ADD YOUR VOICE: MEANINGFUL USE REGULATIONS MUSTN'T LEAVE PATIENT ENGAGEMENT IN THE DUST

Guest Post by David Harlow | May 20, 2015

There are two sets of Meaningful Use draft regulations out for comment at present: (1) Proposed revisions to Meaningful Use Stage 2 ("MU2"), with comments due June 15 and (2) Proposed Meaningful Use Stage 3 ("MU3") regulations, to be effective in 2017 at the earliest. The Society for Participatory Medicine has filed comments on both of these. (See the discussion, and links to the comment letters, below. See further discussion of MU2 and #NoMUwithoutMe last month on e-patients.net.) We urge everyone reading this post who cares about empowering patients through better engagement with the health care system to file comments as well. In order to expedite this process, you can copy and edit the Society's comments found here: MU2 and MU3, and then just paste them into the appropriate comment web pages. Each document includes at the top instructions for submitting comments online directly to the federales.

Numbers matter — but the only numbers that matter in cases like these are the numbers of comments filed through official channels. Tell your friends and neighbors. And do it now. The deadline for comments on MU3 is May 29, 2015, 11:59 pm ET. The MU2 comments are due a couple weeks later, but please file them at the same time as your MU3 comments.

The MU2 regs have captured the attention of many because they propose a revision to the patient engagement measure, reducing the threshold for compliance from requiring that 5% of patients seen by a provider in the attestation period view, download or transmit ("VDT") his or her health data, to requiring that ONE PATIENT VDT.

The Society for Participatory Medicine filed a strongly-worded comment letter today opposing the proposed change to MU2.

The MU3 regs are even more important, because they are going to form the basis of the "permanent" MU regulations going forward. Even after the MU incentive dollars run out, CMS will continue to require compliance with these requirements as a threshold matter for other

program purposes. Of course, they may be tweaked in the future; but the initial form of the permanent regs is very important.

The MU3 regs broaden the notion of patient engagement into a measure with multiple options. To get credit for this measure, a provider must attest as to all three, but must hit the thresholds for at least two:

1.25% of patients VDT health information

a. via portal; or

b. via APIs

2.Secure message sent to 35% of patients

3.Incorporating data obtained in a non-clinical setting and transmitted to the EHR for 15% of patients.

There are exceptions for rural providers (due to lack of broadband) and the definition of “non-clinical setting” includes all clinicians and health care facilities that are not participating in Meaningful Use, thus ensuring that no provider will bother to work on integrating patient-generated health data (“PGHD”), which is a key portion of what this provision was supposed to be about.

The Society for Participatory Medicine filed another comment letter today on MU3, supporting the future strengthening of patient engagement, as follows:

1.Supporting the increased threshold for VDT/API access. (I am concerned that since the “one patient” proposal for MU2 was published after the MU3 proposal, that the physician lobby will propose that the 25% threshold be rolled back to “one patient” as well.)

2.Opposing the rural provider carveout since patient access via APIs on smartphones is not broadband-dependent

3.Supporting the secure messaging threshold

4.Supporting the requirement that non-clinical data be transmitted for at least 15% of patients, and broadening the definition so that providers would have to both (a) incorporate PGHD into the EHRs of 15% of patients and (b) incorporate data sent by other providers not participating in Meaningful Use into the EHRs of 15% of patients.

(There is a set of certification standards for EHRs that was released the same day as the MU3 reg, but in keeping with the S4PM policy of remaining technology-agnostic, we have not delved into them. The proposed comments are purely focused on the patient engagement piece of Meaningful Use.)

Please add your voice to the public conversation about the importance of patient engagement through EHR-based tools — and please do so in the only way that the federales can take to heart officially: file written comments on MU2 and MU3 before May 29.

How to Submit Comments The public can submit comments in several ways, including via electronic submission or mail:

1. Electronically
   - You may submit electronic comments to **http://www.regulations.gov**.
2. By regular mail
3. By express or overnight mail
4. By hand or courier

For More Information For more information on the Stage 3 and 2015 Edition certification criteria proposed rules, review the **press release** and **fact sheet**

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CHANGING THE WORLD OF MEDICINE, ONE INNOVATION AT A TIME

Thomas Edison once said: "There's a Way to do it Better, Find it" The convergence of digital imaging, wireless biosensors, genome sequencing and other digital innovations makes it possible to use portable devices to monitor patient's vital signs, test for infections from antibiotic resistant bacteria and, virtually digitize the human body to provide information in granular detail, in ways that people never dreamed would be possible.

This information can be integrated with traditional medical data, and constantly updated so that each heartbeat, moment-to-moment blood

pressure reading, the rate and depth of breathing, body temperature, and oxygen concentration in the blood, glucose, brain waves, activity, and mood can be continuously monitored. Additionally, every part of the body can be imaged and a three-dimensional reconstruction can be graphically depicted.

From wearable E-skin that can measure heart rate and blood pressure, to paper diagnostic machines the size of a credit card that can give instant readings on blood and saliva samples, labs throughout the world are producing remarkable new technologies. And this is only the tip of the iceberg.

The following are some examples of where technology and innovation are going to take us in the very near future.

Remote Patient Monitoring (RPM) Surveillance

Incorporating RPM in chronic disease management is significantly improving the quality of life for many individuals, helping them maintain independence, preventing complications that naturally emerge from their multiple chronic conditions. All of this reduces emergency room visits, reduces hospital stays and lowers the cost of care.

For patients with dementia who are at risk for falls, RPM technology promotes safety and prevents harm through continuous surveillance. RPM sensors can be affixed to the individual or their assistive mobility devices such as canes and walkers. These sensors monitor the individual's location, gait, linear acceleration and angular velocity, and utilize a mathematical algorithm to predict the likelihood for falls, detect movement changes and alert caregivers.

Surgical Models

Surgeons facing complex surgeries are preparing for such operations by using 3-D printers to replicate parts of the body, enabling them to touch, feel and cut just as they will during actual surgery. The 3-D models are developed using digital data from scans such as MRIs and CTs. At the Brigham and Women's Hospital in Boston, MA such test runs are being used to practice some of the most difficult surgeries of all — the face transplant, and for treating tumors in vital body parts like the head, neck, and spine.

Advances in Understanding the Brain

At the World Medical Innovation Forum on Neurosciences, sponsored by Partners Healthcare, April 27-29, scientists talked about research into brain circuitry and electrical activity, via available technology, MRI, EEG and PET Scan, combined with landmark genetic discoveries. These innovations in technology now enable scientists and physicians to begin to understand the intricacies of autism, depression, schizophrenia, bipolar disorder, as well as diseases such as Parkinson's and dystonia. This work is also unveiling novel approaches to surgery and treatment for epilepsy, traumatic brain injury and stroke. Control of a brain's activity with light, called Optogenetics is also under study. This technology could have far-reaching benefit to help better understand the complex network of neurons that make up the brain and provide us with insight into how we create thoughts, emotions and behaviors. It could also help detect flaws or deformities in the various neurons in the brain that cause devastating mental disease and disorders.

Nanobots Wandering in our Blood Stream

Experimentation in robotics promises a future where tiny robots could function like our own white blood cells and destroy bacteria and other pathogens inside our blood stream. These miniature robots will use their own sensors, and propulsion systems to perform small tasks like delivering chemotherapy 1000 times more powerful than the traditional drugs in use today, with fewer side effects. There are also cellular repair nanobots that will have the potential to destroy bacteria, carry oxygen, create blood clots for wounds and repair cells.

CRISPR Technology

Instead of taking prescription pills to treat their ailments, patients may one day opt for genetic 'surgery' — using an innovative gene-editing technology called CRISPR, (Clustered Regularly Interspaced Short Palindromic Repeats), to snip out harmful mutations and swap in healthy DNA. First unveiled in 2012, CRISPR is a revolution in genetic engineering and already is generating novel strategies for gene therapy and the genetic study of disease. The technique makes it quick and easy to knock out genes in human cells or in animals and

determine their function. This has the potential to speed the identification of new drug targets for disease. Scientists hope CRISPR may one day help rewrite flawed genes in people, opening tremendous new possibilities for treating, even curing, diseases. Researchers are already adapting CRISPR technology to reprogram stem cells to regenerate damaged organs such as the liver and to reprogram immune cells to cure AIDS in HIV-positive patients. The good news is that with CRISPR, we can now turn genes off or on at will, to study normal gene function and understand how genetic defects do their damage at the molecular level. The bad news is that editing genes can cause unethical alterations in the human species that would not be good for anyone.

Liquid biopsy

A new type of blood test is starting to transform cancer treatment, sparing some patients the surgical and needle biopsies long needed to guide their care. The tests, called liquid biopsies, capture cancer cells or DNA that tumors shed into the blood, instead of taking tissue from the tumor itself. When cancerous cells die they release DNA into the bloodstream, typically in very small quantities. A simple blood test could detect these strands of DNA and allow doctors to begin early treatment. The ability to find cancer early could revolutionize treatment of the disease and save lives.Although a lot is still unknown about the value of these tests, they provide the first noninvasive way to repeatedly sample a cancer so doctors can profile its genes, target drugs to mutations, tell quickly whether treatment is working, and adjust as the cancer evolves. Potentially this is a huge advance that could make personalized medicine possible for far more people. These are only a few of the incredible innovations and technologies that will revolutionize the way medicine is practiced and delivered in the future. Although there are always new conditions and healthcare problems, the promise of such vast innovation is that many of the worst conditions that man suffers will be detected and eradicated.