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AdvaMed
Advanced Medical Technology Association

August 25, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher Lane
Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-D-0798
Draft Guidance for Industry and FDA Staff; Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

Dear Sir or Madam:

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide comments in response to the Food and Drug Administration (FDA) Draft Guidance for Industry and FDA Staff; Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices.

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies.

AdvaMed understands that the changing environment may warrant the use of enforcement discretion as a first step in shaping the regulatory environment for Health IT. Nonetheless, we encourage FDA to solidify this framework with appropriate rulemaking in the future. Guidance and enforcement discretion are adjuncts to a solid regulatory framework.

The guidance should provide clarification on required submission documentation when an MDDS is part of a larger Class II or Class III system such that the MDDS does not lose its non-regulated status because is it part of a larger regulated system.

It is critical that "active patient monitoring" should be more clearly defined. Doing so will clarify where the line is drawn between actively regulated and enforcement discretion eligible devices. The key term is "active". We presume the guidance document's authors mean active patient monitoring offering potential for immediate action. Furthermore, simple analyses of

patient-specific disease management data as part of a tracking and trending functionality, such as identifying the highest or lowest results, determining the average or percentage of the data that fall within a sub-region of the range of results in a data set, do not pose significant risk to patients. Health IT devices with simple data analysis capability within the trending and tracking functionality should be eligible for enforcement discretion.

AdvaMed requests clarification, via regulation, that specifies which FDA regulations are no longer applicable to these devices and, if applicable, which regulations may still be necessary to manage modifications in claims/functionality of the devices within scope of this guidance.

In order to foster the innovation sought by the FDASIA group, the regulatory structure must be formally and clearly defined so that everyone understands the rules and requirements for their class of product. The agencies need to make a clear determination on oversight responsibility based on risk. If you have any questions of would otherwise like to contact me, I can be reached at 202-434-7442 or jsecunda@advamed.org.

Please see detailed comments attached to this letter.

Respectfully submitted,

Jeffrey Secunda
Vice President, Technology and Regulatory Affairs

Attachment

AdvaMed Comment Form

Date: August 25, 2014

Document Title: MDDS Guidance - June 20, 2104

Submitters Name: Jeffrey Secunda **Company: AdvaMed**

#	Page/ Section/ Paragraph/ Line	Type: Technical Editorial	Proposed Change	Comment: Rationale/Justification for Change
1	N/A	General	We understand that the changing environment may warrant the use of enforcement discretion as a first step in shaping the regulatory environment for Health IT. Nonetheless, we encourage FDA to solidify this framework with appropriate rulemaking in the future. Guidance and enforcement discretion are adjuncts to a solid regulatory framework.	Need for future accessment of changes for exempted MDDS products.
2	Page 6 / Section III / 2nd para / Lines 1-4	Technical	"This means that for devices that meet the definitions in the regulations listed above, the FDA does not intent to enforce compliance with the regulatory controls, including registration and listing, pre-market review, postmarket reporting and quality system regulations for manufacturers of these types of devices. When an MDDS is part of a larger Class II or Class III system and one or more of those Class II or Class III system components are being submitted for clearance/approval, the required submission content for the MDDS component of that larger system submission will be limited to the system level. In other words, the submission regarding the MDDS portion of the system will be limited to information about its interrelation to the Class II or Class III device, such as a system description/architecture and end to end system verification and validation testing. Documentation specific to the MDDS by itself, as a Class I device – such as requirements specifications, software / firmware / hardware testing, and component level testing -- will not be required as part of the Class II or Class III system submission."	Providing clarification on required submission documentation when an MDDS is part of a larger Class II or Class III system.

3	Page 6 / Section III / 3rd para, Lines 4-7, Lines 1-2 at the top of page 7	Technical	"However, even when subject to these limitations, FDA does not intend to enforce compliance with the regulatory controls for devices that meet the definitions identified by the above regulations with regard to MDDS, MISD or MICD components of those systems. For example, to the extent that these limitations apply, FDA does not intend to enforce compliance with regulatory controls for MDDS intended to be used in a system 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))."	Even though diabetes management (for example) is specifically called out as a limitation still requiring a submission per those regulations, we understand FDA does not intend to enforce compliance for the MDDS component of that system. Providing clarification to align with the example provided.
4	Page 9 / Appendix D / 1st para / Line 1	Technical	"FDA would remove the row for regulation 880.6310 from the Table; however FDA intends to maintain 880.6310 in the Code of Federal Regulations."	Even though FDA is proposing to remove the MDDS Rule from the table, it is assumed MDDS as a medical device will be maintained as 880.6310 in the Code of Federal Regulations, and the requirements for MDDS will remain, save for FDA exercise of enforcement discretion. Providing clarification.
5	Page 6 Section III		Identify requirements for these products with regards to UDI – not required.	Include statement that these products are exempt from Unique Device Identification based on other regulatory controls FDA does not intend to enforce.

6	Page 7 / Section IV / Subsection V-A-1 / First bullet point	Editorial	"Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring[1] or simply analyzing medical device data for purpose of trending and tracking[2]." [1.] Active patient monitoring must offer potential for immediate action. Health IT devices that analyze patient disease management data for the purpose of identifying patients that should be offered additional training or education, e.g., patients reporting hypoglycemic blood glucose test results, does not constitute active patient monitoring. [2.] Simple analyses of patient-specific disease management data as part of a tracking and trending functionality, analyses such as identifying the highest or lowest results, determining the average or percentage of the data that fall within a sub-region of the range of results in a data set, do not pose significant risk to patients. Health IT devices with simple data analysis capability within the trending and tracking functionality are eligible for enforcement discretion.	1. *Active patient monitoring* should be more clearly defined. Doing so will clarify where the line is drawn between actively regulated and enforcement discretion eligible. The key term is *active*. We presume the guidance document's authors mean active patient monitoring offering potential for immediate action. Health IT devices that comb through patient disease management data to identiy patients experiencing difficulty managing their disease, e.g., hypoglycemic level blood glucose test results, for the purpose of identifying those patients needing additional education and/or assistance does not constitute *active patient monitoring*; Health IT devices limited to this functionality should be eligible for enforcement discretion. 2. Simple analyses of patient-specific disease management data as part of a tracking and trending functionality, analyses such as identifying the highest or lowest results, determining the average or percentage of the data that fall within a sub-region of the range of results in a data set, do not pose significant risk to patients. Health IT devices with simple data analysis capability within the trending and tracking functionality should be eligible for enforcement discretion.

7	Page 6/ Section III/ First paragraph	Technical	Clarification on: "The FDA does not intend to enforce compliance with the regulatory controls that apply to the following devices: a) MDDS subject to 21 CFR 880.6310, b) Medical image storage devices subject to 21 CFR 892.2010, and c) Medical image communications devices subject to 21 CFR 892.2020. This means that for devices that meet the definitions in the regulations listed above, the FDA will not ~~does not intend to~~ enforce compliance with the regulatory controls, including registration and listing, premarket review, postmarket reporting and quality system regulation for manufacturers of these types of devices."	Request clarification, via regulation, that specifies which FDA regulations are no longer applicable to these devices and, if applicable, which regulations may still be necessary to manage modifications in claims/functiionality of the devices within scope of this guidance. Without specific reference, it will be difficult to ensure that all manufacturers interpret this guidance in the same manner. For example, it is unclear if the "limitations of exemptions" under the section 21 CFR XXX.9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9) would continue to be enforced in the same manner for the image management devices in light of this guidance. For example, a device modification may exceed the exemption for two reasons. 1) It may introduce a new technology that isn't part of the generic type of device described in the regulation (e.g. Wired to wireless transmission); or 2) it may add a new functionality that does not conform to the device described in the regulation (e.g. an MDDS modified to alter parameters of connected devices'). It is not clear in the guidance if the FDA intends to enforce the exemption for both of these cases. See additional justification from comment #4 above.

8	Page 6/ Section III/ First paragraph	Technical	Clarification on: "FDA does not intend to enforce compliance with the regulatory controls"	Request clarification on how this concept will be implemented for the Health Management classification of products. Recommend formal assignment, by the three agencies, of enforcement responsibility to the appropriate agency. It appears that this is currently targeted to ONC; however, it is recommended that this is formally documented and agreed upon by both agencies to ensure predictability and clarity in the process for manufacturers. In order to foster the innovation sought by the FDASIA group, the regulatory structure must be formally and clearly defined so that everyone understands the rules and requirements for their class of product. The agencies need to make a clear determination on oversight responsibility based on risk.
9	Page 6, 3rd bullet (Section II)	Technical	Update to remove reference to 3rd party: "Custom software that ~~is written by entities other than the original medical device manufacturer (for example, hospitals, third party vendors) that~~ directly connects to a medical device, to obtain medical device information."	Why is bullet applying only to third parties? If the functionality is the same, why does it matter who develops the MDDS. The risk is the same