Agency	Who	What	When	Why	How
	Who is responsible for adhering to the regulations?	***What is regulated?***	***When will the regulations apply?***	***Why is this being regulated?***	***How will the regulation be enforced?***
Health Insurance Portability and Accountability Act (HIPAA): Health and Human Services, Office for Civil Rights	Individuals, organizations, and agencies that meet the definition of a covered entity under HIPAA must comply with the Rules' requirements to protect the privacy and security of health information and must provide individuals with certain rights with respect to their health information. Most doctor offices, hospitals, health plans and insurance companies are covered entities. **Are You a Covered Entity?**	Under the HIPAA Privacy and Security Rules, covered entities are required to take certain steps to ensure that their patients' **protected health information** remains private and secure. The Security Rule requires appropriate administrative, physical and technical safeguards be in place to ensure the confidentiality, integrity, and availability to those who are authorized to see and use electronic protected health information. The Privacy Rule gives the patient rights over his/her health information and sets rules and limits on who can view or receive his/her health information.	In effect.	To protect the privacy of the consumer's personal health information.	The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) is responsible HIPAA enforcement.
Meaningful Use: Health and Human Services, Center for Medicare and Medicaid Services	In Development Processes: EHR Vendors In Practice: Ambulatory Physicians and Acute Care Facilities	Electronic Health Records. Mobile is specifically mentioned in regard to CPOE order placement.	Currently Meaningful Use is in its first stage, incentives are being distributed in this stage.	To improve quality and reduce the costs of healthcare.	Penalties will begin in 2015 for Medicare Eligible Providers and Eligible Hospitals which fail to achieve Meaningful Use requirements.
National Institute of Standards and Technology	In Development Processes: EHR Vendors, ATCBs In Practice: Ambulatory Physicians and Acute Care Facilities	Electronic Health Records. Mobile is specifically mentioned in regard to CPOE order placement.	In effect as part of CMS and ONC's Meaningful Use requirements.	To ensure EHRs function in a manner which enables providers to achieve Meaningful Use.	Prerequisite for Meaningful Use (above)

Agency	Who	What	When	Why	How
Mobile Medical Apps: Health and Human Services, Food and Drug Administration	Device Manufacturers- the people who design, manufacturer, label, or create software applications. This includes health systems, insurance companies, private Health IT vendors and others who market mobile medical applications (apps.). Distributors – platforms for selling/advertising the application. Not responsible for the applications functionality, but are responsible for cooperating with updating the product in alignment with the Manufacturers.	Mobile Medical Apps: a mobile app that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and its *intended use* is: 1. as an accessory to a regulated medical device 2. to transform a mobile platform into a regulated medical device Regulations apply to displaying, storing and transmitting information; controlling connected medical devices; transforming mobile platforms, and interpreting medical device data.	In effect.	To protect patients from unintended, potentially dangerous, effects of mobile medical applications which are ineffective or might cause harm.	If the mobile medical app falls within a specific medical device classification or augments functionality to a specific medical device classification, manufacturers are immediately subject to meet the requirements of that classification (either I, II, or III).
Federal Communications Commission	Device Manufacturers- the people who design, manufacture, label, or create software applications.	Mobile devices with radio functions.	In effect.	• Protects human health from negative Radio Frequency exposure • Prevents interference with other mobile devices	If the FCC learns a device does not conform with the test report upon which FCC approval is based, the FCC can withdraw its approval and pursue and enforce action against the appropriate party.
Federal Trade Commission	Business and Policymakers who collect data through computers, mobile devices, and mobile applications.	Computers, mobile devices, and mobile applications.	Utilizes existing FTC Act and other laws to determine violations. No additional requirements are part of this guidance.	• Privacy of PHR (PII and non-PII) • Protects the data of Minors • Protects consumers from deceptive marketing/advertising • Prevents Spam/Spyware	This is a proposed framework, not a regulation.