ACP
American College of Physicians
Internal Medicine | Doctors for Adults®

March 10, 2010

Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave, S.W.
Washington, DC 20201
Via http://www.regulations.gov

Re: Document ID HHS-OS-2010-0001-0002

Dear Dr. Blumenthal:

Thank you for the opportunity to comment on the Interim Final Rule (IFR) that would implement provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5) that provide incentive payments to eligible professionals and hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology.

The American College of Physicians, representing 129,000 internal medicine physicians and medical student members, believes that the focus on meaningful use is the right way to promote and assess adoption of EHRs. We offer the following comments and recommendations in the interest of improving the implementation of ARRA 2009 and ensuring that the goals set forth by the legislation are attained expediently without creating unintended consequences.

This document has two sections:
1. Key Concerns
2. Specific responses to IFR sections

1. Key Concerns

A. Narrow Focus of Meaningful Use versus Needs of the Practice

ACP believes that technology which only meets the criteria for meaningful use will not necessarily meet the needs of practice. HITECH will provide significant funds for physicians to invest in health IT systems. ACP is concerned that as written, the IFR will encourage the implementation of systems that are designed to meet the meaningful use criteria but which are incapable of meeting the full needs of our members now and in the future as requirements change. Absent recognition of these significant limitations by incorporating criteria for functionality in practice, the long term effect may be that thousands of medical practices

implement technology that does not meet the needs of their complex practices or the patient for whom they provide care.

Recommendation: The final rule should specify in greater detail that the definition of meaningful use was created for an incentive program and as such certified EHR technology may not meet all the needs of a practice. The Certification Commission for Health Information Technology (CCHIT) did try to assess such functionality and usability in practice. Future iterations of meaningful use should include such features.

B. Complete EHR

ACP has grave concerns with this approach which puts the full burden of responsibility to determine the capabilities and interoperability of complex software modules on individuals with none of the necessary training or expertise. We doubt that the typical IT experts who manage health IT systems are capable of meeting this requirement – especially those who provide support to small/medium-sized practices. While ACP supports innovation, this attempt to provide flexibility in EHR functionality may result in significant failure to meet meaningful use performance by well-intentioned eligible providers (EPs) and a waste of HITECH funding.

It is unrealistic to think that EPs will be able to identify and integrate the required EHR Modules to satisfy all MU criteria. Further, doing so may be less costly in the short run, but more costly in the long run without assurances that these independent EHR Modules will continue to relate to each other as new standards/code sets are introduced and others "phased out." As standards change and individual modules are updated, there is the potential that asynchronous implementation of these new updated codes/standards will result in dysfunction of the disparate systems. Whereas larger health care entities may have the technical support to manage these issues, small/medium-sized practices may be put at risk for failing to meet MU criteria as a consequence of the patchwork of EHR modules.

How will ONC determine whether or not a particular collection of modules meets the definition of qualifying system? If ONC or another body has the capability to determine which collections are acceptable and which are not, such knowledge should be made available to implementing practices in the form of guidance that will prevent them from making incorrect selections.

What if part of the process to aggregate information to support meaningful use is done using non-certified EHR technology as a bridge between two certified EHR modules? Will this still qualify as MU?

Recommendation: CMS should consider altering this position to avoid some of the challenges that practices will have integrating disparate, yet certified, EHR modules.

C. Continuity of Care Document (CCD) versus Continuity of Care Record (CCR)

ACP has serious concerns about the continuation of debate previously settled, now revisited by the IFR relating to CCD and CCR.

To begin with, in Table 2A, CCR should be followed by an asterisk. “An asterisk indicates that the standard was neither recommended by the HIT Standards Committee nor part of the prior

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

ONC process." CCR has never been the recommendation of any US body that has ever examined CCR and CCD and made a recommendation.

The HITSP specification of the HL7 Continuity of Care Document (CCD) has been formally recognized by the Secretary of Health and Human Services, and has been implemented by many health IT systems vendors. While it has been argued by a few that CCD is difficult to implement, we feel that the ultimate value to our entire healthcare delivery system of specifying a single standard for clinical summary documents far outweighs any anecdotal stories of implementation difficulties. Further, most EPs are completely unaware of the standards that drive their health IT programs – and that is the way it should be. Introducing unnecessary complexity to an already complex decision-making process is not warranted.

The IFR does not provide any explanation of the need for CCR given the existence and formal acceptance of the CCD by the Secretary of Health & Human Services. If there is a technical reason or operational justification for considering CCR, the IFR should list such reasons so that we can address these specifically in our comments. Absent any rationale for including CCR as a standard, there is no apparent reason for there to be a competition between the CCD and CCR standards. This is not the time for an inappropriate of waste of resources.

While the benefits of a single standard to doctors and other healthcare professionals seems obvious, the benefits to systems developers are just as clear, as we have been told by many developers. Developers must be able to support the processing of many types of clinical documents besides clinical summaries. It is indisputable that all other types of clinical documents either are or will be based on the HL7 Clinical Document Architecture (CDA). CCD is also based on CDA. Once a developer has implemented support for one type of CDA-based clinical document, the effort required to implement the next type is far less. Vendors have told us that they do not want to be obligated to support two entirely different formats for clinical documents - one format for all of the clinical document types that they must support except for clinical summaries, and an unrelated format for clinical summaries. Also, while PHR vendors might not perceive a need today for all of the functionality available in the CCD/CDA, their more limited current requirements must not drive a decision that impacts other stakeholders with more demanding requirements. If PHRs are ever to achieve their goal of support for value-added patient-care processes (increased quality, decreased cost), they will eventually find that they need the more robust functionality of CDA/CCD.

<u>Recommendation</u>: There is no justification for selecting two standards for clinical summaries. CCD should be the standard.

D. <u>Discounting Previous Standards Work</u>

The decision to ignore previously recognized standards work is troubling. This decision sends a signal to the entire health IT industry that what appear to be definitive actions of the Secretary of Health and Human Services (HHS) can be reversed by a succeeding Secretary. This process results in unnecessary and inappropriate uncertainty for standards developers, EHR vendors, and others in the industry. Systems implementers must have confidence that formal action will allow them to proceed with development without fear that their efforts will be wasted. There must be a

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

very high bar set before re-examination of a standards decision is contemplated. It is extremely difficult, expensive, and time-consuming for industry to implement any technical standard – and even more so when efforts need to be redirected unexpectedly due to changes in the status of previously accepted standards without any reasonable justification. This action impedes the work that we all want to accomplish.

Recommendation: ACP recommends that HHS reinstate standards that were previously recognized by the Secretary to that status. Further ACP calls on ONC to develop certification criteria that recognize the full range of complex needs of modern medical practices.

E. Risk of Bifurcation of Standards and Infrastructure

We are disturbed by ONC's apparent desire to let the simplest data sharing use cases drive the selection of standards. We understand the desire to "start simple" and then grow to the more complex. However, there are serious risks with picking simple approaches. While simple approaches may work for trivial uses, they will not suffice when it is time to address the more complex cases that our systems must be able to handle. We cannot let the adoption of simple solutions now delay the efforts to prepare and handle complex needs. We can adopt and implement standards *now* that are appropriate for both situations. If we choose the "simple" solutions now for the sake of expediency, then when these choices fail to address more complex needs, we will have no choice but to build and support two fundamentally different infrastructures. This would be costly, confusing, and an entirely avoidable consequence of poor decisions made now.

Recommendation: ONC must not ignore more complex data sharing requirements in a race to build an infrastructure that accommodates only the simplest needs.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

2. Specific Responses to IFR Sections

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
I.C.1. - ONC's Processes prior to the HITECH Act - page 24	As a result, we have, after considering the input received through the recommendations of the HIT Policy Committee and HIT Standards Committee, adopted an initial set of standards, implementation specifications, and certification criteria to, at a minimum, support the achievement of what is being proposed for meaningful use Stage 1. We have noted in section III of this rule, where applicable, those standards and implementation specifications that were previously accepted or recognized by the Secretary under this prior process and those that were not. Due to our approach of aligning adopted certification criteria with the proposed definition of meaningful use Stage 1, the Secretary has decided not to adopt previously recognized certification criteria developed in 2006 as any of the certification criteria in this interim final rule.	See **Key Concerns**
I.C.2, p29 - HITECH Act Requirements for the Adoption of Standards, Implementation... p32 - "...phasing out certain alternative standards that have been adopted in this initial set"	If the Secretary determines to propose the adoption of standards, implementation specifications, or certification criteria, the Secretary is permitted to adopt any grouping of standards, implementation specifications, or certification criteria.	See **Key Concerns**
III.B. - Definitions - page 37	5. Definition of EHR Module We have defined the term EHR Module to mean any	This definition ignores the fact and there are fundamental, overarching criteria, such as all

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
	service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.	privacy, security, and audit requirements, that must be met by all modules that will deal with individually identifiable health information [IIHI] in any way. ACP recommends that the definition of EHR Module be expanded to include all criteria that all modules must be able to meet.
III.B. - Definitions - page 37 Page 41 -	5. Definition of EHR Module (Continued) While the use of EHR Modules may enable an eligible professional or eligible hospital to create a combination of products and services that, taken together, meets the definition of Certified EHR Technology, this approach carries with it a responsibility on the part of the eligible professional or eligible hospital to perform additional diligence to ensure that the certified EHR Modules selected are capable of working together to support the achievement of meaningful use. In other words, two certified EHR Modules may provide the additional capabilities necessary to meet the definition of Certified EHR Technology, but may not integrate well with each other or with the other EHR technology they were added to. As a result, eligible professionals and eligible hospitals that elect to adopt and implement certified EHR Modules should take care to ensure that the certified EHR Modules they select are interoperable and can properly perform in their expected operational environment. p41 - To clarify, we are not requiring certification of combinations of EHR modules, just that the individual EHR modules combined have each been certified to all applicable certification criteria...	See **Key Concerns**.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
III.B. - Definitions - page 38 -	6. Definition of Complete EHR We fully expect some Complete EHRs to have capabilities beyond those addressed by certification criteria adopted by the Secretary.	ONC should state clearly that any system that does not go well beyond the minimal requirements of certification will not be likely to be useful to practices.
III.C.1 - Adopted Certification Criteria - page 48	Finally, we understand that certain types of standards, specifically code sets, must be maintained and frequently updated to serve their intended purpose effectively. Code sets are typically used for encoding data elements, such as medical terms, medical concepts, diagnoses, and medical procedures. As new medical procedures, technologies, treatments, or diagnostic methods are developed or discovered, additional codes must be added or existing codes must be revised. In some cases, new codes are necessary to reflect the most recent changes in medical practice, involving perhaps revised medication dosage, updated treatment procedures, or the discovery of new diseases. In many cases, the new codes must be disseminated and implemented quickly for patient safety and significant public health purposes. To address this need and accommodate industry practice, we have in this interim final rule indicated that certain types of standards will be considered a floor for certification. We have implemented this approach by preceding references to specific adopted standards with the phrase, "at a minimum." In those instances, the certification criterion requires compliance with the version of the code set that has been adopted through incorporation by reference, or any subsequently released version of the code set. This approach will permit Complete EHRs and EHR Modules to be tested and certified, to, "at a minimum," the version of the standard that has been adopted or a more current or	See **Key Concerns**.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
	subsequently released version. This will also enable Certified EHR Technology to be updated from an older, "minimum," adopted version of a code set to a more current version without adversely affecting Certified EHR Technology's "certified status." ... If a code set that we have adopted through incorporation by reference is modified significantly, we will update the incorporation by reference of the adopted version with the more recent version of the code set prior to requiring or permitting certification according to the newer version.	
Table 1 – Certification Criteria - pages 51-61 (Criteria for Eligible Professionals or joint criteria) Use Computerized Provider Order Entry (CPOE)	Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: 1. Medications; 2. Laboratory; 3. Radiology/imaging; and 4. Provider referrals.	ACP agrees with this expectation.
Implement drug-drug, drug-allergy, drug-formulary checks	1. Automatically and electronically generate and indicate (e.g., pop-up message or sound) in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and CPOE. 2. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in Table 2A row 2.	1. What does "...and CPOE" mean at the end of this requirement? 2. This presumes that there is a formulary or preferred drug list. 4. What qualifies as a "response" to an alert? Who is defined as a "user" - physicians, nurses, medical assistants, administrative staff?

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
	3. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking. 4. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.	
Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®	Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care (i.e., over multiple office visits) in accordance with the applicable standards% specified in Table 2A row 1.	While ACP supports this goal, a reasonable expectation of what "up-to-date" means should be included. ACP proposes that up-to-date mean clinically relevant problems/diagnoses added based on the professional judgment of the EP.
Generate and transmit permissible prescriptions electronically (eRx)	Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in Table 2A row 3.	ACP agrees with this expectation.
Maintain active medication list	Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care (i.e., over multiple office visits) in accordance with the applicable standard specified in Table 2A row 1.	ACP agrees with this expectation.
Maintain active medication allergy list	Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care (i.e., over multiple office visits).	ACP agrees with this expectation.
Record demographics	Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth.	ACP agrees with this expectation.
Record and chart	1. Enable a user to electronically record, modify, and	ACP agrees with this expectation, though the

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
changes in vital signs: • height • weight • blood pressure • calculate and display: BMI • plot and display growth charts for children 2-20 years, including BMI	retrieve a patient's vital signs including, at a minimum, the height, weight, blood pressure, temperature, and pulse. 2. Automatically calculate and display body mass index (BMI) based on a patient's height and weight. 3. Plot and electronically display, upon request, growth charts (height, weight, and BMI) for patients 2-20 years old.	requirement for growth charts to age 20 is unrealistic and is not currently part of standard practice. A more appropriate age cut-off would be 15 or 16 years old.
Record smoking status for patients 13 years old or older	Enable a user to electronically record, modify, and retrieve the smoking status of a patient to: current smoker, former smoker, or never smoked.	ACP agrees with this expectation.
Incorporate clinical lab-test results into EHR as structured data	1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format. 2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes. 3. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).6 4. Enable a user to electronically update a patient's record based upon received laboratory test results.	This assumes that interfaces with local labs, hospital labs, etc are in existence and have been purchased/implemented. Small/medium-sized practices have not always been able to gain the attention of commercial laboratory vendors to provide the necessary interfaces for this functionality - and then, usually only at great cost. Laboratory vendors typically are not enthusiastic about connections to small practices which do not provide the volume of laboratory referrals in comparison to larger offices.
Generate lists of patients by specific conditions to use for quality	Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user defined demographic data, medication list, and specific conditions.	ACP agrees with this expectation.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
improvement, reduction of disparities, and outreach		
Report quality measures to CMS or the States	1. Calculate and electronically display quality measure results as specified by CMS or states. 2. Enable a user to electronically submit calculated quality measures in accordance with the standard specified in Table 2A row 5.	These systems must be able to capture and calculate denominators for many of the clinical measures (as well as the exceptions) to avoid significant manual processes that will far exceed the 1 hour time expectation used for the economic impact analysis on the NPRM.
Send reminders to patients per patient preference for preventive/ follow up care	Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list.	The systems should also be able to record patient preferences including the option NOT to receive reminders. Those who choose not to receive reminders should not be included in the denominator for the MU reporting requirements.
Implement 5 clinical decision support rules	1. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to specialty or clinical priorities that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list. 2. Automatically and electronically generate and indicate (e.g., pop-up message or sound) in realtime, alerts and care suggestions based upon clinical decision support rules and evidence grade. 3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.	3. Is it the number of alerts that is important or the type of alerts that are responded to that is important? Further, how an EP responds to an alert (e.g., changes treatment, orders a different test) is even more important. What qualifies as a "response"? Does clicking through an alert qualify as a response? Changing a medication in response to an allergy alert is what is probably intended. Need to define "user" as previously noted. Nurse, PA, NP, MA, physician....
Check insurance eligibility	Enable a user to electronically record and display patients' insurance eligibility, and submit insurance eligibility	This function is usually handled by a practice management system (PMS), not by an EHR

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
electronically from public and private payers	queries to public or private payers and receive an eligibility response in accordance with the applicable standards specified in Table 2A row 4.	system. While some EHR systems may include PMS functions, this is not the norm. Is ONC implying that a PMS is to be considered as an EHR Module subject to certification and other requirements? If so, the process for certifying a PMS should be described. Given the number and variety of PMSs, certification could be extremely difficult. If PMS vendors are unwilling or unable to get certified, where will the practices that depend upon them be left? Will practices be expected to abandon working systems upon which they depend for their ultimate survival as businesses, and implement new certified systems that may meet the needs of meaningful use, but which may not meet the needs of a small business at all? ACP believes that administrative functions cannot be included in the definition of meaningful use, without jeopardizing the viability of thousands of practices and the livelihoods of tens of thousands of physicians and other healthcare providers.
Submit claims electronically to public and private payers.	Enable a user to electronically submit claims to public or private payers in accordance with the applicable standards specified in Table 2A row 4.	This function is usually handled by a practice management system (PMS), not by an EHR system. While some EHR systems may include PMS functions, this is not the norm. Is ONC implying that a PMS is to be considered as an EHR Module subject to certification and other requirements? If so, the process for certifying a PMS should be described. Given

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
		the number and variety of PMSs, certification could be extremely difficult. If PMS vendors are unwilling or unable to get certified, where will the practices that depend upon them be left? Will practices be expected to abandon working systems upon which they depend for their ultimate survival as businesses, and implement new certified systems that may meet the needs of meaningful use, but which may not meet the needs of a small business at all? ACP believes that administrative functions cannot be included in the definition of meaningful use, without jeopardizing the viability of thousands of practices and the livelihoods of tens of thousands of physicians and other healthcare providers.
Provide patients with an electronic copy of their health information upon request	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in: 1) human readable format; and 2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	ACP agrees with this expectation.
Provide patients with an electronic copy of their discharge instructions and procedures at time	No Associated Proposed Meaningful Use Stage 1 Objective	ACP agrees with this expectation.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
of discharge, upon request		
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the eligible professional	Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures.	There should be an indication of medical appropriateness and professional judgment in providing this information unfiltered and without explanation to patients online. "And procedures" needs to be defined - is this a list of procedures, the operative note, any video/digital pictures? Only procedures done by the reporting physician? Should this be "upon request"?
Provide clinical summaries for patients for each office visit	1. Enable a user to provide clinical summaries to patients (in paper or electronic form) for each office visit that include, at a minimum, diagnostic test results, medication list, medication allergy list, procedures, problem list, and immunizations. 2. If the clinical summary is provided electronically (i.e., not printed), it must be provided in: 1) human readable format; and 2) accordance with the standards specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	The linkage of this requirement to "office visit" is incomplete; why shouldn't this apply to any clinically relevant encounter (e.g., office visit, telephone visit, email interaction)?
Capability to exchange key clinical information among providers of care and patient	1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying	ACP agrees with this expectation.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
authorized entities electronically Provide summary care record for each transition of care and referral	it in human readable format. 2. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with the standards% specified in Table 2A row 1.	
Perform medication reconciliation at relevant encounters and each transition of care	Electronically complete medication reconciliation of two or more medication lists (compare and merge) into a single medication list that can be electronically displayed in real-time.	ACP agrees with this expectation.
Capability to submit electronic data to immunization registries and actual submission where required and accepted	Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards specified in Table 2A row 8 or in accordance with the applicable state-designated standard format.	The ability of EPs to comply with this expectation will depend on the availability of registries prepared to receive data in standards-based, non-proprietary form. As a capability of the system, ACP agrees with the expectation. However, the expectation to transmit this information should be adjusted based on the environment in which an EP practices.
Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards%	No Associated Proposed Meaningful Use Stage 1 Objective	Why should small practices not have the capacity to electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards specified? All EHR systems should support this function.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
specified in Table 2A row 8 or in accordance with the applicable state-designated standard format. Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received		
Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Electronically record, retrieve, and transmit syndrome-based (e.g., influenza like illness) public health surveillance information to public health agencies in accordance with the standards specified in Table 2A row 7.	The ability of EPs to comply with this expectation will depend on the availability of registries prepared to receive data in standards-based, non-proprietary form. As a capability of the system, ACP agrees with the expectation. However, the expectation to transmit this information should be adjusted based on the environment in which an EP practices.
Protect electronic health information created or maintained by the certified EHR	1. Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. 2. Permit authorized users (who are authorized for emergency situations) to access electronic health	ACP agrees with this expectation.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
technology through the implementation of appropriate technical capabilities	information during an emergency. 3. Terminate an electronic session after a predetermined time of inactivity. 4. Encrypt and decrypt electronic health information according to user-defined preferences (e.g., backups, removable media, at log-on/off) in accordance with the standard specified in Table 2B row 1. 5. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in Table 2B row 2. 6. Record actions (e.g., deletion) related to electronic health information in accordance with the standard specified in Table 2B row 3 (i.e., audit log), provide alerts based on user-defined events, and electronically display and print all or a specified set of recorded information upon request or at a set period of time. 7. Verify that electronic health information has not been altered in transit and detect the alteration and deletion of electronic health information and audit logs in accordance with the standard specified in Table 2B row 4. 8. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information. 9. Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in Table 2B row 5. 10. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in Table 2B row 6.	
III.C.1 - Adopted Certification	In adopting these certification criteria, we attempted to balance specificity with flexibility and the opportunity for	See comments above.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
Criteria - page 62	innovation. However, in taking this approach we recognize that certain tradeoffs exist. On one hand, we anticipate that flexibility will allow Complete EHRs and EHR Modules to evolve over time to meet these criteria in increasingly efficient, useable, and innovative ways. On the other hand, any lack of specificity concerning the capabilities Complete EHRs or EHR Modules must include risks the possibility that Certified EHR Technology may inadequately support an eligible professional or eligible hospital's attempt to achieve meaningful use Stage 1, once finalized. Therefore, we request public comment on whether any of the adopted certification criteria above are insufficiently specific to be used to test and certify Complete EHRs or EHR Modules with reasonable assurance that the technology will effectively support the delivery of health care as well as the achievement of meaningful use Stage 1, once finalized.	
III.C.2 - Adopted Standards - page 64-65	The initial set of standards and implementation specifications in this interim final rule was adopted to support the proposed requirements for meaningful use Stage 1. We have added a column in Table 2A to illustrate the standards that we believe Certified EHR Technology should most likely be capable of to support meaningful use Stage 2 (although as explained in the Medicare and Medicaid EHR Incentives Program proposed rule, CMS intends to engage in rulemaking to adopt Stage 2 criteria for meaningful use and ONC would adopt standards consistent with this effort). We developed this list of candidate Stage 2 standards by considering the recommendations made by the HIT Standards Committee related to standards to support meaningful use Stage 2 and developing our own estimates of what it would take to advance interoperability. We have added a column in Table 2A to illustrate the standards that	

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
	we believe should be included in Certified EHR Technology to support meaningful use Stage 2. With the exception of standards that are tied to other HHS regulatory requirements, this additional column represents our best estimate and does not in any way imply the Secretary's adoption of these standards or limit the Secretary's discretion to adopt different standards in the future. We look forward to receiving recommendations from the HIT Standards Committee to advance interoperability in line with these estimates and welcome comments on the industry's ability to implement these candidate standards in time to support meaningful use Stage 2 (which is proposed to begin in 2013).	
III.C.2 - Adopted Standards - page 66	We believe the use of LOINC®, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), and other vocabulary standards will accelerate the adoption and use of clinical decision support. Requiring LOINC® as a vocabulary standard that Certified EHR Technology must have the capability to support for meaningful use Stage 1 provides an incremental approach to achieving these future goals.	
III.C.2 - Adopted Standards - page 66	A final example would be, if an eligible professional uses Certified EHR Technology that has implemented the continuity of care document (CCD) standard for the exchange of a patient summary record and receives a patient summary record formatted in the continuity of care record (CCR) standard, their Certified EHR Technology must be capable of interpreting the information within the CCR message and displaying it in human readable format. We do not expressly state how this should be accomplished or in what format human readable information should be displayed (e.g., information in a CCR message could be	Requiring all vendors to provide even limited support for two different standards is not justifiable. The excess cost in dollars and labor across all of the US healthcare system is enormous, wasteful, and counter-productive. See **Key Concerns** at the beginning of this document.

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Page/Section#/Title	Description of Rule	ACP Analysis/Comments
	converted to a text file or PDF). We only require that Certified EHR Technology must be capable of performing this function. We believe this requirement is critical and have included it to allow flexibility in the marketplace during meaningful use Stage 1 and to prevent good faith efforts to exchange information from going to waste (i.e., information is exchanged, but is unreadable to both Certified EHR Technology (machine readable) and humans).	

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org

Conclusion
Despite the criticisms and concerns identified in this document, ACP strongly supports the Centers for Medicare and Medicaid Services and the Office of the National Coordinator for Health IT in the effort to transition the healthcare delivery system from paper to connected, robust, health information technology. We believe that well designed health IT is critical to improving the quality of healthcare and will likely contribute to reducing the cost of evidence-based care. However, in general, the IFR introduces unnecessary complexity, while under-estimating the potentially negative impact that too much flexibility in standards, technology, and definitions create.

Thank you very much. ACP looks forward to working with CMS and ONC on the implementation of HITECH 2009.

Sincerely,

James M. Walker, MD, FACP
Chair, Medical Informatics Subcommittee
American College of Physicians

25 Massachusetts Avenue, NW, Suite 700, Washington, DC 20001-7401, 202-261-4500, 800-338-2746
190 North Independence Mall West, Philadelphia, PA 19106-1572, 215-351-2400, 800-523-1546, www.acponline.org