ONC Health IT Safety Program –
Progress on Health IT Patient Safety Action and Surveillance Plan

In July 2013, the Office of the National Coordinator for Health IT (ONC) published the Department of Health and Human Services' (HHS's) Health IT Patient Safety Action and Surveillance Plan ("Health IT Safety Plan" or "Plan"). The National Coordinator also established ONC's Health IT Safety Program to coordinate activities related to the Plan. This is a brief overview of some of the activities of the ONC Health IT Safety Program since publication of the Plan.

Background

Patient safety is a foundational value in health care, but it was not until the Institute of Medicine (IOM) released its report To Err is Human: Building a Safer Health System in 1999 that a spotlight shined on the epidemic of avoidable harm and deaths in healthcare. Since then, the IOM and Congress, among many others, have recognized the potential of health IT to promote safety and prevent harm. Indeed, that potential was one reason for the creation of ONC.

In 2010, to better understand the impact of health IT on patient safety, ONC commissioned the IOM to summarize the existing knowledge of the effects of health IT on patient safety and to make recommendations for both federal and private sector organizations to maximize health IT safety and patient safety. The resulting report, *Health IT and Patient Safety: Building Safer Systems for Better Care* ("IOM Report"), was released in November 2011.

Building upon the 2011 IOM Report and incorporating input from other federal agencies, stakeholders, and public comments, ONC developed the HHS Health IT Safety Plan. The Plan addresses health IT as integral to HHS's commitment to patient safety through two related objectives: (1) to use health IT to make care safer; and (2) to continuously improve the safety of health IT. To achieve these objectives, the Plan relies upon existing authorities but with an enhanced focus on the role of health IT in patient safety efforts across government programs and the private sector.

Since publication of the Health IT Safety Plan, the ONC Health IT Safety Program has pursued the strategies and activities laid out in the Plan, while also working on the closely related FDA Safety and Innovation Act (FDASIA) Report on health IT safety (discussed below). A great deal of work has been done by ONC to improve the safety and safe use of health IT as well as the use of health IT to improve patient safety. This work has been conducted in close coordination with ONC's federal partners, including the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA), and other public and private health IT stakeholders. Some of the activities in which ONC has been most directly engaged are described below under the strategic headings identified in the Health IT Safety Plan – Learn, Improve, and Lead. ONC knows and deeply appreciates that many other federal organizations are working on programs that further the objectives of the Health IT Safety Plan, although they are not all identified below.

Learn

The 2011 IOM Report emphasized the need for more and better information on the role of health IT in patient safety, and the 2013 Health IT Safety Plan identified ways in which the Department would address that need. ONC has supported activities in the following areas identified in the Health IT Safety Plan.

Facilitate reporting to Patient Safety Organizations (PSOs) and provide support to identify, aggregate, and analyze health IT safety event and hazard reports

ONC has funded the following guides, reports, and projects intended to facilitate reporting of health IT events and to analyze adverse event databases to better understand the role of health IT in patient safety.

- Guide by ECRI Institute on *How to Identify and Address Unsafe Conditions Associated with Health IT*. This Guide helps healthcare providers and EHR technology developers identify and report health IT-related events to PSOs.

- Report by RAND on *Promoting Patient Safety Through Effective Health Information Technology Risk Management*. This Report identifies challenges and success factors for implementing effective risk management related to health IT, including reporting to PSOs. Appendix A includes analysis by ECRI PSO of reports submitted during the project by participating entities.

- Guide by the National Center for Human Factors in Healthcare on *The Role of Health IT Developers in Improving Patient Safety in High Reliability Organizations*. This Guide makes 18 recommendations on how health IT developers can help their clients optimize the safety and safe use of their products and services, including by supporting reporting and working with PSOs.

- Analyses and reports of health IT-related events in two large PSO adverse event databases by University HealthSystem Consortium Safety Intelligence PSO and ECRI Institute PSO, under contract to Westat. The results will be available Fall 2014.

- Analysis by The Joint Commission of its sentinel events database (after de-identification) involving 120 sentinel events in which health IT was a contributing factor (out of 3,375 reported events). This analysis will be available Fall 2014.

ONC and AHRQ have held regular meetings to coordinate health IT and patient safety activities related to research and reporting on health IT and patient safety. AHRQ has recently awarded $4 million in new research grants to improve the safety of health IT. More information can be found at healthit.ahrq.gov. AHRQ is also funding and conducting research on the impact of health IT on specific medical conditions and outcomes. A study published in the summer of 2014 funded by AHRQ found that Florida hospitals who adopted all five core measures of meaningful use for medication management in 2010 had the lowest rate of adverse drug events of all hospitals in the state.

Incorporate health IT safety in post-market surveillance of certified EHR technology

Post-market surveillance and testing have been a core component of ONC's Health IT Certification Program since the program was permanently established in 2011. Surveillance provides assurance to users of health IT that capabilities that were certified in a controlled testing environment will continue to perform in an acceptable manner when they are properly implemented and used in the field. Immediately upon releasing the Health IT Safety Plan, ONC issued detailed guidance to its ONC-Authorized Certification Bodies (ONC-ACBs) explaining their responsibilities for conducting post-market surveillance of the health IT products they have certified. The guidance prioritized key safety-related capabilities such as CPOE and included a focus on health IT developer's processes for collecting and addressing user complaints. In August 2014, ONC issued additional, annual guidance clarifying ONC-ACBs' continuing surveillance responsibilities for calendar year 2015. Under the updated guidance ONC-ACBs will continue to prioritize health IT safety in their surveillance activities while incorporating refinements and improvements based on their experiences to date.

Align CMS patient safety initiatives with the safety of health IT

CMS is committed to ensuring that EHR-enabled health care facilities surveyed by State surveyors on behalf of CMS comply with health and safety requirements for participation in Medicare and Medicaid, including requirements related to internal reporting and analysis of adverse events to improve patient safety, and the adequacy, accuracy, and availability of medical records. ONC and CMS's Survey and Certification Group have jointly conducted two webinars, with a third planned for fall 2014, to help surveyors evaluating hospitals better understand and evaluate compliance and patient safety in an EHR-enabled environment.

Upon CMS request, ONC has also provided technical insight into deficiencies involving EHRs uncovered during specific CMS surveys.

Identify opportunities to make care safer through the use of health IT

ONC is developing new clinical decision support (CDS) interventions for high priority health conditions, such as HIV, hepatitis C, cardiovascular disease, and opioid prescribing in sharable, standards-compliant formats to facilitate local quality improvement initiatives, including adverse event reporting. These are matched to e-clinical quality measures in the Meaningful Use program and other CMS quality reporting programs using the same underlying logic. These new CDS interventions will be platform neutral and available for implementation in any certified EHR.

Improve

Use Meaningful Use and the National Quality Strategy to establish and advance health IT patient safety priorities

Since publication of the Health IT Safety Plan, ONC, in close coordination with CMS, has pressed ahead on the next phases of regulation and implementation under the EHR Meaningful Use Incentive Program, in particular under Stage 2 of the CMS Meaningful Use regulations and

ONC's 2014 Edition of EHR certification. Evidence increasingly suggests that the adoption and use of EHRs with the functionality required by these regulations reduces adverse events and will improve patient safety and quality. For instance, an ONC-funded review of published studies from January 2010 through August 2013 -- **Health Information Technology: An Updated Systematic Review With a Focus on Meaningful Use** -- found that health IT had statistically and clinically significant benefits, often associated with the meaningful use functionalities of clinical decision support, computerized provider order entry, patient access, lists, and reminders.

Incorporate safety into certification criteria for health IT products.

Even before publication of the Health IT Safety Plan, ONC finalized two certification criteria for the 2014 Edition — on user-centered design and quality management systems — specifically designed to enhance the safety of certified EHRs. Since then, ONC has continued to work with the National Institute of Standards and Technology (NIST) to review ways to strengthen ONC's certification and surveillance program to enhance the safety and usability of health IT products, with a focus on user-centered design and quality management systems.

In addition to incorporating safety in certification criteria for health IT products, ONC has published test results and other information related to the safety enhanced design criteria on its Certified Health IT Product List (CHPL). This information enables health IT users to make more informed purchasing decisions by enabling evaluation and comparison of developers' safety-related design and development processes. ONC is exploring additional opportunities to enhance transparency around user-centered design and quality management processes and other aspects of health IT product safety.

Support research and development of testing, user tools, and best practices related to health IT safety

Since the Health IT Safety Plan was published, ONC has made a substantial contribution to the safety and safe use of EHRs by the creation and publication, in January 2014, of nine Safety Assurance Factors for EHR Resilience (SAFER) Guides. These guides contain 158 recommended practices in areas of recognized risk. The self-assessment guides, developed by recognized experts, are based upon the best evidence available and are designed to help EHR users evaluate their own practices with regard to the safety of EHR technology itself, the safe use of EHRs, and continual monitoring and improvement.

This year the Turf – EHR Usability Toolkit was published. ("Turf" stands for "Toward a Unified Framework for EHR Usability".) The Toolkit was developed under an ONC cooperative agreement with the National Center for Cognitive Informatics and Decision Making in Healthcare at the University of Texas Houston, and it is designed for usability evaluation, testing, measurement and design of EHRs in accordance with ONC certification requirements and NIST guidance.

Investigate and take corrective action to address serious adverse events or hazards involving health IT

ONC has promoted private sector investigation and corrective action in response to health IT related patient safety events. ONC funded The Joint Commission to conduct "learning visits" to better understand health IT events, and this fall the Joint Commission will produce educational material to help healthcare providers identify, investigate, and address health IT related events.

ONC has supported strengthening the role of PSOs in health IT-related investigations. As part of ONC and AHRQ's coordinated activity, AHRQ published guidance through frequently asked questions on how EHR technology developers can participate in investigations of health IT related events with health care providers and PSOs. ONC then published a guide on *How to Identify and Address Unsafe Conditions Association with Health IT* (see above), which addresses how healthcare providers, PSOs, and EHR developers can work together, under the Patient Safety and Quality Improvement Act of 2005, to investigate health IT-related events.

Lead

Encourage private sector leadership and shared responsibility for health IT patient safety

As a result of the Congressional requirement to draft a risk-based regulatory approach for health IT that promotes safety and innovation and reduces regulatory duplication (see the FDASIA Report below), ONC has proposed the creation of a **Health IT Safety Center**. Recently, ONC (through the Program Support Center) has solicited offers on a contract to develop a road map for a Health IT Safety Center as a public-private partnership. We expect to award the contract by the end of September 2014.

ONC, as convener and coordinator, has and will continue to encourage and support private sector activity related to health IT safety. One example from September 2013 was a day long summit on the SAFER Guides, with stakeholders from across the healthcare industry, including EHR technology developers, professional associations representing physicians and nurses, hospitals, PSOs, accrediting and certifying bodies, risk management organizations, and liability insurers. ONC also convened a day-long meeting with representatives of the Pharmacy Health IT Collaborative, pharmacies, organizations that provide services related to e-prescribing, and medication safety related organizations to discuss health IT-related medication safety and e-prescribing. ONC has engaged with the full range of stakeholders, often at their request, since July 2013 related to patient safety and health IT.

ONC funded research on effective health IT risk management (see above, *Promoting Patient Safety Through Effective Health Information Technology Risk Management*), which confirmed a commitment to health IT safety, while describing very real challenges – limited financial resources, limited knowledge of what is involved in health IT safety, few tools, and the need to align health IT safety activities with other priorities, including regulatory compliance and attestation to meaningful use. The research highlighted the importance of executive and board leadership and of knowledgeable risk management leadership with health IT expertise. This research will help ONC more effectively engage with the private sector on health IT safety.

Develop a strategy and framework for an appropriate risk-based regulatory framework for health IT

As required by the FDA Safety and Innovation Act (FDASIA), ONC, FDA, and FCC published the draft [FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework,](#) in April 2014. The Draft Report published for comment proposed that reliance on ONC coordination and private sector capabilities was the preferred approach to oversight, with no new or additional reliance on regulatory oversight:

> "We believe a limited, narrowly-tailored approach that primarily relies on ONC-coordinated activities and private sector capabilities is prudent. We also recommend that no new or additional areas of FDA oversight are needed. Rather, we believe a better approach is to foster the development of a culture of safety and quality; leverage standards and best practices; employ industry-led testing and certification; and selectively use tools such as voluntary listing, reporting, and training to enable the development of a healthcare environment that is transparent and promotes learning to foster continual health IT improvement. Overall, we do not believe that regulation should be or needs to be the first approach used to reach this outcome."

ONC convened a FDASIA Work Group of the Health IT Policy Committee to make recommendations to inform the report. Following publication of the Draft Report, ONC, FDA, and FCC convened a three day public workshop in May on topics in the Draft Report. In June 2014, ONC charged a Safety Task Force from the HIT Policy Committee to review the FDASIA Health IT Report and provide recommendations on the governance and value of a potential ONC Health IT Safety Center. ONC, FDA, and FCC are currently reviewing comments and working on a final FDASIA Report.

ONC will continue to rely on the Health IT Policy Committee for insight and recommendations on actions that promote health IT safety. In August, we convened a work group of the Health IT Policy Committee on **Health IT Implementation, Usability, and Safety** to provide input and make recommendations on policy issues and opportunities for improving how health IT is designed, certified, implemented and used to minimize safety risks and leverage data to support improvements in patient care and health outcomes.

Establish an ONC Health IT Safety Program to coordinate implementation of the Health IT Safety Plan

The ONC Health IT Safety Program continues as a high priority within ONC. This spring, ONC created a new Office of Clinical Quality and Safety, which has lead responsibility for ONC's Health IT Safety Program, coordinating with ONC's Office of Policy. ONC's Health IT Safety Program will continue to coordinate with our federal colleagues on an ad hoc basis to promote health IT and patient safety.

Conclusion

With the widespread adoption of EHRs, the potential for health IT systems to dramatically improve patient safety is within our reach. Over the next year, ONC expects to see more evidence of significant reductions of patient safety events associated with use of health IT.

We realize, however, that this potential requires that the health IT systems are themselves safe, and that they are used in ways that take advantage of their potential to make care safer. We have learned a great deal from research we have funded and from private sector safety activities about what this requires, and we expect to learn more.

ONC will continue to drive toward the objectives in the Health IT Safety Plan. Our success will require cooperation from many individuals and organizations. The potential to dramatically improve patient safety through health IT is, however, a very powerful motivation.