



**WRITTEN COMMENTS OF  
VERIZON COMMUNICATIONS INC.**

**for**

**FEDERAL TRADE COMMISSION  
HEARINGS ON  
EXAMINING HEALTH CARE COMPETITION**

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**EXAMINING HEALTH CARE COMPETITION—COMMENT, PROJECT NO. P13-1207**

## **VERIZON COMMENT, PROJECT NO. P13-1207**

### **Executive Summary**

The FTC's study of the health care marketplace comes at a critical time. Technology is poised to reduce health care costs, improve health outcomes, and play an important role in facilitating the coordination of care. Technology cannot revolutionize the health care marketplace, however, if regulatory regimes designed for bygone eras continue to get in the way. Policymakers should work to modernize the legal and regulatory frameworks that govern the health care marketplace to make it easier for technology companies like Verizon and other new entrants to offer innovative new solutions that can improve patient care.

First, outmoded state medical licensure requirements stand as a barrier to the practice of telemedicine, inhibiting access to technology that can provide care to underserved communities, reduce hospital readmission, reduce costs, and address physician shortages. Second, the lack of interoperable electronic health record ("EHR") systems increases the cost and complexity of creating health care solutions, in some cases leaving innovative providers with the difficult task of making a patchwork of implementations to suit individual EHR providers. Third, new entrants in the medical device space face significant uncertainty as to the scope of regulation by the Food and Drug Administration ("FDA"), which increases time to market and discourages innovation. To promote access to new and potentially life-saving technologies, the FTC should highlight impediments to competition in these areas and urge policymakers to update old laws that have not kept pace with technology.

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### I. INTRODUCTION

Verizon, through its health care practice group, offers a comprehensive portfolio of mobile health, managed IT, and consulting services for the health care industry. As the Internet of communications, devices, and applications transforms health care, Verizon will have a leading role in the health care ecosystem, combining integrated communications, IT solutions, and professional services expertise with a high-IQ global IP network and the nation's largest 4G LTE network to enable access to information, content, and communications.

As a technology solutions provider, Verizon understands first-hand the tremendous opportunities for improvements in health care that result from innovation in information technology. Technology can support a broad array of services that promote patient care, reduce costs, and improve health outcomes, revolutionizing traditional provider models of health care. It can transform the way doctors and patients interact by putting new tools in the hands of consumers, thereby placing the consumer at the center of the health care system. Technology may also help physicians achieve better patient outcomes by bridging the information gap between physicians and patients.

Verizon offers three industry-leading health care products. First, Verizon has launched a cloud-based, end-to-end mobile remote health monitoring platform called Converged Health Management that will enable clinicians to collaborate with patients to manage their health between visits. Home monitoring devices collect biometric data (such as weight, blood pressure, blood glucose levels, etc.) that can be electronically sent to and analyzed by clinicians to determine when interventions are necessary. Verizon's offering enables integration with more than 30 different EHR systems that are widely deployed in provider organizations today.

Verizon also recently launched a product called Virtual Visits. Virtual Visits provides end users with a telemedicine service that allows anytime, anywhere access to a clinician using mobile technology, video conferencing, tablets, and smartphones. If a clinician's care plan includes prescriptions, the clinician will have the ability to e-prescribe to the end user's selected pharmacy as part of the service in certain states. Each end user will be routed to a "virtual clinic" of clinicians licensed and located in his or her state based on the user-provided location at the time of the visit.

Third, with Verizon's Healthcare-Enabled Services, companies can store, manage, and safeguard electronic protected health information ("PHI") in Verizon's secure hosting environment, making it easier to collaborate and coordinate care. Healthcare-Enabled Services for cloud, hosting, and colocation provide connectivity, availability, and reliability that can be prohibitively expensive for companies to manage themselves. Healthcare Enabled Services aligns with applicable Health Insurance Portability and Accountability Act ("HIPAA")<sup>1</sup> security requirements and supports a connected infrastructure to manage and exchange PHI.

As Verizon's services demonstrate, the health IT industry is at an important time in its development, but hospitals, doctors, and patients will not adopt this beneficial technology if the

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<sup>1</sup> Pub. L. 104-181, 110 Stat. 1936 (1996).

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government does not adopt clear and consistent policies that provide opportunities for all providers (new entrants and incumbents alike) to participate and compete on a level playing field. Participants in the FTC's workshop and commenters in this proceeding have provided details on the many barriers that stand in the way of innovation, including challenges involving technical, IT, clinical, regulatory, financial, legal, and reimbursement issues. Health IT innovators – and the millions of Americans they serve – need policies that promote the secure exchange of information without regard to state boundaries, a clear understanding of where regulation begins and ends, transparent approval and streamlined review processes, and timely regulatory decisions. The FTC can play a role in promoting these policies, and it is for this reason that Verizon provides these comments on the FTC's Examining Health Care Competition Project.

### **II. STATE LAWS AND POLICIES STAND IN THE WAY OF TELEHEALTH SERVICES**

The widespread adoption of online care is hampered by laws and policies that discourage telehealth visits, whether by imposing onerous cross-state physician licensure or through the patchwork of laws governing whether and under which conditions a physician can write a prescription during a telehealth visit. Many states place restrictions on providing care in states where a physician is not licensed to practice, and many states require a pre-existing provider-patient relationship in order for a valid prescription to be written. Currently only 28 states permit physicians to issue prescriptions during a telehealth visit. As telehealth visits become more broadly used, these laws and policies will need to be updated to remove barriers and accommodate the growing demand for these efficient services.

#### **A. There Are Myriad Benefits to Telehealth Services**

The potential benefits of telehealth services are well documented.<sup>2</sup> Telehealth enables doctors to provide quality medical care to patients without regard to location, addressing critical physician shortages and facilitating access to care, particularly in rural and underserved communities where socio-economic conditions or advanced age makes getting care difficult. Telehealth promotes the reduction of hospital readmission, coordination of care, and patient monitoring, which can improve outcomes. Telehealth also has a key role to play in reducing costs, which will only grow with the larger percentage of the population covered under the Affordable Care Act.

Verizon has focused its efforts with respect to telehealth in two areas: (1) partnering with private and public health-related organizations to target areas of need; and (2) developing a product called Virtual Visits that will enable clinicians to use video-conferencing to interact with a patient in an online telehealth visit. In both cases, Verizon is leveraging technology to build healthier communities.

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<sup>2</sup> Daniel J. Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospect of Practicing Globally While Regulating Locally*, 14 J. Health Care L. & Pol'y 87, 89 (2011) ("Telemedicine has the potential to improve access to health care and lowers its costs via the use of increasingly efficient and rich tools for gathering, processing, and disseminating health information.")

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### 1. Verizon employs a variety of strategies for improving the health of underserved communities.

By 2016, over 80 percent of broadband access is expected to be mobile, providing many with their first and only access to the Internet.<sup>3</sup> Such connectivity, combined with advanced, low-cost devices, provides unprecedented opportunities to empower people and improve livelihoods. Verizon is leveraging this mobility trend to create patient-centered care models that pair technology with targeted disease education programs. Empowering patients to make better health-related decisions enables improved disease management, which will result in better health outcomes.<sup>4</sup>

#### a. Children's health: connecting kids to quality health care.

In the United States, millions of children do not get the health care they need for a number of socio-economic and geographic reasons. Nearly four million children, including those with insurance, cannot get to a doctor because there is no local public transportation or the family cannot afford a car or the gas to drive it, according to the W.K. Kellogg Foundation. Couple this with the time it takes to go to the doctor, often at the expense of work hours and pay, it is no surprise that medical conditions that could be prevented or cured are left untreated, and that there is excess use of the emergency room as the primary method of care.

Children and family members across the country in need of healthcare are benefiting from an innovative partnership under which 15 of the Children's Health Fund's mobile medical clinics will be equipped with the latest health information technology from the Verizon Foundation. The partnership's national initiative launch debuted in Miami last July, with the first telemedicine-enabled mobile medical clinic for the Children's Health Fund Miami/South Florida program, which is operated by the University of Miami ("UM"). Children's Health Fund is the nation's leading pediatric provider of mobile-based health care for homeless and low-income children and their families.

The Miami pediatric mobile medical clinic enables underserved local patients to consult with specialists from the UM Health System, using UM's advanced telehealth program. The Verizon Foundation enabled the mobile clinic with a high-speed 4G LTE wireless broadband connection and upgraded telecommunications equipment that allow the clinic to provide telehealth services from any of its many delivery sites. The Children's Health Fund's "doctor's office on wheels," which travels to patients at schools, community centers, and churches in Miami-Dade County, is a lifeline for thousands of children and families that otherwise have little

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<sup>3</sup> Transformative Solutions for 2015 and Beyond: A Report of the Broadband Commission Task Force on Sustainable Development, ITU Report at 12 (<http://www.broadbandcommission.org/documents/working-groups/bb-wg-taskforce-report.pdf>).

<sup>4</sup> Verizon has developed a framework for measuring the social value of its philanthropic work. In health care, the Company is measuring changes such as increased access to providers and improved disease management in the near term and plans to measure health outcomes and health care costs over the long term. During 2013, the Company focused on implementing these health care initiatives and in 2014 will report on the shared value that Verizon is creating through this and its other philanthropic programs.

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or no access to medical care. Approximately 69 percent of the families who get their healthcare from UM physicians and staff on the mobile clinic are of Hispanic/Latino origin and 20 percent are of Haitian origin. More than 75 percent have been living in the United States for less than five years, and the vast majority – 97 percent – is uninsured, according to Children’s Health Fund.

The new telemedicine technology provides a secure, safe, and reliable platform for sharing patient information, as well as the acceleration of doctor response times and the delivery of life-saving treatments. The mobile clinic staff schedules telemedicine patient visits with specialists on specific days, so care is coordinated. As a result, adherence to referral appointments has seen a 110% increase since the program was initiated.

Patients are virtually connected with specialists through live streaming on tablets powered by Verizon’s 4G LTE network. The reliable 4G LTE broadband connectivity that links the mobile clinic to the medical center requires the installation of enterprise-grade routers and small antennas in the mobile clinic. Prior to this, healthcare professionals in the mobile clinic could not easily connect to their patients’ electronic health records to update files, order tests, review diagnoses, make referrals, or access immunization records. Telemedicine consultations were not possible. UM doctors and clinic staff now are able to upload patients’ records in real time, which can reduce medical errors and improve the quality of care for children and families.

### **b. Women’s health: empowering women to manage their care.**

Many women lead busy lives as heads of households and care givers and cannot find time to visit the doctor or take adequate care of their health. Underserved women are also diagnosed with chronic disease at greater rates and have higher mortality rates than men. If these women are struggling socio-economically, the demands of work and family combined with limited transportation, inadequate housing, and other barriers can have even more negative health consequences. To address this, Verizon is working in partnership with the Society for Women’s Health Research as well as academic health centers associated with the medical departments at Johns Hopkins University and Emory University. The focus of the partnership is on helping women with socio-economic barriers to accessing care to improve chronic disease self-management through technology. For example, a wireless glucometer for diabetes patients or a wireless weight scale for heart failure patients can transmit data to an online portal that a care manager can access, enabling clinicians and patients to work together remotely. This improves a patient’s ability to follow her clinician’s care plan and provides management of chronic conditions for better long-term outcomes.

### **c. Senior health: extending independent living.**

In partnership with several strategic Community Health Centers across the U.S., Verizon is focused on using technology to enable underserved seniors with diabetes, heart, and lung disease to age in place longer with the help of remote monitoring devices and telemedicine. The longer seniors can avoid hospitalizations and assisted care, the better their long-term health outcomes may be. In addition, the changing demographics in the senior population add increased pressure on the health care system to find innovative ways to address chronic disease

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management. Community health centers in three locations are partnering with Verizon to deploy remote biometric technology in the homes of senior patients. This will enable them to send daily readings of their blood pressure, weight, glucose, or lung capacity to a care manager. The program will also utilize tablet-enabled telemedicine to improve disease education and care plan adherence.

### **d. Global health: expanding access to care around the world.**

The Verizon Foundation, Swinfen Charitable Trust, and the University of Virginia Health System have initiated an innovative telemedicine program in rural communities in India and the Philippines. This program utilizes mobile and cloud-based technology that connects renowned physicians around the world to doctors in these communities to assist them with patient diagnoses and care. The program's expansion extends the reach of the UK-based Swinfen Charitable Trust, which currently uses telemedicine to connect clinicians at 260 hospitals in 68 developing countries, with more than 550 medical specialists around the world, including 68 at the University of Virginia.

Verizon will support the telemedicine program to be used on mobile devices, making it easier and faster for doctors to share mission-critical information with specialists. For the first time, healthcare providers in resource-limited environments will be able to access the telemedicine system from mobile devices to communicate with specialists around the world. These highly secure and reliable solutions will enable fast transfer of information; the ability to accommodate multiple, simultaneous users; GIS (geographic information systems) mapping; and other capabilities that will enhance the Swinfen Charitable Trust's current telemedicine program. Healthcare workers in developing countries who participate in the program will be able to send secure patient information to expert medical specialists – including medical images, X-rays and medical histories – through Verizon's cloud-based service.

### **2. Verizon's Virtual Visits product enables remote access to care.**

Virtual Visits is a new product that Verizon recently launched that will revolutionize access to remote care. Virtual Visits is a platform that will serve as an alternative “place-of-service” for end users to access care for simple conditions such as influenza, colds, sore throats, sinus infections, allergies, tobacco cessation, and acne. If the end user requires medical attention beyond these types of conditions, he or she will be directed to seek another method of securing access to a clinician.

The Virtual Visits platform incorporates a software-based symptoms questionnaire designed to collect and document for the clinician the symptoms that an end user may be experiencing, much like the clipboard questionnaires that are completed in the waiting room of a doctor's office. The questionnaire utilizes simple branching logic (*i.e.*, the follow-up question asked is dictated by the response to the prior question) as it prompts the end user to answer a series of questions to ascertain the reason for virtual visit and the end user's symptoms. The clinician reviews the collected content prior to visiting with the end user. The questions and corresponding end user answers are presented to the healthcare provider in a summary narrative format. Using the video-conferencing capabilities of Virtual Visits, the clinician can interact

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with the end user to fill in any gaps in information needed to complete his or her assessment of the end user. The clinician is responsible for determining if he or she has enough information to render care consistent with applicable standards of care, and any resulting care plan.

### **B. Despite the Benefits of Telehealth Services, Outmoded State Regulatory Regimes Create Barriers to Adoption**

Telehealth services, by their nature, can facilitate the exchange of information across state lines and around the world. Yet existing laws unduly impede the ability of providers to use technology even as simple as email and text messaging when they are treating their patients. In many states, doctors must seek full medical licensure to provide telehealth services to a patient not present in the doctor's home state, even, for example, when that individual is a long-standing patient on vacation.<sup>5</sup> And even when a physician has been able to hold a telemedicine consultation that results in the need for the patient to receive a prescription, many states do not permit the physician to issue a prescription or require a prior patient-doctor relationship before the doctor can issue the prescription even if such a prior relationship would not be required for the doctor to write the same prescription in person.<sup>6</sup> Non-reciprocal state licensing requirements and the patchwork of licensing requirements that exist across the states increase regulatory costs and stand as a barrier to expansion of efficient and advantageous telemedicine services.<sup>7</sup>

In a current example of state activity that could be harmful to telemedicine, the Tennessee Board of Medical Examiners ("Board") recently issued a notice of rulemaking hearing requesting input on telemedicine practice guidelines.<sup>8</sup> Despite the fact that the Tennessee General Assembly recently passed a telehealth parity bill for private insurance, Medicaid, and state employee plans, the Board's proposal would create additional barriers and more stringent standards for all physicians practicing telemedicine in Tennessee. For example, among other things, the Board's proposal: (1) requires a face-to-face examination before a telemedicine encounter if there is no existing relationship; (2) requires a health care provider to be present with the patient during a telehealth visit; and (3) ceases the issuance of "telemedicine licenses" to out-of-state providers and requires all physicians to be fully licensed in Tennessee.

State medical boards and legislatures currently control access to national telehealth services, and technology companies are forced to design their services to avoid issues with physician licensure and e-prescribing, resulting in inefficiencies and cost. For example, to comply with outmoded state regulations, Verizon's Virtual Visits product prevents a call from an

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<sup>5</sup> See, e.g., AK Stat. 08.64.170; 200; IA Code 147.2; 32 M.R.S.A. 3270; N.J.S.A. 45:9-6; 45:9-21; 26 V.S.A. 1314.

<sup>6</sup> According to our research, 29 states prohibit the issuance of a prescription by a physician solely on the basis of a patient's answer to an Internet or electronic questionnaire. Fifteen states and the District of Columbia prohibit the issuance of a prescription on the basis of a telemedicine visit by either requiring an in-person visit or prohibiting the issuance of a prescription based on an Internet consultation. Twenty-nine states require a pre-existing patient-provider relationship prior to issuance of a prescription. Only six states either expressly permit or do not otherwise specifically place restrictions on the issuance of a prescription in a telemedicine visit, including Maryland, New Mexico, North Carolina, South Dakota, Utah, and Wisconsin.

<sup>7</sup> Gilman, *supra* note 1, at 105, *citing* U.S. Dep't of Commerce & U.S. Dep't of Health & Human Servs., Telemedicine Report to Congress (1997).

<sup>8</sup> Tennessee Board of Medical Examiners, Chapter 0880-02, Rule 0880-02- 16, General Rules and Regulations Governing the Practice of Medicine; Telemedicine Licensure (Feb. 11, 2014).



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end user from being routed to a clinician in a different state from where the patient is located. The patient provides information about his or her location, and if the platform determines that a clinician is not available in that state, then Virtual Visits informs the patient that service in his or her location is not currently available. These limitations have forced Verizon to find virtual clinician networks that have broad access to physicians in all states and that understand the regulatory environment for each state. This can be difficult for virtual clinician networks because it requires them to offer clinicians in states where there may not be sufficient demand even though they may not be able to offset their costs or compensate their clinicians equitably. The effect of this is that patients may not be adequately served or have access to specialists that match their individual needs, which could be one of the key benefits of telemedicine services. Ironically, these barriers to adoption mean that oftentimes specialists in a state find it easier to offer their expertise to patients in India and elsewhere in the world than to patients in need of their care in neighboring underserved U.S. states.

Likewise, without the ability to issue a prescription in all cases where it is appropriate, services like Virtual Visits become less valuable and may not be adopted as readily. End users that need a prescription but cannot receive one using the service are less likely to use the service again if they are told during a visit that this is not possible. Physicians should be able to use their judgment about whether they need to see a patient in person in order to issue a prescription, and it is not clear why this should vary by state. As set forth below, there are a variety of approaches to creating an environment more conducive to telemedicine.

### **C. FTC Should Urge Policymakers to Discard Outdated State Laws that Impede Competition in Telemedicine**

The success of telemedicine as a service hinges upon enhancing licensure portability and expanding access to the ability to issue a prescription during a telemedicine visit. Verizon has supported Federal telemedicine legislation that seeks to expand the availability of telemedicine within Federal programs, as well as legislation to change interstate licensing laws for Medicare providers.<sup>9</sup> Verizon also notes that the Federation of State Medical Boards (“FSMB”) has recognized that licensure must evolve to support the national telemedicine trend. Verizon believes that a state compact similar to the Nurse Licensure Compact in FSMB’s proposal to adopt one full, unrestricted telemedicine license that is processed through a commission or clearinghouse is a good first step. Although such a step would create an improved regulatory environment than in existence today, a better approach would be 50-state reciprocity that could be recognized by each state legislature. Although FSMB’s proposal would expedite physician licensing for telemedicine, it would still require doctors to seek an additional license, which is

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<sup>9</sup> Among the bills currently being considered in Congress are: (1) VETS Act of 2013, H.R. 2001, introduced May 15, 2013 (improves the ability of Veterans Administration health care professionals to treat veterans by telemedicine); (2) TELE-MED Act of 2013, H.R. 3077, introduced Sept. 10, 2013 (allows Medicare providers to treat Medicare patients electronically across state lines without the need to obtain multiple state licenses); (3) Telehealth Enhancement Act of 2013, H.R. 3306, introduced Oct. 22, 2013 (authorizes an accountable care organization to include coverage for telehealth and promote remote patient monitoring services as supplemental health care benefits); and (4) The Telehealth Modernization Act of 2013, H.R. 3750, introduced Dec. 12, 2013 (sets forth Federal conditions that states may adopt for the delivery of health care through telehealth by a health care professional).

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duplicative and unnecessary, particularly if the state compact defines the standards and scope of care for telemedicine.

The FTC can support this debate by impressing upon policymakers that competition issues such as the barriers to entry posed by antiquated state laws must be considered when they are contemplating approaches to telemedicine policy. The FTC's recent report on the regulation of advanced practice nurses raises some of the same concerns relevant to the telemedicine issue: that (1) consumer access to safe and effective health care is of critical importance; (2) licensure and scope of practice regulations can help to ensure treatment by properly trained professionals; (3) health care quality, competition, and regulatory failures can have serious health and safety consequences; (4) potential competitive effects can be especially striking in underserved areas; (5) effective collaboration among clinicians is important; (6) scope of practice limitations should be narrowly focused to address well-founded health and safety concerns; and (7) it is necessary to define safety and quality evidence to determine whether legitimate safety concerns may exist and whether regulatory intervention is necessary.<sup>10</sup> Advocacy along these lines on the topic of telemedicine and physician licensure requirements would play an important role in educating lawmakers about the need to modernize outdated laws that stand in the way of competition.

### **III. THE LACK OF INTEROPERABILITY BETWEEN ELECTRONIC HEALTH RECORDS IMPEDES COMPETITION**

In the future, patients and clinicians should be able to exchange information securely and seamlessly through communications networks, and this information should be able to be stored in a secure cloud environment that is accessible with the right privacy protections through interoperable technologies. EHRs are increasingly being adopted by clinicians, hospitals, and other providers across the United States due in large part to considerable Federal investments in such technologies. Health IT and the electronic sharing of information across the various settings play a critical role in improving the coordination, quality, safety, and cost of health care. New modes of delivery and payment that focus on outcomes and efficiency will rely heavily on health IT. Despite Federal investments and increasing levels of adoption of EHRs among hospitals and office-based physicians, however, the level of interoperability and information sharing across disparate systems remains low.

In 2009, President Obama signed the American Recovery and Reinvestment Act, which created through the Health Information Technology for Economic and Clinical Health ("HITECH") Act<sup>11</sup> incentives for the meaningful use of certified electronic health records. Under the incentive program, eligible professionals can qualify for Medicare and Medicaid incentive payments when they adopt certified EHR technology and use it to achieve certain objectives. Congress created the program to support several complimentary goals – chief among them to reduce healthcare costs, increase efficiencies between health care providers, and improve the quality of care.

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<sup>10</sup> *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses*, Federal Trade Commission at 34 (March 2014).

<sup>11</sup> Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act, Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009), *codified at* 42 U.S.C. §§ 300jj *et seq.* and §§ 17901 *et seq.*

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The requirements that are imposed with respect to certification of EHRs and their meaningful use suggest the importance of interoperability. For example, the HITECH Act amendments to the Social Security Act place three general requirements on an eligible provider or hospital to be a “meaningful EHR user”: (1) meaningful use of certified EHR technology; (2) information exchange, which requires that the eligible professional or eligible hospital “demonstrate[] to the satisfaction of the Secretary . . . that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination”; and (3) reporting on measures using EHRs.<sup>12</sup>

Similarly, the law highlights the importance of standards. The role of the Office of the National Coordinator for Health IT (“ONC”) with respect to the adoption of standards for health information technology, including EHRs, is described as “perform[ing] the duties [of the National Coordinator, including endorsement of standards, etc., for the electronic exchange and use of health information] in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information” to accomplish a list of purposes/objectives, many of which entail the successful exchange of information, including, for example: (1) “reduc[ing] health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information,” and (2) “improv[ing] the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information.”<sup>13</sup>

Unfortunately, in adopting a staged approach in defining what amounts to “meaningful use,” the ONC and Centers for Medicare and Medicaid Services (“CMS”) have focused more on providing incentives for the purchase of new technologies than on the ability of different software systems to “talk” to one another.<sup>14</sup> Without adequate incentives to deploy systems that allow the free exchange of information and rules that prohibit information blocking, technology companies that seek to connect innovative services to EHRs face high barriers in developing products that promote efficiency, convenience, access, and coordination of care. Doctors cannot obtain vital information because the systems they use are not operable with other technologies. Without robust standards for interoperability, patients and doctors cannot benefit from coordinated care across the health care spectrum, resulting in a fragmented health care system that limits collaboration between medical professionals. Without the free flow of information, physicians may rely on inaccurate, incomplete, or outdated patient treatment plans, needlessly

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<sup>12</sup> Social Security Act §§ 1848(o)(2)(A) (Medicare providers), 1886(n)(3)(A) (Medicare hospitals), 42 USC §§ 1395w-4(o)(2)(A), 1395ww(n)(3)(A). (States are required to impose requirements similar to those imposed on Medicare providers and hospitals (under the above noted provisions) in the Medicaid EHR Meaningful Use Incentive Program. SSA § 1903(t)(6)(C), 42 USC § 1396b(t)(6)(C).)

<sup>13</sup> Public Health Service Act, § 3001(a) & (c); 42 USC § 300jj-11(a) & (c). Regulations adopted by ONC (certification of EHR technology) and CMS (meaningful use of certified EHR technology) implement these requirements with respect to electronic exchange of health information.

<sup>14</sup> Senators Thune, Alexander, Rogers, Burr, Coburn, and Enzi, *Reboot: Re-Examining the Strategies Needed to Successfully Adopt Health IT* at 11 (April 16, 2013). HHS is expected to take comments on the third stage of “meaningful use” later this year.

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repeating services like laboratory and radiology tests, prescribing medications that may not be needed (or worse, resulting in negative interactions with other prescribed medications), and ultimately increasing the cost of health care.

Given the proliferation of non-standard technology, there have been concerns raised, including those referenced at the FTC workshop, that closed data networks are trapping patients and providers in proprietary networks.<sup>15</sup> FTC should investigate any claims of unlawful information blocking and promote policies of openness in business models and standards setting contexts. Open business practices that permit the ready exchange of data are critical in this emerging area.

Even when information is not proactively being blocked, non-standard technology can still be an issue. Verizon's CHM product has the capability to integrate with EHR systems to populate EHRs with biometric data collected from home monitoring devices, but its ability to do that effectively is impeded by the lack of standards governing how biometric values from remote monitoring devices will be displayed or where the information will be stored in EHRs. In addition, there are thousands of healthcare support systems that all need to be integrated into EHRs. As a result, care providers have two options when they seek to integrate. They can custom-integrate their systems individually with all of the systems they support, or they can work with an integration "engine" that enables the care provider to focus on one communication protocol while the integration engine manages the communications with other support systems. The majority of care providers choose the second option, but even with the services of such an integrator, the typical time to integrate with an EHR is between 14 and 24 weeks. All care providers have highly customized EHR systems, meaning that no two implementations are the same, resulting in new costs for each implementation. Verizon has had to hire the services of a systems integrator for its CHM product, adding a costly and inefficient layer that could have been avoided had there been standards in place to facilitate the exchange of information. This has clear implications for consumer welfare.<sup>16</sup>

Standardization and increasing requirements for interoperability are necessary to promote the growing market for the exchange of personal health records. As the FTC and DOJ have explained, standards make networks "more valuable by allowing products to interoperate."<sup>17</sup> Providers must be able to locate, retrieve, or determine whether the patient information is up to date or accurate and still qualify for incentive payments. Information blocking practices devalue the utility of EHRs and should have no place in a taxpayer-financed incentive program. The FTC should provide input to policymakers such as ONC and CMS on how standardization and interoperability can promote competition.

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<sup>15</sup> For example, at the FTC workshop, Dan Haley, Vice President of Government and Regulatory Affairs at athenahealth, talked about the need for information fluidity in a market where there are market disincentives for providers to share data.

<sup>16</sup> See, e.g., U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 36 & n. 17 (2007).

<sup>17</sup> *Id.* at 33.

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### IV. THE HEALTH IT INDUSTRY NEEDS CLARITY ON WHEN REGULATION BEGINS AND ENDS

Innovation is a key driver of improvements in health care, both in terms of improved outcomes and cost reduction. There should be no doubt that technology can disrupt markets and strain traditional regulatory frameworks. Technology can support a broad array of services that promote patient care, reduce costs, and improve health outcomes, but not if the marketplace is hampered by an outmoded or overly burdensome regulatory framework. Government policies should encourage the development of new, innovative healthcare services and avoid the creation or continuation of roadblocks to them.

Many of the exciting health care solutions in the future will use wireless technologies. Mobile technologies have the potential to put tools in the hands of end users, including those in remote areas and underserved communities, who can use them in everyday life. Creating the right regulatory regime for mobile health products, along with rules to ensure the doctors are able to use them, is therefore critically important to ensuring that innovative products are given a chance to cut costs and improve lives. While healthcare products and services do require some degree of evaluation in order to protect consumers, the government should endeavor to ensure that regulatory burdens do not discourage innovative approaches to solving health issues in this important area.

Verizon believes that any regulatory framework for health IT should be tailored appropriately and based on the potential risk of patient harm caused by the use of the device, software, or application. Different technologies contain different degrees of patient risk and should therefore be subject to varying degrees of regulation. For example, while an informational database containing patient identifiable medical records could potentially create privacy and security risks, the possibility of actual harm to patient safety is relatively low, so regulation should be minimal. Conversely, systems that control the physiology of a patient have the potential to cause serious patient harm and should be regulated more stringently. If the FDA were to impose costly and burdensome medical device regulation on the informational database, or impose regulation on some providers but not others of this type of service for reasons that had nothing to do with patient safety, this would impede competition and harm the marketplace for this type of service.

#### A. FDA Medical Device Regulation is in Need of Reform.

As a relatively new entrant in the health IT market, Verizon has come to learn how challenging it is to navigate the existing health IT regulatory environment. Innovators need clarity on when they are subject to FDA regulation because of the significant burdens and uncertainty that come with FDA medical device regulation. For example, even if a product could be considered a medical device under the Food, Drug, and Cosmetic Act (“FDCA”),<sup>18</sup> it

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<sup>18</sup> 21 U.S.C. § 321(h). In relevant part, the FDCA defines a device to include: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is... (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through

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may not be clear what type of regulation will apply until the applicant has engaged in a complex analysis of the function, advertising, labeling, and intended use of the product because, under Federal law, the same product may be regulated differently depending on how it is marketed and sold.<sup>19</sup> In Verizon's experience, the FDA regulatory process can require a company to substantially revise its product during a filing cycle given the uncertainty surrounding the process, causing substantial delays to market. This uncertainty is heightened due to the emergence of exciting new technologies never contemplated by existing laws.

The level of FDA review also varies. The more novel and potentially impactful on patient health and diagnosis or treatment of a disease that a product regulated as a medical device is, the more onerous and lengthy the FDA review will be. If the product is brand new, with no similar precedential products that the FDA has approved in the past, the clearance process, called *de novo* review, can take years. If a product is subject to the clearance process, the company developing the product has to submit details about the product, including testing and other data, to the FDA, and the company has to refrain from marketing the service until it receives FDA clearance. Moreover, the company has to put in place complex physical, technical and administrative safeguards to secure patients' protected health information under HHS HIPAA regulations and develop process management procedures called a quality management system to comply with FDA regulations.

Given the burden that FDA regulation entails, more clarity is needed to define the types of functions that fall within the FDA's regulatory purview. In recognition that the industry needs more certainty, the FDA issued nonbinding Mobile Medical Applications Guidance on September 25, 2013.<sup>20</sup> The MMA Guidance provided a series of examples of the types of mobile apps that would not be subject to FDA regulation, those that are the focus of FDA's oversight, and those over which FDA plans to exercise enforcement discretion.

Although FDA is clearly the expert agency charged with regulating medical devices, the FTC has an important voice in the discussion of the regulatory framework for health IT. Just as business models and standardization should not stand in the way of a robust market for electronic health records, unnecessary FDA regulation of software and applications should not serve as a barrier to entry for innovation. In the MMA Guidance and elsewhere, the FDA has interpreted the definition of "medical device" expansively to apply to evolving new products and technologies likely never envisioned upon enactment and/or amendment of the definition in the FDCA. Under its statutory authority, the FDA must limit regulation to products that diagnose or treat disease. Yet, as one example, FDA has stated in the MMA Guidance that regulation should apply to the simple transfer of medical device data from one system to another,<sup>21</sup> which has a tangential role at best in the diagnosis or treatment of disease. Application of the medical device definition to products should be as narrow as possible for health care devices that present low or minimal risk of harm to users. Otherwise, the FDA may unintentionally discourage valuable

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chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

<sup>19</sup> Under 21 C.F.R. § 801.4, intended use may be shown by labeling, claims, advertising, or oral or written statements by manufacturers or their representatives.

<sup>20</sup> Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (Sept. 25, 2013) ("MMA Guidance").

<sup>21</sup> *Id.* at 28.

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innovation and application of helpful emerging technologies in a manner that is well beyond what is reasonably necessary to protect consumers.

### **B. Government Efforts to Clarify and Reform FDA Regulatory Authority Should Continue**

Recognizing that it might be time to reform the regulation of health IT, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act (“FDASIA”) to revise and extend the user-fee programs for prescription drugs and medical devices, to establish a user-fee program for generic drugs, and for other purposes.<sup>22</sup> Section 618(a) of FDASIA directed the Department of Health and Human Services (“HHS”), acting through the FDA and in consultation with ONC and the Federal Communications Commission (“FCC”) (collectively the “Agencies”), to publish a report to Congress outlining recommendations for a policy framework for regulating health IT (the “Report”). As authorized by FDASIA, to assist the Agencies in preparing the Report, and pursuant to direction from the Secretary of HHS, ONC formed a workgroup under its Health IT Policy Committee referred to as the FDASIA Workgroup. On April 3, 2014, the Agencies published the Report, which proposes a strategy and recommendations on an appropriate risk-based regulatory framework for health IT, including mobile medical applications, which will promote innovation, protect patient safety, and avoid regulatory duplication.<sup>23</sup>

In the Report, the Agencies suggest a number of strategies to promote innovation and ensure patient safety, including ways to foster the development of public and private sector practices around safety and quality, leveraging standards and best practices, employing industry-led testing and certification, and using tools such as voluntary listing, reporting, and training to promote transparency and positive outcomes.<sup>24</sup> The Agencies have identified three categories of health IT: 1) administrative health functions, (2) health management health IT functions, and (3) medical device health IT functions.<sup>25</sup>

Prior to the issuance of the Report, two bills were introduced, one in the House and one in the Senate, that each seek to add clarity to the FDA’s regulatory process. The Sensible Oversight For Technology Which Advances Regulatory Efficiency (“SOFTWARE”) Act, H.R. 3303 (introduced Oct. 27, 2013), would amend the FDCA to apply it to medical software to the same extent and in the same manner as it applies to devices. The SOFTWARE Act defines three categories of software: medical software, clinical software, and health software. Subsequently, Senators Fischer, King, and Rubio introduced the Preventing Regulatory Overreach To Enhance Care Technology (“PROTECT”) Act of 2014, S.2007 (introduced Feb. 10, 2014), which would focus FDA’s attention on technologies that pose the greatest health risk. The PROTECT Act creates two new categories, (1) clinical software, and (2) health software. These bills have continued the discussion started by FDASIA on how to reform the regulation of the innovative products that are possible given the advent of new technology.

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<sup>22</sup> Pub. L. 112-144, 126 Stat. 993 (2012).

<sup>23</sup> *FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework*, FDA, FCC, and ONC (April 3, 2014).

<sup>24</sup> *Id.* at 3.

<sup>25</sup> *Id.*

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Verizon supports the efforts of the Agencies and Congress to define the scope of the appropriate regulatory authority of the FDA. The various efforts of FDA, the Agencies, and Congress represent positive momentum toward policies that will foster pro-innovation, pro-consumer outcomes, eliminating barriers to health IT where they exist and modernizing regulations to enable health IT to keep pace with emerging technologies and to accelerate advances in improving patient care. Given that the process for reforming FDA's regulatory structure has only begun, it is timely for the FTC highlight concerns about the barriers to entry facing new entrants in the mobile medical application marketplace. The FTC may wish to consider coordinating with the Agencies and lawmakers – perhaps via comments on the Report -- to make sure they consider competition issues as they develop the regulatory framework that will govern health IT.