



March 12, 2010

Submitted via the Federal e-Rulemaking Portal: <http://www.regulations.gov>

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-0033-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

RE: Proposed Regulations for the Medicare and Medicaid Electronic Health Record Incentive Program

Dear Sir or Madam:

I am writing on behalf of Molina Healthcare to offer comments in response to the proposed regulations that were issued in the *Federal Register* on January 13, 2010. (75 Fed. Reg. 1844).

Molina Healthcare has 30 years of experience serving individuals who receive health benefits through Medicaid, the Children's Health Insurance Program (CHIP), and Medicare. Molina Healthcare's operations in California, Florida, Michigan, Missouri, New Mexico, Ohio, Texas, Utah, Virginia, and Washington State currently serve about 1.5 million low-income vulnerable Americans who otherwise would be unable to obtain insurance coverage.

Our 19 primary care clinics in California, Washington and Virginia serve as the medical home for almost 100,000 individuals. They are located in predominately economically disadvantaged and underserved areas where care coordination is even more critical for the health and well being of individuals. Our clinics treat not only Molina members, but the uninsured as well. Our clinics are staffed by 45 physicians, physician assistants and nurse practitioners who see almost 200,000 patient encounters per year.

We support initiatives to advance the use and exchange of health information and to make such information more readily available to providers and other covered entities. We believe this can lead to improved quality and efficiency of health care services. Providing incentives through the Medicare and Medicaid programs is a logical approach to achieving these objectives.

After reviewing the proposed rule, we have identified several issues that we believe should be addressed in the final regulations. Our comments and recommendations are attached.

Thank you for the opportunity to comment on these important issues.

Sincerely,

Joseph M. Molina, MD

Molina Healthcare's Comments on CMS Proposed Regulations for the Medicare and Medicaid EHR Incentive Program

General Comments

We believe the U.S. health care system has an important opportunity to fundamentally change how it manages patients' health records in ways that will directly improve the quality of care delivered to patients. With recent Congressional initiatives aimed at reforming the health care system to improve access to care while systematically reducing costs, the time is ripe for federal agencies to implement the HITECH Act's legislative mandates and set ambitious, yet achievable, goals to ensure the effective investment of federal funds to create incentives for eligible providers (EPs) and hospitals to implement and use electronic health records (EHRs).

As a health plan which both contracts with Medicare and Medicaid providers and also operates clinics, we are concerned about the ability of small and safety net providers to qualify as "meaningful users" of EHR under the standards and objectives within the timeframes laid out in the proposed rule. Although we appreciate the incentives offered by the federal government to providers to adopt EHR, as currently written, the proposed rule favors larger health entities with greater resources at their disposal. We are concerned these incentives may be too challenging and stringent for small and traditional safety net providers to meet in a short timeframe and may lead to provider non-participation in the incentive program. **The federal government must, therefore, allow providers more flexibility in meeting the standards and criteria outlined in the proposed rule.**

In addition, uniform standards of care and measurement are an important policy mechanism to not only improve the quality of healthcare but also control costs. Quality data is used for assessment, but more importantly to make improvements in health care delivered, and to design effective interventions that result in improved health for patients. It is, therefore, essential that any new requirements are streamlined with or replace existing standards to limit the burden on providers. **Molina recommends that NCQA HEDIS measure specifications be used wherever possible.** These measures, which are respected by the clinical community, have been endorsed by the National Quality Forum (NQF), have been in use for several years, and have produced results that allow for direct comparison between states and plans.

Furthermore, we appreciate CMS's efforts to link the Medicare and Medicaid EHR incentive programs. Consistency in the programs, as encouraged by the HITECH Act, will lead to more efficient, streamlined processes throughout the health care system.

We believe that in the final regulations and in future rulemaking or guidance it is critical for CMS to provide more information about its strategic direction and the rationale for establishing the selected requirements. We encourage CMS to be as transparent as possible about the short and long-term objectives of implementing and using EHRs and to explain how the objectives will be used to improve care delivery. For example, EPs and eligible hospitals, and other health care entities would benefit from understanding why specific reporting objectives and measures were chosen (i.e., based on improving care for a specific population, targeting areas where needed

improvements in care have been identified), how the objectives and measures may change or expand, what can be expected in future stages, and how the data reported will be used to benefit patient outcomes and physician and hospital practice patterns. Particularly as the industry begins to implement the meaningful use requirements, we support using the first year as a test year to better understand how the new requirements will be implemented and practically used within the health care industry.

In addition, we recommend that as CMS promulgates final regulations related to the Stage 1 meaningful use requirements, proposes future meaningful use regulations, and issues related guidance, the agency should strive to include more details about how collected data will be used to benefit individual health outcomes and improve clinical practice patterns. For example, it would be helpful to understand the criteria being considered for requirements that will be used in upcoming stages. We believe such information should be shared with the industry as soon as practical since we expect EPs and hospitals to devote a significant amount of financial and administrative resources to select and install qualified EHRs. CMS should strive to set reasonable objectives and expectations for EPs and hospitals to help ensure that financial and administrative resources devoted to EHR initiatives are well-planned and spent. **Thus, CMS must strive to make information available about the Stage 2 and future requirements as soon as possible. Doing so will reduce the risk that EPs and hospitals may make purchases and devote time to projects that do not satisfy program requirements.**

If the preceding goals can be met, then we urge CMS to maintain the expectations for timing and implementation of the requirements and incentives and strongly advise against delaying these important objectives, particularly as they relate to the quality reporting requirements. We believe that the proposed rule should not be modified in ways that would create delays for EPs or eligible hospitals to implement the requirements or to receive incentives. While delays may allow for additional time for affected entities to learn about and gain comfort with the program requirements, we believe any delays will directly undercut improvements in healthcare quality and affordability, which are needed and long overdue in the U.S. health care system.

Specific Comments

We offer the following specific comments and recommendations to address some of the more technical issues raised by the proposed rule.

State Flexibility in Setting Standards

Issue: In the case of the Medicaid EHR Incentive Program, CMS has indicated it will allow States to add additional standards to the definition of meaningful use or modify how the existing standards are measured. The preamble solicits comments as to whether there exist compelling reasons to give the states additional flexibility in creating disparate definitions beyond what is proposed. (See, Section II. A. 2.c)

Discussion: As a multi-state Medicaid health plan operating in ten states, we are very concerned that allowing states flexibility to implement different guidelines would undermine standardization processes, potentially delay the availability of incentive funds to providers, and lead to significantly higher administrative costs to health plans, providers, and states.

Multi-state providers like Molina would be required to customize EHR systems to meet each state's unique requirements resulting in significant implementation costs as well as ongoing maintenance and reporting expenses. Further, Molina strongly encourages that any quality assessment measures be uniformly applied and not implemented on a state-by-state basis. A tremendous amount of administrative waste goes into shaping individual standards and processes.

We are also concerned about the impact on and the readiness of state Medicaid programs in moving to implement new objectives. If states' efforts to add additional objectives or modify how the existing objectives are measured are not accomplished in a timely fashion, it is critical Medicaid providers are not unfairly penalized.

Finally, a national, uniform set of standards and objectives are needed to allow for the design and development of standardized software programs and provider solutions. With the possibility of fifty different set of standards, the number of software programs available for provider use in each state may be limited and therefore cost-prohibitive.

Recommendation: We recommend that states should not be permitted to add additional objectives to the definition of meaningful use or modify how the existing objectives are measured. If the requirements to participate in the Medicaid incentive program are overly burdensome, providers who operate in multiple states will likely opt out. Lack of consistency complicates the process and as a result, providers may find it costly and difficult to reach the objectives.

However, if CMS chooses to allow states to add additional objectives, then we propose, as an alternative, that Stage 1 contain national criteria only. During Stage 2 or 3, states may be permitted to adopt some state specific criteria that build on the national criteria. This proposal would allow providers to move forward and receive Medicaid meaningful use incentive payments without being slowed by the state criteria development process.

Definition of Hospital-Based Eligible Professionals

Issue: The proposed rule defines "hospital-based eligible professional" to mean an EP, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of his or her Medicare covered professional services during the relevant EHR reporting period in a hospital setting (whether inpatient or outpatient) through the use of the facilities and equipment of the hospital, including the hospital's qualified EHRs.

Discussion: The definition of "hospital-based" physicians should be expanded to include other providers such as hospitalists, intensivists, and SNFists. Excluding these providers from meaningful use requirements would be missing a significant component of health care system.

These providers should be required to adopt EHRs and be allowed to qualify for the incentive program. The assumption that these providers would have an incentive to shift patients to the inpatient setting is countered by medical management processes such as utilization management review currently under the Medicare and Medicaid programs administered by CMS.

Recommendation: The final regulation should broaden the definition of hospital-based providers to include providers such as hospitalists, intensivists, and SNFists, which are a significant part of the health care system today.

Qualifying Medicaid EPs

Issue: The proposed rule defines “Medicaid Eligible Professionals” as physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in an FQHC or RHC, which is so led by a physician assistant.

Discussion: Eligible healthcare professionals, who are employed by staff-model health maintenance organizations (HMOs), such as Molina Healthcare, provide critical health care services to individuals enrolled in Medicaid.

Recommendation: We recommend that the definition of “Medicaid EPs” include staff model EPs of HMOs meeting certain Medicaid thresholds (similar to the definitions provided for Medicare Advantage HMOs).

Pathways of Meaningful Use

Issue: CMS is proposing a phased approach to defining meaningful use and intends to update the criteria of meaningful use through future rulemaking.

Discussion: While we support the phased approach, the assumption that subsequent stages are inclusive of previous stage requirements may not be technically correct. For example, eligible professionals may be able to adopt patient self management tools (Stage 3) without first implementing computerized provider order entry (CPOE) (Stage 2). We believe the system is better served if providers meet the objectives set forth in each stage. Therefore, EPs should be required to achieve the preceding stage objectives in order to qualify for incentives available to those providers who meet later stage objectives.

Recommendation: The final rule should clarify that as a prerequisite to being eligible for incentives under Stages 2 and 3, EPs must satisfy the objectives that are set forth in Stage 1.

Stage 1 Criteria for Meaningful Use

Issue: To qualify as a meaningful EHR user for 2011, CMS proposes that an EP or eligible hospital must demonstrate that they meet all of the objectives and their associated measures as set forth in 42 CFR §495.6.

Discussion: While we generally support the objectives and measures in proposed regulation §495.6, to reiterate our general comments, we are concerned about challenges the objectives and timelines will impose on small and safety net providers to meet in a short timeframe. Most Medicaid providers work in small practices and have limited staff resources to implement EHR, even with incentive payments. We anticipate that many Medicaid providers will have difficulty meeting all of the currently proposed meaningful use criteria.

Recommendation: We recommend that CMS provide more flexibility to small and safety net providers to meet Stage 1 criteria.

Medicare Advantage Payments

Issue: The proposed rule would require that, “before payments can be made to qualifying MA organizations for MA EPs, [CMS] must first determine if a maximum incentive payment under the Medicare FFS program has been previously earned by potential MA EPs.”

Discussion: We appreciate the efforts of CMS to avoid duplicate payments to providers. However, we are concerned with potential delays that may occur in making payments to qualifying MA organizations for MA eligible providers while CMS determines the eligibility of providers. In many cases, MA EPs may provide services only to MA enrollees and therefore, would not qualify for any amounts under the Medicare FFS incentive program. In such circumstances, it would be unnecessary for CMS to delay payments to MA organizations pending final determinations under the Medicare FFS EHR incentive program in order to guard against duplicate payments.

Recommendation: To provide timely payments to qualifying MA organizations, CMS should permit such organizations to attest that MA EPs are not eligible for EHR incentive payments under the Medicare FFS program for a payment year. We also recommend that based upon these attestations, CMS make incentive payments to MA organizations for meaningful use of EHR technology by such MA EPs as soon as possible after the deadline for MA organizations to provide final identification to CMS of potentially qualifying MA EPs, which is December 31 of each payment year, and the deadline for submission of attestations, which is January 30 of each year.

Medicare Advantage Quality Measures Reporting

Issue: Under the proposed rule, “for clinical quality measures which overlap between the existing MA quality reporting program and under the HITECH program, [CMS] proposes to allow qualifying MA organizations to continue reporting under the existing MA quality reporting program. For those HITECH clinical quality measures that do not overlap and that are appropriate for the MA program, [CMS is] considering requiring that qualifying MA organizations that receive an incentive payment report those measures to CMS.”

CMS also proposes an alternative approach “to require that qualifying MA organizations that receive an incentive payment report all of the HITECH clinical quality measures under section II.A.2 of this proposed rule that are appropriate for the MA program directly to CMS, while also reporting those HEDIS, HOS, and CAHPS measures under the existing MA quality program.”

Discussion: Under current law, qualifying MA organizations sponsoring coordinated care MA plans are already required to report HEDIS, HOS, and CAHPS measures. These reporting data measures are respected by the clinical community and have been successfully used for several years. In addition, plans report operational and clinical data through Part C and Part D Reporting Mechanisms. Special Needs Plans report on a number of additional measures, which include quality indicators. Finally, some MA plans choose to go through NCQA accreditation. The addition of new reporting measures will lead to additional administrative costs to plans and providers.

Recommendation: We support allowing qualifying MA organizations to continue reporting under the existing MA quality reporting program. However, we are concerned about adding further reporting measures as these will lead to additional administrative costs. In addition, we do not support the alternative approach proposed by CMS as it will lead to costly duplicative reporting.

Clarification on Potential Payments and Funding to Medicaid Health Plans

Issue: The proposed rule requires states to attest that the entire incentive payment has been forwarded to the eligible Medicaid provider. In many cases, the State may have no existing relationship with the provider and may rely on the managed care plan to pass along the incentive to the EP. The proposed rule also stipulates that any existing state relationships with managed care plans do not result in payments that exceed 105 percent of the capitation rate to pass incentive payments along to providers.

Discussion: As a Medicaid managed care plan, we seek clarification on how states should manage pass-through payments given that most providers contract with multiple managed care plans. Specifically, we seek a clearer understanding of the 105 percent of capitation rate and the entities affected. For example, does the proposed rule indicate that the provider cannot be paid more than 105% of the capitation rate? If a managed care plan currently pays a provider at 105% of the Medicaid fee schedule, would that render the provider ineligible for the incentive? Or does the proposed rule indicate that a plan’s premium cannot go above 105% (i.e., by paying a plan 100% of the premium, the plan would have 5% to allocate to administrative expenses)? We seek clarification on these issues.

In addition, the management and attestation of these payments would result in additional administrative processes and thus, increased costs for Medicaid health plans. Finally, several states have imposed insurance premium taxes on Medicaid health plans. We are concerned these pass-through payment amounts will be used by states when calculating insurance premium taxes, again resulting in increased costs to Medicaid plans.

Recommendation: We seek further clarification from CMS on the role of Medicaid managed care plans in administering the pass-through payments to providers. We also recommend that states forward the state administrative payments to managed care plans to cover the costs of administering the pass-through payments. In addition, we believe these administrative payments should be outside of the 105% rule.

Medication Lists and Reconciliation Processes

Issue: Proposed regulation §495.6 sets forth “maintaining active medication lists” as a Stage 1 objective in determining meaningful use.

Discussion: We support tools that help empower consumers with making informed decisions at the point of care while helping to reduce adverse events. To this end, we recommend that the proposed rule mandate a patient independent verification process. We believe the rule would be improved if it required providers to ask patients to describe the medications they are currently taking. Such a process will help ensure the accuracy of an individual’s information, ensure that the information being used to make decisions in fact is attributable to the individual patient, and serve as a key component of helping to prevent potential safety issues and errors. This requirement should extend to over-the-counter medications and herbal and dietary supplements. This information could also be obtained from an interoperable exchange of data from a personal health record (PHR).

Recommendation: The proposed rule should require EPs and eligible hospitals to verify an individual’s medication lists from electronic data sources compared to information provided directly from the individual patient. The regulation could include a requirement to “maintain an active medication list reflecting the outcome of a medication reconciliation involving the individual patient, if applicable.”

In addition, the Stage 1 objectives should go farther than requiring functionality for drug-drug, drug-allergy, and drug-formulary checks. The meaningful use Stage 1 measures should require EPs and eligible hospitals to acknowledge at least 80% of drug-drug, drug-allergy, and drug-formulary checks since performing these functions will be vitally important to understanding drug selections at the point of care, while providing valuable data on how such processes reduce adverse events.

Insurance Type

Issue: Proposed regulation §495.6 criteria sets forth recording “insurance type” as a Stage 1 objective in determining meaningful use.

Discussion: We recognize there can be great value in CMS receiving data that can be subsequently used to compare patient health outcomes and provider practice patterns as these data relate to Medicare, Medicaid, or commercial insurance carriers. This is one area where more information about how the data will be used (e.g., physician peer-to-peer comparisons, public vs. private health coverage types, etc.) would be highly beneficial in understanding what information is to be reported.

Requiring an “insurance type” may be interpreted to mean the type of insurance coverage (e.g., Health Maintenance Organization, Preferred Provider Organization, etc.) rather than the source of health coverage (e.g., Medicare, Medicaid, or commercial products). We believe the source of health coverage is as important as insurance type. Therefore, we recommend that “insurance type” be revised to refer instead to “health coverage information.” Secondly, we recommend that CMS provide further guidance that health coverage information includes insurance type and source of coverage. Finally, clarification is needed to determine the type of information reported for individuals who are uninsured or who are insured but self pay.

Recommendation 2: The final regulations should require EPs and eligible hospitals to record “health coverage information.”

Race and Ethnicity Information Collection

Issue: Proposed regulation §495.6 sets forth recording of “race” and “ethnicity” in determining meaningful use.

Discussion: We applaud CMS for attempting to reduce health disparities by requiring EPs and eligible hospitals to collect consistent information about individuals’ race and ethnicity. We expect that such data may be used by the agency or others to conduct legitimate studies that help identify health disparities that occur in specific populations and how health care providers and hospitals can attempt to mitigate such disparities when providing medical care. We are concerned, however, that some EPs and hospitals may be unable to collect this information if an individual declines to provide the information, or that inaccurate data may be compiled if EPs and hospitals attempt to complete the information without an individual’s verification. In addition, the lack of uniform data categories utilized by different agencies makes it difficult to compare gaps in care for these subgroups across the health care sector. Recommendations from the 2009 Institute of Medicine report on the standardization of race, ethnicity and language categories should be taken under consideration.

Recommendation: We recommend that CMS modify the reporting requirements for race and ethnicity data and change them to voluntary standards for the Stage One requirements. CMS should continue to evaluate whether and how EPs and eligible hospitals can accurately collect

and report this information, and should consider including these data fields in future meaningful use stages. CMS should also consider the privacy implications of this reporting requirement and whether individuals should effectively be required to disclose ethnicity information to EPs and eligible hospitals in order to receive health care services.

Care Goals

Issue: The proposed regulations appear to deviate from the Health Information Technology (HIT) Policy Committee's documented recommendations to HHS that would require EPs and eligible hospitals to implement one clinical decision support rule relevant to specialty or high clinical priority.

Discussion 4: The Stage 1 meaningful use criteria for EPs and eligible hospitals do not include a care goal with a functionality measure that is related to either generic drug utilization or high-cost imaging services (e.g., collecting data on brand and generic prescriptions for a pharmaceutical product and comparing the data for utilization results). We believe that the Stage 1 requirements should include at least one care goal that is directly linked to efficiency improvements or costs of care because such a measure is consistent with HITECH goal of developing a nationwide health information technology infrastructure that "reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information."

Recommendation: **The final regulations should include one care goal and functionality measure related to either generic drug utilization or high-cost imaging services. For example, CMS could accomplish this change by requiring the generation and transmission of electronic prescriptions to indicate whether a generic substitution for a prescription is permitted for the individual patient.**

Preventive Care Age Groups

Issue: Proposed regulation §495.6 sets forth "send reminder to patients per patient preference for preventive/follow-up care" as a Stage 1 objective determining meaningful use. The objective requires reminders to be sent to at least 50 percent of all unique patients seen by the EP that are 50 years of age and over.

Discussion: We believe preventive care is a critical component of improving quality for health care and patient satisfaction, and preventive care may also help reduce health care costs. Preventive care is important for all age groups, not just those 50 years of age and over. This is especially true for the dual eligible population. We therefore encourage CMS to include all age groups in the Stage 1 measures related to preventive care reminders.

Recommendation: **CMS should include all age groups in the Stage 1 measure for preventive care reminders, rather than limiting the criteria to individuals age 50 or older. We encourage CMS to look to existing guidelines and information developed by the Agency for Healthcare**

Research and Quality's U.S. Preventive Services Task Force or NCQA HEDIS measures and align the meaningful use requirements with those recommendations.

Administrative Transactions

Issue: The final regulations should include administrative transactions in the Stage 1 meaningful use criteria, but should allow EPs and eligible hospitals more flexibility to ensure that the required administrative transactions are conducted electronically, even if that functionality exists external to an EHR.

Discussion: Molina supports establishing meaningful use criteria that require EHRs to have the capability of and functionality for checking insurance eligibility and submitting health care claims **or equivalent encounter information** to public and private payers. Fostering the use of these electronic processes for such commonly-used transactions within the health care industry will help to reduce administrative costs for EPs and eligible hospitals and provide greater transparency for patients, while achieving the goal of administrative simplification. However, we question whether these two transactions should be required as part of the EHR, particularly since a variety of tools exist for EPs and hospitals to conduct these transactions electronically (e.g., practice management systems, multi-payer web portals, etc.). In addition, it is unclear whether a professional or hospital that uses such systems or tools would be deemed in compliance with the meaningful use requirements since the capability to conduct the required administrative transactions exists external to the EHR.

Furthermore, we believe the Medicaid and Medicare incentive programs should be flexible enough to accommodate different payment or reimbursement mechanisms other than just fee-for-service (FFS) payment methodologies. As such, we advocate for the inclusion of "equivalent encounter information" in the regulations.

Recommendation: CMS should broaden the criteria to include "equivalent encounter information" as well as health care claims. It is critical that EPs can receive credit towards the 80% criterion if they submit capitated encounters as well as claims.

We recommend CMS consider additional options to support use of administrative transactions under the HITECH Medicare and Medicaid EHR Incentive Programs. For example, in the Stage 1 criteria, CMS should permit the electronic submission of claims or equivalent encounter information and the verification of insurance eligibility to take place outside of the EHR.

CMS should also take the opportunity in future rulemaking addressing meaningful use requirements to signal its approach for administrative transactions in Stage 2. For example, additional administrative transactions could be included in Stage 2 criteria (e.g., electronic claims payment and electronic claims attachments). We also encourage CMS to: evaluate whether an EP's or eligible hospital's existing certification, such as certification under the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE)

project, would deem compliance with the meaningful use requirements to conduct eligibility transactions.

Improve Care Coordination

Issue: Improving care coordination should be a key objective of the meaningful use regulations.

Discussion: The proposed rule cites a lack of infrastructure to exchange information electronically as the rationale behind the Stage 1 requirements, particularly as they relate to the exchange of clinical information and the defined measures to evidence their meaningful use. We believe that EPs and eligible hospitals should have and continue to develop the capability to exchange key clinical information (e.g., discharge summary, procedures, problem lists, medication lists, allergies, diagnostic test results among providers of care). As such, we support Stage 1 criteria as well as future meaningful use criteria designed to accomplish this primary objective. We recommend that CMS revise the meaningful use requirements to identify a wide-range of technical approaches for EPs and eligible hospitals to demonstrate how EHRs accomplish and improve care coordination.

Recommendation: CMS should evaluate how the Stage 1 and future meaningful use requirements will strengthen information sharing to prepare EPs and eligible hospitals for care coordination requirements.

Improve Population and Public Health

Issue: The Stage 1 meaningful use requirements should include public health objectives as part of the required criteria in regulation §495.6, and should use future rulemaking to expand the development and use of EHRs to support public health initiatives.

Discussion: The preamble to the regulations discusses a lack of existing public health electronic infrastructure to support the exchange of immunization and public health information. Thus, the proposed regulations would allow states the flexibility to establish more stringent requirements for EPs and eligible hospitals if such an electronic infrastructure exists.

Health plans have demonstrated value in the public health arenas in a number of ways, including participating in state immunization registries and electronically submitting health data. Based on our experience, we believe that EPs and hospitals can serve a helpful role in promoting public health initiatives as part of the meaningful use measures. As such, we support including public health measures in the meaningful use criteria and we encourage CMS to use future rulemaking to solidify requirements for EPs and eligible hospitals to demonstrate the capability to conduct and to submit electronic data in support of public health initiatives. We recognize that these requirements may take time and will likely require CMS to work in concert with the Centers for Disease Control (CDC) and the states to ensure that the capability to accept electronic information can be performed in a standard format and consistently, without enabling significant state or other variations.

A key basis of this work should be that health care entities and individual consumers understand for what purposes the data is being solicited and for what purposes the data will be used. This will allow entities and consumers to understand how the data relates to a specific state initiative or specific project (e.g., disease registries), and will also ensure that national objectives can be met (e.g., influenza surveillance, biosurveillance, etc.), when applicable. In addition, it would be helpful to understand how the regulations will be implemented if a state fails to issue regulations or guidance or to take other action.

Recommendation : The final regulations should discuss how public health measures will be addressed in the meaningful use criteria and future rulemaking should solidify requirements for EPs and eligible hospitals to demonstrate the capability to conduct and to submit electronic data to support public health initiatives as part of the Stage 2 phase. CMS should work with the CDC and the states to accomplish the meaningful use of EHR data for defined public health objectives.

Ensure Adequate Privacy and Security Protections for Health Information (PHI)

Issue: Meaningful use regulations should continue to reference the HIPAA Privacy and Security Rules and set requirements and stay consistent with those regulatory requirements.

Discussion: We appreciate that proposed regulation §495.6 sets goals for ensuring privacy and security protections for PHI that are consistent with the HIPAA Privacy and Security Rules. We support the Stage 1 recommendations that would require EPs and eligible hospitals to conduct or review a security risk analysis pursuant to 45 C.F.R. §164.308(a)(1) and implement security updates as necessary.

We are concerned, however, with the meaningful use regulations use of the term “patient authorized” since this implies that patient authorization would be required for uses and disclosures of PHI currently permitted under the HIPAA Privacy Rule, which applies to all PHI, irrespective of format. We are concerned that if implemented, requiring patients to authorize uses and disclosures of health information that are currently permitted or required under the HIPAA Privacy Rule (i.e., for treatment, payment, and health care operations) would substantially change the policies and procedures for using and disclosing health information and would directly conflict with the HIPAA privacy requirements. In addition, creating a greater level of individual control over an EHR vs. a paper medical record could have unintended consequences on clinical care, research, and clinical initiatives that would benefit high-risk patients (e.g., care coordination efforts that occur between health insurance plans and health care providers) and also discourage provider adoption of EHRs.

Recommendation: The final regulations should stay consistent with the existing HIPAA Privacy and Security Rules. To meet this objective, the term “patient authorized” should be removed from the meaningful use regulations as it describes the practices for the exchange of clinical information. Although we strongly support removing the term “patient authorized” since it creates a different set of uses and disclosures or privacy requirements for EHRs, we would propose, as an alternative, the term “uses permitted or required under applicable law” in place of “patient authorized uses.”

Reporting of Ambulatory and Hospital Quality Measures to CMS or the States

Issue: The preamble to the regulations solicits public comments about whether it may be appropriate to defer some or all clinical quality reporting measures until the 2012 payment year.

Discussion: CMS will begin clinical quality reporting in the 2011 payment year through an attestation process but will not require electronic reporting of clinical quality measures until 2012. We believe that reporting of clinical quality data should be a primary goal for realizing the positive benefits that can result from the use of EHRs and can help to alleviate the disparate reporting that occurs currently.

We recognize that EPs and eligible hospitals may advocate for additional time to implement these requirements to ensure that the data sought can be accurately provided in the requested timeframes. However, we believe that implementing EHRs in clinical settings will help to measure patient outcomes attributable to EPs and hospitals, which ultimately demonstrates the value of creating and using EHRs. Perhaps for the first time in the health care system, information about performance and the quality of care delivered to individuals can be systematically reported and collected and can result in immediate improvements in the quality of care provided to individuals. Thus, requests to delay data reporting of quality information to 2012 or beyond would result in unnecessary delays and missed opportunities for improving patient care and health outcomes.

Recommendation: The final regulations should require the reporting of clinical quality measures, including outcome measures (e.g., readmission rates), as soon as possible to realize quality improvements and better health outcomes for individuals. We support using the first year as a “test year” to validate the data as accurate and reliable and to better understand how the data will be used to directly improve health care.

Process Versus Outcomes Measures

Issue: The proposed quality measures appear to be based on process of care measures rather than outcomes measures.

Discussion: In order to assure continued success of the EHR program, health plans will be aligning their quality improvement initiatives with the quality reporting being required by EPs and eligible hospitals. Some industry initiatives have been focused on rewarding health care providers based on outcomes that resulted in better quality of care for individual patients. We recognize that the proposed regulations include measures that are currently being collected in the Medicare quality reporting programs (e.g., PQRI, RQHDAPU) and those that are endorsed by the National Quality Forum. However, broader quality reporting initiatives are needed and there are limited, nationally-endorsed standards which assess patient outcomes.

We believe that the meaningful use regulations present a prime opportunity for CMS to enhance and address these deficiencies through the adoption of additional outcomes measures (e.g., measures that are currently reported by health plans through the HEDIS processes be used as a basis for EPs’

and hospitals' reporting). The regulations present a unique opportunity for harmonizing the various standards used and reported within the industry (e.g., HEDIS accreditation measures, state reporting requirements).

Recommendation: We recommend that CMS provide information about its strategic direction and the rationale for establishing the selected requirements, and explain how the objectives and measures will be used to improve care delivery. A strategic roadmap should be developed documenting the affected entities, proposed stages, the defined objectives and measures, the current reporting requirements, and the potential for future goals and metrics.

Clinical Reporting by EPs

Issue: The preamble explains that EPs will report on two measure groups: (1) one core set of three measures (i.e., inquiry regarding tobacco use, blood pressure measurement, and drugs to be avoided in elderly); and (2) a subset of clinical measures based on an EP's specialty group (e.g., pulmonology, endocrinology, etc.).

Discussion: We believe that quality reporting by EPs on the proposed measures are appropriate, but we would recommend expanding the number of measures reported in the EP core and specialty sets. In particular, we support new reporting criteria related to prevention measures such as body mass index and follow up, cancer screenings (e.g., breast, cervical, and colorectal), cholesterol assessment, appropriate medications for asthma patients, and diabetes care.

Recommendation: As discussed in the recommendation above, we support the development of a strategic roadmap. We also recommend that CMS expand the core quality measures reported by EPs. These measures should be designed to capture specific information related to preventive care.

Clinical Reporting by Hospitals

Issue: Clinical reporting by hospitals will vary.

Discussion: The proposed rule explains that eligible hospitals will be required to report summary data to CMS on clinical quality measures starting in the 2011 payment year. For the 2012 payment year, hospitals are provided some flexibility in reporting.

We expect that most hospitals will comply with the electronically submitting measures to CMS that meet requirements for the Medicare and the Medicaid incentives. Reporting requirements can vary, however, if a hospital is eligible for only the Medicaid EHR incentive program, or if the required measures do not apply to the patient population.

Recommendation: We believe the proposed regulations implement a flexible and reasonable approach for hospitals to report quality data. We recommend that the final regulations require any hospital that uses a variable reporting process (i.e., quality reporting that varies

based on a hospital's eligibility for incentives or patient population) to work with CMS when determining which reporting requirements will apply.

Collection of Quality Information

Issue: The preamble explains that CMS has interpreted the HITECH Act as giving the agency authority to collect summarized clinical quality measures for all patients to whom a clinical quality measure applies (i.e., individuals covered by public and private health insurance), rather than limiting the data collection to the Medicare or Medicaid beneficiaries.

Discussion: The proposed regulations are unclear how CMS expects to collect data on commercial enrollees and uninsured patients and whether such an approach could result in challenges from consumers and other groups who disagree that the HITECH Act gave the agency broad authority to mandate the reporting and collection of such data. It is also unclear whether EPs and eligible hospitals could be subject to penalties or other sanctions if an individual or group believes that the reporting process violates the federal HIPAA or state privacy requirements.

Recommendation: We urge caution in implementing interpretations that could result in legal challenges to the reporting requirements that cause delays, mistrust from patients, and potential liability for entities that want to work with CMS and comply with the meaningful use requirements. In these preliminary stages, we believe it would be prudent for CMS to base its reporting initiatives on existing industry models and develop a strategy that uses public-private partnerships and "lessons learned" for building a healthcare infrastructure with meaningful information.