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HIT Policy Committee
Certification Hearing
Washington Plaza Hotel, 10 Thomas Circle, NW, Washington, DC 20005

To: Members of the Health IT Policy Committee
From: Emily Richmond, MPH; Senior Manager, Health Care Quality on behalf of Practice Fusion, Inc.

Date: May 7, 2014

Re: Vendor panel on EHR certification program

This testimony to the HIT Policy Committee (HITPC) reflects Practice Fusion's experiences and participation in the Office of the National Coordination for Health IT (ONC) Electronic Health Record (EHR) certification program. Practice Fusion is the nation's largest cloud-based ambulatory EHR and patient portal platform and we offer our product to health care providers completely free of charge. Practice Fusion's mission is to connect doctors, patients and data to drive better health and save lives. We offer our testimony on the questions posed by the members of the HITPC below.

1. Assuming we could design an ideal program, what is the benefit of having a certification program, from the perspective of vendors?
2. What are the challenges you have experienced with the current certification program?
3. How would you propose changing the certification program to enhance its value to you, while minimizing the burden to the participants?

Benefits of certification from the EHR developer perspective
One of the benefits of the EHR certification program is that it offers healthcare professionals a performance standard for determining whether a software system meets the regulatory requirements for use as part of the EHR Incentive Program. In addition, the designation of certain systems as "certified" EHR technology gives healthcare providers the confidence that the product offers the features and functions necessary to meet the functional requirements of Meaningful Use and improved patient care through the integration of health IT.

When considering the benefits of the certification program to EHR developers, Practice Fusion looks to the technology industry where efforts to advance and spread the adoption of certain standards has been extremely successful. The most well-known example of the widespread adoption of standards occurred with the internet. The internet was developed after groups of stakeholders came together and agreed upon certain protocols that would serve as the foundation for the services and functions of the internet that are still used today. With standards in place, but implementation specifications left up to the market, the user experience of the internet was able to rapidly advance in response to user feedback, allowing for the growth of features that served the needs of different audiences while remaining compatible across different platforms and products over time.

We bring this historical reference to the forefront because it represents an example of how interested stakeholders can come together, decide upon certain standards, and implement those standards in a way that can make a substantial impact on our society. The ONC EHR certification program had the opportunity to provide similar benefits to the health IT industry by selecting standards that EHR developers could implement in order to facilitate interoperability and improve compatibility across EHR products, but unfortunately these benefits have been overshadowed by the volume of requirements and prescriptiveness of certain criteria.

When we think about how the certification program differs from the early days of internet protocols, the most obvious variance is that internet standards lack prescriptive implementation requirements, one of the reasons they were as able to flourish the way that they did. In our view, the ideal certification program would take standards that were developed and selected by health IT stakeholders and allow EHR developers the opportunity to prove that their products support those standards, while still encouraging innovation. Practice Fusion acknowledges that some healthcare provider certification benefits may have been realized, but from our perspective the EHR vendor benefits were frequently overshadowed by the challenges we experienced.

Challenges of the EHR certification program
There are a number of challenges that exist for companies that wish to develop, test, and implement EHR technology that meets certification criteria. Specifically, Practice Fusion dealt with challenges related to the volume and specificity of certification criteria as well as challenges related to implementing the certified product with our customers.

Practice Fusion offers a cloud-based EHR product completely free to healthcare professionals and we also recognize that the needs of healthcare providers are constantly changing. As such, we have chosen to incorporate agile methodology and the scrum framework in our software development process. While agile principles and the scrum framework are used by many software companies in order to execute on what is sometimes called "rapid software development," Practice Fusion combines rapid development with a rapid release cycle in order to release small, incremental product changes to our customers that include bug fixes, new features and improved functionality approximately once every two weeks. Despite this unique development model, Practice Fusion still faced challenges because of our desire to balance the extremely large volume of work that was required for EHR certification with the need to continue delivering product features that were specifically requested by our customers in a manner that did not disrupt their clinical workflows and practices. We want to highlight these challenges because although an agile software development process like the one used at Practice Fusion may appear to reduce some of the difficulties related to the certification timeline, this is not necessarily the case.

By the time Practice Fusion chose to begin the development needed for 2014 EHR certification, the ONC had clarified many EHR developer questions through the use of sub-

regulatory guidance. However, we were still faced with a huge volume of product changes and very specific implementation criteria that needed to be researched, analyzed, scoped for level of effort, designed, developed, and tested – all before we could even begin preparing for the Authorized Certification Body (ACB) tests. Had we started the process sooner, we would have had to pivot and change course quickly on multiple occasions, expending time and resources, as updates to test procedures and FAQs were released that altered the interpretation of certain requirements, thus changing the acceptance criteria needed to develop software to meet those requirements. As it was, we still had to find, review, and analyze upwards of six different sources of information, including the EHR certification final rule, ONC test procedures, CMS specification sheets for Meaningful Use, standards documents, various FAQs and testing body test methods, before being able to determine with some level of confidence how the software would need to function so we could move forward with design and development.

Another challenge that we faced was in finding a way to integrate the certification requirements into our product without compromising the user experience for our customers or their ability to provide high quality patient care. The current certification program challenges usability in two ways: one through dictating very prescriptive functional requirements that allow little room for innovation and another because the program requires that healthcare providers adapt large volumes of product and clinical workflow changes in a short amount of time. While we understand that some prescriptiveness is necessary in order to support interoperability, and that certain functional changes are needed in order to support the advancing requirements of Meaningful Use, we feel that certification is moving in a direction of incorporating higher volumes of requirements that do not serve either of those goals, which could have a negative impact on both providers and patients in the long run. More specifically, since we released our 2014 certified technology to customers in mid-December 2013, we have received a an increase in negative feedback related to ONC-required functionality, even though we implemented those features according to certification requirements.

How would you propose changing the certification program to enhance its value to you, while minimizing the burden to the participants?
Practice Fusion proposes that the certification program reduce its overall scope and complexity while offering a platform for the adoption of health IT standards that can be used to improve interoperability, care coordination, and improved patient care. We also propose that changes be made to how certification requirements, testing documentation, and guidance are created and delivered to EHR developers. As it stands, many of the requirements that are given to EHR companies are created by stakeholders who do not have experience in software development or are not aware of the various development methods that exist. This results in requirements that do not align with the capabilities of EHR technology and the development of software that meets test requirements versus the true requirements of our customers participating in federal quality improvement programs, both of which can have a significant negative impact on EHR usability.

Due to the complex nature of EHR certification and the many stakeholders that are involved, we believe that the certification program would greatly benefit from a thorough review using the Kaizen approach which focuses on eliminating waste in order to foster the continuous improvement of integrated processes. Through collaborative efforts that involve all relevant stakeholders, we truly believe the certification program can be optimized in a way that provides ongoing and continual benefits to EHR companies, healthcare providers, and patients.