**McKesson Corporation**
One Post Street
San Francisco, CA 94104

www.mckesson.com

**Ann Richardson Berkey**
Senior Vice President, Public Affairs

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Farzad Mostashari, M.D., ScM.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

**RE: Public Comments on Health Information Technology Patient Safety Action and Surveillance Plan**

Dear Dr. Mostashari:

On behalf of McKesson Corporation ("McKesson"), I am pleased to submit comments to the Office of the National Coordinator for Health Information Technology ("ONC") on the Health Information Technology Patient Safety Action & Surveillance Plan ("Plan"). We commend the ONC for their efforts to ensure patient safety through appropriate oversight, and we applaud ongoing efforts to support innovation and promote the broad adoption of health information technology (health IT).

For 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the largest health IT company in the world, we are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency. McKesson has decades of experience serving the health IT needs of the largest and most diverse provider base in the industry, including 50 percent of all health systems, 77 percent of health systems with more than 200 beds, 20 percent of all physician practices and 25 percent of home care agencies, which support more than 50,000 home care visits annually. We process billions of financial healthcare transactions annually among physicians, hospitals, pharmacies, insurers and financial institutions, and provide care and claims management solutions to most of America's health insurance companies.

Through RelayHealth, McKesson's connectivity business, we manage millions of aggregated personal health records as the leader in connecting patients online with their physicians, hospitals, reference laboratories and health plans and as a participant in community and regional health information exchanges.

Our perspective on the proposed Plan is based on our extensive experience with health IT and the improvements in quality, safety and efficiency that can be realized by hospitals, health systems, physicians and pharmacies. McKesson has a long history of leadership and collaboration with the industry in the area of patient safety.

Eleven years ago, together with the American Hospital Association, we established the McKesson-AHA Quest for Quality Prize. Since then, we have contributed millions of dollars to recognize and reward hospitals that have excelled in integrating the six aims of the Institute of Medicine and in disseminating best practices. In conjunction with the National Patient Safety Foundation (NPSF), the American Organization of Nurse Executives (AONE), the Institute for Safe Medication Practices (ISMP) and the American College of Physician Executives, we have also created an annual clinical leadership forum for Chief Nursing Officers and Chief Medical Officers to develop and implement consensus recommendations on advancing patient safety (www.nursingleadershipcongress.com).

McKesson also collaborates with NPSF in supporting their Leadership Day for executives and sponsors and their learning module on advancing patient safety through health IT. Additionally, we have joined ISMP in developing consensus recommendations on the safe implementation of medication dispensing and administration technology. Patient safety remains a major priority for us.

Most recently and under the auspices of the Bipartisan Policy Center (BPC), McKesson has partnered with three other organizations to lead an effort among hospital, physician and patient organizations and IT companies to develop consensus recommendations for the Food and Drug Administration (FDA), ONC and Federal Communications Commission (FCC) as they respond to the congressional requirement to develop a new risk-based regulatory framework specific to health IT.

Drawing upon our decades of experience and long-standing commitment to patient safety, we outline a number of recommendations on the proposed Plan. These recommendations are guided by three overarching principles:

1. Health IT has the power to transform healthcare, and its safe deployment must be viewed as a shared responsibility among the multitude of stakeholders. As such, appropriate oversight must ensure patient safety, while supporting innovation and promoting the broad adoption and use of health IT.

2. Appropriate oversight must be specific to health IT and should be risk-based. Health IT should not continue to be constrained by existing medical device authority. Instead, a new pathway with varied levels of oversight based on risk should be developed.

3. Efforts to develop a new risk-based pathway should be coordinated across agencies. ONC's Plan should be aligned with the development of a new regulatory pathway recommended in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) and coordinated with other efforts to provide oversight and promote adoption of health IT.

**Ensure Appropriate Oversight of Health IT to Support Patient Safety and Innovation**
McKesson applauds the ONC's commitment to coordinate efforts by public and private parties to improve the safety of health IT and to use health IT to improve patient safety. Health IT plays a critical role in improving the quality, safety and cost-effectiveness of care. Rapidly emerging delivery system and payment models designed to reduce costs, improve quality, and improve the patient's experience of care each require a solid health IT foundation to be successful.

Any oversight framework for safety in health IT should have strong support from and involvement of all stakeholders: patients, health IT developers, implementers, and users. A framework for safety in health IT must also be flexible and promote, not stifle, the innovation needed to drive further improvements in healthcare. Current regulatory frameworks which are oriented towards manufactured devices that change infrequently and are not typically customized to the needs of the user will neither effectively support nor promote the current and anticipated rapid development of health IT.

**Establish Consensus Standards for Appropriate Safety Tools, Quality Systems and Surveillance**
Health IT is an essential component of a comprehensive approach to improving patient outcomes and assuring the quality, safety and efficiency of healthcare. Any oversight framework for health IT should align with and leverage existing processes, systems and standards in healthcare, and should discourage or prevent duplicative or inconsistent requirements.

McKesson agrees that health IT safety is a shared responsibility, and we support using some of the work that has already been funded to develop tools to help advance appropriate oversight of health IT. We believe that the first step should be an analysis and prioritization of key areas for further development. While we support the use of solutions to effectively manage the process, we recommend that a group of all stakeholders be convened to identify best practice solutions, specific tools and formulate consensus recommendations for this purpose.

We recognize and commend the Agency for Healthcare Research and Quality (AHRQ) and the ONC for funding projects in the area of patient safety. Together with the National Library of Medicine (NLM), they are disseminating information and piloting solutions today to improve health IT safety. The development of tools such as Hazard Manager and SAFER guides can be greatly enhanced, however, through the active engagement of a broader group of stakeholders. To that end, we strongly recommend that a stakeholder group, including health IT developers, be established to provide recommendations and share relevant experience. All best practices and safety solutions should be considered in the final Plan. McKesson is extremely interested in participating in this process. We stand ready to share our experience and expertise with building industry consensus in important areas such as medication error surveillance and other patient safety innovations. Additionally, safety solutions should be prioritized based on evidence of need, derived by consensus, created using established standards and tested across multiple practice areas and health IT environments.

As the ONC collaborates with educational organizations, professional associations and liability insurers to foster a culture of safety and disseminate best-in-class solutions and strategies to effectively reduce health IT-related adverse events, we urge the development of health IT guidelines through standard setting organizations such as ISO. ISO standards should be used as a point of reference to inform the development of industry standards for design, implementation and quality management in software development. ISO Technical Committee 215, Health Informatics, is currently preparing a technical report assessing which standards are most relevant for the various stages of the software lifecycle, identifying where gaps exist and providing practical guidance on best practices for developers, implementers, owners and users in applying the relevant standards. ONC should leverage this activity in its Plan.

*Quality Management Systems*
Other industries have successfully established strong safety programs for software development environments using consensus standards and public/private consortiums to enhance quality and reduce risk. Policies, processes and systems associated with assuring safety in health IT should be aligned with and integrated into well-established patient safety and quality programs, including those that involve accreditation, certification and reporting. Quality management principles, processes, and standards, which are well-established and common to other industries, also exist in the health IT area and should be leveraged by ONC.

*Reporting Tools*
There are multiple tools currently in use to report safety events. Event reporting systems typically have workflow that enables the initial identification of issues, requires follow-up to determine if an event actually occurred and then assures a root cause analysis of an adverse event. Usually, this assessment is performed by clinicians, risk managers or patient safety officers who will then determine if there is a reportable event.

We agree that it would be useful to explore how electronic health records (EHRs) can be used to enhance reporting of safety events and risks in general. At the same time, it is essential to consider appropriate workflows of providers. Most patient safety reporting will not be conducted by a single EHR user; rather, it will occur within intra-organizational workflows and review processes. Therefore, it is critical to consider how EHRs can help collect the data needed by healthcare organizations as they review safety issues internally and potentially report externally. Any required reporting tool should not interfere with the existing provider patient safety investigation and reporting workflow or be redundant with existing systems. Therefore, we would discourage creating the actual report at the point of care; it will not be well accepted by providers if the report process interrupts the clinical workflow process.

The model illustrated in the ONC Plan promotes the flow of information only from providers to Patient Safety Organizations (PSOs), whereas the developer relies heavily on timely access to this information. We strongly recommend that information be provided to both the PSO **and** the vendor. Regardless of the patient safety reporting and analysis system, it is absolutely critical to patient safety that such a system not distance providers from their EHR developer. When a patient safety event occurs, it is imperative that the affected provider report the issue directly and immediately to their vendor, thereby allowing the developer to assess and investigate the event, inform other affected clients if necessary and, most importantly, resolve it. A national reporting or analysis system should work in concert with the vendor-client relationship.

The Plan calls for ONC to work with developers on a code of conduct that commits developers to work with PSOs or similar entities to report, aggregate, and analyze health IT-related safety events, support providers in reporting safety events and collaborate with private sector efforts to share user experience with different EHR systems. McKesson supports an industry code of conduct that ensures business practices promote the use of quality management systems and adverse event reporting.

We note that the model provided on the last page of the ONC Plan shows that providers will submit complaints to the developers, the ONC and Office of the National Coordinator-Authorized Testing and Certification Body (ONC-ACBs). ONC's Safety Plan relies on certification and reporting, but ONC does not specify the standards and measures for those actions. McKesson recommends that health IT developers provide comments on the Plan; it will only be successful if providers, implementers and developers are all involved in the process.

Additionally, we strongly recommend that health IT developers be granted confidentiality protection after meeting standards and achieving certain measures. It is important that the safety framework provide a non-punitive learning environment through the use of confidential event reporting. We have observed in other industries that such reporting systems are effective in increasing reporting, enabling data aggregation and trending, and developing consensus recommendations and best practices which are shared broadly. We strongly recommend that confidentiality be applied to the patient, provider, vendor and products for the purposes of aggregate data analysis and reporting. This confidentiality will not shield parties from responsibility or liability for problems that may have been caused by the technology; rather it is necessary to generate open and transparent discussions to enable problem resolution of adverse events.

*Surveillance Mechanisms*
McKesson supports the use of existing organizations and is committed to working with the ONC to report patient safety events to the Network of Patient Safety Databases (NPSD). We also support the use of standardized reporting formats and existing capabilities as outlined in the Plan. However, we suggest that ONC conduct demonstration projects to involve stakeholders in advance of this implementation.

The Plan calls for ONC to inform ONC-ACBs of surveillance priorities in order to identify those EHR technology capabilities that may pose the greatest potential for patient harm and opportunity for improvement. McKesson agrees with the concept of surveillance; however, we do not agree that surveillance should be performed by the ONC-ACBs. The ONC-ACBs do not have expertise in clinical workflow or in coordinating existing processes and reporting systems that are in place today. We seek clarification of what these bodies will survey and in what setting. Recommendations should be solicited from health IT developers and providers to coordinate the feasibility and best approach for successful surveillance.

**Utilize AHRQ Common Formats and Existing Risk Management Processes in Conjunction with PSOs**
We commend the ONC's commitment to work with the Centers for Medicare and Medicaid Services (CMS) to align health and safety standards with the Plan and train surveyors to improve their ability to identify safe and unsafe practices related to health IT.

We recognize that ONC's regulations establish standards and certification criteria for certified EHR technology; however, we are concerned that the ONC intends to use certification criteria to ensure that, where appropriate, EHR technology is used to report safety events. While we support ONC's intent to leverage EHRs to automate data collection, hospitals and other provider organizations have already established risk management processes. To avoid redundancy and potential conflict, we recommend that ONC collaborate with providers and health IT vendors to develop a process to evaluate existing processes and determine the minimal data set required to facilitate a coordinated approach to utilize EHRs in reporting safety events.

We agree that data standardization is needed in order to successfully report and aggregate data and support the use of current modified or enhanced versions of the AHRQ common format specifications. In standardizing the reporting of adverse events, the common formats represent a good starting point and should be reviewed and updated through the National Quality Forum (NQF) process as needed. It should also be recognized that there may be significant workflow implications for providers. Therefore, we recommend that careful consideration is given to defining the ***minimum*** data set required to achieve the

objective in order to avoid excessive and costly development efforts. The inclusion of health IT developers in these activities will ensure that the end-product of the Quality & Safety Review System (QSRS) is both effective and successful.

Collaboration with the private sector is critical. Today, there are over 80 PSOs who perform their functions with wide variation. To ensure that the various PSOs operate in a uniform manner, we recommend the creation of certification requirements for PSOs who analyze health IT-related events. We also urge ONC to partner with the private sector to establish the requirements or metrics to be used for quality management systems and safety event reporting. The ONC Plan states it will work with AHRQ, the PSOs and the FDA to collect and analyze reports of health IT-related deaths, serious injuries and unsafe conditions. There are many outstanding questions as to how these efforts will coordinate with the multiple PSOs in various states today.

**Synchronize Patient Safety Plan with Related Meaningful Use and Other Health IT Requirements**
We concur with the stated importance of ensuring that the use of health IT does not create patient safety concerns. There are several initiatives underway to address these objectives, including the Meaningful Use program, the Health IT Patient Safety and Surveillance Plan and a provision in FDASIA, which calls for a coordinated plan to address a risk-based regulatory framework for health IT. Since these initiatives may create additional requirements for developers, hospitals and providers, any requisites must be coordinated to avoid redundant or conflicting requirements.

McKesson urges ONC to include any anticipated near-term patient safety requirements as it finalizes the scope of Meaningful Use Stage 3. The Plan states that "the ONC intends to continue using its standards and certification criteria and certification program rulemaking in ways that enhance health IT patient safety, focusing on human factors, safety culture, and user-centered design." We are concerned that additional patient safety requirements could be expensive to implement retrospectively. Therefore, we strongly recommend that any patient safety initiatives and requirements be carefully coordinated with the Meaningful Use program and incorporated into Health IT Policy Committee (HITPC) recommendations to the ONC.

**Incorporate Other Safety Initiatives and Vendor Input into the ONC Patient Safety Program**
Although the Plan does not call for the creation of a Council, the ONC intends to establish a Safety Program to provide feedback to developers and providers and eliminate or significantly reduce inefficiencies across programs through the identification of unnecessary overlaps. McKesson supports the establishment of an ONC Safety Program and concurrently recommends that any patient safety initiatives and requirements be carefully coordinated with the Meaningful Use program and incorporated into the HITPC recommendations to the ONC.

Many organizations are actively involved today in patient safety initiatives, including the FDA, FCC, AHRQ, state programs, PSOs, ONC-ACBs, National Institute of Standards and Technology (NIST), the NLM and the Center for Medicare and Medicaid Innovation (CMMI). The ONC has stated that it will function as a "convener." In this role, ONC should coordinate with all relevant agencies and stakeholders to ensure that authority and accountability is aligned and synergies are created. It will also be important for ONC to be prepared to mediate conflicting situations among agencies when requests are made for similar quality performance metrics using different data requirements. An example where greater coordination and synergy between agencies could occur would be in the case of CMS and core measures and the ONC and clinical quality measures.

In advance of launching the Safety Program, we recommend that ONC convene a technical advisory group to define technical specifications, test plans and requirements. McKesson is engaged in many patient safety initiatives, Meaningful Use workgroups and technical advisory teams today and stands ready to share our experience in the development of the ONC Safety Program.

We concur with the ONC that it is well positioned to oversee and assure health IT safety. As the ONC considers the development and implementation of a risk-based regulatory framework for health IT, we strongly recommend that health IT developers, providers and other stakeholders be included in this process. A framework is needed to ensure both continuous quality improvements in patient safety as well as ongoing innovation in the development of health IT.

**Conclusion**

We appreciate the opportunity to provide comments to the ONC and to share our perspective on the proposed Health Information Technology Patient Safety Action & Surveillance Plan. In order to successfully implement such a Plan and continue to improve patient outcomes while maintaining safety, quality and efficiency, we recommend that the following be incorporated into the final Plan:

- Clearly identify ONC as the agency to exercise appropriate oversight of health IT to support both patient safety and innovation;
- Establish consensus standards for appropriate safety tools, quality systems and surveillance;
- Utilize modified AHRQ Common Formats and existing risk management processes in conjunction with Patient Safety Organizations;
- Synchronize the Patient Safety Plan with related Meaningful Use and other health IT requirements;
- Incorporate other safety initiatives and recommendations from health IT developers into the ONC Patient Safety Program; and
- Address the issue of vendor confidentiality protections as part of a plan to promote reports on patient safety events and data aggregation and analysis.

We hope these recommendations provide constructive insights for the development of the final Plan and ONC Patient Safety Program. Should you have questions or need further information, please contact me at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,

Ann Richardson Berkey