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The Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
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Dear Dr. DeSalvo:

On behalf of Health IT Now's XX members, thank you for the opportunity to provide comments on the *Federal Health IT Strategic Plan*.

Overall, we are pleased to see that the interoperability of health information systems is a cornerstone of the strategic plan. We are concerned the Office of the National Coordinator for Health Information Technology (ONC) is not achieving the goals set out by Congress, namely increased efficiency, improved health outcomes and better access to electronic information, largely because the program has failed to facilitate interoperation across systems and providers. We look forward to continuing to work with the ONC to ensure interoperability through ONC's work, as well as through the *Nationwide Interoperability Roadmap*.

Generally, we are concerned that the Administration has spent too much time and money encouraging simple adoption and not enough time asking adoption of what? What we should be encouraging are the tools that will empower providers to be successful in delivering highly effective and efficient health care. From our perspective, ONC has focused too much on getting people to adopt and not enough on ensuring tools work for providers.

Specific Comments

Information blocking. While the strategic plan addresses interoperability, we believe that the ONC should specifically address one of the biggest barriers to interoperability – information blocking. The Department of Health and Human Services Office of the Inspector General identified "costs to establish the capability to share data" as a key factor impeding the interoperability of electronic health records.[1] While the Center for Medicare and Medicaid Services (CMS) notes this is a major problem in the Stage 2 Final Rule[2], it is only monitoring the

[1] U.S. Department of Health and Human Services Office of the Inspector General (2014). *Fiscal Year 2014 Top Management and Performance Challenges Identified by the Office of Inspector General*. Retrieved from https://oig.hhs.gov/reports-and-publications/top-challenges/2014/.
[2] Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2. 42 CFR Parts 412, 413, and 495 (2012).

situation and not taking action to address this problem until 2016 at the earliest. Meanwhile, taxpayers are subsidizing business practices in an information sharing program that blocks information. We encourage ONC to coordinate with the Federal Trade Commission (FTC) to address disincentives for information sharing.

Standards development. Throughout the strategic plan, there are many references to government agencies developing health IT standards. HITN believes that industry and the private market should be the major driving forces behind developing standards, and the government should work to adopt these standards. We believe that the federal government should establish a single national consensus-based approach to create a technology architecture and for identifying, and routinely reviewing and updating a broad and flexible set of standards for certification of health management software that can be applied to a diverse range of processes, products, and settings including: current good manufacturing processes; quality management procedures; best practices for development, implementation, customization, operation, and maintenance of health IT; and NIST defined test bed and process for regression, performance, and integration testing including reference model.

ICD-10. HITN supports the strategic plan's objective to protect and promote public health and healthy, resilient communities. We also believe that public health entities need interoperable health information to detect, track, and manage disease outbreaks. In order for this to be possible, ICD-10 must be implemented on the current schedule. We encourage ONC to work with CMS and Congress to ensure there are no additional delays of ICD-10.

Increasing the adoption and effective use of health IT products, systems, and services. HITN agrees that health IT adoption remains low among some practitioners, including behavioral health professionals. We believe that in order to remedy this issue, Meaningful Use incentives must be expanded to the behavioral and mental health community. Congressional approval of the HITECH Act was a critical step in standards adoption, and incentivizing provider adoption of technologies that will improve the efficiency of both Medicare and Medicaid. The utility and effectiveness of health IT enabled care delivery networks are limited when certain providers are excluded from incentives to adopt and use technology and to coordinate care. This is especially true for those providers who treat those with mental and behavioral health conditions. Many providers that have invested in heath IT to better manage their patients with life-threatening mental illnesses are unable deliver the highest quality of care possible because other providers in a patient's care network may still rely on paper based records. We urge ONC to work with Congress and CMS to expand Meaningful Use incentives to behavioral and mental health providers.

We are also similarly concerned about the low utilization of telehealth and mobile health technologies. HITN believes this is largely due to the significant legislative and regulatory barriers to the use of telehealth. ONC should work with CMS and Congress to make significant changes to the current restrictions on the reimbursement of telehealth services through Medicare. We also urge the federal government to come together to address the important issue of interstate medical licensure. The current system of state-based licensure is not sufficient to support a technology-enabled health care system, and we believe every patient should receive the best care, regardless of location. Efforts at the state level to remedy this situation have not made

meaningful changes and we believe the federal government must act – at least on federal programs such as Medicare. As the report states, greater use of these technologies has the potential to significantly impact the quality and cost of care. However, HITN believes these barriers must be addressed before usage is widespread.

Frameworks for health IT safety and innovation. HITN agrees with the statement that health IT products can also lead to medication errors and other adverse outcomes. We also support the 3-Year Outcome of refining and implementing frameworks for health IT safety and innovation. Within the broad community of healthcare stakeholders there is near universal agreement that regulatory certainty is essential for continued innovation. We are concerned that there is significant confusion in the market about what technologies may be regulated, by which agencies, and to what standards. This uncertainty creates barriers to the development of promising technologies that can help clinicians access more evidence-based medicine, provide patient populations with specific needs more individualized care, and generate better patient-caregiver-provider engagement. The potential cost and delay created by current regulatory uncertainty may further deter software and system developers from creating products that have the ability to greatly benefit patients. HITN believes that the regulatory framework is broken at the written law level, and we've been active with Congressional leaders on their efforts to reform the structure. When Congress passes this legislation, we support ONC and other agencies implementing this framework and look forward to continuing to be engaged in this important process.

Precision medicine. HITN strongly supports promoting data collection, clinical decision support, and analytic capabilities to allow for precision medicine. As smart phones, tablets, "big data" and constant internet connectivity increasingly become the ever-present technologies affecting our daily lives, it's time to fully utilize these advancements in America's health system. Since the enactment of the HITECH Act in 2009, taxpayers and the medical industry have collectively invested more than $100 billion in an information technology infrastructure to try and meet America's 21st century health needs. These investments hold vast potential for revolutionizing medical science, population health and cost management, but the potential has not yet been realized. Truly realizing this promise requires progress on a wide range of market, regulatory and legislative obstacles, many of which are relics of a "pre-data" era. Nowhere are the potential opportunity costs greater than in genomic medicine—a type of "precision medicine" that involves the mapping and sequencing of genes to discover and create individualized treatments for genetically driven diseases like cancer and diabetes. The emergence of genomic medicine has the U.S. on the threshold of a true golden age of cancer treatment. At its core, cancer is a genetic scourge, the result of millions of errors in gene replication. This makes cancer treatment highly individualistic and dependent on each patient's genetic makeup and ever-changing environmental factors. Gene sequencing, a relatively new technology, involves the creation of a personal database comprising about 3.2 gigabytes for every individual. Modern data analytics can sift genetic information for enormous populations to yield valuable insights capable of pinpointing, for example, which treatments may offer the highest probability of success for an individual patient. This saves time, eliminates errors and reduces unnecessary suffering from side effects of trial and error treatment – not to mention it can also offer significant cost reductions in the process. We propose the following policy changes to fully realize the potential of precision medicine:

First, we need to invest in a 21st Century Data Infrastructure. Realizing the potential of genomics and individualized medical treatments will require large investments in data infrastructure coupled with updated 20th century privacy laws.

In terms of privacy, it is abundantly clear that current medical privacy laws are not in line with most Americans' priorities. There is a massive disconnect between HIPAA's regulatory framework and what patients actually want. For example, the current default setting is to require a separate and new patient authorization each time researchers seek to use de-identified health information to find cures. HITN believes patients should be given the choice to share their information for research.

Second, systemic efforts to digitize patient records and extract value from data suffer from a lack of interoperability and, in many cases, a lack of access to the raw genomic data collected in various research settings around the U.S. Some of the best records systems are proprietary with limited accessibility across platforms. We must foster the sharing of clinical, claims, real world and other information and data across systems and providers as electronic health records and other technologies become both more ubiquitous and more confounding.

Third, data with detailed information on patients' conditions could better match patients to promising clinical trials, thereby speeding their results and conclusions. This would lead to the more rapid approval of new treatments for cancer and other debilitating diseases.

Medication adherence. HITN supports improving adherence to evidence-based medicine by increasing implementation of supportive health IT technologies and applications. However, we believe there are steps that can be taken now to improve health outcomes through medication adherence, and the timeline should be shorter than 6 years. The following are our recommendations for health IT policy changes needed to increase medication adherence:

HITN believes the main priority to increase medication adherence should be interoperability. Many elements of current health IT policy are already focused on medication-related tasks, both directly and indirectly. However, bidirectional exchange and interoperability, especially in care coordination models, remain under utilized. Stage 2 Meaningful Use standards are mostly designed to improve the overall safety and therapeutic effectiveness of each patient's medication regimen (i.e. drug-drug interaction checks, medication reconciliation). Because successful medication adherence strategies often require a team based approach and enhanced communication between providers and patients and their caregivers, systems must be interoperable to facilitate coordination and to maximally assist successful adherence interventions.

HITN supports efforts to decouple or untether the transport standard from the data content standards in order to promote interoperability. This change will help ensure flexibility in the transport of data based on a provider's needs or workflow, and will help facilitate information exchange. We would urge ONC to go further so that developers may certify a product to use Direct or the alternative standards in the 2014 criteria (Direct+XDR/XDM and SOAP). Patients and their caregivers are given options in how their health information will be sent to a third party

in the View, Download, and Transmit (VDT) criterion. We believe providers should be allowed similar flexibility in exchanging Transitions of
Care (ToC) documents with other providers.

We also support adding a performance score that would require EHR technology to successfully electronically process validly formatted Consolidated CDAs no less than 95 percent of the time. ONC has proposed to reference this performance standard as a capability that must be demonstrated to meet the certification criteria of the 2015 Edition. This means that most EHRs would be able to parse and consume data within a summary of care record. Practically, it means most providers using certified EHR technology would have access to usable information across a patient's care team members related to medications and allergies, problems and care plan. We believe such information is important to promote effective adherence interventions, which is why we support the addition of the performance score.

For adults aged 65 or older, more than half see two or more prescribing physicians. Directory services will thus be central in identifying and sending information to the various providers seen by patients. The 2014 Edition includes a view-download-transmit (VDT) criterion that allows patients and their caregivers to self-direct their health information to a subsequent provider. We support ONC's effort to clarify that certified EHR technology must, at a minimum, support the entry of a "Direct Address." To make this functionality meaningful, we urge ONC to require all MU providers to have a Direct address as a way to facilitate the sharing of information related to medications, problems and care plans.

Enabling prescribers to check a patient's formulary at the point of care is an important step toward improving adherence as it provides an opportunity for additional dialogue between prescriber, pharmacist and patient on the right drug for the right patient. For this to work well, however, ONC should ensure EHRs include functionalities to enable these capabilities, including those providers ineligible for MU incentives. Specifically:

- Medication history is necessary for obtaining an accurate picture of all of the prescription medications a patient is taking;
- Formulary check is necessary to determine coverage levels for certain medications;
- Fill history can be used in combination with medication history to determine if a patient initiates or continues to obtain their prescribed medications; and
- Electronic prior authorization to facilitate coverage.

We appreciate the opportunity to share our thoughts with you about the federal priorities for health information technology and look forward to continuing engagement with the ONC and other relevant federal agencies.

Sincerely,

Joel C. White
Executive Director