PREMIER

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Ms. Charlene Frizzera
Acting Administrator
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Re: Comments on CMS Notice of Proposed Rulemaking: Medicare and Medicaid Electronic Health Records Incentive Program, Dated January 13, 2010, CMS-0033-P

Dear Ms. Frizzera:

On behalf of the Premier healthcare alliance serving more than 2,300 leading not-for-profit hospitals and health systems and 66,000 other healthcare sites, including large multi-hospital healthcare systems, small and rural community hospitals, urban hospitals and academic medical centers, we appreciate the opportunity to comment on the January 13, 2010, CMS Notice of Proposed Rulemaking on the Medicare and Medicaid Electronic Health Records Incentive Program, File Code: CMS-0033-P (the "NPRM"). Hospitals in the Premier alliance are collecting, analyzing, and sharing knowledge nationwide to transform healthcare by improving quality and safely reducing costs.

Premier is committed to facilitating rapid implementation of electronic health record ("EHR") technology by all Premier alliance members. Premier operates the nation's most comprehensive repository of hospital clinical information and has formed an HIT Collaborative composed of Premier alliance members. Our HIT Collaborative has been providing technical assistance to Premier alliance members regarding EHR implementation and the requirements of the HITECH

Act. The HIT Collaborative focuses on best practices and knowledge sharing to enable our alliance members and their medical staffs to meet the HITECH Act EHR incentives qualification requirements as quickly as possible.

Our objective in submitting these comments concerning the NPRM is to identify issues on which our alliance members believe clarification, and in some cases correction, is required to ensure that the EHR incentives program is implemented in accordance with the HITECH Act's goal and requirements. Our overarching concern regarding the NPRM is that it establishes a number of requirements and restrictions that are diametrically opposed to accomplishing the HITECH Act's goal of implementing a nationwide HIT infrastructure in a timely manner. It is clear the HITECH Act is designed to infuse substantial funds into the economy so that as many eligible providers as possible can rapidly implement functioning EHRs to serve as the backbone for the nation's HIT infrastructure. Congress recognized that most eligible providers would require EHR incentives quickly in order to actually get their EHR projects off the ground.

Our comments below are intended to identify our members' key issues where clarifications and corrections are necessary to ensure that the final meaningful use rule is consistent with the HITECH Act's goal of implementing a nationwide HIT infrastructure. As requested in the NPRM, each comment below is titled using the "issue identifier" for the section of the NPRM to which our comment pertains. Where appropriate, we also have identified for each comment the applicable section(s) of the NPRM's preamble.

<u>Comment 1</u>: Qualifying as a Meaningful User in Stage 1 Should Not Require an Eligible Provider to Satisfy 100 Percent of the Meaningful Use Criteria - NPRM Rule Section 495.6[1]

As a general matter, we believe the focus of the NPRM's proposed Stage 1 meaningful use criteria is reasonable and appropriate with respect to establishing a nationwide HIT infrastructure. However, the HITECH Act's goal is to establish a nationwide HIT infrastructure *as rapidly as possible*. Achieving that goal will only be possible if most eligible providers actually receive EHR incentives in Stage 1. As discussed more fully below, we believe that will only happen if eligible providers are permitted to qualify as meaningful users in Stage 1 by meeting fewer than all of the NPRM's proposed meaningful use criteria.

We are concerned it will be impossible for a substantial number of eligible providers to qualify for EHR incentives in Stage 1 if they are required to comply with every one of the NPRM's

[1] Please also see the NPRM preamble Section IIA2d(2) "Health IT Functionality Measures." 75 Fed. Reg. 1844, 1858 (Jan. 13, 2010).

proposed Stage 1 meaningful use criteria. The reality is that many eligible providers have not even begun planning for EHR implementation because they simply have not had the funding or personnel necessary to consider such a project. Furthermore, for every one of our alliance members which has implemented an EHR, the numerous tasks involved just in acquiring, installing and providing training concerning the EHR have taken many years to complete, even when the member has had substantial funding and personnel to devote to the project.[2] Under the NPRM, an eligible hospital[3] would have to complete all of those tasks in about 14 months to have any chance to qualify for EHR incentives for the 2011 Reporting Period.[4] And, even if an eligible hospital were able to meet that daunting challenge, the hospital and its personnel would immediately have to come into full compliance with all of the NPRM's Stage 1 meaningful use criteria, without any phase-in period. That is because as of the close of the above-mentioned 14-month period, only 90 days would remain in the 2011 Reporting Period for eligible hospitals, which the NPRM sets as the minimum amount of time an eligible provider must be in full compliance with all of the meaningful use criteria during the first Reporting Period in which the provider qualifies for EHR incentives.[5]

Based on the foregoing realities regarding the time necessary to implement an EHR, we believe the NPRM's proposed approach for Stage 1 must be modified to achieve the HITECH Act's goal of establishing a nationwide HIT infrastructure as rapidly as possible. We believe the necessary modification to the NPRM's proposed Stage 1 meaningful use criteria involves setting a lower

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[2] One Premier alliance member that is an established and well-funded integrated delivery system with a large medical center and many employed physicians informed us that it has taken 10 years of concentrated efforts for the member to implement its system-wide EHR.

[3] As CMS is aware, the term "eligible hospital" under the HITECH Act and the NPRM does not apply to hospitals eligible for Medicaid EHR incentives, but rather only refers to a hospital that is eligible for Medicare EHR incentives as a subsection (d) hospital. 75 Fed. Reg. at 1911. For simplicity's sake, the term "eligible hospital" as used in these comments generally means a hospital that is eligible for either Medicare or Medicaid EHR incentives (not including any critical access hospitals or children's hospitals).

[4] The NPRM preamble states that CMS is trying to issue the final meaningful use rule by May 2010. If CMS were to issue that final rule and the final EHR certification process rule on April 30, 2010, there would be a 14-month period between the issuance of those two final rules and July 1, 2011. The NPRM sets 90 consecutive days as the minimum amount of time an eligible provider must be in compliance with all of the meaningful use criteria during the first Reporting Period in which the provider qualifies for EHR incentives. 75 Fed. Reg. at 1849. Consequently, under the NPRM an eligible hospital would have to be in full compliance with all of the Stage 1 meaningful use criteria from no later than July 2, 2011, through September 30, 2011, to qualify for EHR incentives for the 2011 Reporting Period (which for eligible hospitals is the federal fiscal year running from October 1, 2010, through September 30, 2011). Since the 2011 Reporting Period for eligible professionals is the 2011 calendar year, the above-mentioned 14-month period would be 17 months for eligible professionals.

[5] NPRM Rule Section 495.4.

threshold regarding the number of those criteria an eligible provider must meet in Stage 1 to qualify as a meaningful user. Under the NPRM, an eligible provider must meet 100 percent of the proposed meaningful use criteria. We are recommending that CMS lower that Stage 1 compliance threshold, thereby permitting an eligible provider to qualify as a meaningful user in Stage 1 even if the provider does not satisfy every one of the Stage 1 meaningful use criteria.

While we believe the Stage 1 compliance threshold should be substantially less than 100 percent, we are not at this time proposing a particular percentage for the threshold. We believe CMS will be in the best position to set a reasonable Stage 1 compliance threshold after its review and analysis of all comments submitted regarding the NPRM. In setting a lower Stage 1 compliance threshold, we believe CMS should take into account the following factors:

i. The threshold must be set at a level that accounts for the fact that many eligible providers are only now beginning the planning process for acquiring an EHR. As such, most of these eligible providers will need the remainder of 2010 and much of Stage 1 just to get to the point of having a functioning EHR and personnel who are fully trained to use the EHR.

ii. Many, and arguably all, eligible providers that already are using EHRs will have to upgrade their EHRs, change their EHR workflow patterns, and provide significant additional EHR-related training to their personnel in order to comply with the final meaningful use rule. Since that final rule is not likely to be published until late in the second quarter of 2010, or later, even providers with functioning EHRs today will face substantial timing challenges in qualifying as meaningful users for the 2011 Reporting Period.[6]

iii. Eligible providers will face additional timing challenges based on the fact that the proposed EHR certification process rule was just released in pre-publication form on March 2, 2010. Given that several months, at a minimum, will pass before the final EHR certification process rule is published, and the additional time thereafter that will be required for an EHR or EHR module to become certified under the new certification process, it is likely that a significant portion of the 2011 Reporting Period will have expired by the time that any eligible hospital

[6] Some Premier alliance members with operating EHRs are being told by their EHR vendors that it will be at least two years before the vendor can furnish an upgrade to bring its EHR into compliance with the EHR certification standards in the interim final rule published on January 13, 2010.

using an EHR today actually knows for sure whether its EHR qualifies as "certified EHR technology."

iv. The HITECH Act's goal of rapidly implementing a nationwide HIT infrastructure can only be met if a significant portion of the EHR incentives funding available under the Act actually is disbursed to eligible providers before 2013. As mentioned above, most eligible providers do not have the funds necessary to implement an EHR project. Those providers and their prospective lenders need to know that qualifying for EHR incentives sometime during Stage 1 is an attainable objective for most eligible providers. Receiving EHR incentives as early as possible during Stage 1 is particularly critical for the many facilities for which EHR incentives are the only viable source of funds for an EHR project. Consequently, the Stage 1 compliance threshold must be set at a level that is reasonably achievable by most eligible providers.

v. Setting a Stage 1 compliance threshold at less than 100 percent of the NPRM's proposed meaningful use criteria will not undermine or materially delay achievement of the HITECH Act's goal. In fact, lowering the Stage 1 compliance threshold is likely to accelerate achievement of the HITECH Act's goal because it would allow more eligible providers to qualify for EHR incentives, thereby providing increased funds for EHR implementation.

We believe all the foregoing factors demonstrate that a Stage 1 compliance threshold substantially below 100 percent is reasonable, and in fact is essential to achieving the HITECH Act's goal of establishing a nationwide HIT infrastructure as rapidly as possible. Setting a Stage 1 compliance threshold at less than 100 percent will provide each eligible provider with the flexibility it needs to develop and follow the implementation strategy and timetable which the eligible provider deems optimal for ultimately complying with all of the meaningful use criteria as quickly as reasonably possible.

As stated above, we generally support the focus of the particular Stage 1 meaningful use criteria proposed by the NPRM. However, that support is qualified in two respects. First, and more importantly, we have serious concerns about the NPRM's statement that the meaningful use criteria will be changed significantly in unspecified ways several times over the course of the next

five years (i.e., during Stages 2 and 3).[7] That approach puts eligible providers and EHR vendors in an untenable situation for the following reasons:

i. The typical eligible provider will not be willing to expend the substantial funds necessary in connection with an EHR acquisition or a significant EHR upgrade unless the EHR vendor unconditionally guarantees its products will remain "certified EHR technology" under the HITECH Act for at least some reasonable number of years (i.e., long enough to furnish benefits that the eligible provider deems sufficient to justify the substantial funds the provider must expend on the EHR project). Without such an unconditional guarantee, the useful life of the EHR or EHR upgrade would be cut short if the vendor cannot maintain its products' HITECH Act certification. Given the substantial amount of funds at issue in an EHR acquisition or substantial upgrade, a two-year guarantee by an EHR vendor (i.e., the duration of Stage 1) simply is too short.

ii. Since the NPRM does not clarify precisely how the meaningful use criteria will change after Stage 1, and since any changes in the meaningful use criteria will almost certainly result in changes to the EHR certification requirements, EHR vendors are not likely to provide unconditional guarantees that their EHR products will maintain their HITECH Act certifications beyond Stage 1.

iii. Based on the points in clauses i and ii above, the only way an eligible provider and an EHR vendor will strike a deal on the acquisition of an EHR or a substantial EHR upgrade is if they can reach agreement on allocating the uncontrollable risk arising from the fact that neither of them can know for certain whether the EHR products at issue will be certified under the HITECH Act after Stage 1. That risk is substantial because it concerns one of the core reasons for the eligible provider's desire to acquire the EHR products at issue – obtaining EHR technology that will permit the eligible provider to receive EHR incentives and avoid the HITECH Act's penalties. It is extremely difficult, and often impossible, for parties to strike a deal if either or both parties to a transaction must assume all or a portion of an uncontrollable risk that goes to the heart of the transaction.

iv. In addition to creating the HITECH Act certification risk allocation problem mentioned in clauses i-iii above, the prospect of several rounds of significant

[7] 75 Fed. Reg. at 1852.

> changes in the meaningful use criteria over the next few years makes it extremely difficult for eligible providers to develop viable and useful EHR implementation plans. Typically an EHR implementation plan spans a long time period because the time from EHR acquisition through full EHR implementation generally runs at least several years. Any significant changes in the meaningful use criteria during the course of an eligible provider's EHR implementation plan are likely to render infeasible or impractical substantial portions of the plan, thereby requiring the eligible provider to change its EHR implementation process and incur additional costs involved in complying with the new meaningful use criteria.

To avoid the foregoing problems, we believe CMS should establish now all the meaningful use criteria that will be required during the period from 2011 through at least 2017. Establishing all those meaningful use criteria now will give eligible providers and EHR vendors a clear and fixed target for their respective EHR efforts over an extended period of time, and will eliminate the inefficiencies and waste of resources that inevitably will result from multiple significant changes in the meaningful use criteria over the next few years.

The second qualification regarding our support for the NPRM's proposed meaningful use criteria is that there are a number of points regarding particular meaningful use criteria on which we believe clarifications and corrections are necessary. Those points are discussed in separate comments below, but we would like to identify here two broad concerns we have regarding the meaningful use criteria applicable to eligible professionals. First, the 80 percent CPOE requirement for eligible professionals is far too stringent for Stage 1, and is likely to preclude a great number of eligible professionals from qualifying for EHR incentives in Stage 1. Second, even if an eligible professional is able to meet the 80 percent CPOE requirement, his/her practice is not likely to have the excess personnel time and resources required to implement the extensive workflow changes and conduct the extensive reporting to CMS necessary to qualify for EHR incentives. To a large extent the NPRM imposes on physician practices the same requirements as it imposes on hospitals. Since major hospital systems with more resources and personnel than the typical physician practice will face substantial challenges in meeting those requirements, it simply is not reasonable or appropriate to expect physician practices to meet those same requirements given their limited resources and personnel. Our above recommendation to reduce the number of meaningful use criteria with which an eligible provider must comply in Stage 1 would ameliorate these concerns to some extent. However, the fundamental realities are: (i) successfully implementing a nationwide HIT infrastructure will require the active involvement and commitment of eligible professionals and their practices across the country; and (ii) most eligible professionals and their practices will not be able to devote the necessary

time and resources to EHR implementation if doing so would divert an unreasonable amount of their already limited personnel time and scarce resources away from other essential practice functions. For these reasons, we believe the meaningful use requirements for eligible professionals, particularly the CPOE requirement, should be reduced to ensure that a substantial percentage of eligible professionals will be able to qualify for EHR incentives in Stage 1.

As mentioned above, we have discussed in separate comments below specific concerns regarding several of the NPRM's proposed meaningful use criteria. Prior to discussing those concerns, however, we would like to comment on several of our more global concerns regarding the NPRM, the first one being the NPRM's proposed definition for the term "hospital-based eligible professional."

<u>Comment 2</u>: EHR Incentives Should be Available to Eligible Providers Working in Hospital Ambulatory Clinics - Rule Section 495.4 Definitions: Hospital-Based EP Definition[8]

The NPRM's definition of "hospital-based eligible professional" ("HBEP") is overbroad because it prohibits EHR incentives for many more eligible professionals than Congress intended under the HBEP provisions in the HITECH Act.[9] The HITECH Act defines an HBEP as:

> …an eligible professional, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of [his/her covered] services in a hospital setting (whether inpatient or outpatient) and through the use of the facilities and equipment, including qualified electronic health records, of the hospital.[10]

The HITECH Act's HBEP definition and the Act's other HBEP provisions are designed to accomplish a single narrow objective: to exclude EHR incentives for a limited subset of eligible professionals (such as anesthesiologists, pathologists and ER physicians) for whom EHR incentives would constitute windfall payments. Congress recognized EHR incentives for this limited subset of eligible professionals are unnecessary and inappropriate because the EHR-

[8] Please also see the NPRM preamble Section II6 "Hospital-based Eligible Professionals." 75 Fed. Reg. at 1904.

[9] The HITECH Act's Medicare Program HBEP exclusion is set forth at 42 U.S.C. 1395w-4(o)(1)(C)(ii). The HITECH Act's Medicaid Program HBEP exclusion is set forth at 42 U.S.C. 1396(b)(t)(3)(D). These exclusions are stated using identical statutory language.

[10] As used in this comment the term "covered services" means: (i) Medicare covered services in connection with the HITECH Act's Medicare Program HBEP exclusion, and (ii) Medicaid covered services in connection with the HITECH Act's Medicaid Program HBEP exclusion.

related needs of any such eligible professional can be fully met by a "hospital-oriented EHR" (i.e., an EHR used by a hospital to satisfy its own EHR-related needs).[11] Since eligible hospitals can qualify for their own HITECH Act EHR incentives, separate EHR incentives for this limited subset of eligible professionals are not warranted because neither they nor anyone else incurs separate EHR costs solely to address such eligible professionals' EHR-related needs.

Although the NPRM's HBEP definition appropriately prohibits EHR incentives for this limited subset of eligible professionals, it also would prohibit EHR incentives for *every* eligible professional who furnishes substantially all of his/her covered services in any hospital setting. As a result, the NPRM's HBEP definition far exceeds the narrow scope and objective of the HITECH Act's HBEP provisions. If the NPRM's HBEP definition is not brought into alignment with the HITECH Act's HBEP provisions, many eligible professionals will be prohibited from qualifying for a significant amount of EHR incentives that Congress and the Administration deemed essential to achieving the HITECH Act's overall objectives of promoting and subsidizing the rapid implementation of a nationwide HIT infrastructure.

The HITECH Act's HBEP statutory provisions and legislative history both clarify that the exclusion of EHR incentives for HBEPs was never intended to apply to an eligible professional merely because substantially all of his/her covered services are furnished in a hospital setting (which is the sole criterion under the NPRM for determining whether an eligible professional is an HBEP). The HITECH Act clarifies this point by expressly establishing the following two HBEP criteria, both of which must be met for an eligible professional to be deemed an HBEP:

> First Criterion: The eligible professional must furnish substantially all of his/her covered services in a hospital setting; *and*
>
> Second Criterion: The eligible professional must use the hospital's facilities and equipment, including the hospital's EHR, in the furnishing of substantially all of his/her covered services.

[11] The term "hospital-oriented EHR" as used in these comments refers to an EHR that only has the functionality and capabilities necessary to serve a hospital's own EHR-related needs (including, for example, the EHR-related needs of the hospital's pathologists, anesthesiologists and emergency physicians). We are not using the term "hospital-oriented EHR" to include an EHR to which additional modules or products have been added to expand the EHR's functionality and capabilities to serve the EHR-related needs of any eligible professionals other than those listed in the preceding sentence.

The Conference Committee Report language on the HITECH Act's HBEP provisions further clarifies the limited scope of those provisions, and the narrow objective they are designed to achieve, by stating the following comments twice in the Report:

> The conference agreement, like the House and Senate-passed bills, prohibits payments to hospital-based professionals (because such professionals are generally expected to use the EHR system of that hospital). This policy does not disqualify otherwise eligible professionals merely on the basis of some association or business relationship with a hospital. Common examples of such arrangements include professionals who are employed by a hospital to work in an ambulatory care clinic or billing arrangements in which physicians submit claims to Medicare together with hospitals or other entities.[12]

Notwithstanding the express provisions of the HITECH Act and the above-quoted Report language, the NPRM's proposed HBEP definition would sweep in *every* eligible professional who furnishes substantially all of his/her covered services in a hospital setting. The excessive scope of the NPRM's HBEP definition stems from the fact that the definition's sole criterion for determining if an eligible professional is an HBEP is whether substantially all of his/her covered services are furnished in a hospital setting (i.e., the First Criterion under the HITECH HBEP provisions). The NPRM's HBEP definition effectively eliminates the Second Criterion under the HITECH Act's HBEP provisions by assuming that any eligible professional who satisfies the First Criterion invariably satisfies the Second Criterion.[13] CMS does not state that this assumption must be tested against the facts on a case-by-case basis, so CMS apparently believes this assumption is appropriate in all cases, even if:

- The eligible professional at issue *does not actually use* the hospital's EHR with respect to substantially all of the covered services he/she furnishes; or

- The eligible professional use of the hospital's EHR is not – and never could be – *meaningful* because the hospital's EHR does not provide the functionality and capabilities necessary to meet the eligible professional's EHR-related needs; or

[12] H. Rep. 111-16, at 741 (2009). The HBEP definition of the Medicaid incentives program may be found at page 752.

[13] 75 Fed. Reg. at 1904-05.

- Paying EHR incentives to the eligible professional at issue would not result in the kind of windfall payments that the HITECH Act's HBEP provisions are designed to prevent.

It is clear that the NPRM's foregoing assumption ignores an express statutory pre-requisite for an eligible professional to be deemed an HBEP. Equally important, however, is the fact that CMS's assumption severs any rational connection between the HITECH Act's HBEP provisions and the single narrow objective those provisions are designed to achieve – preventing windfall EHR incentives for eligible professionals whose EHR-related needs are fully met by their hospital's *hospital-oriented EHR*. Most eligible professionals working in a hospital setting today do not fall into the limited subset of eligible professionals whose EHR-related needs can be met by a hospital-oriented EHR.[14] Rather, the majority of eligible professionals working in a hospital setting today furnish their services in hospital ambulatory care clinics and physician offices. As a result, these eligible professionals require the EHR functionality and capabilities furnished by the kind of EHR used in a physician practice (i.e., a "physician-oriented EHR"), not the functionality and capabilities furnished by a hospital-oriented EHR.

Since these kinds of eligible professionals (referred to below as "non-HBEPs") cannot rely on a hospital-oriented EHR to meet their EHR-related needs, they (or more typically each hospital, medical practice or other entity where they work) must incur significant costs to acquire, operate, maintain and provide training regarding a separate physician-oriented EHR, or at least separate physician-oriented EHR modules, with the functionality and capabilities necessary to meet these non-HBEPs' EHR-related needs. Naturally, in cases where the costs for these physician-oriented EHRs or EHR modules are incurred by a hospital, medical practice or other entity, rather than by a non-HBEP, any EHR incentives for which the non-HBEP qualifies should be reassigned to such hospital, medical practice or other entity.[15]

Based on the foregoing, it is clear that EHR incentives for non-HBEPs would not constitute windfall payments to anyone. Consequently, prohibiting EHR incentives for non-HBEPs bears no rational connection to the HITECH Act HBEP provisions' single narrow objective of

[14] Several Premier alliance members which are large integrated healthcare delivery networks have informed us that the NPRM's proposed HBEP definition would prohibit EHR incentives for virtually all eligible professionals on their respective medical staffs, including almost every primary care physician.

[15] Comment 6, below, discusses the importance of an eligible professional's EHR incentives being transferred to the hospital, medical practice or other entity which incurs the costs for a physician-oriented EHR or physician-oriented EHR modules required to serve the eligible professional's EHR-related needs.

preventing windfall EHR incentives payments for the limited subset of eligible professionals for whom no one incurs any separate EHR costs.

The NPRM is silent on how or why CMS views the NPRM's HBEP definition as being rationally connected or consistent with the single narrow objective of the HITECH Act's HBEP provisions. Possibilities for CMS's views on this issue include the following:

First, it is possible CMS believes the requirement in the Second Criterion that an eligible professional must use a "hospital EHR" should be deemed satisfied if the eligible professional uses *any* EHR operated by a hospital (including, for example, a physician-oriented EHR or physician-oriented EHR modules). However, that belief would be logically inconsistent with the above-quoted Report language, which clarifies the following points:

A. The mere fact that a physician works in a hospital ambulatory care clinic (i.e., a hospital setting) is not sufficient to render that physician an HBEP. Also, nothing in the Report language states or indicates that such a physician would become an HBEP if the amount of his/her covered services furnished in the hospital ambulatory care clinic met or exceeded the "substantially all" threshold. Stated differently, the Report language does not say or indicate that a physician working in a hospital ambulatory care clinic would be deemed an HBEP if he/she satisfied the First Criterion. Consequently, the basis for the Report language's statement that such a physician is *not* an HBEP must relate to the Second Criterion.

B. To satisfy the Second Criterion, an eligible professional must use: (i) the hospital's facilities; (ii) the hospital's equipment; and (iii) the hospital's EHR. It is self-evident that every physician working in a hospital ambulatory care clinic would meet the requirements in clauses (i) and (ii). For that reason, the basis for the Report's statement that such a physician is *not* an HBEP must relate to the requirement in clause (iii) regarding use of a "hospital EHR." Since the EHR-related needs of a physician working in a hospital ambulatory care clinic cannot be met by a hospital-oriented EHR, the Second Criterion's requirement regarding use of a "hospital EHR" must refer only to a *hospital-oriented EHR*. Thus, the Report language must mean that a physician is not an HBEP if substantially all of his/her covered services are furnished in a hospital setting using the hospital's *physician-oriented EHR* or *physician-oriented EHR modules* (as

> would be the case for a physician working in a hospital ambulatory care clinic).[16]

Interpreting the phrase "hospital EHR" in the Second Criterion to mean only a *hospital-oriented EHR* is completely consistent with the single narrow objective of the HITECH Act's HBEP provisions, and the above-quoted Report language, because the windfall EHR incentives that the HITECH Act's HBEP provisions are designed to prevent could only occur with respect to an eligible professional whose use of a hospital-oriented EHR serves all of his/her EHR-related needs. As mentioned above, that is not the case for non-HBEPs because they require the use of physician-oriented EHRs or physician-oriented EHR modules. The significant acquisition, operating, maintenance and training costs concerning such physician-oriented EHRs or physician-oriented EHR modules must be borne by someone (typically the hospital where the non-HBEPs work). Those costs are in addition to the substantial costs a hospital incurs to acquire, operate, maintain and provide training regarding the hospital-oriented EHR used by the hospital to serve its own EHR-related needs. As a result, providing EHR incentives for non-HBEPs would not constitute windfall payments to anyone.

Second, it is possible that CMS believes the HITECH Act's EHR incentives for an eligible hospital are intended to subsidize not only the hospital's costs pertaining to its own EHR-related needs, but also the hospital's costs pertaining to the EHR-related needs of *every* eligible professional who furnishes substantially all of his/her covered services on the hospital's premises. This position also is logically inconsistent with the Report language above, which clarifies that every eligible professional who furnishes substantially all of his/her covered services in a hospital setting is *not* an HBEP.

There simply is no logical or compelling reason, or any support in the HITECH Act or its legislative history, for the NPRM's proposal that an eligible professional's status as an HBEP should rest solely on whether substantially all of his/her covered services are furnished in a hospital setting. Furthermore, by taking that approach, the NPRM's HBEP definition is likely to cause substantial delays in the implementation of the nation's HIT infrastructure for the following reasons:

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[16] It would be specious to suggest that a non-HBEP should be deemed to have met the Second Criterion requirement regarding use of a "hospital EHR" merely based on his/her use of a hospital EHR for any purpose whatsoever, without regard to whether the hospital's EHR has the functionality and capabilities necessary to satisfy the non-HBEP's own EHR-related needs. Likewise, a non-HBEP's use of a hospital-oriented EHR that has been augmented to include additional physician-oriented EHR modules to serve the non-HBEP's EHR-related needs should not be considered a "hospital EHR" for purposes of the Second Criterion requirement regarding use of a "hospital EHR."

i. Under the NPRM's HBEP definition, most eligible professionals who work primarily in a hospital setting would be shielded from the HITECH Act's financial penalties for failing to become a meaningful user of certified EHR technology by 2016. That fact, in conjunction with the absence of any EHR incentives for these eligible professionals, would eliminate any urgency for these eligible professionals, or for the hospitals or medical practices where they work, to ensure that these eligible professionals become meaningful users of certified EHR technology as quickly as possible.

ii. Due to the absence of EHR incentives or penalties for non-HBEPs, any hospital with a material number of non-HBEPs working on its premises is certain to focus its efforts and limited resources on qualifying for the EHR incentives available to the hospital itself. In most cases that focus will have the effect of delaying the hospital's implementation of EHR technology for the hospital's non-HBEPs.

iii. Even in cases where the absence of EHR incentives for non-HBEPs does not divert a hospital from focusing on implementation of EHR technology for its non-HBEPs, the reality is that every such hospital will have much less money to fund EHR implementation if non-HBEPs cannot qualify for any EHR incentives. As a result, each such hospital's already limited resources available for EHR implementation efforts will be stretched even further, which inevitably will delay hospital-wide EHR implementation.

iv. Under the NPRM's proposed HBEP definition, no eligible professional working primarily in a medical practice furnishing outpatient services in hospital premises would be eligible for any EHR incentives. That result would be particularly anomalous given the dramatic increase over the last 20 years of medical practices locating on hospital premises as part of joint efforts by hospitals and physicians to implement closer care coordination activities to improve quality and reduce costs. In fact, most of the care coordination concepts at the heart of the healthcare reform proposals Congress has considered over the last year are likely to prompt more medical practices to locate on hospital premises. Precluding EHR incentives for eligible professionals merely because they furnish most of their services in hospital outpatient settings would be completely at odds

with those healthcare reform concepts and the prevalence of medical practices being located on hospital premises.

Although financial considerations are not likely to be the sole factor regarding most hospitals' EHR implementation decisions, financial considerations certainly will affect every hospital's decisions regarding the timing of its EHR implementation. As such, the NPRM's HBEP definition would likely result in significant delays for the EHR implementation efforts concerning most eligible professionals working primarily in a hospital setting. It is inconceivable that Congress intended that result in enacting the HITECH Act or in including the HBEP provisions in the Act.

The NPRM's HBEP definition far exceeds the very limited scope and purpose of the HITECH Act's exclusion of EHR incentives for HBEPs, and thereby blocks payment of substantial EHR incentives funding that Congress and the Administration deemed essential to creating the nation's HIT infrastructure. CMS can easily correct the overbroad scope of the NPRM's HBEP definition by limiting the HBEP definition to eligible professionals who furnish substantially all of their covered services in either: (i) a hospital *inpatient* setting; or (ii) a hospital *emergency room* setting. Limiting the HBEP definition in this way would ensure that: (a) the exclusion of EHR incentives for HBEPs only applies to eligible professionals working primarily in a hospital setting who can rely on their hospital's *hospital-oriented EHR* to meet all of their EHR-related needs; and (ii) EHR incentives are available for eligible professionals working primarily in a hospital setting whose EHR-related needs cannot be met by a *hospital-oriented EHR*. We believe correcting the NPRM's HBEP definition as stated above is necessary to align the final meaningful use rule with the purpose and scope of the HITECH Act's HBEP provisions.

The next global comment we have regarding the NPRM concerns the calculation of EHR incentives for hospitals with multiple inpatient facilities operating under a single provider number.

<u>Comment 3</u>: Eligible Hospitals with Multiple Inpatient Facilities Operating Under One Provider Number Should Receive EHR Incentives for each such Inpatient Facility - Rule Section 495.104 Incentive Payments to Eligible Hospitals, and Rule Section 495.302 Definitions

The NPRM's proposed methodology for calculating a qualifying hospital's Medicare and Medicaid EHR incentives creates an arbitrary and inequitable distinction between identical hospital systems based solely on whether a system has multiple inpatient facilities operating

under a single provider number.[17] Under the NPRM, Medicare EHR incentives for a hospital system with multiple inpatient facilities operating under a single provider number would be calculated including only one $2 million annual base payment amount for all inpatient facilities that share a provider number. Also, the inpatient discharges from all of those inpatient facilities would be aggregated for purposes of the 23,000 annual cap on the discharge-related amount included in calculating the hospital system's Medicare EHR incentives. By contrast, for an identical hospital system that has a separate provider number for each of its inpatient facilities, the NPRM would calculate the hospital system's Medicare EHR incentives by including a separate $2 million annual base payment amount *for each* such inpatient facility, and the 23,000 annual cap would be applied separately to each such inpatient facility. Furthermore, since an eligible hospital's Medicaid EHR incentives are calculated based on the hospital's projected Medicare EHR incentives, the two hospital systems described above also would receive dramatically different Medicaid EHR incentives amounts solely based on whether the system's inpatient facilities share a provider number or have separate provider numbers.

There is no justifiable basis for this arbitrary and inequitable calculation of Medicare and Medicaid EHR incentives by reference to an eligible hospital's provider number. The HITECH Act is designed to subsidize and promote the creation of a nationwide HIT infrastructure. For that reason, the EHR incentives calculation formula for eligible hospitals should be rationally related to the costs that the Act is intended to subsidize. An eligible hospital's costs to acquire, implement, provide training for and maintain its EHR will vary directly and significantly based on the number of inpatient facilities where the EHR is deployed (and whether those inpatient facilities share a provider number is completely irrelevant with respect to such costs). As a result, tying the calculation of a qualifying eligible hospital's EHR incentives to provider number rather than the number of inpatient facilities comprising the hospital will misalign EHR-related costs and EHR incentive payments, and inevitably will result in insufficient EHR incentives funding to hospital systems with multiple inpatient facilities that share a provider number.

We recognize that the HITECH Act defines the term "eligible hospital" for Medicare EHR incentives purposes as a "subsection (d) hospital" under the Medicare Program.[18] We also know that in most circumstances the term "subsection (d) hospital" under the Medicare Program includes all of a hospital system's inpatient facilities that operate under a single provider number. However, for the reasons stated below, and notwithstanding the HITECH Act's definition of the

[17] The term "provider number" as used in these comments means a hospital's "CMS Certification Number" or "Medicare Provider Number."

[18] 42 U.S.C. 1395ww(n)(6)(B).

term "eligible hospital" to mean a "subsection (d) hospital," we believe CMS has the authority, and in fact an obligation, under the HITECH Act to establish Medicare and Medicaid EHR incentives calculation formulas that are based on the number of inpatient facilities comprising a hospital, regardless of whether any of those inpatient facilities share a provider number.

First, as CMS is aware, there is longstanding precedent – under the Medicare wage index adjustment methodology – for multiple inpatient facilities comprising a single subsection (d) hospital to be treated as distinct entities for payment purposes under the Medicare Program. The Medicare wage index is premised on the logic that multiple inpatient facilities comprising a single subsection (d) hospital nevertheless should be treated separately for Medicare payment purposes in limited circumstances where such separate treatment is necessary to account appropriately for facility-specific costs. Those circumstances exist with respect to an EHR deployed at multiple inpatient facilities comprising a single subsection (d) hospital because such a hospital will incur specific EHR-related costs for each of its facilities. The NPRM effectively ignores the existence of those facility-specific ERH-related costs by calculating such a hospital's EHR incentives as if the hospital were comprised of only a single inpatient facility. By contrast, if each of the hospital's inpatient facilities had its own provider number, the NPRM would calculate the total EHR incentives for such hospital's inpatient facilities in a manner that reflects the fact that the hospital incurs separate EHR-related costs for each of its facilities. To avoid this inequitable and unjustified result, CMS should establish EHR incentives calculation formulas that treat each inpatient facility as a distinct "eligible hospital" for purposes of calculating the Medicare and Medicaid EHR incentives payable to the hospital system of which the inpatient facility is a part.

Second, we believe a close comparison of the HITECH Act's Medicaid and Medicare EHR incentive provisions indicates that Congress intended that such incentives should be calculated in a manner that treats each inpatient facility separately regardless of whether it shares a provider number with any other inpatient facility(ies). The Act's provisions concerning Medicaid EHR incentives for acute care hospitals do not use the term "eligible hospital." Rather, the Act states that Medicaid EHR incentives are available to "an acute-care hospital that is not [a children's hospital] and that has at least 10 percent of the hospital's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title."[19] If Congress had intended the term "acute-care hospital" to be interpreted as meaning collectively every inpatient facility that is operating under

[19] 42 U.S.C. 1396b(t)(2)(B)(ii).

a single provider number, one would have expected some clear guidance to that effect in the HITECH Act itself or its legislative history. In fact, no such guidance, either express or implied, exists in the HITECH Act or its legislative history. The absence of any such guidance in the HITECH Act, along with the fact that the term "acute-care hospital" has no accepted meaning or definition under the Medicaid Program, indicates that Congress was using the term "acute-care hospital" in a commonsense way to mean an inpatient facility that furnishes acute care services.[20] In other words, Congress intended that each inpatient facility would be eligible to qualify for its own Medicaid EHR incentives, regardless of whether the facility shares a provider number with any other inpatient facility(ies). And, since there is no basis in the HITECH Act – or any logical basis – for treating inpatient facilities differently for purposes of their eligibility to qualify for Medicaid versus Medicare EHR incentives, Congress must also have intended that each inpatient facility could qualify for its own Medicare EHR incentives, even if the facility shares a provider number with any other inpatient facility(ies). Any other interpretation of the terms "acute-care hospital" and "eligible provider" in the HITECH Act would lead to arbitrary and inequitable distinctions based on whether a hospital's inpatient facilities share a provider number.

Finally, CMS's interpretations of the terms "acute-care hospital" and "eligible provider" in the HITECH Act must be rationally related to, and in accord with, the Act's primary purpose of implementing a nationwide HIT infrastructure as quickly as possible. The NPRM's proposed formulas for calculating Medicaid EHR incentives for acute-care hospitals and Medicare EHR incentives for eligible hospitals would undermine the Act's purpose by arbitrarily and inequitably limiting the EHR incentives for inpatient facilities that share a provider number. Since CMS has a duty to interpret the HITECH Act in a manner that is faithful to the Act's purpose, and since CMS has a duty to promulgate regulations in furtherance of the Act's purpose, CMS has an obligation to modify the NPRM's proposed formulas for calculating Medicare and Medicaid EHR incentives to allow each inpatient facility operating as an acute-care hospital to qualify for its own Medicare and Medicaid EHR incentives, regardless of whether the facility has its own provider number.

[20] The NPRM's inclusion of a definition for the term "acute-care hospital" demonstrates that CMS also recognizes that term does not have an accepted meaning or definition under the Medicaid Program which clearly should be applied under the HITECH Act. NPRM Rule Section 495.302. Significantly, the NPRM defines the term "acute-care hospital" in part by reference to the facility's CMS Certification Number, which would not have been necessary if the HITECH Act or any other statute, regulation or sub-regulatory guidance regarding the Medicaid Program had previously stated or indicated that the term "acute-care hospital" should be interpreted to mean collectively all of the inpatient facilities operating under a single provider number.

We recognize that efficient administration of the EHR incentives program requires CMS to have clear standards for distinguishing when an inpatient facility that shares a provider number with one or more other inpatient facilities should be treated as a separate facility which can qualify for its own Medicare and Medicaid EHR incentives. For that reason, we believe CMS should adopt the following definitions of the terms "eligible hospital" and "acute-care hospital" for purposes of identifying inpatient facilities that can qualify for their own Medicare and Medicaid EHR incentives:

> Eligible Hospital Definition Concerning Medicare EHR Incentives: The term "eligible hospital" means a subsection (d) hospital; provided that if a subsection (d) hospital has more than one inpatient facility operating under a single Centers for Medicare & Medicaid Services certification number or a single Medicare provider number, any such inpatient facility that satisfies either of the following criteria shall be deemed an "eligible hospital" under this subsection that can qualify for its own Medicare EHR incentives:
>
> i. The facility is (or in the past was) required by applicable federal or state legal requirements to apply for, obtain or maintain a Medicare certification or provider number or other government-issued provider number, license, or certificate of need separately from every other inpatient facility which during the applicable EHR Reporting Period is operating under the same Centers for Medicare & Medicaid Services certification number; or,
>
> ii. The facility has an emergency room.
>
> Acute-Care Hospital Definition Concerning Medicaid EHR Incentives: The term "acute-care hospital" means a healthcare facility that: (i) is not a children's hospital; (ii) has an average length of stay of 25 days or fewer; and (iii) has at least 10 percent of the facility's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under Title XIX; provided that if an acute-care hospital has more than one inpatient facility operating under a single Centers for Medicare & Medicaid Services certification number or a single Medicare provider number, any such inpatient facility that satisfies either of the following criteria shall be deemed a 'Medicaid provider' under this subsection that can qualify for its own Medicaid EHR incentives:

i. The facility is (or in the past was) required by applicable federal or state legal requirements to apply for, obtain or maintain a Medicare certification or provider number or other government-issued provider number, license, or certificate of need separately from every other inpatient facility which during the applicable EHR Reporting Period is operating under the same Centers for Medicare & Medicaid Services certification number; or,

ii. The facility has an emergency room.

If a hospital has more than one inpatient facility operating under a single provider number, for each such inpatient facility that is qualifying for its own EHR incentives, the hospital should be required to file with CMS an attestation stating the name of the inpatient facility and the applicable criterion above that the inpatient facility satisfies with respect to Medicare and Medicaid EHR incentives, respectively.

Comment 4: The NPRM's Proposed Clinical Quality Reporting Measures - Rule Sections 495.6(d)(3)(iii) and (e)(2)(ii), Rule Section 495.314

We agree that achieving the HITECH Act's goal of establishing a nationwide HIT infrastructure ultimately will require eligible providers to report appropriate clinical quality data to CMS. However, for the reasons stated below, we believe the NPRM's proposed clinical quality reporting measures are unattainable in Stage 1, and should be imposed in Stage 2 only after all of the issues identified below have been resolved.

First, and perhaps most importantly, virtually every EHR in operation today must be modified to add the functionality needed to capture and report the necessary data in structured format to comply with the NPRM's 35 proposed clinical quality reporting measures.[21] And, only 15 of those measures currently have specifications applicable to EHRs. As a result, even if an eligible provider at this very moment has a fully operational EHR and is in full compliance with every

[21] For example, for each of the NPRM's proposed clinical quality reporting measures, every EHR vendor must do at least the following: (a) map the data required for such measure back to the applicable screens and options in the vendor's EHR software where such data could be captured; (b) determine the best way for its EHR to capture the required data; (c) develop, test and perfect the modifications to its EHR software necessary to capture and report the required data; and (d) obtain HITECH Act certification for its EHR as modified.

other Stage 1 meaningful use criterion, that eligible provider could not qualify as a meaningful user until after all of the following steps have occurred:

i. The above-mentioned modifications to the provider's EHR must be acquired, installed, tested and functioning properly;

ii. The eligible provider's EHR, as modified under the preceding clause, must be approved as a "certified EHR" under the HITECH Act;

iii. The eligible provider must develop and implement all workflow changes necessary with respect to the foregoing modifications to its EHR; and

iv. The eligible provider's personnel and medical staff must be fully trained regarding the foregoing modifications to the provider's EHR and any workflow changes related to those modifications.

Accomplishing the above tasks in Stage 1 would be extremely challenging for an eligible provider that is otherwise fully in compliance with the Stage 1 meaningful use criteria today. Since the vast majority of eligible providers are nowhere near to complying with any of the Stage 1 meaningful use criteria, it is inconceivable that many eligible providers will be able to satisfy the NPRM's proposed clinical quality reporting measures in Stage 1.

Second, since the meaningful use criteria are not likely to be finalized until at least several months following the March 15, 2010, deadline for public comments on the NPRM, EHR vendors probably will not be able to begin any substantial modifications to their EHR products until mid- to late 2010. Given the lead time necessary for an EHR vendor to develop, test, perfect, obtain HITECH Act certification for, and make commercially available any such modifications to its EHR, it is extremely unlikely that any vendor's certified EHR or EHR modules will be ready for installation until mid-2011 at the earliest. And meeting that aggressive timetable assumes that EHR vendors will have the necessary sales force resources to consummate sales transactions quickly with their customers for these EHR modifications, and the necessary installation and training resources to rapidly install these modifications and train their customers in the use of these modifications. Further, eligible providers must implement work flow changes that match the EHR modifications, which will add additional time. Hastily implemented workflow changes could have the unintended consequence of adversely affecting quality of care rather than enhancing it.

Third, the NPRM's three proposed emergency department clinical quality reporting measures have never been used by either CMS or the Joint Commission, so eligible hospitals have no experience with these measures. Also, only two of these emergency department measures have EHR specifications, so no EHRs on the market today have the requisite functionality regarding these measures.

Fourth, the current EHR clinical quality measures concerning stroke and venous thromboembolism ("VTE") are based on Healthcare Information Technology Standards Panel ("HITSP") Quality Measures that identify standards gaps that have not been fully addressed for data elements that provide patient specific exclusions for the stroke and VTE measures.[22] Since the inclusion or exclusion of a patient in a performance measure is dependent on the ability to accurately capture these data elements, these EHR standards gaps must be fully resolved before requiring an eligible hospital to report on the stroke and VTE measures.

Fifth, although the NPRM preamble states that CMS intends to establish procedures that will avoid redundant or duplicative reporting of measures for Medicare quality reporting programs, those procedures and the infrastructure necessary to support them do not exist at this time. As a result, eligible hospitals are likely to be forced to spend significant time and resources in redundant and duplicative reporting on quality measures to comply with both the meaningful use criteria and the various other Medicare quality reporting programs.

Sixth, every clinical quality reporting measure should be tested thoroughly in appropriate clinical settings prior to its inclusion in the meaningful use criteria, to ensure that complying with the measure is feasible in practice. In addition, to facilitate smooth transitions regarding any additions or changes to the meaningful use clinical quality reporting measures, new or modified measures should be phased in over time along with other similar or clinically related quality measures that are new or modified.

At stated above, we believe the foregoing concerns must be resolved before any clinical quality reporting requirements can be included in the meaningful use criteria. CMS should be able to resolve these concerns prior to Stage 2, allowing appropriate clinical quality reporting measures to be included in the Stage 2 meaningful use criteria.

If CMS believes that it is essential to include some form of clinical quality reporting requirement in the Stage 1 meaningful use criteria, we believe CMS should take the following approach:

[22] Technical Note Version 0.0.1 in Table 2.7 of the HITSP Quality Measures issues in September of 2009.

i. Any clinical quality reporting measures for eligible hospital in Stage 1 should be limited to CMS's and the Joint Commission's National Hospital Quality Measures for which EHR specifications are currently available.

ii. No clinical quality reporting measure for Stage 1 should require an eligible provider to engage in any manual review of records.

iii. Eligible providers should be able to satisfy any Stage 1 clinical quality reporting requirement by complying with fewer than 100 percent of the clinical quality reporting measures identified in the final meaningful use rule. This flexibility will permit each eligible provider to develop the EHR implementation strategy that is best suited to such eligible provider's particular situation.

Comment 5: The States' Role in Determining Meaningful Use

We believe CMS should clarify in the final meaningful use rule that no state can establish meaningful use requirements that are more stringent than the meaningful use requirements to qualify for Medicare EHR incentives. We believe this prohibition should apply even in a circumstance where the eligible provider at issue has not qualified for Medicare EHR incentives. If CMS does not clarify this point, eligible providers face the prospect of multiple, and potentially conflicting, meaningful use requirements for Medicare and Medicaid EHR incentives (which would be particularly difficult for eligible providers who operate in more than one state). Congress made clear in the HITECH Act that eligible providers should not be subjected to multiple meaningful use requirements,[23] and we have concerns that some of the statements in the NPRM's preamble could be construed as permitting states to establish their own meaningful use requirements.[24] To avoid that possibility, CMS should expressly state in the final meaningful use rule that the same criteria are applicable with respect to qualifying for Medicare and Medicaid EHR incentives (except for the requirement that an eligible professional must waive his/her rights to Medicare EHR incentives to qualify for Medicaid EHR incentives).

[23] 42 U.S.C. § 1396b(t)(8).

[24] See 75 Fed. Reg. at 1851-52.

Comment 6: Reassignment of Eligible Professionals' EHR Incentives to Employers and Other Entities - Rule Sections 495.10(f) and 495.332(c)(9)(i)

The NPRM states that an eligible professional is *allowed* to reassign his/her EHR incentives to an employer or other entity to which the eligible professional has reassigned his/her payments for covered services.[25] In fact, we believe the HITECH Act requires that in cases where an eligible professional has reassigned his/her pa/yments for covered services to an employer or other entity, any EHR incentives for which the eligible professional qualifies *must* be paid to such employer or entity (subject to two limited qualifications discussed below).

The HITECH Act provision concerning transfer of an eligible professional's Medicare EHR incentives says that such incentives:

> …*shall be paid* to the eligible professional (*or to an employer or facility in the cases described in [the Medicare reassignment provisions in the Social Security Act]*…[26]

(Emphasis added.) Likewise, the HITECH Act provision concerning transfer of an eligible professional's Medicaid EHR incentives says that the eligible provider's state must provide assurances to HHS that such incentives:

> … *are paid* directly to such provider (*or to an employer or facility to which such provider has assigned payments*)…[27]

(Emphasis added.) We believe the above-quoted phrases "shall be paid" and "are paid" can only be interpreted as meaning that an eligible professional's EHR incentives must be paid to an employer or other entity to which the eligible professional has reassigned his/her payments for services. In other words, the above-quoted HITECH Act provisions mean that the existence of a valid reassignment of payments for services is all that is necessary to *require* CMS or the applicable state agency to pay an eligible professional's EHR incentives directly to the employer or other entity to which the eligible professional's payments for services have been reassigned.

Our sense from the NPRM's preamble statements on this point is that CMS may believe the above-quoted HITECH Act provisions necessitate the existence of a document executed by an eligible professional that under applicable state contract law would affirmatively transfer the

[25] Id. at 1910.

[26] 42 U.S.C. 1395w-4(o)(1)(A)(i).

[27] 42 U.S.C. 1396b(t)(6)(A)(i).

eligible professional's EHR incentives to an employer or other entity. Such an affirmative transfer of EHR incentives certainly is not a requirement under the above-quoted HITECH Act provision concerning Medicare EHR incentives, which refers only to reassignment of payments for services in accordance with the Medicare reassignment rules. Since the two HITECH Act provisions quoted above deal with the same exact issue and are essentially parallel in structure, we believe Congress must have intended to impose the same criteria for the transfer of Medicare and Medicaid EHR incentives for eligible professionals. As such, we believe the HITECH Act requires that any EHR incentives for an eligible professional who has reassigned his/her payments for services to an employer or other entity in accordance with the Medicare reassignment rules must be paid to such employer or entity.

Our interpretation of the above-quoted HITECH Act provisions is completely consistent with Congress' clear intent to prevent windfall EHR incentives to eligible professionals who incur no EHR-related costs because they rely, at no charge, on EHRs furnished by their employers or entities to which they have reassigned their payments for services. If CMS does not clarify that an eligible professional's EHR incentives are automatically paid to an employer or other entity to which the eligible professional has reassigned his/her payments for services, every eligible professional who uses an EHR furnished at no charge by an employer or entity to which he/she has reassignment payments for services will be in a position to receive such windfall EHR incentives.

Beyond creating a substantial risk of many eligible professionals receiving windfall EHR incentives, CMS's failure to address this issue will trigger an enormous waste of time and resources by hospitals, medical practices, medical clinics and every other entity that employs or contracts with eligible professionals to furnish services. Each of these entities will have to enter into negotiations with every one of its eligible professionals to obtain a separate agreement transferring the eligible professional's EHR incentives to the entity. It is possible that some of those negotiations will be quick and perfunctory in nature, but it is equally possible (and probably more likely) that eligible professionals will use these negotiations as an opportunity to extract concessions from their employers and entities through which these eligible professionals furnish services. It is inconceivable that Congress intended to trigger these kinds of negotiations, particularly since the rationale and objective of the HITECH Act provisions regarding transfer of eligible professionals' EHR incentives are merely to align EHR incentives and EHR costs, thereby avoiding windfall EHR incentive payments to eligible professionals.

As mentioned above, we believe there are two limited circumstances in which an eligible professional's EHR incentives should not be paid to an employer or entity to which the eligible

professional has reassigned his/her payments for services. First, we agree with the NPRM that if for any particular EHR Reporting Period an eligible professional has reassigned his/her payments for services to more than one employer or entity, only one of those employers or entities should receive the eligible professional's EHR incentives for such Reporting Period. We believe that in such a case an eligible professional's EHR incentives should automatically be paid to the employer/entity that has received for such Reporting Period the largest percentage of the eligible professional's Medicare or Medicaid payments for services (depending on whether the EHR incentives at issue are paid under Medicare or Medicaid). We do not believe an eligible professional in such a case should have any involvement in determining which employer/entity should receive his/her EHR incentives because providing an eligible professional with that right inevitably would result in the kind of counterproductive and wasteful negotiations mentioned in the preceding paragraph.

Second, if an eligible professional has actually incurred out-of-pocket costs in connection with an EHR provided by any employer or entity to which the eligible professional has reassigned his payments for services, we believe the eligible professional should be permitted to keep an amount of his/her EHR incentives equal to the amount of such costs. Any eligible professional desiring to take advantage of this option should be required to submit documentation to CMS evidencing the EHR-related costs he/she has incurred.

In addition to the foregoing fundamental issues regarding reassignment of eligible professionals' EHR incentives, there are two technical issues that we believe CMS must address concerning such reassignments. CMS should clarify that if an employer or other entity receives a reassignment of an eligible professional's EHR incentives under any circumstances:

1. The employer or entity shall by deemed authorized to provide on the eligible professional's behalf any documentation necessary for the eligible professional to qualify for EHR incentives (including, for example, any waiver of EHR incentives the eligible professional must furnish to CMS pursuant to the HITECH Act or any regulations promulgated thereunder); and

2. Any such reassignment of the eligible professional's EHR incentives should be deemed not to constitute a financial arrangement within the meaning of the federal Stark Law, or remuneration within the meaning of the federal anti-kickback law.

Comment 7: Meaningful Use Requirements for Eligible Professionals in a Group Practice

The HITECH Act expressly authorizes the Secretary to establish an "alternative means for meeting the [HITECH Act's meaningful use requirements] in the case of an eligible professional furnishing covered professional services in a group practice (as defined by the Secretary)."[28] The NPRM does not include any provisions regarding an alternative compliance methodology for eligible professionals practicing in group practices. We believe CMS should exercise the above-mentioned authority under the HITECH Act to facilitate the process by which eligible professionals in a group practice can qualify for EHR incentives. At a minimum, we believe CMS should use this authority to clarify the following points:

1. A "group practice" for purposes of the HITECH Act means a medical practice with two or more licensed medical practitioners (i.e., a "group practice" under the HITECH Act does not have satisfy any of the criteria applicable to be a "group practice" under the federal Stark law).

2. A group practice is only required to make a single submission to CMS each year on behalf of all of the group's eligible professionals who qualify as meaningful users.

3. Information in a patient's record that is applicable to an eligible professional's compliance with any meaningful use criterion should apply with respect to each of the group's eligible professionals who have treated such patient in the EHR Reporting Period at issue. For example, if a patient's smoking status has been recorded in the patient's record in the group's EHR, that should be sufficient for each eligible professional treating that patient to meet the meaningful use criterion concerning patient smoking status.

4. Any EHR incentives for which an eligible professional in a group practice qualifies shall be paid to his/her group practice, subject to the two limited qualifications mentioned in Comment 6, above, regarding circumstances in which: (i) an eligible professional has reassigned his/her payments for services to more than one group practice or other entity (in which case the EHR incentives would be paid to the employer/entity receiving the largest portion of the eligible professional's Medicare or Medicaid payments for services for the applicable EHR Reporting Period); or (ii) an eligible professional has actually incurred out-of-pocket costs concerning his/her group's EHR (in which case the eligible

[28] 42 U.S.C. 1395w-4(o)(2)(A).

professional would be entitled to keep an amount of his/her EHR incentives equal to such actual out-of-pocket costs); and

5. In the case of an eligible professional practicing in a group practice with multiple practice locations, the only data that *must* be included in determining whether the eligible professional is complying with the applicable meaningful use requirements is data from the group's practice locations that meet both of the following requirements:

    a. The practice location is one where eligible professional has actually furnished covered services during the EHR Reporting Period at issue; and

    b. As of the commencement of the EHR Reporting Period at issue, the practice location has a functioning certified EHR which the eligible professional can use to satisfy all of the meaningful use requirements applicable to such eligible professional (e.g., if the eligible professional is a cardiologist, the certified EHR at the practice location at issue must have the capabilities and functionality necessary for the eligible professional to satisfy the cardiology-specific clinical quality reporting measures).

We also believe CMS should clarify that if during the course of an EHR Reporting Period certified EHR technology is deployed at a group's practice location where an eligible professional furnishes services, the eligible professional or his/her group shall have the option, but not the obligation, to include data from that location for purposes of determining whether the eligible professional has met the meaningful use requirements for such Reporting Period. We believe this option could be helpful for an eligible professional who otherwise might not be able to qualify as a meaningful user for a particular Reporting Period. An eligible professional who elects this option would include data from the practice location at issue commencing as of the first date that the eligible professional uses such certified EHR during the Reporting Period at issue.

Comment 8: EHR Incentives Should Not Affect Hospitals' Other Payments under Medicare or Medicaid

It is clear Congress intended HITECH Act EHR incentives for eligible providers to be in addition to all other payments to providers under Medicare, Medicaid and all other federal or state governmental healthcare programs. However, given the complexities involved in the calculation of various hospital payments under Medicare, Medicaid and other governmental healthcare

programs (e.g., disproportionate share payments, graduate medical education and indirect medical education payments, un-compensated care payments, etc.), we believe it is appropriate and necessary for CMS to clarify in the final meaningful use rule that any EHR incentives that an eligible provider qualifies for or receives under the HITECH Act or regulations promulgated thereunder (whether directly or pursuant to an assignment, reassignment or other transfer) shall not affect or be taken into account in the calculation or payment of any other amount to such eligible provider under any federal or state healthcare program other than the EHR incentives program under the HITECH Act.

Comment 9: Technical Clarifications Concerning Particular Meaningful Use Criteria

A. Required Use of EHR for Electronic Submission of Claims[29] - The NPRM's proposed requirement that an eligible provider must use a certified EHR for electronic claims submission is unwarranted and impractical for a number of reasons. First, most providers today submit claims electronically through a billing system that does not, and cannot, communicate information electronically with the provider's EHR. In fact, many eligible providers outsource their billing to third parties who use their own billing systems to submit their customers' claims electronically. Requiring each eligible provider's EHR to become interoperable in Stage 1 with the billing system used for electronic submission of the provider's claims would be extremely costly and time consuming without providing any benefit to patients, providers, commercial payors, or any governmental healthcare program.

   Second, satisfying the NPRM's proposed electronic claims submission requirement would require separate HITECH Act certification for every billing system used for electronic claims submission, including billing systems used by third party billing agents. Such certification would further increase the costs and time involved in complying with this criterion.

   Third, the NPRM's proposed electronic claims submission requirement is likely to give many EHR vendors monopolistic leverage over their eligible provider customers, who will be forced to rely on their respective EHR vendors to supply the products and services necessary to accomplish the required electronic interoperability link between each provider's EHR and the billing system used for electronic submission of the provider's claims.

[29] 75 Fed. Reg. at 1863-64.

Fourth, the NPRM's proposed electronic claims submission requirement will divert the scare resources of eligible providers (and EHR vendors) away from activities and efforts related to complying with the meaningful use criteria that actually will improve the quality of care.

Finally, there is nothing materially wrong or dysfunctional with the manner in which electronic submission of claims occurs today, so there is no need to use the meaningful use criteria to prompt any changes regarding electronic claims submission.

For all of the foregoing reasons, we believe the NPRM's proposed electronic claims submission criterion should be deleted from the Stage 1 meaningful use criteria. However, if CMS believes it is essential that this criterion remain in the Stage 1 meaningful use criteria, eligible providers should be deemed to have satisfied this criterion if at least 80 percent of their claims for services furnished in an EHR Reporting Period have been submitted electronically through any means (i.e., not just using a certified EHR). In addition, if this criterion is not eliminated from the Stage 1 meaningful use criteria, we believe CMS should clarify the following points regarding this criterion:

a. A "claim" should include only a provider's first submission to a payor with respect to the services at issue, and should not include any subsequent submissions to the payor regarding those same services (e.g., answers to follow-up requests from the provider for information).

b. A "claim" should merely be a provider's request for payment for specified services rendered (i.e., it should not be necessary for such a request for payment to meet any "clean claim" requirements, or to include all the information that a payor may request or require for payment).

c. Calculation of the compliance percentage for this HIT functionality measure should exclude private pay patients, charity care patients, and any patient whose insurer cannot receive electronic claims submissions from a provider's EHR (regardless of whether the insurer can receive electronic claims submissions from any EHR of another provider or EHR vendor).

d. A provider's *attempt* to electronically submit a claim should be included in the numerator of this calculation, even if there is a communication receipt problem at the insurer, or with respect to transmission of the provider's submission to the insurer.

e. An eligible provider should have the option of excluding from this calculation any of the provider's claims that are rejected by an insurer (regardless of the grounds for rejection by the payor).

B. Issues Concerning the CPOE Criteria[30] - We believe CMS should clarify the following points regarding the CPOE criteria for eligible providers:

a. CPOE Percentage Denominator - The NPRM's proposed CPOE criterion for eligible hospitals would require a hospital to have some means of electronically tracking the total number of orders issued by all authorized providers in the hospital during the EHR Reporting Period at issue. The reality is that the typical hospital does not have any ability to track that information (other than through a laborious manual review of records). Consequently, measuring an eligible hospital's compliance percentage for this criterion will be impossible in most cases. We believe the solution to this problem is to establish a compliance percentage that is calculated by dividing: (i) the total number of orders entered during the EHR Reporting Period using CPOE functionality; by (ii) an objectively verifiable statistic for such Reporting Period (such as all patient admissions to the eligible provider) which the eligible provider can determine without resorting to any manual review of records. Needless to say, depending on which objectively verifiable statistic is designated by CMS in the final meaningful use rule to serve as the denominator for this criterion, a compliance threshold of 10 percent may or may not be appropriate.

This concern regarding the calculation methodology for the CPOE compliance percentage also is an issue for eligible professionals because they and their practices do not have the ability to track electronically an eligible professional's total orders during an EHR Reporting Period. As such, we believe the final meaningful use rule also must establish for eligible professionals an objectively verifiable statistic for the denominator of the CPOE compliance percentage that eligible professionals and their practices can determine without resorting to a manual review of records. Regardless of which objectively verifiable statistic CMS designates to serve as the denominator for this criterion for eligible professionals, we believe the 80 percent compliance threshold is far too stringent for the CPOE requirement for eligible professionals.

[30] 75 Fed. Reg. at 1858-60.

Failure to address this issue for all eligible providers will lead to a tremendous waste of time and resources in manual reviews of records that will furnish absolutely no benefit to anyone.

b. Inclusion of Emergency Room Orders in the CPOE Percentage Calculation - We believe the CPOE percentage for eligible hospitals should include not only orders for inpatients but also orders for patients admitted to an eligible hospital's emergency room (i.e., regardless of whether such patients ultimately are admitted as hospital inpatients or discharged directly from an emergency room). Expanding the CPOE percentage to include orders for emergency room patients would provide eligible hospitals with greater flexibility in prioritizing their EHR implementation projects, and would not lead to unwarranted delays in hospital-wide EHR implementation for any eligible hospital.

c. Persons Authorized to Enter Orders - We believe the final meaningful use rule should clarify that for purposes of Stage 1, an order that is entered using CPOE functionality shall be included in the numerator of a CPOE percentage as long as: (i) the order is issued and authenticated by an eligible professional; and (ii) the person who enters the order into the eligible provider's EHR is authorized to do so under such eligible provider's applicable policies and procedures.

As currently drafted, the NPRM's CPOE criteria can only be satisfied if an eligible professional actually enters his/her orders into an EHR. That would be completely at odds with the manner in which most eligible professionals practice today. The reality is that eligible professionals rely heavily on support staff to enter many orders because that is the only way most eligible professionals can maximize the time they have to spend directly with their patients. Also, a material percentage of most eligible professionals' orders must be issued via telephone because in many cases delaying order entry until the eligible professional at issue can access an EHR would be contrary to furnishing necessary high quality care consistent with the best interests of the patient. And, in circumstances where clinical care is furnished by a team comprised of professionals and support staff, the applicable clinical protocols, policies and procedures often are developed and implemented based on an understanding that order entry by an ordering physician is not necessary to ensure optimal patient care.

We recognize that requiring eligible professionals to enter virtually all of their own orders is intended to improve patient care by reducing order communication errors. However, given the realities of how medicine is practiced today, we believe imposing the NPRM's proposed order entry requirement for eligible professionals simply will reduce the number of eligible providers who are able to qualify for EHR incentives in Stage 1, and thus will not result in any reduction in order communication errors. For Stage 1, we believe it is far more important that any CPOE requirement be structured to promote successful adoption and implementation of EHRs. For that reason we believe the final meaningful use rule should clarify that complying with any CPOE criterion in Stage 1 does not require that any ordering eligible professional to enter his/her orders.

d. Supervising Physicians - We believe CMS should clarify that when an eligible professional is supervising another licensed physician in specialty training at an eligible hospital (such as in a residency program), orders issued by the supervising physician as well as those issued by the physician being trained should be counted toward the eligible hospital's CPOE requirement.

C. Problem Lists[31] - The meaningful use criterion concerning problem lists requires that for each Reporting Period at least 80 percent of the unique patients of an eligible professional or eligible hospital must have at least one entry in their respective records (in structured data, based on ICD-9-CM or SNOMED CT) of an active problem or diagnosis, or an indication of "none." As currently structured this measure is not feasible for at least the following reasons:

First, physicians currently do not maintain problem lists at the point of care, nor do they rely on coding systems such as ICD-9-CM or SNOMED CT when making diagnoses at the time of a patient encounter. Rather, when these problem lists are maintained, they are compiled by coding specialists analyzing physician documentation that is accumulated well after a patient encounter. As a result, substantial workflow redesign would be necessary for eligible hospitals and eligible professionals to capture and record current and active diagnoses using ICD-9-CM or SNOMED CT. For example, physicians would need to be trained in the coding systems required to maintain such problem lists, or personnel trained in these coding systems would have to accompany each physician

[31] 75 Fed. Reg. at 1860.

and contemporaneously convert the physician's clinical diagnoses into the appropriate codes in real time.

Second, notwithstanding that the ONC's interim final rule on certification requires the use of ICD-9-CT or SNOMED CT to maintain problem lists, it remains to be seen whether EHRs currently on the market will have the functionality and clinical dictionaries needed to convert clinical diagnoses into coded format. As CMS moves to implement ICD-10 by 2013, it is imperative that we address the intersection of ICD-10 and meaningful use.

The HIT Policy Committee may have been mindful of these kinds of feasibility issues when it proposed in its Meaningful Use Matrix that the electronic recording of all clinical documentation be a 2013 criterion. When eligible professionals are required to document their progress notes electronically in an EHR (i.e., a Stage 2 meaningful use criterion), eligible providers will be able to maintain up-to-date problem lists based on that information. Until that time, however, maintaining up-to-date problem lists is not a reasonably achievable meaningful use criterion because the requisite information will not be available to eligible providers in electronic format. Even if the requisite information were available to an eligible provider in non-electronic format, a monumental and unwarranted expenditure of time and resources would be required to conduct the ongoing manual review of records that would be necessary to collect such information, and to manually input such information into an EHR.

For all of the foregoing reasons, we believe the up-to-date problem list criterion should be moved to the Stage 2 meaningful use criteria. If CMS decides to keep some form of up-to-date problem list requirement in the Stage 1 meaningful use criteria, it will be essential to restructure this criterion to make it reasonably achievable by eligible providers without the need for substantial workflow redesign or any manual review of records.

D. EHR Incentives for Eligible Professionals in Health Professional Shortage Areas ("HPSAs")[32] - The HITECH Act provides a 10 percent increase in Medicare EHR incentives for each eligible professional "who predominantly furnishes [Medicare-covered services] in … a health professionals shortage area."[33] The NPRM

[32] 75 Fed. Reg. at 1908.

[33] 42 U.S.C. 1395w-4(o)(1)(B)(iv).

proposes limiting these increased EHR incentives to eligible professionals who furnish more than 50 percent of their Medicare-covered professional services in an HPSA. We believe this limitation ignores the reality that many eligible professionals who work in an HPSA do so only on a part-time basis, and most of them would not satisfy the 50 percent minimum threshold proposed by the NPRM.

We recognize that the HITECH Act itself limits this 10 percent EHR incentives increase to eligible professionals who work "predominantly" in an HPSA. In the context of the HITECH Act's primary purpose – creating a nationwide HIT infrastructure as rapidly as possible – we believe an eligible professional should be able to qualify for this 10 percent EHR incentives increase if at least 25 percent of his/her Medicare-covered services during an EHR Reporting Period are furnished in an HPSA.

E. Eligible Professionals Working in Locations Without a Certified EHR[34] - The NPRM states that the HIT functionality measures for eligible professionals are "limited to actions taken at practices/locations equipped with certified EHR technology…at the beginning of the EHR reporting period for a given location."[35] CMS should clarify that for any particular eligible professional a practice/location shall be deemed to not be equipped with certified EHR technology unless the eligible professional has the right at such practice/location to use certified EHR technology that has the requisite functionality and capabilities for the eligible professional to qualify as a meaningful user (taking into account, for example, the meaningful use requirements applicable to the eligible professional's area of specialization). For example, if a cardiologist practices at a location with a certified EHR that is lacking the functionality or capabilities necessary for the cardiologist to satisfy the clinical quality reporting measures specifically applicable to cardiologists, that location should be deemed to not be equipped with certified EHR technology (at least with respect to cardiologists). Likewise, if a primary care physician practices at a hospital location with a certified EHR that is only a hospital-oriented EHR (i.e., an EHR lacking in the functionality and capabilities necessary for the primary care physician to qualify as a meaningful user), that location should be deemed to not be equipped with certified EHR technology (at least with respect to primary care physicians and other eligible professionals who cannot use a hospital-oriented EHR to satisfy the meaningful use criteria applicable to them).

[34] 75 Fed. Reg. at 1859.

[35] Id.

For the same reasons as mentioned in Comment 7, above, we believe CMS should clarify that if during the course of an EHR Reporting Period certified EHR technology is deployed at a practice location where an eligible professional furnishes services, the eligible professional shall have the option, but not the obligation, to include data from that location for purposes of determining whether the eligible professional has met the meaningful use requirements for such Reporting Period. In such case, the eligible professional would include data from the practice location at issue commencing as of the first date that the eligible professional uses such certified EHR during the Reporting Period at issue.

F. Updating/Correcting Records Following the Close of a Reporting Period - The NPRM preamble provisions regarding many of the meaningful use criteria refer to data that is entered *during* an applicable EHR Reporting Period. For example, the preamble provisions regarding the CPOE measure for eligible hospitals states:

> The numerator for this objective is orders entered in an inpatient facility/department that falls under the eligible hospital's CCN and by an authorized provider using CPOE functionality of certified EHR technology *during the EHR reporting period*...The denominator for this objective is all orders entered in an inpatient facility/department that falls under the eligible hospital's CCN and issued by the authorized providers in the hospital *during the EHR reporting period.*[36]

(Emphasis added.) CMS should clarify that for purposes of complying with any meaningful use criterion referring to orders or data entered *during* an EHR Reporting Period, an eligible provider may take into account any relevant information pertaining to such orders or data including, for example, information that actually is entered following the close of an EHR Reporting Period to update or correct an order or data that originally was entered during the EHR Reporting Period.

G. EHR Downtime - Eligible providers should be given the option of excluding from the compliance calculation for any meaningful use requirement data from any calendar week during an EHR Reporting Period when the provider's EHR was experiencing excessive downtime. The minimum acceptable uptime performance standard for the typical EHR is 99.99%, based on the eligible provider's normal hours of operation (i.e., 24 hours a day,

[36] Id. at 1859.

seven days a week for eligible hospitals, and normal business hours for most eligible professionals). Based on that uptime performance standard, excessive downtime should be defined as downtime of one (1) business day or more during any calendar week. An eligible provider who elects to exclude any data due to excessive EHR downtime should be required to notify CMS regarding each time period in an EHR Reporting Period for which data has been excluded, and the percentage of EHR downtime that the provider experienced for each such period.

H. Required Use of EHR for Checking Patients' Insurance Eligibility[37] - We believe the meaningful use criterion regarding checking patients' insurance eligibility using an EHR should be eliminated because complying with this criterion will require a substantial investment of time and resources by eligible providers without any benefit to patients, providers, commercial payors or government healthcare programs. Checking a patient's insurance eligibility is not a capability that typically is part of an EHR, and our understanding is that most EHR vendors do not intend to add this functionality to their EHRs. As such, no eligible provider would be able to comply with this criterion without obtaining "EHR module" certification for the provider's patient accounting system, patient admitting system or other electronic system used by the provider to check patients' insurance eligibility electronically. The time and expense involved in obtaining such separate certification, and in ensuring that the separately certified system interfaces with a provider's EHR, are unwarranted given that the existing protocols used by eligible providers to check patients' insurance eligibility electronically are functioning adequately. Eliminating this criterion will allow eligible providers to focus their efforts on complying with meaningful use criteria that actually will improve the quality of care and facilitate cost savings.

   If CMS determines that retaining some form of this criterion is essential in Stage 1, CMS should clarify that:

   a. For any EHR Reporting Period the compliance percentage for this measure for any particular eligible provider should include in the denominator only insurers which at the beginning of such Reporting Period have the capability to permit such eligible provider to conduct electronic checking of insurance eligibility with the actual certified EHR used by the provider (i.e., even if an insurer has such capability for some EHRs, if an insurer does not have that capability regarding a

[37] Id. at 1863.

particular provider's EHR, that insurer should be excluded from the denominator in this calculation for such provider).

b. A provider's *attempt* to electronically check insurance eligibility should be included in the numerator of this calculation, even if there is a communication receipt problem at the insurer, or a problem with respect to transmission of the provider's request to the insurer.

c. With respect to this calculation for any particular provider, only one electronic check per year should be required for each unique patient served by that provider during the Reporting Period.

d. This calculation should exclude private pay patients, charity care patients, and any other patients for whom a provider is not able to contact a governmental or commercial insurer to verify such patient's insurance eligibility.

I. Clarifications Regarding Electronic Copies of Health Information and Discharge Summaries to Patients[38] - For the meaningful use criterion regarding the provision of electronic copies of health information and discharge summaries to patients, CMS should clarify that:

a. Calculation of the compliance percentage for this measure only includes requests that are submitted by patients in accordance with the applicable provider's policies and procedures.

b. A provider's *attempt* to electronically submit copies of health information or discharge summaries to patients should be included in the numerator of this calculation, even if there is a communication receipt problem, or a problem with respect to transmission of the information to the patient.

The NPRM is silent on how an eligible provider should confirm a patient's identity in connection with an electronic transfer of information, or how the eligible provider should document the chain of custody regarding any such information. The final meaningful use rule should expressly address these points so that eligible providers will be able to develop and implement appropriate policies and procedures regarding electronic transfer of information to patients.

[38] Id. at 1864.

J. Alternative Means of Data Submissions to CMS - Several of the meaningful use criteria require that certain information be submitted to CMS or an eligible provider's applicable state agency using the provider's certified EHR. We believe CMS should clarify in the final meaningful use rule that at least during Stage 1 an eligible provider shall be deemed to have complied with any such meaningful use criterion as long as the information at issue has actually been submitted to CMS or the applicable state agency (even if the submission was not via the provider's EHR).

We recognize that the HITECH Act states that being a meaningful user requires, in part, that an eligible provider use:

> …certified EHR technology [to submit] information…in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary … [39]

We believe the phrase "in a form and manner specified by the Secretary" provides sufficient authority to CMS to clarify in the final meaningful use rule that a provider's failure in Stage 1 to submit any required information using the provider's certified EHR shall not constitute noncompliance by the provider with any particular meaningful use requirement as long as the information at issue is actually submitted to CMS or to the authorized state agency (whichever is applicable).

K. Medicaid EHR Incentives for Providers Engaged in Efforts to Adopt, Implement or Upgrade Certified EHR Technology - The HITECH Act authorizes Medicaid EHR incentives to any Medicaid provider[40] during the provider's first year of being "engaged in efforts to adopt, implement or upgrade certified EHR technology."[41] However, the NPRM's definitions of the terms "adopt," "implement" and "upgrade" substantially narrow the scope of this HITECH Act provision by requiring that to qualify under this provision a provider must at least install certified EHR technology in the EHR Reporting

[39] 42 U.S.C. 1395w-4(o)(2)(A)(iii) (i.e., definition of "meaningful use" with respect to Medicare EHR incentives for eligible professionals); and 42 U.S.C. 1395ww(n)(3)(A)(iii) (i.e., definition of "meaningful use" with respect to Medicare EHR incentives for eligible hospitals). It is worth noting that the HITECH Act provisions regarding Medicaid EHR incentives do not require use of a certified EHR to submit any information to CMS or any state agency.

[40] As discussed above in Comment 5, the term "Medicaid provider" with respect to Medicaid EHR incentives is essentially comparable to the term "eligible provider" with respect to Medicare EHR incentives.

[41] 42 U.S.C. 1396b(t)(6)(C)(II).

Period at issue.[42] The effect of these definitions is to require a provider to go far beyond simply being "*engaged in efforts* to adopt, implement or upgrade certified EHR technology," which is the express standard set by the HITECH Act. (Emphasis added.)

We believe the final meaningful use rule must change the NPRM's construction of the "engaged in efforts" standard to permit Medicaid providers to qualify for their first year of Medicaid EHR incentives even if they have not actually installed certified EHR technology. We believe CMS will be in the best position to establish a more reasonable construction of the "engaged in efforts" standard after reviewing all of the comments on the NPRM. At a minimum, we believe a Medicaid provider should be deemed to have met the "engaged in efforts" standard if the Medicaid provider spends, or is committed to spend on its EHR project an amount equal to at least the lesser of $50,000 or 5 percent of the Medicaid EHR incentives amount that the provider is eligible for in its first year of Medicaid EHR incentives. A Medicaid provider should be deemed to have "committed to spend" an amount if the provider executes a contract with an unrelated third party that obligates the provider to spend such amount over the life of the contract.

L. Furnishing Patients with Electronic Copies of their Health Information or Other Information - Several of the meaningful use criteria require an eligible provider to furnish patients with certain information electronically, such as discharge instructions, clinical summaries of office visits, copies of health information, etc.[43] We believe CMS should expressly state in the final meaningful use rule that compliance with any meaningful use criterion does not require an eligible provider to interface electronically with any patient's electronic personal health record. Since there currently are no accepted standards for interfacing with electronic personal health records, it would be extremely extensive and time consuming for each eligible provider to implement an interface with every electronic personal health record used by the provider's patients. Also, we are concerned that requiring eligible providers to interface with their patients' electronic personal health records would increase the risk of malware and viruses corrupting an eligible provider's EHR and electronic data. Furthermore, we are concerned any such requirement is likely to give each EHR vendor an effective monopoly with its own eligible provider customers regarding the sale of products necessary for an eligible provider to implement such interfaces. To avoid these problems, the final meaningful use rule should expressly state that: (i) complying with any meaningful use criterion shall not require any eligible

[42] 75 Fed. Reg. at 1942.

[43] See id. at 1864-66.

providers to interface electronically with any patient's electronic personal health record; and (ii) each eligible provider is allowed to select the means deemed appropriate by such eligible provider to satisfy any meaningful use criteria involving furnishing of electronic information to patients.

The final meaningful use rule also should expressly state the specific information that an eligible provider must furnish to its patients to satisfy the meaningful use criterion regarding providing patients with electronic copies of their health information. The NPRM does not specify the particular information that must be furnished by an eligible provider to satisfy that criterion, or how far back in time the required information must cover. If CMS does not clarify these points, eligible providers will not be able to determine whether the electronic information they furnish to their patients is sufficient to comply with this criterion.

Finally, we do not believe it is reasonable or practical to implement during Stage 1 the criterion requiring eligible providers to respond within 48 hours to at least 80 percent of all patient requests for medical records. Meeting this criterion will require significant workflow changes and increased personnel for most eligible providers to develop and implement processes for updating and furnishing medical records to patients in an approved electronic format within the required 48-hour time frame. Since patients rarely need their medical records that quickly, imposing this criterion in Stage 1 will create an extremely difficult, and we think impossible, target for most eligible providers without providing any meaningful benefit to patients. We believe this criterion should be eliminated in Stage 1 so that eligible providers can focus their efforts on meeting meaningful use criteria that actually will provide benefits to patients, other providers, commercial payors and governmental healthcare programs.

M. Requirement that Eligible Hospitals Record a Patient's Cause of Death[44] - We believe qualifying as a meaningful user should not require an eligible hospital to record in its EHR any patient's cause of death. First, cause of death often is not known until after a patient's body is removed from the hospital. In such cases the hospital may never be informed regarding the cause of death. Second, every patient's cause of death is officially recorded on the patient's death certificate, which is available as a public record. For these reasons we believe this criterion should be eliminated from the meaningful use criteria for Stage 1 and all subsequent stages.

[44] Id. at 1861.

Comment 10: Inclusion of critical access hospitals in Medicaid EHR incentive program

A. Premier is concerned that CMS has proposed to exclude critical access hospitals (CAHs) from the Medicaid meaningful use EHR incentive program. We urge CMS to reverse this decision.

We appreciate this opportunity to comment on the NPRM. As mentioned above, Premier is committed to working with its alliance members and their respective medical staffs to implement certified EHR technology as rapidly as possible. We believe CMS addressing the points and concerns identified in these comments will be a significant step toward accomplishing that objective.

Any questions regarding these comments should be directed to Blair Childs, senior vice president of Public Affairs, 202-879-8009, Blair_Childs@PremierInc.com.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs