May 29th, 2015

To:
Centers for Medicare & Medicaid Services, Department of Health and Human Services,
Attention: CMS-3310-P, P.O. Box 8013, Baltimore, MD 21244-8013

File code: CMS-3310-P
RIN: 0938-AS26

Comment on Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3

Dear Secretary Burwell and all,

I hope your day is treating you splendidly.

As a current brain tumor patient, I wanted to provide a first-hand experience of patient data access, interaction, and sharing from a top hospital system in Boston. I hope these comments can add context to the direction of the Proposed Stage 3 regulations. As a summary, I want to discuss how critical an open API under patient control is for the future of networked healthcare and precision medicine. I fully support the Alternative B or Alternative C for the Proposed Measure 1 under Objective 5 for ensuring an ONC-certified API under patient control for 3rd party export. Further details are below on the rationale and lessons I've learned from exploring the current state of patient data access. In short, from a patient perspective, we need low barriers removed, easy access to export to 3rd parties, simplicity, standardization, and tangible benefits. As well, clarification of legal grey zones surrounding the designated record set, open posting/sharing for research, and access to raw data formats for patient data would be helpful.

My name is Steven Keating and I am a PhD student at Massachusetts Institute of Technology (MIT) studying Mechanical Engineering and Synthetic Biology at the MIT Media Lab. From a voluntary research scan in 2007, an abnormality was detected in my brain, and the information led to a further diagnosis in 2014 when I noticed smell-inducing seizures. I had a large astrocytoma tumor removed and have been interested in understanding my condition - for treatment, for decisions, for support, for research, and for curiosity. I am being treated at top hospitals in Boston and have had excellent medical treatment. My doctoral teams are amazing, have been supportive in the most important ways, and I am doing well. I highly recommend these great medical centers and have been extremely grateful for their care. Though from a data perspective, it has been quite interesting to learn about the systems and the issues I ran into (and currently am still dealing with).
Simply put: I was flabbergasted that the patient, of all people, has the least access to their own information.

There are low barriers that add up quickly, such as restrictions to accessing/exporting data, difficulties in finding useful data benefits, a lack of tools to interpret, and a lack of transluency everywhere. As well, it took significant work to share data with family, friends, other doctors, patient communities, and medical researchers. I found that the patient, who has to make the final treatment decisions, has the least access to their own information and tools to share it.

While there is a legal access route for data in the “designated record set” (DRS), it is unclear in what is included and the barriers to wrangling the data are steep. For instance, in the DRS, I can access hundreds of pages of reports (some scanned) and MRI/CT imaging on tens of CDs. For most people, this is close to useless. It puts the burden on the patient. It requires significant time to read through complex medical terminology, see trends in the data, and figure out how to interact with difficult imaging data sets on CDs. To acquire a digital copy, many have to transcribe records manually and if we want to upload to patient community sites for tools (like PatientsLikeMe for example, https://www.patientslikeme.com/), the burden is on the patient. While that might seem like a low barrier, it is a huge barrier to patients in a stressful hospital time.

Doctors can log in, even from home, and view everything in a nice format with interactive tools. Their systems can view MRIs, compare test results over time, and reference aggregate data. However, a patient has to wait, often for many days, to access the full data. For exporting to 3rd parties, patients are then required to transcribe it, to upload it, deal with tens of CDs, and buy a suitable computer program to interact with it. Also, it is not legally clear if that data (DRS data) can be posted openly online by the patients (copyright issues, fair use, interpretations of data, imaging, etc).

For research data, it becomes more legally grey. For example, I am currently awaiting a response from the legal team at my hospital to clarify if I can access my own whole genome sequence. It has already been sequenced, as I volunteered my brain tumor tissue for a research study, conducted by my hospital and my university. So ironically, my pathologist and researchers at my university can see my genome, but I am not allowed to. They can see if I have future potential conditions, but I am not allowed to. While there are issues around genetic data, interpretation and data-overload that are important to note, I have a background understanding and my PhD minor is in Synthetic Biology. All I am asking for is the raw data, not an interpretation. The grey zone of policies between the two establishments is currently being discussed and I look forward to their decision hopefully soon.

So why is there not a “share” button at the hospital? Allow patients, under their own choice, to access their own information, and share it with family/friends and 3rd party applications if desired. Give patients a key to their own data, and a method to control exports to 3rd party applications, under their own privacy comfort level. If patients want full privacy, that is their right and no need for them to access or share anything. Though if patients have control over their data and want to use it, let capitalism function and 3rd party developers will make the equivalents of Google Maps, Dropbox, and Facebook for health.

To do this, we need an open API that patients can control. I’m focusing on this one specific point, to keep it simple, as this is a critical first step.

We cannot keep an API optional if they offer a provider patient portal as in the current proposal. Why? Talk to folks who have used it, the patients. Each hospital will have a unique portal with different standards, exporting/compatibility issues, and problems with providing tangible benefits. For instance, if you want to look at my situation, I’ve posted parts of my own patient data on my
website (www.stevenkeating.info). Try downloading my e-summary, from the provider portal (shortcut link: http://stevenkeating.info/Steven_Keating_Health_Summary_Report_BWH.pdf). As a patient, this is supposed to contain a relevant summary of my treatment and status in a few pages. However, it does not contain any of the key details and is not useful to me. The only mention of my main medical issue is a few words - “malignant neoplasm of brain” – and some prescription details with basic blood work results. There is no mention of my surgery, radiation treatment, genetic details, what type of tumor, plan of care moving forward, or past history. If you look at my full legal health record, these details are there, but buried deep in the details of hundreds of pages. With an API, this data could be wrangled by 3rd party developers if the patient chooses. As well, if the patient chooses, it could even be shared with other doctors for 2nd options, with family/friends for support, other patients for improving care, and medical researchers for furthering science. And it could allow for novel patient incentives, which may seem trivial, but are important. Examples like smartphone applications to view MRIs, 3D printing applications to produce physical visualizations of broken bones, tools to share data with medical studies, and applications to understand how well the recovery is going. And even silly ideas, like a PDF textbook using the patient’s own microscopy/MRI images or a Facebook video showing a medical x-ray ‘selfie’. The APIs could be for input as well, allowing patients to add data and share treatment information. The ideas are limitless and full of potential to improve quality, access, and cost of care. We need to enable patient access through an API with standardized export under patient control.

Look at precedents - projects like Open Notes (http://www.myopennotes.org/) and Apple’s ResearchKit. With Open Notes, 3 hospitals participated in sharing doctor’s notes with patients, and the results were powerful. After one year, ~99% of patients wanted continued access, 4 out of 5 patients said it would impact their future choice of provider, ~70% reported taking better care of themselves, and ~60% wanted to input data to the system. All participating doctors were given the chance to turn off Open Notes, and none did. And while data has liabilities, even just for the patients to view it themselves, we need to allow patients the right to their data, and to 3rd party exports to generate tools for simplicity, understanding, interaction, and research.

Some argue about too much data or that people would never want to share their health data. Looking at Apple’s ResearchKit results provide different evidence. Upon launching their initial 5 ResearchKit applications, within the first week over 50,000 people were using the applications and over 70% opted to share their de-identified data with researchers. If the NIH is interested in a 1 million cohort now, imagine where the future could lead. If patients were in control of their own data and could see tangible benefits through interaction and sharing, is a 1 billion cohort possible?

If certain providers cannot create an API option, due to cost, complexity, or other concerns, perhaps an incentives route could be developed. We need some of the bigger hospitals to try an open API under patient control, and most already have patient portals (with serious exportability issues). Therefore we need to incentivize (or require) some of these providers to have an API in addition to their portals. As well, to reduce the burden on providers, I do not think requiring a certain amount of patients to use the system is needed. It is not the providers’ fault if their patients are not interested in accessing their information. Rather, if an open API is in place, it is up to 3rd party developers to offer their services to attract patients and show tangible benefits. The possibilities are incredible for the future, with patients able to control their own data.

Thank you for your time and please let me know I can help in the future. One of the most pressing issues is to ensure patients have a voice at these discussions. I read through the previous comments and was shocked at how few patients had submitted comments compared to corporations. Though it makes sense, it is a complex proposal document, difficult to interpret, and not advertised publically to patients in many ways. As well, it is the large corporations and
providers that will respond as they have legal teams and financial interests. So what would patients say in a simple form? I would bet on simplicity, access, easy tools, tangible benefits, and removing low barriers. And while this is not evidence of any reliable form, I can vouch that many patients are frustrated with this issue. There has been some press on my own medical situation (http://www.nytimes.com/2015/04/01/technology/the-healing-power-of-your-own-medical-data.html) and I have been doing talks at MIT (https://www.youtube.com/watch?v=94FCaVRxkJA). Since some of the articles and talks were published, I have received thousands of emails from people frustrated with the same issues, with notes of support for more access, and for ensuring patients can be partners in their own health.

I hope by focusing on the most important issue in this proposal, rather than the many others I have thoughts on as well, the viewpoint can be heard more clearly. Again, I fully support the Alternative B or Alternative C for the Proposed Measure 1 under Objective 5 for ensuring an ONC-certified API under patient control for 3rd party export. It is a first step. And if not possible for all providers, an incentives route for API implementation would ensure we have a few hospitals that explore this path. Once patients can see the potential power and tangible benefits from a few innovative hospitals and 3rd party developers, they will start requesting it from other providers. An open, patient-controlled API is crucial to allow growth and change to be driven by the most important people in the healthcare system, the patients.

Thank you again for your time and please feel free to contact me if I can help.

Sincerely,

Steven Keating
PhD Candidate, Massachusetts Institute of Technology
20 Highland Ave, Unit #2
Cambridge, MA 02139
Email: stevenk@mit.edu
Phone: 617-386-3501
Website: www.stevenkeating.info