

Distinguished Members of the HIT Policy and HIT Standards Committee,

I am honored to be given an opportunity to present before you today. My name is Michael Stearns. As brief background I am physician by training with about 15 years of experience with direct patient care in clinical and academic settings. I am currently the President and CEO of e-MDs, a vendor that provides EHR and practice management software and services to about 10,000 providers in the United States. In the past I also served as the international director of SNOMED during the formation of SNOMED CT and managed the SNOMED CT clinical and technical design teams. I am a Certified Professional Coder (CPC) and Certified Family Practice Coder (CFPC). I have presented testimony to various working groups of the ONC on four occasions in the past 2 years and 3 months, including venues that focused on patient safety, patient privacy, the PCAST model for HIT, and the future stages of Meaningful Use. Other policy efforts I have been involved with include being the founding president of the Texas e-Health Alliance.

I would like to thank several members of my staff who contributed to these comments, including David Winn, MD, Chuck Frederick and Robyn Leone.

I was asked by the Office of the National Coordinator of HIT to address the following 6 questions:

1. What factors limit health IT's ability to support quality measurement/improvement?
2. How can health IT better support quality measurement/improvement?
3. How can the quality lifecycle be accelerated?
4. What is the role of Clinical Decision Support in the quality lifecycle? How does CDS relate to quality measurement?
5. What is the HIT vendor role in quality improvement programs?
6. Are there viable business models in which vendors can/should share risk/reward with providers?

In the interest of continuity I have taken the liberty of combining my responses to the first two questions regarding quality measurement and improvement challenges and solutions in the section below:

Part I. HIT: Factors limiting its ability to support quality measurement and improvement, and how these can be overcome.

There are several factors that limit the ability of health information technology to achieve the stated goals of the health care quality initiatives in the United States. These include:

1. Somewhat limited involvement of providers in quality incentive programs.

The EHR incentive program tied to Meaningful Use (MU) is arguably a major driving factor in the significant increase we have seen in EHR adoption in the United States. However, challenges remain with getting users to attain MU. At the end of April, slightly more than 56,000 EPs had

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successfully attested for MU and received payment from CMS. This is roughly 18% of all Medicare EPs.

The early stages of MU were designed to encourage providers to adopt EHR technology rather than to create a marked improvement in the quality of care. Later stages of MU, in particular Stage 3 and beyond, as planned, will focus on quality. This will in turn require relatively advanced use of EHRs and health information exchange. A significant number of additional providers will need to achieve at least Stage 1 “meaningful” use of their EHRs in the near future in order for them to achieve later stages of quality centric MU.

The incentive payments timelines for Medicare providers may represent another challenge. Ambulatory providers who first achieve MU in years 2011 and 2012 or 2012 and 2013 will have already received \$30,000 of the total \$44,000 in incentive payments. Those whose first year of MU is 2013 or later will receive lower reimbursements. Unfortunately the end result is that incentive payments will drop off markedly while providers are being asked to invest greater amounts of time and capital into the technologies and workflow needed to achieve the later stages of MU, where the quality benefits should be most pronounced.

One approach might be to adjust the incentive payments in a way that provides greater reimbursement for those who achieve Stage 3 and later stages of MU. This could help to prevent attrition in the MU program, as providers will see a clear financial offset for investing in the technology and level of effort needed to attain Stage 2 and 3 MU.

Current health IT programs are designed to have as many healthcare providers participating from as many specialties as possible. Significant quality improvements are more likely to come from programs where the emphasis on care coordination and quality outcomes is greater, like PCMH and Pay for Performance. As national Health IT Programs mature, and more healthcare providers are using their EHRs to enhance the care they provide to their patients and not just to obtain meaningful use, quality improvements will likely be more pronounced.

2. Continued expansion and harmonization of the Clinical Quality Measures and related quality reporting initiatives.

The proposed changes to the CQM process in Stage 2 including an expanded number of CQMs and greater harmonization with other programs is applauded. Alignment of quality programs across disparate agencies and programs will allow healthcare providers to focus on quality measures that provide the greatest impact to their patient populations. There will be less emphasis on meeting the requirements of an incentive program, and more towards using the tools as effective methods of providing care regardless of your specialty.

Another area of refinement for the CQM and CDS process is to develop and refine mechanisms whereby the CQMs and CDS rules can be contained in standardized files that can be consumed by EHRs. This would significantly reduce the burden upon EHR users and EHR vendors to adopt new and updated CQMs and CDS rules in their systems. Progress has been made in this domain, but a web services model that would allow vendor applications to call for updated quality incentive files and install them without the need for direct provider involvement would expedite improvements. This would allow vendors to pass patient parameters to a web service that

would compare the patient's state of health against quality measure criteria and then return CDS and quality measure information back to the vendor. This could include the latest treatment protocols and would likely be seen by providers as an attractive feature of EHR usage.

3. A lack of fully implemented national terminology standards for health information exchange.

Quality measurement and improvements depend on data that is accurate, complete, and current. Data currently is stored and used in a wide variety of forms, including text, claims data, XML metadata, and codified data. Data must be shared between numerous sources, including acute care facilities, ambulatory settings, laboratories, registries, personal health records, ancillary services, home monitoring systems and numerous other sources. At this time there remains a need for standards that support the seamless interoperability of codified and non-codified data between healthcare enterprises. The information would ideally be actionable in real-time clinical care decision, decision support applications and for reporting purposes without the need for human review. However, given the high degree of variability of data sources and data types, a great deal of harmonization of how data is captured, codified, used locally within a given facility, shared via a health information exchange or stored in a registry, and then imported into another application is needed before health information technologies can accurately assist providers with patient care activities.

One of the core requirements is the use of a codified clinical terminology that serves as a common language of health information exchange. Unfortunately in a large number of instances the only available codified language is in the form of claims data designed for an entirely different purpose. At this time in many communities in America, health information exchange, quality analysis, and the information used to evaluate physician quality of care rankings are based upon data captured and stored as ICD-9-CM codes. This code set, like ICD-10-CM, which also suffers from many of the same limitations, was not designed for use in clinical information systems at the level of detail needed to support advances in health care. Physicians are also often forced to choose an ICD-9-CM code due to lack of content or reimbursement purposes that is the best available code. It may or may not represent the patient's actual medical condition.

Claims data code sets such as ICD-9-CM and ICD-10-CM are not concept oriented. This creates a fundamental barrier to reliable machine processing of data in ways that can benefit the quality of care through accurate reporting and clinical decision support. An ICD-9-CM or ICD-10-CM code can represent multiple distinct concepts, making their use in information systems potentially hazardous. For example, the two highly distinct and clinical relevant clinical conditions staphylococcal pericarditis and streptococcal pericarditis and both represented by one ICD-9-CM code. Unless proper steps are taken, the machine could in theory provide a care recommendation such as antibiotic therapy that is based on the wrong clinical condition.

Unfortunately claims data is ubiquitous in healthcare and is being used today to drive advanced HIT activities. Given this a goal of knowledgeable organizations should be to educate HIT stakeholders on the need to validate information received and used by clinical applications.

The pending implementation of ICD-10-CM, a code set that has been expanded in several domains that will be useful for auditing and epidemiology, is not a suitable alternative to a

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concept oriented terminology such as SNOMED CT. This is particularly important when the codified data is being used in clinical applications such as reporting and decision support that require highly accurate data to safely contribute to patient care. Of note, the World Health Organization has specifically targeted making ICD-11 applicable for electronic health records and information systems (<http://www.who.int/classifications/icd/factsheet/en/index.html>). One of the proposed goals of this process is to convert ICD into a concept oriented terminology, possible through a deeper integration with SNOMED CT. This, combined with a potential delay in releasing ICD-10-CM in the U.S., has led some to suggest that ICD-10-CM adoption would be less desirable than waiting until 2015 to adopt ICD-11. However, the Clinical Modification process to form an ICD-11-CM version could delay its use in the U.S. by several years beyond 2015. Regardless, a formal strategy that results in the wide adoption of a single concept oriented terminology for clinical care is warranted at this time. This will be central to driving improvements in our ability to assess and improve the quality of care provided to patients in this country.

4. Natural language challenges associated with accurately representing clinical knowledge that has been abstracted from patient records.

Even if all systems were capable of capturing and using data as SNOMED CT or ICD-11 concepts today, a number of challenges remain before this information can be used with impunity for quality reporting and before the information captured, stored and reused as codified data can be exchanged and used safely during health information exchange. Much of the information captured during clinical care is in the form of complex clinical expressions that have various degrees of natural language nuances that are difficult to capture as codified data. This includes even fairly simple expressions such as “doubt spinal cord compression” in the assessment section of a clinical encounter note.

While the concept “spinal cord compression” can be represented by a single code, the supporting modifiers such as “doubt” in this example can markedly change the meaning and clinical relevance of information. If the semantic relationship of any modifying information with the core concept is not maintained, the ability of information systems such as clinical decision support applications can be markedly affected. A mechanism whereby the full meaning of the information is represented as codified data is needed in order for us to be able to rely on the ability of clinical quality efforts and clinical decision support tools to aid patient care. Some of the more encouraging efforts have been tied to have modifiers and core concepts represented as separate codified data elements, and a link between them maintained by an additional concept.

This mechanism is supported in SNOMED CT through the use of concept attributes, and has considerable promise. However, the process of collecting data in this form in electronic health records could be burdensome to providers (e.g., if providers had to actually choose concepts and match them with modifiers manually, a process referred to as post-coordination) during patient care. For this reason interface terminologies are being developed that support extensive pre-coordination, allowing common expressions to be “pre-mapped” to multiple codified data elements. This process is fairly complex, however, and has not been rigorously tested to our knowledge in a clinical setting that involves sharing of information between disparate EHR platforms.

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I would strongly urge those involved with health information exchange efforts to require a link from data used to make clinical decisions back to its source document. Over time data abstracted from source documents will become more reliable once standards and technologies evolve to support a metadata or other approach. Until that information in clinical information systems and stored as codified data will need to be used with some degree of caution. Another important construct is that all HIE organizations have robust quality control programs in place that address potential data misrepresentation issues tied to the use of claims data or core concepts stripped of supporting information. Inaccurate or incomplete data has the potential to compromise efforts to use health information technologies to improve the quality of care provided in this country.

5. A high percentage of clinical information of value to clinical care is stored as free text and is not readily available during patient care or for quality reporting and improvement initiatives.

During patient care it is not uncommon for providers to make clinical decisions based on limited information, as much of this information is stored as free text, data or images that are not readily accessible. With a fairly high degree of frequency this additional information (e.g., prior responses to medications, operative findings, imaging test results, pulmonary function studies, etc.) would have led to a different patient care decision being made. Even though this information might be accessible if the provider had access to where the information was stored, the amount of effort involved to locate this information limits its use. This can have a negative impact on the quality and efficiency of healthcare.

Various approaches tied to natural language and fuzzy logic searches are currently being evaluated that would provide highly efficient access to this type of information. This data can then be used for point of care decisions and quality initiatives. The value of these types of approaches is in the process of being evaluated, with special attention towards the accuracy and reliability of the information returned to the provider, how this impacts workflow, and to what degree providers should rely on retrievals of this nature before they no longer pursue information using traditional methods (e.g., requesting a hospitalization record). We are actively engaged in a pilot program designed to assess the utility, safety, reliability, patient care advantages and potential changes to work flow using this approach in one of our larger healthcare communities and hope to have results that we can share within the next few months.

If clinically significant data that would otherwise not be available is presented to providers in a usable format, efficient to access, and supported by evidence-based medicine recommendations for interventions, (e.g., Pneumovax immunizations for a patient who is status-post splenectomy) this method has the potential to greatly amplify the value of HIT for clinical care and the clinical relevance of HIE.

6. Business barriers related to interoperability

In some settings healthcare enterprises and HIT vendors may not feel it is in their best interest to share their patient data with other parties due to concerns over HIPAA violations, competitive intelligence, provider retention strategies, and the potential monetary value of health care data. Unfortunately this can greatly impede the ability of providers who do not have access to a given

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healthcare enterprise's information system to obtain information that could be essential for point of care decision making and quality efforts.

Another area of emerging and related interest is the impact of the "Stark Law" exemptions tied to EHR adoption that were put into place in 2006 when EHR adoption was very low. Prior to this exemption, the Stark Law prohibited physicians from making referrals to hospitals for certain designated health services payable by Medicaid or Medicare to an entity with which the physician has a financial relationship. This exemption is set to expire at the end of 2013 but has the potential to be renewed.

We are hearing reports from providers about interoperability being used as leverage to get them to change from an EHR that meets their needs (including successful MU attestation) to another EHR that is being subsidized by a local hospital. Some providers have expressed concern that the subsidized vendor is not facilitating the process of providing interfaces to other EHR provided by other vendors in the community. Providers also are often not aware that the hospital's ability to subsidize their EHR may expire at the end of 2013, which should be an important consideration regarding whether or not they should invest in particular EHR technology.

This raises the question of a potential unanticipated consequence of the Stark Law exemption for EHRs, i.e., that being large communities of hospital affiliated providers that have a business relationship to a hospital that has influence over whether or not data will be shared externally. The Stark exemption has clearly helped to accelerate EHR adoption over the past 6 years, but it may be time for it to be reexamined in light of the changing landscape of EHR adoption and its overall impact on healthcare quality and costs.

It is in the long term best interest of society and in particular all healthcare stakeholders to promote policies that require the interoperability of patient data between all healthcare enterprises.

7. Patient role in quality improvement efforts

There has been a surge in the use of home monitoring devices in the U.S., with an accompanying marked increase in the amount of data coming from patients to healthcare providers. Monitoring tools tied to encouraging patients to engage more actively in their care have the potential to improve compliance with medications, exercise, and diet. This has perhaps the greatest potential to improve the quality of health for the greatest number of American citizens given the epidemic of obesity and other maladies influenced by patient behavior. Any gains that can be made in this domain, including incentive programs to get patients to use home monitoring tools, may have the greatest impact on the patients with chronic medical conditions that are influenced negatively by suboptimal compliance with diet, exercise and medication regimens.

The value of the case manager in improving the health of patients with chronic medical conditions or who are at particular risk for preventable hospital admissions has been demonstrated in several settings. HIT tools designed to support and improve the efficiency of case managers have not been a focus on HIT efforts in the past, but as Accountable Care

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Organizations and related quality focused efforts emerge, this is an area where expanded HIT functionality designed for case managers could markedly benefit patient care. The tools would need to be able to access all relevant information in the community (e.g., patient home monitoring data, direct patient communications, hospital records, all ambulatory provider records, etc.) that might impact the patient's care. These would need to be supported by dashboards and tools that promote efficient communication between case managers and clinicians.

8. Make the use of orders tracking modules a requirement of Meaningful Use

The failure to track orders that are lost to follow-up is a leading cause of malpractice suits in this country and one of the areas of greatest impact for HIT in healthcare. Systems that track orders are fairly ubiquitous in EHRs and ensure that each order is tracked until completion. The tools are well established in this industry but their actual use varies considerably. Providing incentives for tracking and managing a high percentage of orders in an ambulatory setting would be a relatively fast and measurable method of accelerating improvements in the quality of care through HIT.

9. Explore the role of HIT in the role of research and care related to genomic medicine

The cost of sequencing of the complete human has been falling steadily over the past several years to the point where it will likely be affordable for patient care. DNA patterns can then be mapped to clinical conditions and responses to therapy in a way that should lead to significant improvements in our understanding of complex diseases processes. This will allow providers to tailor interventions (e.g., preventative medicine screenings and treatments) towards those that are most relevant and cost effective.

However, we have learned that it will require very large amounts of accurate and complete clinical data before genotypes can be mapped to specific clinical conditions and outcomes. Advances in genomic medicine will be tied directly to the amount of available data available for clinical analysis, making the success of these breakthroughs closely aligned to advances in HIT related to the unrestricted availability of usable data.

HIT will also be central to the point-of-care use of genomic information given the large amounts of data that will need to be processed in order to make treatment recommendations tied to the patient's genetic signature. The number of recommendations may also be relatively large, making it important for HIT applications to rank the relevance of each of these items when presenting them to care providers.

10. Develop standards that facilitate the seamless transition of orders from the acute care environment into the ambulatory provider's EHR

In some reports and significant percentage of re-admissions to hospitals have the potential to be prevented with better post-discharge management. At this time discharge orders are typically not provided to the primary care provider and are left to the discretion of the patient. A process whereby the orders are seamlessly transferred from the acute care EHR into the ambulatory provider's EHR and tracked as if they were generated by the outpatient provider, could play a

significant role in improving the care provided to patients post-discharge. This would require a set of standard order sets that would be recognized universally but it should be considered as one of the first steps towards seamless interoperability.

11. Address privacy and data ownership issues

Experience in other countries like the United Kingdom have demonstrated the potential for privacy and data ownership concerns to greatly impact HIT efforts. One could argue that in some settings, HIT vendors and other organizations are not making full disclosure to patients and in some cases providers as to how patient data is being used for secondary purposes. Patient awareness that their personal health information is being used for secondary and sometimes profitable purposes is growing. It would be timely and ethical for all secondary uses of data and their supporting business models to be disclosed to patients, providers and other members of the healthcare enterprise.

Models that support the segmentation of portions of the patient's record are being explored at this time, but the potential dynamic between patient safety and patient privacy has yet to be fully vetted. On one hand not allowing patients to choose what items in their record are shared outside of their confidential relationship with their providers could lead to patients not sharing key aspects of their history, creating a patient safety issue. On the other hand, allowing patients to choose what items in the medical history will be blocked from view by other providers or healthcare situations could have its own patient safety ramifications. It also creates challenges with informing the patient as to what items of their history would or would not be suggestive of certain conditions (e.g., medications for a mental health condition or HIV infection, radiology reports in a patient with a history of multiple sclerosis, etc.) and also the potential patient safety ramifications of suppressing that information to members of the healthcare community.

I would encourage pilot programs that assess the patient safety aspects of segmentation across the entire spectrum of care. It should also assess the process of informing patient of their options regarding segmentation choices. Lastly the medicolegal implications of advising patients on the downstream impact of segmentation should also be evaluated.

Part II: How can the quality lifecycle be accelerated?

1. Remove barriers to data access

As noted above, any barriers to data access need to be removed before the quality improvement processes targeted by HIT efforts in this country can move forward. Once we have the ability to look at large quantities of data across diverse populations we will be in a position to identify improvement programs that have the greatest level of benefit. Sir Roger Bacon once said "Knowledge is Power." This applies to healthcare in that our ability to access the quality of care being provided and also to assess the impact of interventions depends on our degree of "knowledge," and this depends on our access to data. The "power" of this process is weakened when providers, quality assurance officers, and researchers only have access to portions of a patient's record.

2. **Promote the adoption of later stages of MU that are more focused on quality of care improvements (as detailed above).**
3. **Carefully observe the outcomes quality centric programs such as ACOs, the newly announced Comprehensive Primary Care Initiatives from the CMS Innovation Center, and ongoing PCMH programs and take appropriate steps to address any discrepancies or shortcomings.**

These programs may need to be refined on a continuing basis based on their impact on the quality and cost of patient care, and business related concerns. This will be an information intensive process that will depend on access to reliable forms of data being captured and analyzed. This information will need to be refined and “pushed” to the provider in order for it to have the greatest relevance for patient care.

4. **Explore the potential of text data-mining tools as detailed above that have the potential to provide rapid access to clinical relevant information.**

An example of how this might work would be to have a copy of “pushed” documents from providers in community of Direct HIE participants stored in a repository that was accessible to text data-mining tools. This is a low cost approach that is available at this time and one that has the potential to have a marked impact if it empowers providers by giving the access to useful clinical information.

Part III: What is the role of Clinical Decision Support (CDS) in the quality lifecycle? How does CDS relate to quality measurement?

1. **CDS needs to be used in its proper context in order for it to benefit the quality lifecycle.**

Published reports on the value of CDS have demonstrated benefits related to provider adherence to guidelines, however relatively little evidence has emerged that they benefit outcomes or improve the efficiency of healthcare (reference: Bright et al <http://www.annals.org/content/early/2012/04/20/0003-4819-157-1-201207030-00450.long>), However it may be logical to assume that long term studies will demonstrate more pronounced healthcare benefits. The ability to demonstrate outcome benefits would ideally be conducted in a controlled environment with double-blinded participants, however this may not be feasible on a large scale. This leaves us with retrospective data analysis as the most effective method of identifying truly beneficial forms of CDS. This process will depend on high volumes of data that is complete and accurate, adding another point of value for seamless interoperability and standardized terminology code sets.

Meaningful Use should increasingly depend upon the use of CDS but it should also include an interactive process that leads to refinement of the content that drives CDS, i.e., published guidelines. Guidelines are typically developed from data derived in controlled settings that may not be representative of common clinical settings typically include a predominance of multiple comorbidities and polypharmacy. For this reason data obtained during patient care that was performed in more generalized settings and where HIT employing CDS is in active use may guide us as to how to refine guidelines that drive CDS, making them more clinically beneficial.

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However, excessive alerts can result in pop-up fatigue that can lead to these warnings being ignored. CDS applications have to be relatively intelligent and present users with the right level of intervention advice at the right time. This is an area of active research and refinement, but it is unlikely it will be solved in the near future.

Another concern is the potential for overreliance on CDS when making treatment decisions. Providers who would otherwise have not prescribed a certain drug combination without research, for example, may assume that this drug combination is safe if no “pop-up” warning appeared. If the CDS tools are not adequately sensitive or in some cases they become deactivated, providers could make errors that would not otherwise have made to this level of dependency on feedback from the EHR.

Part IV: What is the Health IT vendor’s role in quality improvement programs?

1. User education

We have an obligation to educate our users on the most efficient, and comprehensive way to use our products to provide the highest quality and safest care possible.

2. Commit to interoperability

The vendor community needs to ensure that their products are interoperable with other products, even if this conflicts with other business interests. Vendors with the highest level of integrity, which for HIT means putting patient care ahead of business interests, tend to have the greatest long term success in the marketplace.

3. Commit to patient safety initiatives

The quality of care enhancements tied to HIT depends on it not introducing new patient safety issues. Vendors need to maintain very active patient safety programs that focus on areas that have the potential to create patient safety issues during HIT adoption, such as pre-go-live preparation, implementation, workflow, usability and data feeds from external sources that have not been thoroughly vetted. This last item was discussed previously and relates to HIE data integrity challenges such as the use of claims data and the ability to represent reliably represent clinical knowledge in a codified format. EHR patient safety remains a concern for various entities in the U.S., but there has been less attention paid to the quality of information exchanged by HIEs. Each vendor should institute extensive quality control processes tied to identifying and addressing data integrity challenges that may be present in information received from external sources.

4. Commit to addressing patient privacy issues

Patient privacy issues that could impact the quality of care include segmentation and its downstream impact on later care. This is a complex issue that needs to be addressed by the vendor community and policy makers. If segmentation is not supported, patients may elect not to share sensitive clinical information. If segmentation is supported, its potential impact downstream needs to be evaluated, as the care for numerous clinical conditions could be adversely impacted if the treating provider does not have access to key patient information.

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5. Support data analytics efforts

Vendors should support all efforts to aggregate and analyze data from patient care. This data is key to advances in the quality and efficiency of care. Data ownership needs to be addressed by policy makers, but in my opinion vendors should not claim ownership of data. EHR business models that depend upon the sale of data, even when it is “anonymized,” can create barriers to quality of care efforts. If an organization feels that its data has monetary value they are less inclined to share it with other organizations, as the value of the data becomes instantly diluted. This practice needs to be examined by the vendor community but also by policy makers.

Part V: Are there viable business models in which vendors can/should share risk/reward with providers?

1. Deferred cost programs tied to the achievement of MU

Our company, e-MDs, has implemented a program whereby Medicaid EPs can defer all costs until receipt of their AIU payment from state Medicaid programs is received. This model works well for Medicaid as there is an incentive for investing in technology, and the first payment is received prior to the providers actually having to attain MU.

This program could be extended to Medicare, in theory, whereby EPs could receive some of their incentive funds in advance. This would allow the EHR vendors to defer costs until they receive payment from CMS.

Given the uncertainty of knowing which providers will attain MU and how long the process might take, vendors may have limited options regarding the deferment of payment for software and services tied to the attainment of MU incentive payments following attestation.

The most likely scenario would involve a relationship between a payer, a provider and an EHR company, where all parties were incentivized to meet certain metrics tied to quality of care improvements. In one example, this could lead to a pass through of a payer incentive payment to an EHR vendor.

Respectfully submitted,

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