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October 19, 2011

Department of Health and Human Services
Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, M.D. 20852

Re: FDA-2011-D-0530

Dear Sir or Madam,

Care Continuum Alliance appreciates the opportunity to provide the following comments in response to the Food and Drug Administration's (FDA) Mobile Medical Applications (MMAs) draft guidance.

Care Continuum Alliance convenes all stakeholders along the continuum of care toward improving the health of populations. Through advocacy, research and education, Care Continuum Alliance advances population health management strategies to improve care quality, health outcomes and reduce preventable costs for those who are healthy, at risk of chronic conditions or managing such conditions. Our diverse membership of over 200 organizations and individuals includes physician groups, nurses, other health care professionals, hospital systems, wellness and prevention providers, population health management organizations, pharmaceutical manufacturers, pharmacies and pharmacy benefit managers, health information technology innovators, employers, researchers and academics.

We are pleased by the FDA's focus on ensuring safety and quality in the design and use of MMAs. As remote-based health care increasingly becomes common practice, these technologies complement ongoing innovations in care delivery systems to achieve greater portability in health care practice, health data integration and patient-provider engagement. Care Continuum Alliance recognizes that MMAs are important to the continued success of care coordination and management strategies using remote health monitoring, telehealth services and telephonic or web-based health coaching. Also, MMAs can combine with the proliferation of social media in health care to empower patients to seek greater control and management of their personal health status.[1]

In establishing MMA regulatory standards, the FDA draft guidance should balance safety and quality in health care delivery with the Department of Health and Human Services' broad goal of promoting health technology innovation. Care Continuum Alliance finds the draft guidance is mindful toward the goal of promoting innovation and flexible in permitting manufacturer interpretations to heavily dictate the classification of MMAs. The guidance leaves significant room for manufacturers to demonstrate that the intended use for MMAs rests within an unregulated category of: administrative applications; generic aids; mobile platforms; applications that function like electronic health record systems or personal health record systems; and

[1] Modahl, Mary, Lea Tompsett and Tracey Moorhead, "Doctors, Patients & Social Media," QuantiaMD: September 2011.

applications for maintaining general health and wellness. We also strongly encourage the FDA to consider ways of incentivizing cross-vendor interoperability in the mobile medical arena.

Regarding the FDA's specific request for guidance on MMAs that are accessories to devices, it is not clear that these accessories should be categorically held to the same regulatory standards as the connected devices. As recognized in the draft guidance, certainly some accessories will not fundamentally change or control the nature of a device. A tiered framework that groups accessories by intended use and operational capacity may more accurately evaluate the effect of various accessories on connected devices. Some MMA accessories may then be regulated by lower-level standards. We suggest consulting the mHealth Regulatory Coalition's guidance document entitled *Proposed Guidance for Industry and FDA Staff Regulation of mHealth Technology*. Care Continuum Alliance also recommends that the FDA structure future mobile medical regulatory requirements in the clearest language possible and in consultation with industry members.[2] Continued use of practice-based examples in future draft guidance provides helpful illustrations for mobile medical software manufacturers and distributors.

Care Continuum Alliance members have designed and implemented a variety of mobile medical technologies involving telehealth tools, health data analytics, medication monitoring systems, web-based care collaboration and health records platforms. We would welcome the opportunity to serve as a resource in developing draft guidance documents for mobile medical technologies in the future. Thank you for your consideration.

Sincerely,

Tracey Moorhead
President and CEO

TM/vi

[2] mHealth Regulatory Coalition, "Proposed Guidance for Industry and FDA Staff Regulation of mHealth Technology," September 30, 2011 <http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/MRC-Proposed-Guidance-Document-Presubmission-Draft.pdf>.