PPFS US Public Comment on the draft Federal Health IT Five-Year Strategic Plan
Public Comments must be filed by May 28th at 11:59.59 PM ET.

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Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW., Floor 7
Washington, DC 20201

Re: Public Comment on Draft Federal Health IT Strategic Plan

Dear Dr. Tripathi,

Patients for Patient Safety US (PFPS US) is a patient and family led network of individual patient safety advocates and strategic partner organizations. We are the United States branch of the international Patients for Patient Safety program supported by the World Health Organization (WHO). In alignment with the values, priorities and strategies set forth in the Centers for Medicare & Medicaid Services (CMS) *National Quality Strategy* and Department of Health and Human Services (DHHS) Secretary Becerra's *National Action Alliance to Advance Patient and Workforce Safety*, as well as the WHO *Global Patient Safety Action Plan*, we seek to advance patient safety and health equity goals, which we see as inextricably related. Accordingly, we advocate for increased transparency, accountability, and patient/family engagement as drivers of change.

Although led by users of care, our network includes a wide range of stakeholders with a wide range of skills and experiences. We are concerned with the interoperability of data, health data use and privacy, and the impact of the draft Federal Health IT Strategic Plan (the "Strategic Plan"). We include patients, family caregivers, healthcare providers, researchers, educators, employers, systems safety experts and stakeholder organization leaders, all dedicated to expediting the systemic change needed to reduce preventable harm, bias, and outcomes disparity. We also are actively engaged in our nation's work to ensure timely and accurate diagnosis of medical conditions, appropriately communicated to everyone on a patient's healthcare team that should know, the patient included.

General Comments: We applaud the ONC for the attention prominently paid in the draft Strategic Plan to the issues that matter most to patients: 1) Reducing preventable harm in healthcare, 2) Identifying and mitigating bias that can lead to unfair discrimination and disparity in treatment outcomes, 3) Safeguarding patient privacy and the right of patients to know and consent to how our personal health information will be used, and 4) Improving the accuracy, timeliness and effective communication of diagnoses. We see clear alignment with other patient-centered initiatives of the federal government, including the Centers for Medicare & Medicaid Services (CMS) *National Quality Strategy* and Secretary Becerra's *National Action Alliance to Advance Patient and Workforce Safety,* among others.

While we appreciate the opportunity to provide Public Comment on the draft Strategic Plan, we urge the ONC to do more, strategically, to engage patients and families with lived experience as users of healthcare and, increasingly, users of health IT in the further development and implementation of

Strategic Plan. The Federal Health IT Mission is to "improve the health and well-being of individuals and communities using technology and health information that is accessible when and where it matters most." The vision for enabling that mission to be achieved includes "a health system that uses information to engage individuals." It is critical that the Federal Health IT Strategic Plan ensure that health IT is deployed in a manner that treats individuals as information subjects, not information objects. The most effective and authentic way to accomplish this mission is to robustly engage patients and families in the implementation of the Strategic Plan and its oversight, in addition to its development.

There is room for improvement. Despite important progress such as the 21st Century Cures Act and its attendant medical record access and information blocking rules, health IT today is too often a one-way conduit where providers give information and instructions to patients, but only accept back information that they want to receive. Patients are eager to report errors we find in our health records as well as experiences and outcomes that can contribute to improved care. Patient-reported experience and outcomes measures need to become routinely incorporated into clinical care. More broadly, we urge ONC to recognize in its Strategic Plan that patients are now proactively able to access reliable, personalized medical information outside the information constraints that the current generation of clinicians takes for granted, and learn from our experiences.

Specific Comments

Goal 1 (Promote Health and Wellness): We support all of the objectives under Goal 1. Specifically, under Objective A, we appreciate that the first strategy is to support individuals in accessing and using their electronic health information (EHI) securely, privately and without special effort. This is paramount. We are also supportive of improving the portability of EHI through APIs and other interoperable health IT - patients should not have to worry about their EHI getting siloed. We have a long way to go to make this a reality so we appreciate seeing this prioritized..

We are also supportive of increasing the privacy and security of EHI, especially around consumer health applications. Consumers/patients need to be provided with accurate and fully transparent information about how their information will be used, and if their data will be sold. Patients have the right to know how their health data, even if de-identified, will be used, especially if it is monetized. We encourage further work in this area, policies and procedures for obtaining informed consent to EHI use lags, and patients currently have no remedies under HIPPA to object to the sharing or sale of their health data.

Under Objective B, we support the plan to build on the collection of evidence needed to improve the use of EHI and promote equitable access to health IT literacy resources. Again, we are pleased to see equity centric to this Strategic Plan and this strategic plan. We are also excited to see that there are plans to advance the use of evidence-based, validated clinical therapeutics and diagnostics so that individuals can prevent and manage health conditions using digital tools. We are happy to see attention to equity in the application of digital tools to improve individual-level health management as well as population health. Lastly, we support the promotion of education, outreach, and transparency about the use of AI. Educating the public is crucial, so that individuals, populations, and communities understand the safety, quality, performance and privacy-related issues around the use of AI in healthcare.

Under Objective C, we support the focus on creating healthier and safer communities. Public health data is a treasure trove that we need to tap more and so we support this focus in this Strategic Plan.

Leveraging all available data - from individual to population level - can enable learning and action. We urge ONC to recognize its role in responsibly leveraging the data for the good of humanity. We support the sharing of EHI between healthcare providers and organizations serving communities but it must be done in a way that limits risk of privacy breaches. Lastly, the use of health iT to distribute health education and disease prevention measures to communities is important and we support these strategies.

Goal 2 (Enhance the Delivery and Experience of Care): We support all of the objectives under Goal 2 of the Strategic Plan. We applaud ONC for prioritizing support for clinician delivery of safe and equitable care as Objective A under Goal 2, as patients have the right to expect safe care and delivery of care that is non-discriminatory. We suggest noting under Objective A that increasing transparency and understanding of health data that goes into algorithm-based decision support tools is very important to ensuring the confidence of patients, the general public, and health policymakers, not just providers. Patients have a right to know how their health data will be used by the developers of algorithm-based support tools, and how the use of these tools are monitored once they are implemented. With respect to advancing standardization of social determinants of health (SDOH) data, we also suggest that patient representatives be given a co-creative role in developing these standards, as insights from our lived experience of unintended bias may be a valuable input to accuracy.

With respect to Objective B, which is focused on expanded access to safe care and the elimination of disparities in outcomes and experiences, we reinforce the request that ONC engage patient representatives in its work to advance the collection of SDOH data, both at the algorithm development level and in post-development and post-implementation monitoring and oversight. Engaging patients or their family care managers offers the opportunity for lived experience insights on the unintended perpetuation of bias and discrimination in the collection and use of SDOH data.

While PFPS US strongly supports Objective C, which focuses on improving competition through information sharing on the availability of healthcare services and their cost, we urge ONC to be cognizant of the potential impact of sharing health information could have on services being withdrawn in specific geographic markets or prices being increased where there is no competition to provide services.

Regarding Objective D, PFPS US strongly supports the use of electronic quality measures. Not only do they reduce the administrative burden for staff, they serve to improve the completeness and accuracy of reporting by harvesting data that staff are reluctant to report, forget to report, or report incompletely. We urge ONC to pay close attention to ensuring safeguards on privacy and security, not just in the practices of providers and health plans, but also in the practices of third parties, e.g. businesses developing AI products. Even personal health information de-identified by providers and health plans can be triangulated by big data analytics to re-identify patients with specific health conditions or SDOH. PFPS US is highly concerned that these safeguards may not be in place now.

PFPS US also strongly supports the importance of Objective E: generating confidence in the use of health IT by the healthcare workforce. With that said, we respectfully suggest that this objective be expanded in scope to include generating public trust and confidence as well as provider staff in the use of health IT to improve safety, quality, and efficacy.

Goal 3 (Accelerate Research and Innovation): PFPS US supports all objectives under Goal 3, with the essential caveat that diverse patients, family members, and patient advocates are included as key stakeholders in all discussions regarding the use of healthcare data to accelerate research and innovation. Understanding what matters to patients is particularly important when setting research priorities given the inevitable finite budgets that will be allocated to research and innovation in the health IT space. Similarly, it is important that patients are not limited in accessing their own data that is being used for research and innovation. If their data is available to researchers and other health IT users, it should also be available to patients to support their own healthcare decision-making.

With this in mind, the proposal to accelerate research and innovation through the collaborative efforts of researchers, technology developers, and other health IT users is likely to offer several benefits. First, the advanced use of healthcare data is likely to better inform improvements for specific patient populations. This will enable more targeted interventions for those who need it, while minimizing wasted interventions for those who may not benefit. This is a particularly important approach that will sit at the intersection of two major healthcare challenges: rising healthcare costs and increasing healthcare disparities. However, it is imperative to understand where healthcare data that may be used to inform individual and population health improvement is coming from, as not all data sources are equal. For example, hospital-reported metrics may be biased based on incentive-driven reporting practices. How the data is generated should be reviewed when planning for its use.

Finally, there is a concern that patient data will be used to drive improvements in healthcare economic efficiency, with little benefit to the patients themselves. For example, the cost of care for patients should decrease if patient data is used to train an AI tool that replaces the need for a certain role that is important to patients in their care journey. Again, ensuring patients and family members are involved as key stakeholders in decision-making about research priorities and how healthcare data will be used is essential to mitigate these concerns.

Finally, PFPS supports the Light Collective's AI Rights for Patient Safety statement, particularly with regards to data sharing.

Goal 4 (Connect the Health System with Health Data: PFPS US supports all objectives under Goal 4..

Regarding Object A, which addresses the continued advancement of health IT capabilities, PFPS US urges ONC to recognize the value of patient-reported experiences and outcomes to actually improving the safety and quality of healthcare as well as identifying bias. PFPS US is currently funded to identify and help validate questions patients can be asked about their experiences of safety, discrimination, transparency and diagnosis that they would answer, but are avoided in existing patient experience surveys (See https://www.pfps.us/project-pivot). Research now shows what have long contended: We will report information that providers are reluctant to when we have user-friendly, IT-enabled ways to do so. (See, https://shmpublications.onlinelibrary.wiley.com/doi/10.1002/jhm.2777, https://www.tdcfoundation.com/grants-awarded-and-case-studies/engaging-patients-families-and-caregivers-in-safety-reporting/)

With respect to Objective B, which focuses on advancing shared understandings among health IT users, we reiterate the request that ONC include patients in the development of governance policy and standards, including the Trusted Exchange Framework and Common Agreement (TEFCA), as well as its implementation and oversight.

PFPS US strongly supports the strategies outlined in Objective C to improve access to health IT by underserved communities and populations.

Objective D is focused on the protection of electronic health information. As stated above, PFPS US urges ONC to pay close attention and do what is in its power to develop and enforce policies and standards that ensure that patients know how their EHI is being used – outside the care setting, as well as in their own treatment plans – especially if it is being monetized by AI developers or other 3rd parties. Patients have the right to know and the right to opt out of arrangements where their data is being monetized. Patients and patient representatives should be involved in shaping oversight. PFPS US encourages ONC to think imaginatively about the leakage of private health information to data brokers and other third parties.

As stated above in reference to Goal 4, Objective A, PFPS US strongly believes that patient-reported experiences and outcomes will provide important data not currently reported, therefore an important contributor to public health, the focus of Objective E. Diagnostic safety is a particularly challenging patient safety and public health problem, in that missed or delayed diagnoses fall between the cracks across the continuum of care settings, and therefore are vastly under-reported in current incident reporting systems. Providing portals for patients and their family caregivers to report missed, delayed, uncommunicated, or miscommunicated diagnoses is a ripe public health improvement opportunity.

Concluding thoughts: As one Patients for Patient Safety US Champion, Michael Millenson, recently wrote in a blog post: "Imagine if after being diagnosed with cancer you could access algorithms that would help you find the best treatment, the hospital with the best outcomes and even your likely six-month to five-year chances of survival. All that is possible today…Artificial intelligence (AI) is quietly giving patients the ability to find, create, and act upon an unprecedented breadth and depth of authoritative information." But will our physicians respect the data we share? What data will they share with us?

Today, there are systems that allow physicians to query real-world evidence databases with an individual patient's clinical information and be advised about the probable best course of treatment. Those databases are developed and maintained by for-profit entities, providers, and provider organizations using them have a financial interest in patients relying on their providers for treatment, and patients are regularly having their information sold to third parties without their knowledge or consent. Only the power of the federal government will ensure that patient rights are protected as this field continues to rapidly grow. The ONC Strategic Plan has the potential power to shape the field, by optimizing opportunities for advancing IT use while establishing parameters that prevent misuse.

Thank you for this opportunity to share our views.

Patients for Patient Safety US