



Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

January 9, 2014

Jacob Reider
Acting National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Reider:

The HIT Policy Committee (HITPC) asked the Consumer Empowerment Workgroup to provide feedback on two Meaningful Use Stage 3 recommendations for Patient Generated Health Data (PGHD) (see Figure 1) and to identify any policy issues that need to be addressed in order to facilitate more widespread use of PGHD.

Figure 1: PGHD Recommendations for Meaningful Use Stage 3

NOTE: These recommendations are as of September 23, 2013 and may have been modified since then.

Stage 2 Final Rule	Stage 3 Recommendations
New (204B)	EP/EH MENU Objective: Patients have the ability to electronically submit patient-generated health (PGH) information. EP/EH MENU Measure: Provide the ability to electronically submit PGH information through structured or semi-structured questionnaires (e.g., screening questionnaires, intake forms, risk assessment, functional status) for more than 10 percent of all unique patients seen by the EP during the EHR reporting period.
New (204D)	Provide patients with an easy way to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record) (Certification Only)

This letter provides recommendations to the National Coordinator, Department of Health and Human Services (HHS) based on the discussions that have taken place within the Consumer Empowerment WG in close consultation with the Consumer Technology Workgroup, of the Health IT Standards Committee.

These recommendations were approved by the HITPC on December 4, 2013.

Background

The Consumer Empowerment WG held a listening session on July 18, 2013 with various stakeholders to hear expert testimony to inform what policies are needed to support the flow and use of PGHD by providers, including acceptance of PGHD and expectations of provider review. Additionally, the listening session aimed to explore how best to support inclusion of PGHD for Stage 3 Meaningful Use to



Health IT Policy Committee

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accelerate opportunities for consumers to share data back with providers.

Another input into these recommendations has been the deliberations and outcomes of a Technical Expert Panel on Patient Generated Health Information convened by National eHealth Collaborative (NeHC) on behalf of the ONC throughout 2013. The TEP's work provides insight on PGHD and its value, patient and provider concerns, examples and case studies, factors impacting PGHD, practical guidance on how to implement PGHD, and suggestions on where additional work is needed to advance PGHD.

The TEP defined PGHD as health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, environmental factors and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., informal caregivers) to help address a health concern. PGHD are distinct from other types of clinical data in two important ways:

- First, patients, not providers, are primarily responsible for capturing or recording these data.
- Second, patients direct the sharing or distribution of these data to health care providers and other stakeholders. In these ways, PGHD complement provider-directed capture and flow of health-related data across the health care system.

Based on the listening session as well as joint meetings of the Consumer Empowerment and Consumer Technology workgroups, along with a draft report from the TEP, we make the following recommendations.

Recommendations

Patient Generated Health Data criteria are appropriate for Stage 3 of Meaningful Use, with some modifications:

1. The Stage 3 Menu objective regarding the collection and use of PGHD should give providers an array of options for incorporating PGHD, specifically: secure messaging and provider-selected devices, in addition to structured and semi-structured questionnaires. We acknowledge that additional work is needed and ongoing by the HITSC to advance the standards to support device data.
2. The Stage 3 certification requirement (204D) that would provide patients with an easy way to offer amendments to their record also represents a form of PGHD. As such, the below recommendations regarding the implementation of PGHD also apply to this requirement.
3. EHR technology should have the functionality to allow providers to receive, review, respond (acknowledge), and record PGHD, including amendments and corrections.
4. For provider organizations that choose the menu item for PGHD in Stage 3, they should be encouraged to and supported in establishing policies and procedures for handling PGHD in advance of or during implementation, including, but not limited to, the content to be received; the mechanisms by which it can be submitted/received; and how it will be received, reviewed, acknowledged, and recorded (including but not limited to provenance).
5. Providers should collaborate with patients in implementation – including crafting of policies and procedures to ensure PGHD collection and use works for both parties, as well as selecting the PGHD type.



Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

6. PGHD should be sourced as patient-generated in the record. In addition, sourcing of data as PGHD should follow the data if they are later shared for other purposes, including Treatment, Payment and Operations.
7. ONC should work through its own channels and with federal partners (CMS and others) to equip providers with clear guidance on how to implement the PGHD menu requirement and the amendments criterion:
 - i) This guidance should reference promising practices gleaned from the TEP, including tips on what PGHD is, why it's useful, the need to establish clear policies and workflows, the providers' obligations under HIPAA with respect to corrections/amendments, and how to design and communicate these policies and procedures with patients and families in their preferred language and at the appropriate literacy level -- including information about their rights under HIPAA regarding amendments and corrections.
 - ii) This information should be disseminated through existing mechanisms such as the ONC and CMS web sites, RECs, and National Learning Consortium.
 - iii) Guidance should build off the work currently being done by the Patient Generated Health Data Technical Expert Panel on defining processes and procedures for PGHD.
8. While new policies for PGHD are not needed for Meaningful Use Stage 3 because HIPAA governs PGHD as it does other data in the record, in the future, ONC and the Office for Civil Rights should undertake work to address data sharing by consumer devices and apps that providers may also use in clinical care. Work is also needed in the medium term to examine policy, workflow and liability issues around *unsolicited* PGHD.
9. The work to provide patients with interoperable Direct email addresses should continue in order to open up more options for efficient and effective collection of PGHD in the future.
10. Additional work is needed in the short to medium term to explore shared care plans, which are an important avenue for PGHD. Issues persist with version control, reconciliation, harmonization, etc.

We appreciate the opportunity to provide these recommendations on Stage 3 of the Meaningful Use Program and look forward to discussing next steps.

Sincerely yours,

/s/

Paul Tang
Vice Chair, HIT Policy Committee