

May 8, 2017

Donald W. Rucker, MD  
National Coordinator for Health Information Technology  
US Department of Health and Human Services  
330 C Street, SW  
Washington, DC 20201

Dear Dr. Rucker:

On behalf of the Healthcare Information and Management Systems Society ([HIMSS](#)) and the Personal Connected Health Alliance ([PCHAlliance](#)), we are pleased to offer the following comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the [Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data \(PGHD\) in Care Delivery and Research through 2024](#) Draft White Paper. We support the work that ONC is undertaking to describe key opportunities and challenges for realizing the potential of PGHD use and offering relevant enabling actions that could further enhance PGHD capture, use, and sharing for improved health care delivery and research in the United States.

HIMSS is a global, cause-based, not-for-profit organization focused on better health through IT. In North America, HIMSS focuses on health IT thought leadership, education, market research, and media services. Founded in 1961, HIMSS North America encompasses more than 68,000 individuals, of which more than two-thirds work in healthcare provider, governmental, and not-for-profit organizations, plus over 640 corporations and 450 not-for-profit partner organizations, that share this cause.

PCHAlliance aims to make health and wellness an effortless part of daily life. The PCHAlliance, a non-profit organization formed by HIMSS, believes that health is personal and extends beyond healthcare. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world.

To support its vision, PCHAlliance convenes the global personal connected health community at the annual [Connected Health Conference](#), the premier international event for the exchange of research, evidence, ideas, innovations and opportunities in personal connected health. The Alliance publishes and promotes adoption of the [Continua Design Guidelines](#). Continua is recognized by the International Telecommunication Union (ITU) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices. PCHAlliance accelerates technical, business, policy and social strategies necessary to advance personal connected health through its flagship Academy for Healthy Longevity to promote lifelong health and wellness.

Overall, HIMSS and PCHAlliance offer our support of the White Paper, but would like to suggest that the final paper emphasize an additional overarching theme that encompasses positioning PGHD for an enhanced clinical purpose to be phased-in in the future. The draft paper does make the point that PGHD has the potential to improve practitioner productivity by augmenting traditional patient questionnaires and review of systems with sophisticated integrated data collection through new personal health devices as well as legacy medical devices. While this idea could help give PGHD a clinical purpose, we offer the following goals around this concept to be considered for inclusion in the final paper:

- Near-term: PGHD summary analytics that would mitigate some potentially error-prone tasks on behalf of clinicians to improve patient safety.
- Medium-term: PGHD integrated into electronic health records (EHRs) and clinical workflows to eliminate more data entry that clinicians perform at the point of care (an enhanced focus on productivity built on achieving patient safety).
- Long-term: PGHD truly transforming clinical care by applying machine learning and Artificial Intelligence (AI) to improve clinical workflows in ways not yet possible today (productivity and clinical outcomes improvement), and leveraging PGHD to transform patient-centered outcomes research and post-market surveillance of drugs and treatments.

HIMSS and PCHAlliance support the idea of using the final paper to position PGHD to have a greater future impact on care delivery and research by first enhancing its clinical purpose and further incorporating it into the clinician workflow.

In addition, we suggest that the final paper cover data brokers, data gateways, data aggregators, and data “disaggregators”. Specifically, we suggest that PGHD cannot succeed without them. For example, just as clinicians have “phone brokers” (e.g. call centers) in the middle of many workflows, they need data brokers to take data from patients and synthesize it in ways to make it more useful. Data gateways allow PGHD to flow between institutions with appropriate security and consent rules; aggregators know how to put data together from multiple sources and find trends/patterns.

HIMSS and PCHAlliance note the final paper should also cover directionality of data provenance. We note that the case needs to be made that no PGHD should be trusted without being delivered through a high integrity network with full provenance meta data that is assured to be tamper-resistant through the supply chain (e.g. from the source to brokers, gateways, aggregators, etc.).

We also suggest that the final paper indicate that SO/IEEE 11073 Personal Health Data (PHD) should be the suggested standard unless something better is available immediately. It is better to have a recognized and utilized standard, such as 11073, rather than no standard, as is currently the case.

Moreover, in creating the final report, HIMSS and PCHAlliance encourage ONC to provide an appendix that includes the following information:

1. An example of a clinical workflow (and associated technical workflow) in the ambulatory environment without electronic PGHD, but perhaps showing the patient orally providing history, recollection of medications, diet, and activity.
2. An example of a clinical workflow (and associated technical workflow) in the ambulatory environment showing how sample PGHD can be provided to validate and complement or augment the patient's oral history, recollection of medications, diet, and activity.

3. Diagrams for these examples, that could be limited to, or associated, with studies performed that include a hypertensive patient or diabetic patient, and associated relevant activities, diet (patient diary), and biometrics (blood pressure and blood glucose).

An additional appendix we suggest creating would be one that lists common, existing PGHD-associated standards to ensure that the community has a resource that would be helpful to the field as it advances. This appendix should also include a level-setting discussion for the entire community focused on an environmental assessment of existing standards for applicability to the capture, use, and sharing of PGHD. HIMSS and PCHAlliance made certain assumptions about applicable standards in our comment letter, but an environmental assessment of the available standards (Continua guidelines, IEEE standards, Integrating the Healthcare Enterprise (IHE) profiles, etc.), would create a baseline for what is available, what gaps there are, and what still needs to be developed or modified for PGHD applicability. A public discussion and assessment of relevant standards is imperative to push the entire PGHD effort forward.

Furthermore, we suggest ONC engage with the [IEEE 11073 Personal Health Device Working Group](#) and contact a sampling of device manufacturers, who have won significant market adoption after complying with the standards. HIMSS and PCHAlliance also suggest ONC engage with the [Continua Design Guidelines](#) as these standards are for the benefit of the consumer as well, and incorporating the patient perspective into these discussions is critical.

HIMSS and PCHAlliance are committed to being a valuable resource for ONC as our healthcare system continues to find uses for PGHD as well as for the benefit of patients. We welcome the opportunity to meet with you and your team to discuss our comments in more depth. Please feel free to contact [Jeff Coughlin](#), HIMSS Senior Director of Federal & State Affairs, at 703.562.8824, or [Eli Fleet](#), HIMSS Director of Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

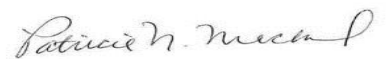
Sincerely,



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