



TELECOMMUNICATIONS
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August 25, 2014

Attn: Bakul Patel
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Comments of the Telecommunications Industry Association concerning the Food and Drug Administration's *Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices - Draft Guidance for Industry and Food and Drug Administration Staff* (Docket No. FDA-2014-D-0798)

Dear Mr. Patel:

The Telecommunications Industry Association ("TIA") commends the Food and Drug Administration ("FDA") on its issuance of draft guidance on medical device data systems ("MDDS"), medical image storage devices, and medical image communications devices,¹ and for seeking stakeholder input. FDA's guidance documents, such as this one, have the potential to enhance healthcare in the United States by providing clarity on FDA's current policies.

I. INTRODUCTION AND SUMMARY

TIA is a trade association representing approximately 400 global manufacturers, vendors, and suppliers of information and communications technology ("ICT"), and engages in policy efforts

¹ Food and Drug Administration, *Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices - Draft Guidance for Industry and Food and Drug Administration Staff* (Docket No. FDA-2014-D-0798), 79 FR 36072 (Jun. 25, 2014) ("Draft MDDS Guidance").

specific to health ICT to promote a modern healthcare system that leverages innovative technologies to transform the way care is delivered and consumed.² Many of TIA's member companies develop, manufacture, and supply health information technologies and medical devices (specifically, MDDS devices, medical image storage devices, and medical image communications devices), producing the tools that allow patients and health care providers to connect virtually anytime, anywhere.

TIA appreciates the FDA's goal to provide clarity in its draft guidance on MDDS devices, medical image storage devices, and medical image communications devices. These products represent an important subcategory of medical devices as they can facilitate the remote monitoring of patient generated health data (PGHD). While MDDS has the ability to aggregate and warehouse data from numerous other medical devices within the primary care setting (for example, numerous medical devices in a hospital room), MDDS also allows for the monitoring of such devices outside the four walls of hospitals and other healthcare institutions (for example, home use blood glucose meters or blood pressure cuff monitors or medical grade weight scales). This data can then be used to track important trends in real-time, or later.

Remote patient monitoring of PGHD must be utilized for any health care system to realize its full potential to deliver care. The known benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.³ In addition, use of virtual chronic care management by the Department of Veterans Affairs resulted in a substantial decrease in hospital and emergency room

² For more on these and other associated TIA policy efforts, see <http://tiaonline.org/policy>.

³ See, e.g., U.S. Agency for Healthcare Research and Quality ("AHRQ") Service Delivery Innovation Profile, *Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs* (last updated Feb. 6, 2013), available at <http://www.innovations.ahrq.gov/content.aspx?id=3006>.

use.⁴ Involving this data will engage patients in their own care, can lead to improved lifestyle choices and improve overall health.⁵ There are also significant potential cost savings, with a recent study predicting that remote monitoring will result in saving \$36 billion globally by 2018, with North America accounting for 75% of those savings.⁶

By providing the means to transmit, store, and convert important medical device data, MDDS are the cornerstone for an interoperable 21st century healthcare system that fully utilizes remote patient monitoring technologies to fully leverage PGHD. Accordingly, in our comments below TIA supports FDA's proposed approach towards MDDS devices, medical image storing devices, and medical image communication devices. We believe this approach will facilitate greater innovation in the medical device industry and consistent with the FDA's stated goals of taking an appropriately-tailored approach to medical device innovation.

⁴ See Darkins, et al., *Telemed J E Health*. 2008 Dec. 14 (10) 1118-26. doi: 10.1089/tmj.2008.0021.

⁵ See, e.g., Sanjena Sathian, "The New 21st Century House Call," *Boston Globe* (July 29, 2013), available at <http://www.bostonglobe.com/lifestyle/health-wellness/2013/07/28/century-house-call/tdupWvOQI6b3dKdKcEgdGM/story.html>.

⁶ See Juniper Research, *Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018* (rel. Jul. 17, 2013), available at http://www.juniperresearch.com/reports/mobile_health_fitness.

II. TIA SUPPORTS THE FDA’S PROPOSED APPROACH TO MDDS DEVICES, MEDICAL IMAGE STORING DEVICES, AND MEDICAL IMAGE COMMUNICATION DEVICES

Advances in technology have drastically changed the way healthcare is delivered and consumed, connecting patients, healthcare providers, loved-ones, friends and medical professionals virtually anywhere, to help facilitate ongoing care and treatment wherever and whenever it is needed. In order to realize a fully interoperable healthcare system, effective policies that promote ongoing investment and innovation are needed. A regulatory framework that provides clarity and predictability instead of barriers that stifle progress are key to developing transformative technologies, including those that support remote monitoring of patient-generated health data. In the Draft MDDS Guidance, the FDA proposes to abstain from enforcing compliance with the regulatory controls that apply to MDDS devices, medical image storage devices and medical image communications devices, based on its experiences with these technologies and their determination that these devices pose a low risk to the public because they do not control or alter the functions or parameters of a connected medical device.⁷ Further, the guidance states “FDA does not intend to enforce compliance with the regulatory controls for devices that meet the definitions identified” by the above regulations.

TIA supports the FDA’s proposed approach towards MDDS, medical image storage devices and medical image communications devices. We are particularly impressed by FDA’s clarifications on the limitations of exemptions and how they apply to MDDS devices. The limitations of exemptions have been an area of intense debate among manufacturers and innovators, which according to our broad membership, has had a deleterious effect on innovation. Under the existing MDDS regulation, many argue that the limitations of exemptions under 21 CFR 892.2020 severely limit, if not eliminates, the relationship between MDDS products and medical devices used for assessing the risk of cardiovascular diseases or for use in diabetes management. However, this draft guidance proposes unequivocally that to the extent these limitations apply, FDA does not

⁷ See Draft MDDA Guidance at 4-7.

intend to enforce compliance with regulatory controls for MDDS intended to be used in systems for assessing the risk of cardiovascular diseases (21 CFR 880.9(c)(4)) or for use in diabetes management (21 CFR 880.9 (c)(5)).

TIA commends FDA's sensible approach which provides regulatory certainty and allows innovation to flourish. As FDA notes, under its approach MDDS developers will be able to focus on making products better able to operate among various devices and technology systems, and to focus less on maintaining compliance with unnecessary regulations (general controls, registration and listing, premarket review, post-market reporting, good manufacturing practices under the quality system regulation, etc.).⁸ TIA applauds FDA for, in essence, deregulating MDDS and allowing the agency to focus on other higher risk devices. In addition, FDA's approach is consistent with Congress' goal of narrowly-tailored regulation of health IT to promote innovation, protect patient safety, and avoid regulatory duplication as enacted by the Food and Drug Administration Safety and Innovation Act ("FDASIA") of 2012.⁹

Based on the above, TIA believes that if the FDA proceeds to finalize the proposed guidance as it has been put forward, medical device innovators will significantly benefit. While the FDA will remove unnecessary barriers from the design-to-market process by taking an appropriate de-regulatory approach based on the low risk posed by MDDS, this approach is also consistent with stated policies in the joint agency FDASIA Health IT Report,¹⁰ which recommends a carefully limited approach to medical device regulation. Moreover, the proposed approach to MDDS continues to build FDA's record of pro-innovation approaches towards medical device regulation.

⁸ <http://blogs.fda.gov/fdavoices/index.php/2014/06/fda-encourages-medical-device-data-system-innovation/>.

⁹ See P.L. 112-144 (Sec. 618).

¹⁰ See FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework (Apr. 2014).

III. TIA SUPPORTS THE FDA’S RELATED PROPOSED CHANGES TO ITS MOBILE MEDICAL APPLICATIONS GUIDANCE

FDA also proposes various changes to its existing guidance on mobile medical applications¹¹ to ensure consistency with the agency’s approach to medical device regulation.¹² These changes appropriately harmonize the approach taken for MDDS devices, medical image storage devices and medical image communications devices. TIA supports the changes proposed to Section V-A-1, V-B, and relevant appendices of the MMA Guidance.

¹¹ See FOOD AND DRUG ADMINISTRATION, MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2013) (“MMA Guidance”), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>.

¹² See Draft MDDS Guidance at 7-10.

IV. CONCLUSION

We appreciate the meaningful steps that the FDA has taken to provide clarity and certainty regarding MDDS, medical image storage devices and medical image communications devices in this matter, and urge consideration of the positions stated above. Please contact the undersigned with any questions.

Respectfully submitted,

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By: /s/ Brian Scarpelli

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