the flexibility CMS proposes to provide hospitals in the initial EHR incentive payment year. Hospitals may demonstrate that they are meaningful users for any 90-day period during the first payment year that they become eligible. We believe this flexibility will encourage hospitals to participate in the EHR incentive program and will allow the time needed in the first year of implementation to work through any adoption challenges.

GNYHA Concerns

GNYHA cautions CMS from imposing overly burdensome reporting requirements for hospitals to demonstrate that they are meaningful users.

GNYHA members have stated that the tracking and reporting of both the meaningful use measures as well as the clinical quality measures would add up to hundreds of hours of additional time spent by hospital staff. Our members also state that the CMS reporting burden estimates in the NPRM for performing these tasks are a gross underestimate of what it will actually require of hospitals. In some cases, hospitals are not certain that the measures can be calculated at all.

GNYHA is especially concerned about objectives with percentage performance measures associated with them, such as the measure for use of CPOE. While hospitals are transitioning to fully implementing the specified functionality, these measures require that a hospital look across both paper and electronic processes to calculate the measure. In addition, unlike the calculation of the clinical quality measures, which are focused in one clinical area and thus are limited to a specific patient population, many of the functionality measures require a review of all charts. For large hospitals and hospital systems, there is an added burden for these measures because of large patient volume.

Therefore, GNYHA urges CMS to re-formulate the percentage performance measures so that:

- ***Numerators and denominators are explicitly specified;***
- ***No measures require hospitals to use paper and electronic processes to develop the measure;***
- ***Each measure provides a minimum threshold of cases for reporting; and***
- ***Any measure that involves manual processing can be demonstrated through a sampling methodology to limit burden.***

GNYHA is also concerned that many measures need to be calculated through a manual process since the interim final rule on certification standards, released by the Office of the National Coordinator for HIT (ONC), does not include EHR-generated functionality measures as a certification requirement, for even those measures presumed by CMS to be generated out of the EHR.

Therefore, we urge CMS not to require submission of HIT functionality measure data that EHRs have not been certified to produce.

QUALITY REPORTING

GNYHA and its members are fully supportive of quality data collection and reporting as a means to improve overall patient care and outcomes. We also look forward to the next obvious step in reporting of quality measures, that of electronic quality reporting, and believe this will decrease the burden of collecting, calculating, and reporting of measures, as well as potentially allowing hospitals to generate an even broader array of quality information to help improve care. However, there is currently no commercial EHR system in use today that is capable of generating the current set of proposed measures.

A majority of the set proposed by CMS in the NPRM has yet to be specified for electronic reporting. CMS has stated its intent to publish specification documents by April 1, 2010, just two weeks after the close of the comment period for the NPRM and six months before the October 2010 start of the incentive payment program. GNYHA is optimistic about the national momentum behind developing, testing, and implementing new electronic specifications for quality measures as part of certified EHR technology; however there is not enough time to fulfill these requirements for measure development by FY 2011.

Furthermore, the measure development and selection process even for manual reporting is a multi-year and multi-stakeholder endeavor and should not be done outside of the RHQDAPU program, which has an established process for implementing new measures. Developing

different sets of measures and reporting requirements outside of the RHQDAPU program is certain to cause confusion and will compromise existing quality improvement efforts.

We are concerned that hospitals will not be able to meet meaningful use criteria, as defined in the proposed rule, due to problems with measure selection, electronic measure specifications, and EHR capabilities. GNYHA's recommendations take these factors into account and offer short- and long-term approaches to advancing quality reporting as part of the EHR Incentive Program.

Measure Selection

Any measures selected as part of EHR meaningful use requirements should come from the adopted RHQDAPU measure set. Selected measures should facilitate quality improvement efforts by establishing condition-specific measure sets and have clear and accepted evidence-based guidelines.

Currently, inpatient prospective payment system (IPPS) hospitals report data on clinical quality measures through the RHQDAPU program. Development and adoption of measures for RHQDAPU are a result of collaboration among TJC, Hospital Quality Alliance, CMS, and other stakeholders. By proposing to use non-RHQDAPU measures for meaningful use it circumvents the established collaborative effort to improve hospital quality in a structured and proven manner. Only nine of the 35 of the proposed clinical quality measures have been selected from the current RHQDAPU measure set.

Selection of clinical quality measures for EHR meaningful use should also have a clear and explicit quality improvement goal. The measures selected should take into consideration their similarity in terms of the conditions they pertain to or related quality improvement actions. Hospitals reporting RHQDAPU measures have been steadily improving their performance over time on many of these measures. Deviating from the measures already found in RHQDAPU would potentially divert quality improvement resources that have been shown to be effective over time. We also urge CMS to continue to consider the feasibility of quality improvement when selecting measures by ensuring that any future measures have clear and actionable evidence-based guidelines to facilitate continuous quality improvement.

Electronic Specifications

No measure should be adopted as a requirement of meaningful use without accurate electronic specifications, thorough field testing, and the ability of stakeholders to provide feedback to measure developers.

The core of any measure is its clinical rationale and clinical interpretation. The measure is operationalized by defining the data elements required in order to calculate the measure. Currently, data elements are manually abstracted from the medical record and the data entered online. The promise of EHRs is to reduce or eliminate manual data abstraction and submission. The first step to achieving that promise is for measures to have accurate electronic data specifications established.

None of the RHQDAPU measures currently have electronic specifications available for review, although there are several other measures for which electronic specifications were proposed for comment. We are not recommending any of these measures for inclusion in the Stage 1

meaningful use criteria, but their electronic specifications can be instructive to illustrate potential problems when establishing electronic specifications for these and other measures.

The electronic specifications must faithfully reproduce the data compared to the current manual abstraction method. If not, data collected using EHRs will not be comparable to data collected using manually abstracted data for a given measure. This may lead to problems with clinical interpretation and measure comparison across time.

For example, the electronic specifications listed for *VTE patients with anticoagulation overlap therapy* require the exclusion of "heparin flush-type products." Notes in the electronic medication code set indicate a limitation in the ability to completely exclude these products. This limitation would cause an inappropriate increase in the numerator.

Another issue is when a measure is specified using incomplete code sets. Specifications for *surgery patients with recommended venous thromboembolism prophylaxis ordered* indicates that the SNOMED CT code set for mechanical prophylaxis, which is required for this measure, has not been completed. Both of these examples illustrate unacceptable problems for these measures in an electronic format. These types of specification problems illustrate the importance of not cutting the measure design process short, thoroughly field testing all measures, and allowing ample time for stakeholders to provide feedback during the measure development process as well as prior to measure finalization.

No clinical quality measures should be considered for inclusion in the meaningful use criteria until the ONC fully specifies the required EHR code sets to be supported, all technical requirements are fully implemented into installed EHRs, and the measures have been reevaluated for compliance with the final EHR specification standards.

Measure developers, in conjunction with the Healthcare Information Technology Standards Panel, worked to create the electronic specifications for the stroke, venous thromboembolism (VTE), and Emergency Department measures. These measures were designed to use a variety of standardized coding systems like SNOMED CT, LOINC, RxNorm, the ICD-9-CM and others. We applaud measure developers for selecting established and standardized coding systems for use in specifying the clinical quality measures electronically. We are concerned that electronically specified measures will not be ready for inclusion as meaningful use criteria until the ONC finalizes the full EHR certification requirements for all stages.

In order for measure developers to adequately create electronic specifications they must know the capabilities of the systems they are designing for. The stroke, VTE, and Emergency Department measures were designed with the expectation that certain standardized coding systems will be supported by certified EHRs. However, in the ONC Interim Final Rule (IFR) the EHR technical requirements for Stage 1 certification do not always align with the manner in which the electronic measure specifications have been written.

For example, several measures require the RxNorm code set to identify medication use. The ONC IFR does not require RxNorm as part of Stage 1 certification for EHRs, but plans on requiring it at a later time. Similarly for the LOINC code set, which is designed to capture laboratory data, the EHRs are only required to code data received from labs that will be part of

the patient summary record. It is unclear if this will produce the level of detail required by some of the electronic measure specifications we have reviewed. Even more problematic is the fact that the ONC IFR allows hospitals to use local or proprietary laboratory codes when LOINC codes are not available, potentially causing a breakdown in standardized data collection.

The ONC IFR Stage 1 requirements are largely no more than a first step in defining technical requirements for certified EHRs. It is helpful for EHR vendors to receive guidance on the certification requirements to begin the process of developing the capabilities of fully supporting the meaningful use criteria. However, meaningful use by hospitals should not be based on EHR systems that have not achieved the full technical capabilities needed to support the clinical quality measures.

To further complicate matters, ICD-10-CM is mandated to be effective beginning in 2013. Measures that use ICD-9-CM codes would need to be updated to ICD-10-CM codes. Given the level of detail that ICD-10 can capture compared to ICD-9 it will be critical to take the time to reevaluate measures in this context. There is a crosswalk allowing conversion of ICD-9-CM to ICD-10-CM, but the granular detail needed for many measures would most likely result in non-comparable data, especially since some codes do not have good counterparts in the two ICD systems.

We again emphasize the importance of not cutting short the measure design process. Electronically specified measures cannot be properly tested and evaluated until EHRs supporting all necessary code sets are available.

Quality Measure Reporting

CMS should reevaluate the timeline for compliance with meaningful use to take into account EHR vendor delays as well as the potential adjustment period hospitals will need to input all required data into their EHRs.

The potential delays EHR vendors may impose on hospitals waiting for new technology due to the increased demand for their products should not be underestimated. This will have a direct impact on hospitals' ability to comply with meaningful use requirements in two ways. The first is the installation of the EHR system and the second is the technical assistance necessary thereafter. Implementing a new EHR system is typically a multi-year process and even existing EHR customers may face wait times of one to two years before their current systems can be upgraded to support meaningful use criteria. Furthermore, ongoing technical assistance will be required by hospitals. We are concerned that the EHR vendors will be overwhelmed by the demand for their products and, as such, not be able to provide timely installations or assistance even to their existing customers. These technical and logistical delays may prevent large numbers of hospitals from being meaningful users if CMS does not alter the timeline for meeting those requirements.

Once specifications for the measures have been established, approved, and EHR installation is complete, hospital personnel must interface with their EHR to ensure that all required data have been entered. This will involve a learning curve for hospital personnel to properly enter their data and use the EHR functionality for reporting purposes. Entering these data may also involve changes in a hospital's workflow or the manner clinical data are documented. Either of these changes would require time to plan and implement.

CMS should not allow hospitals to report some data via EHRs and others via manual abstraction.

We appreciate CMS's consideration of the data abstraction and reporting burden hospitals currently have in order to meet the requirements of the various pay-for-reporting programs. However, we are concerned that data submitted in such a hybrid fashion would not be comparable for the reasons detailed in the electronic measure specification section above. For example, if some hospitals reported select RQHDAPU measures via EHRs and others via manual abstraction and reporting via QualityNet, this may compromise the integrity of the Hospital Compare Web site by introducing non-comparable data into the publicly reported data. Hospitals along with other stakeholders have worked with CMS for many years to establish the current pay-for-reporting programs. While EHRs do promise to improve this process by reducing the data collection and reporting burden on hospitals, we do not feel they are mature enough to fulfill that promise at this time.

There should be no public reporting until EHR based measures have been in use by all eligible hospitals for at least one year. At least one dry run should be performed, and CMS should check for any discrepancy in the data after switching to EHR reporting.

This recommendation is designed to protect the integrity of the currently established public reporting of quality measures on Hospital Compare. It is critical that the measures are fully implemented (all data are entered and measures calculated by the EHR) for at least a year to allow for any workflow or documentation changes within hospitals to have been completely implemented. Hospital staff will also need time to adapt to any needed changes and compensate for any lost productivity during the transition period. Thus, all hospitals should be able to comply with EHR-based measure reporting for at least one year prior to any public reporting.

In addition, prior to public reporting, CMS should perform at least one dry-run allowing hospitals the chance to evaluate their EHR submitted results. CMS should also examine the data for any discrepancies after the switch to EHR reporting. Even if minor discrepancies are found or none at all, CMS should make clear on Hospital Compare that a new reporting protocol is being used and explain to consumers that this may cause changes in the data that may not be reflective of actual changes in quality and may make it difficult to compare data moving forward to data submitted in the past.

Removal of Specific Quality Measures

GNYHA has concerns regarding several of the quality measures that CMS proposes to require as part of quality reporting.

CMS should not require hospitals to report on readmissions data.

Of specific concern are the readmissions rates, which GNYHA believes are inappropriate for electronic reporting to CMS. CMS already calculates 30-day, risk adjusted readmission rates for heart attack, heart failure, and pneumonia through hospitals' claims data. These data are also publicly reported on CMS's Hospital Compare Web site. Although hospitals could provide these data back to CMS on their own readmission rates, they are not capable of doing so for patients readmitted to other hospitals. In addition, hospital EHR systems would be incapable of risk

adjusting the data from their own systems, as the measures require, since they do not have access to the claims information generated by other providers.

CMS should not require hospitals to report on the ventilator-associated pneumonia and urinary tract infection measures until standard definitions and an actionable evidence-base are developed.

Although the ventilator-associated pneumonia (VAP) and urinary tract infection (UTI) measures are both approved by the Hospital Quality Alliance, their approval has been contingent on further development of the definitions for these measures.

A significant challenge for clinicians and data collection efforts, as related to VAP is the lack of a robust definition that uses objective criteria for diagnosis. GNYHA believes that until there is clearer consensus in the medical community on identifying VAP, data collection efforts will lack integrity.

GNYHA also urges CMS to select measures with guidelines that will facilitate continuous quality improvement. Although established evidence-based guidelines for the prevention and treatment of catheter-associated UTIs exist, they still allow for a significant portion of patients to develop this condition despite the implementation of the established guidelines.

Quality Measures and the Medicaid Program

GNYHA agrees with CMS's proposal to remove duplicative and burdensome reporting requirements by allowing hospitals that are eligible for both Medicare and Medicaid incentive payments to report all quality measures once to CMS. GNYHA further appreciates that CMS will provide the relevant Medicaid data to states.

EHR CERTIFICATION

Although a proposed rule was released recently to establish the process for certifying electronic health records, the Federal process for establishing a certification program is in its early stages. There remain many unanswered questions regarding specific EHR systems and the certification bodies that will be authorized to approve them. Once finalized, vendors must then revise their products and get them certified through the new process. Given these time-intensive steps required, and ONC's confirming statement that "it will generally take 6 to 18 months for commercial vendors and open source developers…to prepare for testing and certification."[5] GNYHA is concerned that there will not be many certified EHR systems available to hospitals by the beginning of FY 2011. This will limit the ability of many hospitals to meet the meaningful use requirements in time.

GNYHA recommends that, in the interim and for a period of three years, CMS deem hospitals that are able to meet meaningful requirements through an EHR system eligible for incentive payments.

[5] Federal Register Vol. 75, No. 8, p. 2041

ELIGIBILITY FOR MEDICARE AND MEDICAID INCENTIVE PAYMENTS

The ARRA provides Medicare and Medicaid incentive payments to eligible professionals and hospitals that meet the meaningful use criteria discussed above. GNYHA is very concerned however, that CMS's proposed criteria for defining providers eligible for these payments will inappropriately exclude many physicians and hospitals from qualifying for incentive payments. These concerns are discussed in detail below.

Hospital-based Eligible Professionals

Qualifying physicians who demonstrate meaningful use are eligible to receive either Medicare *or* Medicaid payment incentives. "Hospital-based" physicians are excluded from eligibility for these incentive payments however, because separate hospital payment incentives are available. The statute defines a hospital-based physician for this purpose as "an eligible professional, such as a pathologist, anesthesiologist, or emergency physician who furnishes all or substantially all services (inpatient and outpatient) in a hospital setting using the facilities and equipment, including the EHR of the hospital" from being eligible for incentive payments.

CMS proposes to define physicians who furnish at least 90% of their services in an inpatient hospital, outpatient hospital (including all provider-based on-site and off-site ambulatory care clinics), or emergency room setting as hospital-based for this purpose. In order to make this determination, CMS would analyze Medicare physician claims data and identify physicians who submit at least 90% of their claims with a "place of service" code of 21 (inpatient), 22 (outpatient), or 23 (emergency room). CMS estimates that approximately 27% of physicians would be deemed "hospital-based" and therefore, would be excluded from qualification for incentive payments using this definition.

The primary intent of the incentive payments is to promote the widespread adoption and meaningful use of HIT, which would lead to better care coordination across providers and settings. GNYHA is extremely concerned that the proposed exclusionary criteria for hospital-based physicians is overly broad and will significantly curtail the benefit of ambulatory EHRs in inner-city and rural communities, in particular, where it is extremely difficult to recruit physicians and shortages of physicians are most severe. Hospital ambulatory care sites in these communities are often the only source of primary and ambulatory care services for our society's most vulnerable populations, serving as the private physicians to their communities.

CMS also states that it is concerned that hospitals' investment in their ambulatory care EHRs will lag behind their investment in their inpatient EHRs. As CMS notes in the proposed rule, the hospital HIT incentive payments are based entirely on inpatient hospital services and hospitals with large ambulatory care departments will not receive higher incentive payments. We believe that if physicians practicing in these settings were deemed eligible for incentive payments that the hospital would use them to assist in their investment in integrated outpatient EHR systems. ***GNYHA strongly recommends therefore, that CMS revise its proposed definition to remove certain physicians practicing in hospital ambulatory care settings.***

We note that the cost of implementing an ambulatory care EHR is separate and distinct from that of the inpatient EHR so CMS should not be concerned that it would be "double-paying"

incentive payments to hospitals if it adopted this recommendation. These practice sites utilize an ambulatory EHR that is comparable or equivalent to the EHR platform used in traditional private practice settings and *not* the inpatient module of the hospital EHR. This is necessary because inpatient EHR technology platforms do not have the functionality required and needed for ambulatory care such as modules for appointment scheduling, office and physician workflow automation, prescription tracking and renewal, patient progress notes, patient care coordination such as preventative care reminders, and other practice management tools. In fact, these modules are the same as those used by private physician offices.

Alternative Approach

CMS's stated rationale for its proposal to include all physicians practicing primarily in hospital-based ambulatory care sites in its definition of hospital-based is as follows: "it is CMS's longstanding policy to consider as outpatient hospital settings those settings that are owned by and integrated both operationally and financially into the entity, or main provider, that owns and operates the inpatient setting." *(see 75 FR 1905)* We believe that there is an important precedent however, for CMS to adopt an alternative definition of outpatient as we examined the eligibility criteria that CMS implemented for its physician e-prescribing program, which provides incentive payments to physicians for using a qualified e-prescribing system in an ambulatory care setting, without regard to whether or not the services were provided in a hospital-based ambulatory care site. For this incentive program, CMS identifies services furnished using specific non-emergency department procedure codes, which the Agency defines as services typically billed in the office or outpatient setting furnished by physicians or other eligible professionals. The list of these codes is provided as Attachment B. ***GNYHA strongly recommends that CMS adopt the same approach to define eligible professionals under the HIT incentive program.***

In addition to analyzing the procedure codes used in the e-prescribing initiative, we think that it would be appropriate for CMS to look at the specialty of the physician performing the service. The statute clearly excludes specialties that are using the inpatient and emergency room of the EHR modules of the hospital, including pathologists, anesthesiologists, and emergency room physicians. We also believe that it would be appropriate to exclude hospitalists, intensivists, and other specialties that typically furnish substantially all of their services in the inpatient hospital setting. Physicians not specifically identified through these criteria should be eligible for EHR incentives unless they provide substantially all of their services in an inpatient or emergency room setting. For this purpose, GNYHA supports CMS's proposal to use 90% as the threshold for making this determination.

Multi-Campus Hospitals

The Medicare payment incentives in the ARRA are available to "subsection (d) hospitals" that are defined as "meaningful users" of a certified EHR. In the proposed rule, CMS proposes to use the CMS Certification Number (CCN), or Medicare provider number, to identify hospitals that are eligible for incentive payments. GNYHA strongly opposes this proposal.

How CMS identifies hospitals for this purpose is critically important because the Medicare and Medicaid payment formulas are calculated as a base amount of $2 million plus a per discharge

amount capped at 23,000 discharges multiplied by the hospital's applicable payer share (the Medicare share for Medicare incentive payments and the Medicaid share for Medicaid incentive payments). The use of the CCN would significantly disadvantage multi-campus hospital systems enumerated with a single CCN relative to those enumerated with multiple CCNs because they would be limited to one base payment and would be more likely to exceed the discharge cap. Most importantly, the payment incentives available for multi-campus hospital systems with one CCN would not appropriately recognize the hospital's HIT implementation costs, which are substantial for each campus.

Specifically, hospitals generally do not achieve savings by purchasing a single EHR for multiple sites as the cost of the implementation of the EHR at each site far exceeds the purchase cost of the actual application or software. In addition, multi-site campuses often have IT and clinical reasons for necessitating separate EHR installations for each site. This is due to the fact that each site is at least in part an autonomous unit, with local systems and policies that must be independently reflected in an EHR implementation. For example, site installations must accommodate different network infrastructures, physician preferences, clinical protocols and rules systems, workflows, and ancillary system integration.

In addition, duplicate administrative system costs for things such as workstation installation and staff training must be incurred. Furthermore, differences in clinical services offered at the sites may require additional unique system variations between facilities each requiring different system interfaces and clinical systems. GNYHA does not believe that how a hospital is enumerated for purposes of reporting to Medicare should disadvantage, or advantage them, relative to nearby competing hospitals.

Instead, it would be more appropriate for CMS to calculate the incentive payments based on each hospital campus. CMS currently defines campuses that are distinct from the main provider as remote locations of a hospital for purposes of the Medicare program (see 42 C.F.R. §413.65(a)(2)):

> ***Remote location of a hospital*** *means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term "remote location of a hospital" does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter.*

GNYHA strongly recommends that CMS recognize the main provider, as well as remote campuses as defined above, for purposes of identifying hospitals eligible for incentive payments.

We believe that CMS has the discretion to make payments under ARRA to subsection (d) hospitals based on this definition just as it distinguishes remote locations of hospitals that are located in different Core Based Statistical Areas (CBSAs) as the main provider for payment under its Medicare PPSs. Under this policy, CMS provides the wage-index adjustment to the PPS rate based on the wage index of the CBSA in which the individual hospital is located to appropriately recognize the wage costs incurred by the facility (see 42 C.F.R. § 412.64(b)(5)):

> *For hospitals that consist of two or more separately located inpatient hospital facilities, the national adjusted prospective payment rate is based on the geographic location of the hospital facility at which the discharge occurred.*

Providing incentive payments to eligible hospitals based on this same concept would be consistent with this precedent and would likewise appropriately recognize the unique costs incurred by each of these facilities, in this case for HIT adoption and use.

Implementation Issues

GNYHA recognizes that CMS does not currently have the information needed on each remote location in order to implement this recommendation but does not believe that it would be burdensome on the Agency to collect it. We suggest that CMS either augment the Medicare cost report to collect basic information on each remote location or direct the FI/MACs to use another mechanism such as a survey. The FI/MAC could then use the reported information to assign a hospital-specific "suffix" to the CCN to create a separate Medicare identifier for each remote campus as they do for remote locations of hospitals that are located in different CBSAs for administrative tracking purposes:

> *However, if the campuses are located in more than one labor market area, payment for each discharge is determined using the wage index value for the CBSA (or metropolitan division, where applicable) in which the campus of the hospital is located. When the satellite campus is located in a different labor market area, the fiscal intermediary should assign a unique identifier (usually a 2 digit suffix), which is added after the provider's Online survey and Reporting (OSCAR) number. This provider-specific "suffix" will ensure the campus-specific payment is based on the wage index for the labor market where the campus is geographically located.* (Pub 100-04 Medicare Claims Processing, Transmittal 1067, Change Request 5276, September 26, 2006, page 8)

For the purpose of calculating incentive payments for each campus, GNYHA identified two different approaches that CMS could employ:

- Option 1: Augment the Medicare cost report to collect the data necessary to calculate Medicare and Medicaid incentive payments at the campus-level (i.e. total discharges, and Medicare, Medicaid, and total days). CMS may also want to collect Medicaid discharges as this data could also be used by State Medicaid programs to assist in the eligibility determination for Medicaid incentive payments.

- Option 2: Use the combined Medicare cost report data currently reported for multi-campus systems (at the CCN-level) to determine an average incentive payment for each campus. Under this option, CMS would equally apportion the system's discharges to each campus and apply the same Medicare and Medicaid share based on the applicable payer share derived for the system as a whole. State Medicaid agencies could use the same approach to calculate Medicaid incentive payments. If CMS chose this option, it would need to extend discretion to State Medicaid programs to collect additional data, as needed, to determine whether or not providers met the 10% eligibility threshold for receiving Medicaid incentive payments at each campus.

We are concerned that Option 1 could delay the processing of incentive payments to multi-campus hospitals as CMS collects the data necessary to calculate payments at the campus level. However, if CMS implements this approach expediently, we do not believe that the delay would be untenable if the FI/MACs were directed to make retrospective payments as soon as the cost report data were available, as opposed to waiting until the final cost report reconciliation. Another interim option that we identified would be for the FI/MACs to conduct a special survey in Year 1 to collect the data described above in order to make interim incentive payments until the cost report data could be collected and utilized.

GNYHA defers to CMS on which approach would be preferable to the Agency from an administrative perspective. In either case, we envision that the incentive payments for the remote locations would still be made to the main provider.

We should also note that if CMS was to adopt our recommendation on eligible hospitals, we also believe that it would be appropriate and necessary to make the determination of whether a hospital meets the "meaningful use" criteria at the individual campus level. The information needed to determine whether or not an individual campus qualifies for incentive payments under meaningful use could easily be incorporated into the attestation process that CMS has proposed. In addition, while it is not a subject for comment under the proposed rule, we believe that it would be appropriate to apply the Medicare payment penalties at the campus level for hospitals that do not meet the meaningful use criteria beginning in FY 2015. We will reserve our formal comments on this subject however, until there is future rulemaking addressing the application of the payment penalties.

MEDICARE INCENTIVE PAYMENTS FOR HOSPITALS

Hospital Incentive Payments

The Medicare incentive payment formula prescribed in the ARRA statute provides payments to qualifying eligible hospitals beginning in FY 2011 as follows:

> = ($2 million base amount + $200 per discharge for all-payer acute care discharges 1,150 - 23,000) * the hospital's *Medicare share* / *charity care adjustment* * the applicable transition factor.

We will now discuss several issues related to the calculation of the incentive payments, including the following issues:

- Cost report data used to compute payments;
- Form and timing of payments;
- Calculation of the Medicare share; and,
- Calculation of the charity care adjustment.

Cost Report Data Used to Compute Payments

CMS proposes to use Medicare cost report data as the source for the metrics needed to compute the hospital incentive payments, including discharges, Medicare and total days, and the charity care adjustment. We will provide specific comments on these data elements below. Generally however, CMS would use the cost report data from the hospital FY that ends during the year prior to the payment year to make a preliminary incentive payment to the hospital. The preliminary payment would be adjusted to a final payment based on the final settlement of the cost report for the hospital's FY cost report that ends in the applicable payment year. ***GNYHA recommends that CMS instead use the most recently available cost report data available so as to not unnecessarily delay preliminary incentive payments to any group of hospitals.***

Form and Timing of Payments

CMS proposes to have the FI/MACs calculate the Medicare incentive payments for each hospital and to process the "interim" incentive payments following the process outlined above. The proposed rule does not specifically address the mechanism for payment (i.e. lump sum check or a claims adjustment) or the timing of the payment. ***GNYHA urges CMS to provide incentive payments as a lump sum payment to qualifying hospitals and that it require the FI/MACs to make both the interim and final incentive payments expediently.*** We believe that a timeframe of no more than 60 days after the verification of a provider qualifying as a meaningful user would be appropriate.

With respect to CMS's proposal to have final payments be determined based on the final settled cost report for the hospital fiscal year that ends during the payment year, GNYHA is very concerned about the significant delay that may be incurred through this process. GNYHA has several members with outstanding cost report settlements from as far back as 2002, or nearly seven years old. Instead of waiting for the actual final settlement of the cost report for the hospital's FY that ends in the applicable payment year, we urge CMS to instruct the FI/MACs to make final incentive payments based upon submission of this cost report. In addition, we request that CMS apply the same timeframe of no more than 60 days suggested above for processing interim incentive payments to final incentive payments.

Calculation of the Medicare Share

The ARRA stipulates that the Medicare share of the incentive payment formula be calculated as (Medicare Part A + Medicare Part C inpatient days) / total inpatient days, where the days are

derived as "the estimated number of inpatient bed-days attributable to individuals with respect to whom payment may be made under Part A and Part C" CMS proposes to use Worksheet S-3, Part I, Lines 1, 2, 6-9, 10 and 14 in Column 4 as the data source for this calculation. GNYHA supports the use of these lines as they appropriately reflect the source for Part A and Part C days, but requests that CMS reconfirm that it intends to include exempt unit days in the calculation. The reason for the request is that the proposed rule text states "the data entered on these lines in the cost report include all patient days attributable to Medicare inpatients, excluding those in units not paid under the IPPS and excluding nursery days."

Calculation of the Charity Care Adjustment

The charity care adjustment to the Medicare share is calculated as [1 – (charity care charges / total charges)], which has the effect of providing hospitals with a higher incentive payment as its proportion of charity care increases. CMS proposes to use a revised cost report Worksheet S-10, Hospital Uncompensated Care, as the data source for the charity care charges. The final revised Worksheet S-10 has not yet been released, although CMS anticipates that it would be used for cost reporting periods beginning on or after February 1, 2010.

Under this timeframe, CMS would not have the data necessary on the revised S-10 to calculate the charity care adjustment until Spring 2012 for hospitals with a January 1 cost reporting year. This would be too late for calculating the charity care adjustment for many hospitals qualifying for incentive payments in FY 2011 and while it is unclear in the proposed rule, CMS seemingly proposes to apply an adjustment of "1" for hospitals for which the charity care data are not available.

GNYHA strongly urges CMS to abandon this proposal and to develop an interim mechanism for hospitals to report the necessary information so that no hospital receives a charity care adjustment of "1" merely because of its cost reporting cycle. Furthermore, we request that CMS provide the industry with an opportunity to provide comments on the appropriateness of using Worksheet S-10 for the purpose of computing the charity care adjustment once the final revised worksheet and instructions are released.

Operational Concerns

The proposed rule does not provide detail on many of the operational issues associated with the implementation of the incentive payments, including the process to apply for meaningful use payments and the expected timeframe and process for providers to payments. We therefore request that CMS issue additional information on how it contemplates that this program would be implemented.

In addition, given the complexity and novelty of the program, we suggest that CMS incorporate a contractor and provider education component into its implementation plan.

Appeals Process for Medicare Payments

CMS does not propose an appeals process for Medicare incentive payments.

Given the complexities of this new program, GNYHA recommends that CMS implement an appeals process for Medicare incentive payments that parallels the requirements proposed for state Medicaid agencies. Under these requirements, states must allow for a provider or entity to appeal the following: 1) incentive payments; 2) incentive payment amounts; 3) provider eligibility determinations; and 4) demonstration of meaningful use.

MEDICAID INCENTIVE PAYMENTS

The ARRA provides Medicaid incentive payments eligible professionals and hospitals that meet the meaningful use criteria. In order to qualify for Medicaid incentive payments, hospitals must have a Medicaid percentage of at least 10% or be designated as a freestanding children's hospital. For eligible professionals, the eligibility threshold is a Medicaid share of at least 30%, with two exceptions. The qualifying threshold for pediatricians is 20%, while the threshold for eligible professionals practicing in a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) is 30% but is based on patient volume attributable to "needy individuals," defined as services provided to individuals with coverage under Medicaid or the Children's Health Insurance Program, or who are uninsured.

Calculating Patient Volume Requirements

In order to calculate the patient volume requirements outlined above, CMS proposes to require that acute care hospitals and eligible professionals demonstrate the applicable minimum Medicaid volume threshold over any continuous representative 90-day period. Providers would be required to submit an annual attestation that it met the patient volume thresholds to qualify for Medicaid incentive payments. CMS would allow state Medicaid programs the flexibility to adopt an alternative timeframe for measuring patient volume, subject to CMS approval. ***GNYHA recommends that this proposed flexibility for State Medicaid programs be extended to the calculation of the patient volume thresholds, as well.***

Treatment of Medicaid Incentive Payments for DSH/UPL/CPE

The proposed rule does not address the treatment of the Medicaid incentive payments in the calculation of hospital Medicaid disproportionate share limits (DSH), upper payment limit (UPL) payments, and Certified Public expenditures (CPEs) for public hospitals, or any similar program. ***GNYHA believes that it would be highly inappropriate for CMS to consider the incentive payments in these calculations and requests that the Agency issue guidance that the payments are to be excluded for purposes of these calculations.***

Appeals Process for Medicaid Payments

As discussed above, CMS proposes to require that states to allow for a provider or entity to appeal the following: 1) incentive payments; 2) incentive payment amounts; 3) provider eligibility determinations; and 4) demonstration of meaningful use. ***GNYHA supports the proposed appeals process for providers to appeal aspects of the Medicaid incentive program.***

Medicaid Definition of Meaningful Use

GNYHA agrees with and appreciates CMS's proposal to align Medicare and Medicaid definitions for meaningful use and to set a common definition for both. We believe that this alignment will avoid confusion and allow hospitals to focus on one set of priorities at a time. CMS, however, would permit states to propose additional objectives as long as the objectives do not require additional EHR functionality beyond what would be part of the certification criteria. We fear that this will create unnecessary burdens on hospitals during a time when they will be resource-strapped and struggling to meet the time-sensitive, Federal requirements. ***Therefore, GNYHA cautions against allowing state Medicaid programs to introduce additional meaningful use criteria.***

Medicaid First Payment Year

GNYHA appreciates that hospitals eligible for Medicaid incentive payments may receive payments in the first year for "adopting, implementing, and upgrading" EHR systems. GNYHA is also pleased that state Medicaid programs are permitted to distribute up to 50% of hospitals' estimated total aggregate incentive payments in the first payment year and 90% in the second payment year. This feature of the Medicaid incentive payments is critical to many GNYHA member hospitals, as upfront implementation costs and access to capital were cited as being a major barrier to EHR adoption by 73% of hospitals in New York. This was the top concern cited in a recent survey, followed by ongoing costs, which was identified as a major concern for 46% of responding hospitals.[6] Since financial investments in HIT are often front-loaded, receiving a large portion of the Medicaid incentive payments early in the adoption process will assist hospitals in making significant strides quickly at the beginning of the implementation process. ***GNYHA therefore, urges CMS to instruct states to provide the maximum payment allowable amounts in the first and second payment year for Medicaid-eligible hospitals.***

PRIVACY AND SECURITY

GNYHA and its member hospitals are committed to protecting the privacy and security of their patients' health information. As covered entities under HIPAA, hospitals have to be compliant with strict measures to ensure this protection. For this reason, GNYHA is in full agreement with CMS in that the EHR Incentive Program defining regulation is not the appropriate vehicle to ensure HIPAA compliance. Rather, this authority should remain under the HHS Office for Civil Rights.

[6] McGinnis S, Moore J., et al.

Appendix A. Recommended Set of Alternative Hospital Meaningful Use Objectives			
2011/2012 **Meet 25% (8) of:** **<100 beds Meet 15% (5) of:**	**2013/2014** **Meet 50% (17) of:** **<100 beds Meet 30% (10) of:**	**2015/2016** **Meet 75% (26) of:** **<100 beds Meet 60% (20) of:**	**2017** **Meet substantially all of:**
1. CPOE (activated) 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)	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)	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 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)	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 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)

Appendix A. Recommended Set of Alternative Hospital Meaningful Use Objectives			
2011/2012 **Meet 25% (8) of:** **<100 beds Meet 15% (5) of:**	**2013/2014** **Meet 50% (17) of:** **<100 beds Meet 30% (10) of:**	**2015/2016** **Meet 75% (26) of:** **<100 beds Meet 60% (20) of:**	**2017** **Meet substantially all of:**
18. Reportable lab results (capability) 19. Syndromic surveillance data (capability) 20. Comply with HIPAA Privacy and Security *21. Use of evidence-based order sets (1 condition)* *22. Electronic medication administration record (eMAR) (1 nursing unit)* *23. Bedside medication administration support (barcode/RFID) (1 nursing unit)* *24. Record nursing assessment in EHR (1 nursing unit)* *25. Record nursing plan of care in EHR (1 unit)* *26. Record physician assessment in EHR (10% of patients)* *27. Record physician notes in EHR (10% of patients)* *28. Multimedia/Imaging integration (e.g., X-Ray viewing)* *29. Generate permissible discharge prescriptions electronically (10% of patients)*	18. Reportable lab results (capability) 19. Syndromic surveillance data (capability) 20. Comply with HIPAA Privacy and Security *21. Use of evidence-based order sets (3 conditions)* *22. Electronic medication administration record (eMAR) (3 nursing units)* *23. Bedside medication administration support (barcode/RFID) (3 nursing units)* *24. Record nursing assessment in EHR (3 nursing units)* *25. Record nursing plan of care in EHR (3 nursing units)* *26. Record physician assessment in EHR (10% of patients)* *27. Record physician notes in EHR (10% of patients)* *28. Multimedia/imaging integration (e.g., X-Ray viewing)* *29. Generate permissible discharge prescriptions electronically (10% of patients)* *30. Contribute data to a PHR*	18. Reportable lab results (submit data if possible) 19. Syndromic surveillance data (submit data if possible) 20. Comply with HIPAA Privacy and Security *21. Use of evidence-based order sets (5 conditions)* *22. Electronic medication administration record (eMAR) (5 nursing units)* *23. Bedside medication administration support (barcode/RFID) (5 nursing units)* *24. Record nursing assessment in EHR (5 nursing units)* *25. Record nursing plan of care in EHR (5 nursing units)* *26. Record physician assessment in EHR (50% of patients)* *27. Record physician notes in EHR (50% of patients)* *28. Multimedia/imaging integration (e.g., X-Ray viewing)* *29. Generate and transmit permissible discharge prescriptions electronically*	18. Reportable lab results (submit data if possible) 19. Syndromic surveillance data (submit data if possible) 20. Comply with HIPAA Privacy and Security *21. Use of evidence-based order sets (substantially all)* *22. Electronic medication administration record (eMAR) (substantially all)* *23. Bedside medication administration support (barcode/RFID) (substantially all)* *24. Record nursing assessment in EHR (substantially all)* *25. Record nursing plan of care in EHR (substantially all)* *26. Record physician assessment in EHR (substantially all)* *27. Record physician notes in EHR (substantially all)* *28. Multimedia/imaging integration (e.g., X-Ray viewing)* *29. Generate and transmit permissible discharge prescriptions electronically*

Appendix A. Recommended Set of Alternative Hospital Meaningful Use Objectives			
2011/2012 **Meet 25% (8) of:** **<100 beds Meet 15% (5) of:**	**2013/2014** **Meet 50% (17) of:** **<100 beds Meet 30% (10) of:**	**2015/2016** **Meet 75% (26) of:** **<100 beds Meet 60% (20) of:**	**2017** **Meet substantially all of:**
30. Contribute data to a PHR *31. Record patient preferences (language, etc.)* *32. Provide electronic access to patient-specific educational resources* *33. Reporting of RHQDAPU quality measures through existing process*	*31. Record patient preferences (language, etc.)* *32. Provide electronic access to patient-specific educational resources* *33. Reporting of some RHQDAPU quality measures through EHR* *34. Medication reconciliation across settings of care (pilot)*	*(50% of patients)* *30.* *31. Contribute data to a PHR* *32. Record patient preferences (language, etc.)* *33. Provide electronic access to patient-specific educational resources* *34. Reporting of some RHQDAPU quality measures through EHR* *35. Medication reconciliation across settings of care (if possible)*	*(substantially all)* *30. Contribute data to a PHR* *31. Record patient preferences (language, etc.)* *32. Provide electronic access to patient-specific educational resources* *33. Reporting of all appropriate RHQDAPU measures through EHR* *34. Medication reconciliation across settings of care*

Notes:

1. *ITALICIZED* objectives from the HIT PC recommendations for 2013 and 2015.
2. List excludes proposed objectives on electronic insurance verification and electronic billing in all years, and medication reconciliation in 2011/2012 only.
3. CCD = Continuity of Care Document.

Attachment B: CPT/HCPCS Codes for Reporting on E-Prescribing Under the Medicare Physician Fee Schedule

CPT/HCPCS	Description	CPT/HCPCS	Description
90801	Psy dx interview	99306	Nursing facility care, init
90802	Intac psy dx interview	99307	Nursing fac care, subseq
90804	Psytx, office, 20-30 min	99308	Nursing fac care, subseq
90805	Psytx, off, 20-30 min w/e&m	99309	Nursing fac care, subseq
90806	Psytx, off, 45-50 min	99310	Nursing fac care, subseq
90807	Psytx, off, 45-50 min w/e&m	99315	Nursing fac discharge day
90808	Psytx, office, 75-80 min	99316	Nursing fac discharge day
90809	Psytx, off, 75-80, w/e&m	99324	Domicil/r-home visit new pat
90862	Medication management	99325	Domicil/r-home visit new pat
92002	Eye exam, new patient	99326	Domicil/r-home visit new pat
92004	Eye exam, new patient	99327	Domicil/r-home visit new pat
92012	Eye exam established pat	99328	Domicil/r-home visit new pat
92014	Eye exam & treatment	99334	Domicil/r-home visit est pat
96150	Assess hlth/behave, init	99335	Domicil/r-home visit est pat
96151	Assess hlth/behave, subseq	99336	Domicil/r-home visit est pat
96152	Intervene hlth/behave, indiv	99337	Domicil/r-home visit est pat
99201	Office/outpatient visit, new	99341	Home visit, new patient
99202	Office/outpatient visit, new	99342	Home visit, new patient
99203	Office/outpatient visit, new	99343	Home visit, new patient
99204	Office/outpatient visit, new	99344	Home visit, new patient
99205	Office/outpatient visit, new	99345	Home visit, new patient
99211	Office/outpatient visit, est	99347	Home visit, est patient
99212	Office/outpatient visit, est	99348	Home visit, est patient
99213	Office/outpatient visit, est	99349	Home visit, est patient
99214	Office/outpatient visit, est	99350	Home visit, est patient
99215	Office/outpatient visit, est	G0101	CA screen;pelvic/breast exam
99304	Nursing facility care, init	G0108	Diab manage trn per indiv
99305	Nursing facility care, init	G0109	Diab manage trn ind/group