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FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20580

Office of Policy Planning  
Bureau of Competition  
Bureau of Economics  
Bureau of Consumer Protection

April 3, 2015

Dr. Karen B. DeSalvo  
National Coordinator for Health Information Technology  
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: Shared Nationwide Interoperability Roadmap DRAFT Version 1.0

Dear Dr. DeSalvo:

The staff of the Federal Trade Commission's ("FTC") Office of Policy Planning, Bureau of Competition, Bureau of Consumer Protection, and Bureau of Economics<sup>1</sup> submits this comment to the Office of the National Coordinator for Health Information Technology ("ONC") in response to ONC's call for public comments<sup>2</sup> regarding its draft Shared Nationwide Interoperability Roadmap ("Roadmap").<sup>3</sup>

FTC staff supports the development of the Roadmap, which lays out a ten-year plan to increase the adoption of interoperable health information technology systems ("health IT"). Increasing interoperability may foster innovation and competition in both health IT and health care. The FTC has a long history of engaging in study, enforcement, and advocacy regarding the potential competitive effects of interoperability and standardization. Based on this expertise, we offer several competition points for ONC to consider as it finalizes and implements the plan laid out in the Roadmap regarding: (1) creation of a supportive business environment that encourages interoperability; (2) shared governance mechanisms; and (3) the advancement of technical standards. Increased interoperability, accomplished through standardization, has benefited competition in

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<sup>1</sup> These comments reflect the views from the staff in the FTC's Office of Policy Planning, Bureau of Competition, Bureau of Consumer Protection, and Bureau of Economics. The letter does not necessarily represent the views of the FTC or of any Commissioner. The Commission has, however, voted to authorize staff to submit these comments.

<sup>2</sup> Office of the Nat'l Coordinator for Health Info. Tech., Interoperability Roadmap Public Comments, <http://www.healthit.gov/policy-researchers-implementers/interoperability-roadmap-public-comments> (last visited April 1, 2015).

<sup>3</sup> OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., SHARED NATIONWIDE INTEROPERABILITY ROADMAP DRAFT 1.0 (2015) [hereinafter *Roadmap*], available at <http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf>.

many industries. We respectfully suggest that ONC consider how best to promote competition and innovation when taking steps to speed the adoption of interoperability standards in the marketplace. In addition, as a federal agency that enforces numerous privacy and data security laws, the FTC has extensive experience related to the privacy and security of consumer data and appreciates the opportunity to provide comments on those issues as well.

## **I. INTEREST AND EXPERIENCE OF THE FTC**

The FTC is an independent administrative agency responsible for maintaining competition and protecting consumers. The FTC has a long history of promoting competition in health care markets through a full range of study, enforcement, and advocacy activities. The FTC continues to monitor the impact of the development and introduction of new health IT technologies on competition in the health care industry. In March 2014, the FTC held the first workshop in an “Examining Health Care Competition” series. One panel focused entirely on advancements in health care technology, including electronic health records and health data exchanges.<sup>4</sup> In February 2015, the FTC and the Antitrust Division of the U.S. Department of Justice co-hosted the second workshop in the series. The 2015 workshop focused on recent developments in health care provider and payment models, many of which relate to and are influenced by concurrent health IT developments.<sup>5</sup>

In addition to its experience in health care, the FTC has a long history of examining the role of standardization and interoperability in high technology markets, with a particular emphasis on competitive and innovation effects. The Commission has applied its study, policy, and advocacy expertise to collaboratively set standards for over thirty years.<sup>6</sup> For example, the FTC has studied competition issues relating to interoperability in networked industries<sup>7</sup> and considered how the evolution of interoperable technology can impact consumers of information technology.<sup>8</sup> The FTC also has studied competition in markets shaped by interoperability, such as business-to-business (“B2B”) electronic marketplaces<sup>9</sup> and the deregulated market for electricity.<sup>10</sup> Most recently, the FTC has studied the impact of patented technologies on the

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<sup>4</sup> See Fed. Trade Comm’n, Event Description, Workshop on Examining Health Care Competition (March 20-21, 2014), <http://www.ftc.gov/news-events/events-calendar/2014/03/examining-health-care-competition>.

<sup>5</sup> See Fed. Trade Comm’n, Event Description, Workshop on Examining Health Care Competition (Feb. 24-25, 2014), <http://www.ftc.gov/news-events/events-calendar/2015/02/examining-health-care-competition>.

<sup>6</sup> See, e.g., FED. TRADE COMM’N BUREAU OF CONSUMER PROT., FINAL STAFF REPORT: STANDARDS AND CERTIFICATION (1983) [hereinafter *1983 Standards Report*]; Brief for United States & Fed. Trade Comm’n as Amici Curiae Supporting Respondent, *Allied Tube & Conduit Corp. v. Indian Head, Inc.* 486 U.S. 492 (1987) (No. 87-157); *In re American Society of Sanitary Engineering*, 106 F.T.C. 324 (1985).

<sup>7</sup> See FED. TRADE COMM’N STAFF, ANTICIPATING THE 21ST CENTURY: COMPETITION POLICY IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE (1996) [hereinafter *1996 Competition Policy Report*].

<sup>8</sup> FED. TRADE COMM’N STAFF, PROTECTING CONSUMERS IN THE NEXT TECH-ADE (2008).

<sup>9</sup> FED. TRADE COMM’N STAFF, ENTERING THE 21ST CENTURY: COMPETITION POLICY IN THE WORLD OF B2B ELECTRONIC MARKETPLACES (2000).

<sup>10</sup> See, e.g., FED. TRADE COMM’N STAFF, COMPETITION AND CONSUMER PROTECTION PERSPECTIVES ON ELECTRIC POWER REGULATORY REFORM (2000).

interoperability standards prevalent in the telecommunication industry.<sup>11</sup> Moreover, in several cases, the FTC has brought enforcement actions against parties based upon misrepresentations made during the standard setting process.<sup>12</sup>

On the consumer protection side, the FTC has a long history of engaging in enforcement, research, and education regarding the privacy and security of consumer data. For example, the FTC has brought numerous cases against businesses alleging deceptive and unfair practices with regard to the privacy and security of health data.<sup>13</sup> In addition, the FTC enforces the health breach notification provisions of the HI-TECH Act.

FTC staff also regularly holds workshops to examine the implications of new technologies and business models on consumer privacy and security, including the privacy and security of sensitive health information. For example, in November 2013, FTC staff held a workshop on the Internet of Things,<sup>14</sup> and in May 2014, FTC staff held a seminar on Consumer Generated and Controlled Health Data. Participants at these events discussed the privacy and security implications of connected health and fitness devices and the myriad other ways in which consumers generate and manage their health data, including through personal health records and mobile health apps. Such events raise awareness of the privacy and security concerns associated with health data – especially outside of traditional medical contexts, where consumer-facing products and services may not be covered by the Health Insurance Portability and Accountability Act (“HIPAA”).

At ONC’s invitation, the FTC participates on the Federal Health IT Advisory Council that develops the Federal Health IT Strategic Plan. FTC staff also regularly collaborates with ONC staff to identify potential competition issues relating to health IT platforms and standards, as well as on privacy and security issues.<sup>15</sup>

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<sup>11</sup> FED. TRADE COMM’N, THE EVOLVING IP MARKETPLACES: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION (2011); FED. TRADE COMM’N AND U.S. DEP. JUSTICE, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (2007) [hereinafter 2007 *IP Report*].

<sup>12</sup> See, e.g., Complaint, *In re Dell*, 121 F.T.C. 616, 616-18 (1996) (No. C-3658) (resolved by consent order, 121 F.T.C. at 618-26); Complaint, *In re Rambus, Inc.*, No. 9302 (F.T.C. June 18, 2002); Complaint, *In re Union Oil Co. of Cal.*, No. 9305 (F.T.C. Mar. 4, 2003) (resolved by consent order, No. 9305 (F.T.C. July 27, 2005)).

<sup>13</sup> See, e.g., *PaymentsMD, LLC*, File No. 132-3088 (F.T.C. Jan. 27, 2015) (final decision and order), available at <https://www.ftc.gov/enforcement/cases-proceedings/132-3088/paymentsmd-llc-matter> (alleged collection of consumers’ personal medical information without their consent); *Rite Aid Corporation*, File No. 072-3121 (F.T.C. Nov. 12, 2010) (final decision and order), available at <https://www.ftc.gov/enforcement/cases-proceedings/072-3121/rite-aid-corporation-matter>; *CVS Caremark Corporation*, File No. 072-3119 (F.T.C. June 18, 2009), available at <https://www.ftc.gov/enforcement/cases-proceedings/072-3119/cvs-caremark-corporation-matter> (set of cases, brought in collaboration with the U.S. Department of Health and Human Services Office for Civil Rights, involving faulty data security practices that implicated both the HIPAA and the FTC Act).

<sup>14</sup> See Fed. Trade Comm’n, Event Description, Workshop on Internet of Things: Privacy & Security in a Connected World (Nov. 19, 2013), <http://www.ftc.gov/bcp/workshops/internet-of-things/>.

<sup>15</sup> For example, FTC staff is working with ONC to develop joint guidance for health-app developers to help them incorporate reasonable privacy and data-security protections into their apps. In addition, at ONC’s

We appreciate ONC's willingness to seek input from the FTC and other federal agencies when developing its vision for the future of health IT. FTC staff submits these comments in support of those continuing efforts.

## **II. BACKGROUND**

The Roadmap lays out ONC's vision for a future health IT ecosystem where electronic health information can be freely exchanged between the different health IT systems employed by consumers, health care providers, and public health practitioners.<sup>16</sup> This ecosystem will comprise an array of interoperable health IT products and services.<sup>17</sup> According to ONC, the realization of interoperability is expected to result in lower health care costs, improved population health, empowered consumers and ongoing innovation.<sup>18</sup> ONC observes that the lack of interoperability between existing health IT systems frustrates the realization of these benefits.<sup>19</sup>

The Roadmap presents a plan to achieve industry adoption of an interoperable ecosystem within ten years,<sup>20</sup> based on proposed actions to be taken by both public and private stakeholders.<sup>21</sup> The plan lays out incremental three and six year goals, beginning with the goal of enabling a majority of individuals and providers nationwide to exchange and use a defined common set of electronic clinical information by the end of 2017.<sup>22</sup>

The Roadmap asserts that the consistent implementation and use of interoperability standards is "foundational" for the timely maturation of an interoperable health IT ecosystem.<sup>23</sup> The use of standardized data formats, for example, would be necessary for different systems to exchange information; as the Roadmap explains, "while a health professional would readily understand that 'Tylenol' and 'acetaminophen' are used synonymously; two computer systems exchanging those phrases may treat the terms entirely different, if not bound to a standardized vocabulary or terminology."<sup>24</sup> As the Roadmap indicates, this problem can be overcome by the use of interoperability standards that dictate common data formats.<sup>25</sup> Today, several different standard setting organizations ("SSOs") develop and maintain health IT standards.<sup>26</sup>

Facilitating standardization is one of four immediate actions that the Roadmap proposes: (1) establish a coordinated governance framework and process for nationwide health IT interoperability; (2) improve technical standards and implementation guidance

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invitation, FTC staff currently participates as ex officio members of the Health IT Policy Committee, Privacy and Security Workgroup, which, among other things, is providing input on the Roadmap.

<sup>16</sup> See *Roadmap*, *supra* note 3, at 17.

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

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 8-11.

<sup>20</sup> *Id.* at 4.

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

<sup>22</sup> *Id.* at 10, 25.

<sup>23</sup> *Id.* at 77.

<sup>24</sup> *Id.* at 79.

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

<sup>26</sup> *Id.* at 80.

for sharing and using a common clinical data set; (3) enhance incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarify privacy and security requirements that enable interoperability.<sup>27</sup>

### **III. DISCUSSION**

FTC staff agrees that successful adoption of ONC’s vision has the potential to benefit patients and providers by facilitating innovation and fostering competition in both health IT and health care services markets. Whether these potential benefits will be realized will depend, in large part, on how the Roadmap’s plan is implemented. Drawing on the FTC’s study, enforcement, and advocacy experience regarding the impact of standardization and interoperability on competition, FTC staff offers the following comments to guide ONC’s implementation of three specific aspects of its plan:

- creation of a supportive business and regulatory environment that encourages interoperability;
- shared governance mechanisms; and
- the advancement of technical standards.

In addition, drawing on its experience in consumer protection and privacy, FTC staff offers several comments regarding the privacy and security aspects of the Roadmap.

#### **A. A Supportive Business Environment**

Staff commends ONC for addressing health IT system interoperability. The Roadmap examines the current state of the market and observes that, “despite strong agreement” on the benefits of interoperability, the current market has not yet achieved that goal.<sup>28</sup> The Roadmap acknowledges “countervailing market forces and structural attributes of the health care system” that present challenges to interoperability, and identifies several business and financial incentives that may hinder adoption of interoperable technologies.<sup>29</sup>

The Roadmap notes two interests that, FTC staff agrees, may warrant further consideration:

- (1) Health care providers may resist increased interoperability, which “could also enable individuals and their caregivers to more easily change care providers and transfer electronic health information among providers, thereby reducing providers’ competitive advantages;” and

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<sup>27</sup> *Id.* at 11.

<sup>28</sup> *Id.* at 37.

<sup>29</sup> *Id.* at 38.

- (2) Health IT vendors may favor “a status quo characterized by high costs to switch products and services, greater lock-in and reduced data portability.”<sup>30</sup>

Given that marketplace adoption of interoperable health IT systems will require participation from both of these groups of market participants, ONC may wish to further consider whether, and to what extent, the economic interests of each align with the benefits of interoperability. ONC may also wish to further examine whether, and to what extent, these forces already have delayed the adoption of interoperable health IT systems, despite the potential consumer benefits of interoperability.

In addition, the Roadmap observes that “the fragmented nature of the health care marketplace poses fundamental challenges to interoperability.”<sup>31</sup> This fragmentation may present challenges in coordinating the activities of health IT providers and users. ONC should anticipate any such difficulty, along with other potential challenges such as motivating providers to overcome short-term costs in order to realize the long-term benefits of interoperability, as it implements its plan.

One strategy proposed in the Roadmap is to utilize policy and funding levers to create a business imperative and clinical demand for interoperability.<sup>32</sup> To this end, the Roadmap proposes that health care payers, including federal and state governments, can overcome marketplace resistance by shifting from a “fee-for-service” payment model to a “value-based payment” program.<sup>33</sup> This shift in payment methodology could provide greater incentives for health care providers to improve quality while minimizing costs and increasing efficiency.<sup>34</sup> Providers would achieve these goals, in part, by relying on interoperable health IT to better coordinate care, eliminate duplicative services, measure clinical outcomes, and otherwise facilitate more efficient care delivery. Vendors would, in turn, respond to this increased demand for interoperability by developing and offering health IT systems that meet this market demand.

While the success of this approach will depend on its implementation as well as market characteristics, FTC staff notes that competition and market forces typically are the best way to foster innovation. We therefore encourage the federal government, in its capacity as a market participant (*i.e.*, a major payer), to make an effort to align economic incentives to create greater provider demand for interoperable health IT, thereby incentivizing health IT vendors to compete on the basis of interoperability.

## **B. Shared Governance of Policy and Standards that Enable Interoperability**

The Roadmap explains that the successful implementation of an interoperable health IT ecosystem will require common governance of a number of standards, services,

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<sup>30</sup> *Id.* at 38.

<sup>31</sup> *Id.* at 38.

<sup>32</sup> *Id.* at 37.

<sup>33</sup> *Id.* at 39-42.

<sup>34</sup> *Id.* at 39.

policies, and practices.<sup>35</sup> The Roadmap proposes to promote a cooperative governance approach that will be inclusive of both public and private actors.<sup>36</sup> This includes implementing a common coordinated governance process that includes the participation of competitors and other market participants.<sup>37</sup>

As ONC implements this Roadmap goal, it may wish to consider taking steps to ensure that coordinated governance by market participants does not unduly distort competition. In prior study, enforcement, and advocacy, the FTC has observed that, when market forces are replaced by coordinated action between market participants, competition may be suppressed.<sup>38</sup> In extreme cases, this coordination may be used by market participants to exclude new products or competitors. The Roadmap currently recognizes this concern and explains that, while it will encourage stakeholders to “make collective decisions between competing policies, strategies [and] standards,” it aims to do so “in a manner that does not limit competition.”<sup>39</sup>

To assist ONC staff in identifying and preventing potential pitfalls, FTC staff offers several examples of anticompetitive conduct by industry members participating in collective standard setting and certification, drawn from some of the FTC’s advocacy and enforcement actions in this area. These activities include:

- Improperly refusing to certify a competitor’s product as standard compliant;<sup>40</sup>
- Improperly refusing to adopt or amend a standard to include innovative products developed after the standard was adopted;<sup>41</sup>

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<sup>35</sup> *Id.* at 27.

<sup>36</sup> *Id.* at 30.

<sup>37</sup> *Id.* at 30-31.

<sup>38</sup> See 2007 IP Report, *supra* note 11, at 34 (noting that “agreement among competitors about which standard is best suited for them replaces consumer choice and the competition that otherwise would have occurred in the market to make their product the consumer-chosen standard.”).

<sup>39</sup> Roadmap, *supra* note 3, at 27.

<sup>40</sup> *American Society of Mechanical Engineers v. Hydro Level*, 456 U.S. 556 (1982), illustrates the harm that could occur from this practice. In that case, an employee of a manufacturer, who participated on an SSO committee, misused the SSO process to procure a letter incorrectly stating that a competitor’s product did not comply with the SSO’s safety code, and used that letter to discourage customers from purchasing the competing product. *Id.* at 559-64.

<sup>41</sup> In *American Society of Sanitary Engineering*, the FTC entered into a consent agreement with the industry organization regarding its refusal to modify or adopt a standard for evaluating an innovative plumbing valve that competed with valves sold by some of its members, hindering the sale of the innovative valve. 106 FTC 324 (1985). Similarly, the FTC provided comment to the Public Service Commission of West Virginia recommending that it guard against the manipulation of interconnection standards by utilities to prevent the entry of innovative distributed energy services by raising the costs for connecting the services to the power grid. See Comment of the Staff of the Bureau of Economics and Consumer Protection of the Fed. Trade Comm’n before the Public Service Comm’n of West Virginia, Charleston in the Matter of a Proposed Rulemaking Related to Restructuring the Electric Utility Industry in West Virginia, General Order No. 255 at § V (May 19, 2000), available at [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-public-service-commission-west-virginia-concerning-restructuring-electric-utility/v000008.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-public-service-commission-west-virginia-concerning-restructuring-electric-utility/v000008.pdf).

- Improperly adding members to a SSO to influence its voting;<sup>42</sup> and
- Improperly failing to disclose the existence of patent rights relevant to technology being considered for inclusion into a standard.<sup>43</sup>

In many cases, collectively set standards lower switching costs and barriers to entry, fostering innovation and competition. Nevertheless, the standard setting process does create the potential for opportunism by its participants. We are not suggesting that the FTC currently has evidence of such conduct, but simply offer these examples for ONC’s consideration as it implements a framework for shared governance.

### C. Core Technical Standards and Functions

The development and adoption of interoperability standards is a central feature of the Roadmap’s vision for achieving interoperability. In the Roadmap, ONC suggests that it will be necessary in the long term for industry to converge and agree on the same limited set of standards.<sup>44</sup> The Roadmap lays out a process whereby, in the short term, ONC will publish an annual list of “best available” standards, to be “used by technology developers and to inform coordinated governance efforts.”<sup>45</sup>

The adoption of interoperability standards can often benefit competition in an industry. Such standards have long been recognized as one of the engines driving the modern economy.<sup>46</sup> They have made networks, such as the Internet and wireless telecommunications, more valuable by allowing products to interoperate in a predictable manner.<sup>47</sup> In many cases, these standards increase competition by eliminating switching costs for consumers who want to utilize products manufactured by different companies.<sup>48</sup> Under these circumstances, interoperability standards can create enormous value for consumers by increasing competition, innovation, product quality, and choice.<sup>49</sup>

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<sup>42</sup> In *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, producers and sellers of steel conduit had packed an SSO meeting with new members whose sole function was to vote against a proposal to allow the use of equally viable plastic conduit in the building industry. 486 U.S. 492, 495-98 (1988).

<sup>43</sup> See, *supra*, note 12.

<sup>44</sup> *Roadmap*, *supra* note 3, at 81 (noting that “the use of multiple data formats over the long term is not sustainable and retains systemic costs and burdens that could otherwise be removed from the health care system for health IT developers, providers and individuals.”).

<sup>45</sup> *Id.* at 84.

<sup>46</sup> *2007 IP Report*, *supra* note 11, at 33.

<sup>47</sup> *Id.*

<sup>48</sup> See Fed. Trade Comm’n, Prepared Statement of the Fed. Trade Comm’n before the United States Senate Comm. on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights concerning Standard Essential Patent Disputes and Antitrust Law at 4 (July 30, 2013), *available at* [https://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-concerning-standard-essential-patent-disputes-and/130730standardessentialpatents.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-concerning-standard-essential-patent-disputes-and/130730standardessentialpatents.pdf).

<sup>49</sup> See Fed. Trade Comm’n, Prepared Statement of the Fed. Trade Comm’n before the United States Senate Comm. on the Judiciary concerning Oversight on the Impact on Competition of Exclusion Orders to Enforce Standard Essential Patents at 4 (July 11, 2012), *available at* [https://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-concerning-oversight-impact-competition-exclusion-orders/120711standardpatents.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-concerning-oversight-impact-competition-exclusion-orders/120711standardpatents.pdf).



It is important to note, however, that the effects of standardization on competition are complicated and may have unintended consequences. Industries with standardized platforms frequently exhibit substantial network effects—that is, the value of the platform tends to rise as more consumers adopt the standard.<sup>50</sup> These industries also can be marked by high switching costs for consumers who switch to alternative platforms.<sup>51</sup> For these reasons, once a standard is adopted and implemented by industry, switching to alternative platforms can be difficult. In addition, when standards are collaboratively set by private parties, market-based competition between technologies vying for adoption is replaced by the collective action of market participants themselves. In some cases, this creates a risk that the standard setting process may be used by firms to prevent entry by new products or competitors.<sup>52</sup>

FTC staff notes that the Roadmap already acknowledges these competition concerns. The Roadmap explains that the annual list of “best available” standards will be updated in a manner “that facilitates competition between standards for selection” and, where possible, “the updates to this list will be done in a manner to minimize unnecessary sunk costs and to promote the entry of innovative standards.”<sup>53</sup> As it implements this plan, ONC may wish to further consider how standardization can impact competition. Specifically, standardization may: (1) limit competition between technologies; (2) facilitate customer lock-in; (3) reduce competition between standards; and (4) impact the methods of selecting standards.

*a. Limiting Competition Between Technologies*

While standardization can offer many procompetitive benefits, it does so at the expense of distorting marketplace competition between technologies. Standards—particularly in the information technology and telecommunications industries—are often created through a collaborative standard setting process involving market participants.<sup>54</sup> Firms that participate in the process may be competitors within their particular industry.<sup>55</sup> Rather than firms competing vigorously in the marketplace to make their product the consumer-chosen standard, competition is replaced by agreement among competitors about which standard is best suited for them.<sup>56</sup> Thus, collaborative standard setting can

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<sup>50</sup> For example, “just as a telephone system becomes more valuable as new customers join because more parties can be reached through it, so, too, the English language becomes more important to learn as it becomes more prevalent throughout the world.” *1996 Competition Policy Report, supra* note 7, ch. 9 at 1-2.

<sup>51</sup> *Id.* at 2. The FTC’s report on business-to-business electronic marketplaces observed that the high cost of connecting their computer systems limited switching between electronic marketplaces. FED. TRADE COMM’N STAFF, ENTERING THE 21ST CENTURY: COMPETITION POLICY IN THE WORLD OF B2B ELECTRONIC MARKETPLACES 24 (2000).

<sup>52</sup> *2007 IP Report, supra* note 11, at 34.

<sup>53</sup> *Roadmap, supra* note 3, at 84.

<sup>54</sup> *2007 IP Report, supra* note 11, at 33-34.

<sup>55</sup> *Id.* at 34.

<sup>56</sup> *Id.*

reduce competition, minimize the role of consumers, and prescribe the direction in which a market will develop.<sup>57</sup>

The Roadmap explains that different aspects of health IT systems can be standardized, ranging from vocabulary to security to infrastructure and services.<sup>58</sup> The benefits of interoperability, when compared to the benefits of promoting marketplace competition between alternative technologies, may suggest that both standardized and non-standardized approaches to discrete aspects of health IT may be beneficial. FTC staff recommends that ONC consider the benefits and risks of each approach as it identifies core technical standards to promote.

*b. Lock In*

In addition to affecting competition between technologies for inclusion in a standard, standardization also impacts the adoption of new technologies once a standard is set. Once a standard is adopted and implemented, an industry may become locked into its use, and the costs of adopting alternatives may be much higher than before standardization. This can harm both competition and consumers.

Prior to the adoption of a standard, alternative technologies compete to be included in the standard on the basis of features, quality, or price.<sup>59</sup> However, once the standard is adopted, an entire industry begins to make investments tied to the standard.<sup>60</sup> Because it may not be feasible to deviate from the standard unless all or most other participants agree to do so in compatible ways, and because all of these participants may face substantial switching costs in abandoning initial designs and substituting a different technology, an entire industry may become locked in to a standard.<sup>61</sup> At this point, competition for alternative technologies is diminished by these heightened switching costs. Once an industry is locked in to a standard, these switching costs make adoption of alternative standards less likely. Similarly, consumers of health IT who have incurred sunk costs in adopting health IT systems may be unable to subsequently replace these systems with alternatives compliant with a subsequent standard.<sup>62</sup>

FTC staff recommends that ONC consider these concerns when implementing its processes for promoting the adoption of standards. In particular, because the Roadmap

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<sup>57</sup> *Id.* See also 1996 Competition Policy Report, *supra* note 7, ch. 9 at 26 (“Consumers in some industries may be better served by competition among existing technologies, so that competitors’ agreement on a standard could be an undesirable elimination of product variety. In other industries, especially those characterized by the demand-side scale economies associated with network externalities, consumers may benefit from the presence of a single compatible technology.”). In some cases, anticompetitive abuse of the standard setting process can result in the violation of antitrust laws. See, e.g., *Allied Tube*, 486 U.S. at 511 (party who “bias[es] the process by ... stacking the private standard-setting body with decisionmakers sharing their economic interest in restraining competition” may “expos[e] itself to possible antitrust liability.”).

<sup>58</sup> *Roadmap*, *supra* note 3, at 77.

<sup>59</sup> Fed. Trade Comm’n, *supra* note 49, at 5.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> FED. TRADE COMM’N STAFF, PROTECTING CONSUMERS IN THE NEXT TECH-ADE 16-17 (2008).

lays out a series of both short-term and long-term goals, FTC staff recommends that ONC consider how lock in effects caused by certain strategies to achieve the short-term goals could affect the realization of long-term goals.

*c. Limiting Competition Between Standards*

The Roadmap suggests that it will be beneficial for industry to converge on a limited set of dominant standards. While this approach may enable consumers to more easily switch between different products, thereby stimulating competition between products compatible with the dominant standard, it may also diminish competition between different standards.

The coalescence of industry around particular standards trades off reduced intersystem competition for increased intrasystem competition. Intersystem competition takes place when firms that employ different standards compete in the marketplace.<sup>63</sup> Intrasystem competition, in contrast, takes place between firms that have adopted the same standard.<sup>64</sup> In some instances, intersystem competition can benefit innovation. For example, the need to invent around others' proprietary standards may spur innovation to develop alternative technologies and goods that do not read on the proprietary standard.<sup>65</sup> Also, proprietary control over a closed system may provide an incentive to develop the standard and to provide sponsorship once it is adopted.<sup>66</sup> In other instances, however, intrasystem competition can benefit innovation by reducing consumers' costs of switching to alternative products, thus promoting entry of new technologies that are compliant with the chosen standard.<sup>67</sup>

Different standards may offer different technical benefits and levels of sophistication. Marketplace competition is one means of identifying standards that offer the best technical benefits. Entry by new standards may be beneficial when these standards offer innovative benefits. FTC staff recommends that, when laying out a path to reach its long-term vision, ONC acknowledge and carefully balance the potential benefits of both intersystem and intrasystem competition.

*d. Methods of Selecting Standards*

The Roadmap includes a plan for ONC to release an annual list of best available standards, to be used by technology developers and to inform coordinated governance efforts.<sup>68</sup> ONC already has released a draft of the first version of this list, the 2015

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<sup>63</sup> 1996 *Competition Policy Report*, *supra* note 7, ch. 9 at 10.

<sup>64</sup> *Id.* at 10-11.

<sup>65</sup> *Id.* at 10-11.

<sup>66</sup> *Id.* at 11.

<sup>67</sup> *Id.* at 11; *see also id.* at 18 (“in industries like applications software and computer peripherals where innovation competition is critical, a loss of competition through denial of interface access may deprive consumers not only of lower prices but also of significant innovative products that would advance the state of technology in the industry as a whole.”).

<sup>68</sup> *Roadmap*, *supra* note 3, at 84.

Interoperability Standards Advisory.<sup>69</sup> The document notes that, although the advisory is “non-regulatory and non-binding in nature,” its recommendations may be adopted in regulation, required as part of a testing or certification program, or included as procurement conditions.<sup>70</sup>

Publishing a list of endorsed standards may be necessary to promote the adoption of standards, especially in light of countervailing market forces that otherwise might prevent or hinder the adoption of standards-based interoperable technologies. Nevertheless, in deciding to select standards, we urge ONC to consider the significant impact that government endorsement of standards can have on the marketplace, particularly if ONC’s list is later incorporated into regulation or procurement requirements. Based upon prior research, the FTC has observed that, when a government agency adopts a consensus standard into a regulation or in its own procurement, the standard often has the same practical effect for industry as a rule of law.<sup>71</sup>

If ONC decides to select standards, FTC staff encourages ONC to establish a sound process to identify and endorse them. One way is to rely on private sector solutions for standard setting. Often, private sector parties have substantial knowledge and understanding about both existing technical needs as well as the merits of different proposed solutions. In addition, private sector action can be flexible and encourage innovation and promote consumer choice.

FTC staff recognizes, however, that there may be benefits to a properly implemented government-endorsed standards approach. The federal government frequently relies upon industry-set standards in its regulations and procurement, often to beneficial effect.<sup>72</sup> For example, under similar circumstances, FTC staff has supported the Federal Energy Regulation Commission’s adoption of a modified version of a state-based standard for the interconnection of electrical generation facilities as a national standard.<sup>73</sup>

FTC staff notes that ONC’s Standards Advisory explains that future revisions will be created through a “transparent and structured process” including advice from the public at large, and done in a manner that seeks to minimize competition concerns.<sup>74</sup> FTC

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<sup>69</sup> OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., 2015 INTEROPERABILITY STANDARDS ADVISORY, *available at* [http://www.healthit.gov/sites/default/files/2015interoperabilitystandardsadvisory01232015final\\_for\\_public\\_comment.pdf](http://www.healthit.gov/sites/default/files/2015interoperabilitystandardsadvisory01232015final_for_public_comment.pdf).

<sup>70</sup> *Id.* at 1.

<sup>71</sup> 1983 Standards Report, *supra* note 6, at 28-30, 46.

<sup>72</sup> See 1983 Standards Report, *supra* note 6, at 28-29.

<sup>73</sup> Comment of the Staff of the Bureau of Economics and the Office of the General Counsel of the Fed. Trade Comm’n before the Fed. Energy Regulatory Comm’n, Docket No. RM02-1-000 at § II (Dec. 21, 2001), *available at* [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-federal-energy-regulatory-commission-concerning-interconnection-standards-new/v020002.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-federal-energy-regulatory-commission-concerning-interconnection-standards-new/v020002.pdf) (“We commend FERC for taking the approach of starting with an established standard and working to improve it, rather than ‘starting from scratch.’”).

<sup>74</sup> 2015 INTEROPERABILITY STANDARDS ADVISORY, *supra* note 69 at 1.

staff is encouraged by this approach. As ONC implements the Roadmap, we suggest that ONC staff continue to take these concerns into consideration.

#### **D. Consumer Protection Considerations**

FTC staff commends ONC for highlighting privacy and security in the Roadmap, and for collaborating with numerous stakeholders in the process of developing the decisions and actions set forth in the Roadmap. For example, the Roadmap, which primarily focuses on entities that are covered by HIPAA and their business associates, describes the need for a ubiquitous, secure network infrastructure, including encryption, contractual requirements on business partners, and incident response capabilities, as well as the importance of strong authentication policies. It also emphasizes the importance of controls to restrict the scope and amount of access to consumers' health data.

The importance of implementing appropriate administrative, physical, and technical safeguards such as these to ensure the confidentiality, integrity, and security of consumers' data has long been a key component of the FTC's data security program. Indeed, in several recent cases involving health information, the FTC settled allegations involving the companies' failure to implement reasonable safeguards including, among other things, their failure to restrict access by employees and service providers to consumer information.<sup>75</sup> FTC staff looks forward to working with ONC as it continues to develop these and other protections for the privacy and security of consumer data, both in and out of traditional health care settings.

#### **IV. CONCLUSION**

FTC staff appreciates this opportunity to provide our views on ONC's draft Roadmap. We would be happy to address any questions you may have regarding competition and consumer protection policy in the health IT marketplace.

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<sup>75</sup> See *In re GMR Transcription Services, Inc.*, File No. 122-3095 (F.T.C. Aug. 14, 2014) (final decision and order), available at <https://www.ftc.gov/news-events/press-releases/2014/08/ftc-approves-final-order-case-against-gmr-transcription-services>; *In re Genelink, Inc.*, File No. 112-3095 (F.T.C. May 8, 2014) (final decision and order), available at <https://www.ftc.gov/news-events/press-releases/2014/01/companies-pitching-genetically-customized-nutritional-supplements>; *In re foru™ International Corp.*, File No. 112-3095 (F.T.C. May 8, 2014) (final decision and order), available at <https://www.ftc.gov/news-events/press-releases/2014/01/companies-pitching-genetically-customized-nutritional-supplements>; *In re CBR Systems, Inc.*, File No. 112-3120 (F.T.C. April 29, 2013) (final decision and order), available at <https://www.ftc.gov/news-events/press-releases/2013/01/cord-blood-bank-settles-ftc-charges-it-failed-protect-consumers>.

Respectfully submitted,

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