June 8, 2015

Submitted via www.regulations.gov

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-3311-P; Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Modifications to Meaningful Use in 2015 through 2017

Dear Acting Administrator Slavitt,

Thank you for the opportunity to provide input on the proposed rule on *Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Modifications to Meaningful Use in 2015 through 2017.* While we recognize that the Centers for Medicare & Medicaid Services ("CMS") must be responsive to *legitimate* provider concerns, we believe that CMS also has a duty to ensure that patients are able to exercise the legal right they have to access their health care data under the Health Insurance Portability and Accountability Act ("HIPAA") and associated rulemaking. As outlined in more detail below, we do not believe the proposed modification to the Stage 2 patient engagement requirement strikes an appropriate balance between these two imperatives.

As you may know, Humetrix has developed numerous mobile health applications over the last fifteen years to enable consumers to engage with the world around them in new and innovative ways using their own health care data. One of these applications – iBlueButton – incorporates all existing electronic health record ("EHR") standards (Blue Button+ standards with secure DIRECT messaging for data transport and the HL7 C-CDA format for the content of records), as well as federal program Blue Button data (for Medicare, TRICARE and VA) and allows patients to easily and securely receive, view, and aggregate clinic and hospital discharge summary records from most 2014 certified EHRs on their mobile devices. With iBlueButton, Medicare beneficiaries, TRICARE enrollees and Veterans can also pull the Blue Button records offered by these federal programs which can be aggregated by the app with their EHR data. iBlueButton has won multiple industry innovation awards, including three ONC Industry Innovation awards, and is widely viewed as one of the most usable and novel mobile personal health record ("PHR") applications on the market today.

In our view, the proposed modifications to the Stage 2 view/download/transmit ("VDT") requirements are tipped too heavily in favor of providers at the expense of patients and would be a significant setback to efforts to engage patients in their own health and health care – critical to realizing the promise of value-based care models and advancing interoperability via consumer-mediated exchange. We strongly urge CMS not to finalize these proposals for the following reasons:

First, a threshold of a single patient is so nominal that it is the equivalent of eliminating the requirement in its entirety – a prospect that is likely to be harmful to patients. Such a policy could also constitute information blocking on CMS' part under the definition recently outlined by the Office of the National Coordinator for Health IT ("ONC") in its report to Congress ("information blocking occurs when

persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information"), as we do not believe that CMS has outlined a reasonable justification for eliminating provider incentives to share information with patients in light of the compelling public health interest in doing so.

Indeed, the proposed rule largely ignores the significant body of evidence outlining the tremendous benefits patients realize when they have access to their health records. Research shows that these benefits are enhanced when patients have convenient access to their records on mobile devices. According to a 2014 poll conducted by the Pew Research Institute, the majority (64 percent) of American adults now own a smartphone of some kind, up from 35 percent in 2011. Among these, 19 percent lack other broadband service at home, and/or have limited options for going online other than their mobile device.[1] Previous polling shows that almost a third (31 percent) of mobile internet users say their device is their primary vehicle for web access (compared to a desktop or laptop computer), either due to preference or because of limited alternative options.[2] These findings indicate that the traditional computer may not meet the needs of all, and signal a growing number of mobile-only users. Along those same lines, they also suggest that patients may be more apt to access their EHRs from their mobile device than through an online portal.

Patient safety is also implicated in this policy change, as robust VDT requirements support care coordination and safe transitions of care, especially with the earlier and more convenient push/transmit of a record by Direct messaging from certified EHR technology to a mobile application. With a mobile application like iBlueButton, a patient can be discharged from a hospital or leave any outpatient encounter with his/her discharge summary, discharge instructions, and/or encounter summary record in his/her hands so that it can be shared with the next provider. This ensures safe transitions of care, especially when the patient is discharged to a post-acute care setting that is not subject to meaningful use requirements.

Second, we strongly believe that safe and cost effective care *requires* the transmission of records from providers to patients given the current lack of provider-to-provider exchange. Mobile technologies like Humetrix's iBlueButton are a near-term solution to the challenges associated with traditional patient portals, as they allow patients to immediately receive, view, and aggregate their EHR summaries pushed to their app on their mobile devices using DIRECT (meeting the meaningful use "VDT" requirements) at the point of care. Data aggregation, segmentation and partitioning – as outlined in the proposed rule – can take place immediately on the patient's mobile device without requiring multiple steps of logging into multiple portals, and transmitting EHR records to PHR applications. Patients may also be able to log in and input their own health care information, including data coming from self-monitoring devices, that can be automatically aggregated on their phones (e.g. with the use of HealthKit in iOS 8 mobile devices), potentially contributing new, patient-generated and novel information to their record that could be used by providers to deliver personalized, more precise care.

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[1] Pew Research Center, April, 2015, "The Smartphone Difference" Available at: http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/

[2] Pew Research Center, June, 2012, "Cell Internet Use 2012" Available at: http://pewinternet.org/Reports/2012/Cell-Internet-Use-2012.aspx

Third, CMS' proposal is not consistent with quantitative program data and instead appears to rely on limited anecdotes and other qualitative evidence. CMS notes in the Preamble that many providers have attested that they have in fact satisfied the 5 percent requirement.[3] The challenge instead appears to be the alleged difficulty associated with doing so.

We believe that some of this difficulty could be alleviated by further engagement from and action by CMS to educate providers about what they are actually required to do and to educate patients about mobile tools like iBlueButton that are available to help them use and engage with their data.

Despite the clear evidence of successful patient engagement through mobile devices, many providers and EHR vendors have limited patient electronic access to their EHRs to the sole use of patient portals to meet the existing Stage 2 view/download/transmit ("VDT") requirement. We believe that this is because there is a widespread lack of information and confusion about the types of technology that can be used to meet meaningful use requirements, and many providers are under the mistaken impression that patient portals are required to meet Stage 2 requirements. CMS staff have confirmed in writing to Humetrix that portals are not required and that there is a wide-range of certified technology that could be used today to satisfy patient engagement requirements, including Direct-enabled mobile applications such as the Humetrix iBlueButton mobile app. However, this information has not been clearly communicated to providers.

As an alternative to reducing the Stage 2 VDT requirement as proposed, CMS and ONC should publicly clarify the patient engagement requirements and take steps to further educate providers regarding the various types of technologies that can be used to meet existing requirements. Specifically, we believe that CMS should clarify the following points:

1. Patient portals are not the only means through which VDT may be achieved.
2. Direct-enabled third-party patient facing applications can be used to support VDT. The use of certified EHR systems to transmit records to such applications fulfills meaningful use requirements for VDT, even if a VDT enabled portal is not provided to patients.
3. Direct is an ONC-certified API that is embedded in all 2014 certified EHR systems.

Finally, we do not believe that the proposed modification is necessary because there are already remedies available for at least some of the providers who may have experienced difficulty meeting requirements. For example, there is an existing exclusion for eligible professionals and eligible hospitals who cannot meet requirements due to a lack of sufficient broadband in their area. Providers who do not qualify for an exclusion may still be able to claim a hardship exemption. These remedies offer sufficient relief to providers who are technically incapable of meeting the requirement, rather than just unwilling to spend the time and resources needed to engage their patients and their caregivers in new ways.

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CMS' VDT proposal is inconsistent with other CMS and Administration initiatives to more fully engage patients in their health care, including the federal Blue Button initiative. As health care becomes

[3] In the Preamble to the proposed rule, CMS notes that median performance is 32 percent of patients for doctors and 11 percent of patients for hospitals on Stage 2's measure of actual online access.

increasingly modernized and dependent upon use of advanced information technology and data, patients expect – and we anticipate, will increasingly demand – to electronically access their health care data, use technology to communicate these data with their providers, and employ mobile tools and applications to view and share their data with their caregivers and providers. The proposed modification would greatly reduce, if not eliminate, the incentives for providers to serve as partners in making this a reality for patients.

In conclusion, we believe that CMS should focus not on reducing or eliminating requirements but instead on giving providers tools that can be used to make it easier to educate and engage patients and expanding CMS' own communications efforts to ensure patients are aware of the tools that are available to help them use and understand their health data, including mobile tools. Rather than eliminating the financial incentive for providers to engage their patients, we recommend proactively arming providers with information that can be used to help them engage and educate their patients while also satisfying meaningful use requirements.

We urge CMS not to finalize the patient engagement proposals contained in the proposed rule. Doing so would be a significant setback for Medicare and Medicaid patients across the country. Please do not hesitate to contact me if I can be a resource to you on this or any other issue.

Very truly yours,

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