



May 31, 2017

The Honorable Tom Price  
U.S. Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Price:

The use of technology in healthcare can lower costs and improve care quality by putting timely and actionable information into the hands of providers. Unfortunately, this promise is largely unrealized, due in part to past micromanagement, reporting burdens, and other hardships placed on providers to ensure their Meaningful Use of technology. Under your leadership, the Department of Health & Human Services (HHS) has a fantastic opportunity to change this reality and incent the uptake and use of health IT that makes providers' lives easier and better patient outcomes through more accessible information.

Health IT Now (HITN) is a diverse coalition of health care providers, patient advocates, consumers, employers, and payers who support the adoption and use of health IT to achieve the following goals:

- **Promote interoperability.** The implementation of the Meaningful Use program resulted in automation and digitization of physician offices and hospitals. We must incent the free flow of information to better deliver and pay for care.
- **Reduce regulatory barriers.** Regulatory processes are often outpaced by advances in medicine, technology, and science. We should transform the regulatory system built for yesterday's care to capitalize on tomorrow's innovations.
- **Improve quality of care and reduce costs.** The healthcare sector has not been able to capitalize on new technology to transform the way care is provided as much as most other industrial sectors. To realize efficiencies and to allow innovation and technology to flourish in healthcare, we should reform outdated federal programs to modernize the way care is delivered and regulated. This will not only improve patient outcomes, it will also lead to reduced health costs.

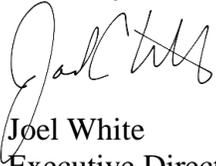
As you implement the *Medicare Access and CHIP Reauthorization Act (MACRA)*, and the *21<sup>st</sup> Century Cures Act* we encourage you to keep these goals in mind and write to provide the following recommendations regarding these statutes.

1. Implement interoperability requirements in a way that maximizes data sharing and private sector standards;
2. Prevent information blocking as counter to patient safety and interoperability;

3. Refocus ONC's role as a coordinator and facilitator of information technology, rather than a heavy-handed regulator;
4. Rescind the ONC Enhanced Oversight and Accountability final rule and conduct a thorough review of ONC's role in the marketplace;
5. Limit the ONC certification program to verification of functionality necessary to perform measures required for participation in MACRA payment models; and
6. Prioritize implementation of virtual groups as mandated by MACRA.

A more detailed explanation of these recommendations is attached. We look forward to working with you to ensure the increasing use of technology through private sector innovation continues to transform health care to the betterment of consumers and patients.

Sincerely,

A handwritten signature in black ink, appearing to read "Joel White". The signature is fluid and cursive, with the first name "Joel" being more prominent than the last name "White".

Joel White  
Executive Director

## Promote Interoperability

Despite the passage of the HITECH Act in 2009, the Meaningful Use program has not achieved its goal of fostering a high value, better functioning health system. Taxpayers have spent \$35 billion on EHRs that are largely not interoperable.

In MACRA, Congress declared it a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018. Further, the *21<sup>st</sup> Century Cures Act* sets up regulatory changes to help meet that goal.

Specifically, the *21<sup>st</sup> Century Cures Act*:

- Repeals the Health IT Policy and Standards Committees and forms a new unified Health IT Advisory Committee that is tasked with recommending a policy framework for advancing certain target areas. The law allows the Secretary to identify additional priority target areas. In the past, the Health IT Policy and Standards Committees have focused on many ONC-defined priority areas, yet lost sight of what should be their ultimate goal – achieving widespread interoperability. The yet-to-be-formed Health IT Advisory Committee will represent many diverse stakeholders, all of whom will have their own individual priorities. **We urge HHS to not lose sight on the end goal again and to ensure that all target areas will help reach interoperability.**
- Gives priority to standards and implementation specifications developed by consensus-based standards development organizations. Focusing on standards used in the private sector is essential to reaching interoperability. Unfortunately, when Meaningful Use was first implemented, ONC decided to require standards that were not widely used in the private sector. This set back the pace of interoperability and led to needless burden on providers. **To correct this mistake moving forward, we encourage HHS use what works in the private sector.**
- Requires HHS to take steps to end information blocking because it is one of the main impediments to widespread interoperability. This business practice barrier to interoperability does not just thwart federal and private efforts to more fully share clinical information, it also poses significant risk to patient safety because providers will not have accurate or complete information on their patients. The law, if implemented correctly, will allow providers and patients to share information when and where it is needed to provide personalized care. The statutory definition of information blocking includes practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and implementing health information technology in nonstandard ways that are likely to substantially increase the complexity of burden of accessing, exchanging, or using electronic health information. The law requires the Secretary of HHS, through rulemaking, to identify reasonable and necessary activities that do not constitute information blocking. **When defining these activities, we encourage you to seek thorough input from stakeholders on what practices they face in the marketplace and be cognizant of the FTC and state Attorneys General investigating information blocking behavior on an anti-competitive basis. From our experience, information blocking can come in many shapes and sizes, and it is essential that HHS gather real-world experience in order to fully grasp the complexity of information blocking and prevent unintended consequences to patients, providers, and vendors.**

- Requires ONC to implement a standardized process for the public to submit reports on claims of health information technology products or developers of such products not being interoperable or resulting in information blocking and actions that result in information blocking. **Instituting a system that captures all necessary information for investigation and enforcement will be crucial to the implementation of this provision.**

### **Reduce Regulatory Barriers and Burdens**

The healthcare industry is one of the most regulated industries in our country. There are steps HHS should take to reduce regulatory burden on providers and health technology vendors that will allow for the flexibility necessary for innovation and at the same time protect patient safety.

#### *The Future Role of ONC*

In 2009, the HITECH law was enacted to provide billions of dollars in taxpayer subsidies for the adoption and use of EHRs. The law also formally established ONC in statute - in part to coordinate health IT activities across federal departments and in part to develop and operate a voluntary certification program in support of the Meaningful Use program. Funds were provided to encourage installation of EHRs, construct Health Information Exchanges (HIE) to facilitate information sharing, and for technology innovation projects under the program.

The health IT marketplace has dramatically changed since 2009. As of 2015, nearly nine in ten office-based physicians had adopted an electronic health record (EHR) compared to less than fifty percent in 2009.<sup>1</sup> The federal government should likewise shift its regulatory approach to recognize the realities of the marketplace.

Specifically, we suggest ONC focus on:

- Coordinating activities across the departments and agencies with an eye towards eliminating regulatory overlap, ending conflicting regulations, and reducing regulatory overlap wherever it is found;
- Work with industry to adopt meaningful interoperability measurements to achieve the legislative goal of systemic interoperability by the end of 2018;
- Enable a healthcare ecosystem that allows innovators room to move by focusing on outcomes and not the means to achieve them; and
- Work closely with OIG in correcting the problem of information blocking in the Meaningful Use program.

Recent actions taken by ONC not only overstep statutory authority, but show dedication to mission creep rather than the core directive from Congress: achieve interoperability and do so quickly. Specifically, we are concerned with the potential impact of the ONC Enhanced Oversight and Accountability final rule. We believe that provisions of this final rule are duplicative and unnecessarily burdensome and seek to extend ONC's regulatory authority to the entire marketplace, rather than just products used by participants in the Meaningful Use program. The ONC final rule sets out actions for ONC and health IT developers when ONC believes certified health IT is causing or contributing to serious risks to public health or

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<sup>1</sup> Office of the National Coordinator for Health Information Technology. 'Office-based Physician Electronic Health Record Adoption,' Health IT Quick-Stat #50. [dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php](http://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php). December 2016.

safety. These actions include steps to bring certified health IT back into conformity with requirements of the Certification Program, and if certified health IT is not brought back into conformity, ONC may decertify those products.

While it is true that most certified health IT products are, by definitions included in the *21<sup>st</sup> Century Cures Act*, considered low risk, and therefore are not subject to traditional medical device approval requirements within the jurisdiction of the Food and Drug Administration (FDA), it is not true that the FDA therefore does not have regulatory authority for the safety of these products after they are in use on the market. Provisions in the *21<sup>st</sup> Century Cures Act* specifically entrust these actions to the FDA, even in the case that the product did not go through the pre-market approval process.

Congress gave regulatory authority to the FDA and requires the agency take specific actions if a health IT product poses a significant risk to patient safety, even if that product was not initially subject to FDA review requirements. Therefore, any regulatory actions that ONC may take with respect to patient safety concerns are not only duplicative, they are also directly counter to legal requirements established by the *21<sup>st</sup> Century Cures* law. **We urge HHS to immediately rescind the ONC Enhanced Oversight and Accountability final rule and conduct a thorough review of ONC's role in the marketplace.**

#### *Advancing Care Information under MACRA*

MACRA includes simplification of the Meaningful Use program into the Advancing Care Information (ACI) performance category for providers participating in the Merit-Based Incentive Payment System (MIPS). Congressional intent was to reduce provider burdens under Meaningful Use, which had evolved into “check-the-box” activities instead of a focus on meaningful outcomes, namely interoperability.

Since MACRA was enacted, CMS has made great progress in implementation of the ACI performance category under MIPS, but ONC has not followed suit in updating their 2015 Edition Health Information Technology Criteria. Health IT Now is concerned that ONC's 2015 Edition Health Information Technology Certification Criteria, which sets system requirements for EHRs used in provider offices, will leave providers not able to meet new ACI requirements. **In order to ensure provider success under MACRA, HHS must limit the ONC certification program to verification of functionality necessary to perform measures required for participation in MIPS or APMs.**

We also believe HHS should go further in removing provider burden under the ACI performance category. Under ACI, many providers will still be required to report on activities that are not directly relevant to their patient care. **To allow flexibility for providers, especially specialists, HHS should recognize providers utilizing an EHR to participate in a clinical data registry as satisfactorily achieving full credit for the ACI performance category.**

#### *Virtual Groups*

One of the first steps that HHS should take to reduce regulatory burden is to prioritize implementation of virtual groups as mandated by MACRA.

Virtual groups were established by Congress to allow varying providers in different physical locations to associate as a group for reporting. The model is intended to allow innovative IT companies to partner with providers who might otherwise have difficulty reporting on meaningful measures under MIPS. Providers with limited direct patient interaction, providers in rural areas, and those who are not able to report on full sets of measures might benefit from this technology-supported reporting option.

Implementation of the MACRA statute will be challenging for both physicians and CMS. Establishment of virtual group reporting options appear no different. We recognize that part of the problem may lie with the CMS legacy IT system, which some suggest are incapable of performing many functions that are commonplace among IT systems today. While we believe it imperative that Congress work with the administration to identify ways that the CMS computer systems can be updated to increase Medicare's efficiency and reduce costs, we do not believe such a barrier need impact the effectiveness of the virtual group concept. Rather, we believe that the solution can be found in closer collaboration with the private sector. Many health technology vendors have platforms and expertise in technology solutions that could facilitate provider engagement in virtual groups, performance feedback in real-time, and other solutions that might better prepare providers to meaningfully engage in APMs. **We encourage HHS to work more closely with private industry to quickly implement virtual groups.**