BIPARTISAN POLICY CENTER

*FDA: Advancing Medical Innovation*

# Recommendations for improving the interoperability of health information technology and increasing regulatory clarity

*Interoperability and electronic information sharing play a critical role in improving the cost, quality, and patient experience of care. Despite federal investments of more than $30 billion in electronic health record technology, the majority of systems are not able to routinely exchange electronic patient information. Also, there is uncertainty regarding regulatory authority associated with oversight.*

## Recommendations:

### Improve the interoperability of health information technology (IT) through the following:

1. Require the federal government to adopt standards for health IT, including those required for accurate identification and matching of patient data, provider identification, transport, terminologies, clinical models, clinical data query language, security, and application interfaces.
2. The federal government should promote adoption through multiple programs, including standards required by certified electronic health record (EHR) technology under the Centers for Medicare and Medicaid Services (CMS) Medicare and Medicaid EHR Incentives Programs, health IT systems procured by federal agencies, various electronic health data submissions required by federal agencies, and health IT systems directly funded through federal agency contracts, grants, and cooperative agreements.
3. Require that any standards for federal adoption be (1) developed by a voluntary consensus body as defined by the National Technology Transfer and Advancement Act and OMB Circular A-119, (2) tested prior to adoption, and (3) established through formal rulemaking and a collaborative, public process, to assure appropriate public input and transparency.
4. Require that standards for federal adoption be published annually and that effective dates for adoption should not occur until at least 12 months subsequent to publication.
5. Require the development and public availability of methods for testing compliance with federally adopted standards and authorize federal agencies to recognize independent testing and certification bodies that will provide assurance that software complies with federally adopted standards.

### Provide clarity regarding regulatory authority of health IT and assure the implementation of a risk-based oversight framework for health IT that both promotes innovation and protects patient safety:

1. Clarify that health IT should not be subject to regulation as a medical device by the FDA, except when determined by the HHS secretary that the product poses a significant risk to patient safety.
2. Require the HHS secretary to recognize independent bodies to develop voluntary consensus standards, evaluate and render decisions on compliance with such standards, and facilitate voluntary patient safety reporting to continually improve the development, implementation, and use of health IT.
3. Clarify that current law enables those who develop and implement health IT to participate in patient safety activities and direct the HHS secretary to extend confidentiality protections to health IT developers to permit them to report patient safety events, view patient safety organization-protected information, receive and analyze patient safety event reports, create and receive quality improvement reports from patient safety organizations, and work with providers to develop strategies for improvement.

For a full list of BPC recommendations on advancing medical innovation, see http://bipartisanpolicy.org/library/advancing-medical-innovation-for-a-healthier-america/