This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

FDA's Enforcement Discretion Policy

Context

The U.S. Food and Drug Administration's (FDA) mission is to protect and promote public health. FDA regulates products that are intended to diagnose, cure, mitigate, treat, or prevent diseases or other conditions. Though some products may meet this definition, sometimes, FDA can exercise "enforcement discretion" when they determine the product poses a lower risk to the public. Enforcement discretion is appropriate for when FDA does not enforce premarket review and other applicable FDA requirements for certain categories of low-risk and/or low priority products, but FDA retains the right to enforce regulation in the future if unpredicted risks emerge for these product categories. Also, it is important to note that another reason for FDA enforcement discretion would be in the instance where a public health emergency occurs and there is an urgent unmet need and/or there is no existing regulatory policy. A recent example of this is what happened during the COVID-19 public health emergency. This document focuses on cases in which enforcement discretion is implemented when the risk associated with the device itself is low.

FDA issues guidance documents to inform the public about the product categories for which they intend to exercise enforcement discretion. These guidance documents clarify which products fall under enforcement discretion and under what conditions. When the enforcement discretion guidance is followed, those designated products can be manufactured, imported, and distributed in the U.S. immediately, meaning **innovators do not need advance approval from FDA.** Typically, these guidance documents explain the use of discretion by FDA regarding the enforcement of some regulatory requirements, such as otherwise mandatory pre-market submissions (e.g., 510(k)s), registration and listing, and quality management system requirements. However, innovators of products under enforcement discretion should still leverage testing standards when applicable and maintain a quality management system to develop and market the highest quality product.

Common Products Under Enforcement Discretion

Some medical device products, including some over-the-counter medical devices, and certain types of software used in (or as) a medical device are the main categories of products for which FDA has issued guidance that provides examples of where and how they intend to exercise enforcement discretion. The following example highlights how FDA applies its enforcement discretion to software as a medical device (SaMD) products.

In the case of device software functions and mobile medical applications, FDA has issued specific guidance document with examples that include the following:

- Software functions that are not considered medical devices (see Appendix A).
- Software functions that FDA intends to exercise enforcement discretion on (see Appendix B).
- Software functions that FDA intends to focus their regulatory oversight on (see Appendix C).

These examples provide a baseline for the types of products FDA has determined may qualify as a medical device but will not actively regulate. The guidance document also provides examples of the level of risk FDA currently views as acceptable for enforcement discretion.

"Can you help me determine whether the FDA would consider my digital health product to be an actively regulated product?"

FDA has developed specific resources that can help answer this question, such as the webpage, Global Approach to Software as a Medical Device. The Digital Health Policy Navigator is a tool that helps in determining whether a software function may be the subject of FDA oversight. The webpage, Examples of Software Functions for Which the FDA Will Exercise Enforcement Discretion, provides a number of examples of when software functions are considered under enforcement discretion for software. Also, the webpage, Examples of Device Software Functions the FDA Regulates, provides examples of software functions that are not under enforcement discretion. The webpage, Examples of Software Functions That Are NOT Medical Devices, also lists examples that are not regulated devices.

The FDA has also developed and adopted some additional resources that focus specifically on software as a medical device. The webpage, Global Approach to Software as a Medical Device, includes resources from the International Medical Device Regulators Forum (IMDRF). Generally, the most important factor when determining if a product that is considered a medical device will fall under enforcement discretion is its risk profile and its corresponding risk categorization. In the document, "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations the IMDRF outlines four levels of risk that can inform one of the required regulatory pathway for a device. The IMDRF framework also provides examples of products that might fall into each risk category.

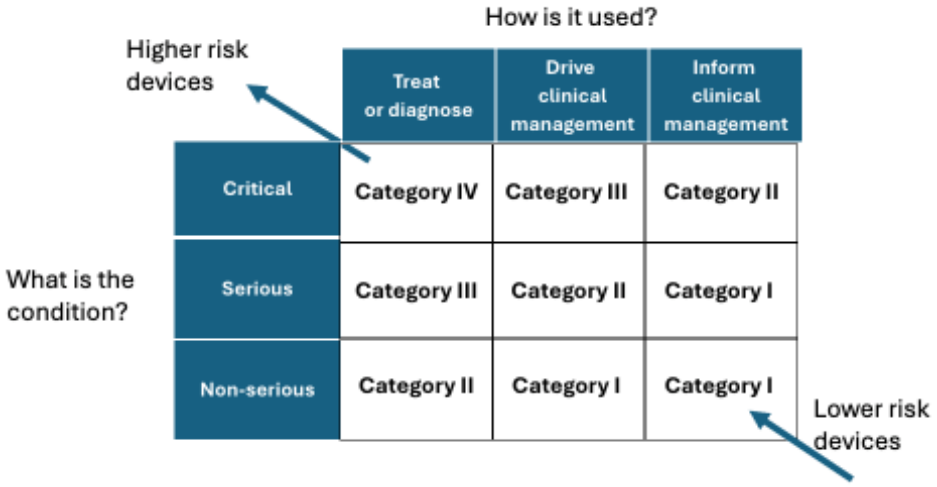

Figure 1: Guiding principles for software assessment by risk categories I-IV (Source: IMDRF)

Software functions that are in Category I are more likely candidates for FDA enforcement discretion.

For more information on FDA adoption of IMDRF documents as an FDA guidance document, please see the webpage about FDA's work in the International Medical Device Regulators Forum. Please also refer to the resources within the section of FDA's website on Software as a Medical Device (SaMD).

If you have further questions on the topic of Software as a Medical Device, you may email subject matter experts at DigitalHealth@fda.hhs.gov.

Determining When Enforcement Discretion Applies

When developing a product, if innovators believe their product falls under enforcement discretion, they may not need to meet with FDA before marketing their product. However, innovators should thoroughly document how they came to the conclusion that their product falls under enforcement discretion if FDA or any other regulatory agency approaches them with questions about their product in the future.

For medical devices in general, if it is unclear if a product meets the definition of a medical device and is therefore regulated by FDA, then the FDA webpage, How to Determine if Your Product is a Medical Device may be helpful. If after reviewing the medical device definition, it is still unclear if the product meets the definition of an FDA regulated medical device, then the innovator can email the FDA device determination experts at DeviceDetermination@fda.hhs.gov.

If a product meets the definition of a medical device, the FDA resource, **How to Study and Market Your Device**, will be helpful in determining the correct regulatory pathway. Note that the FDA product classification of a device determines its regulatory pathway and its regulatory requirements. The FDA Product Classification Database listing for a particular product type will indicate if it is one that is under enforcement discretion or if it requires another regulatory pathway. When using the Product Classification Database in its advanced search mode, there is also a search filter for "Submission Type" that includes "Enforcement Discretion" as an option.

For questions that would most appropriately be addressed by FDA premarket review experts, submitting a Pre-Submission to FDA is an option. There is no user fee associated with a Pre-Submission. The Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program guidance details how one would submit a formal written request to the FDA for feedback prior to an intended premarket submission.

If it is not clear whether a product falls under enforcement discretion, innovators can also contact FDA through DICE for simple questions or clarification on existing FDA guidance.

Regulatory Changes After a Product Is on the Market

It is also important to keep in mind that sometimes, FDA can change their regulatory focus. For example, FDA's regulatory requirements may change after public health emergencies have ended or after new legislation has been passed. Innovators who are marketing products that they have determined to be under FDA's current enforcement discretion should regularly review FDA resources and should consider how changes in the healthcare landscape may affect the risk level of their product.

One example of a change in regulatory oversight is the new FDA rule "Medical Devices: Laboratory Developed Tests." After years of Laboratory Developed Tests (LDTs) falling under enforcement discretion, FDA announced that it is "amending the FDA's regulations to make explicit that In Vitro Diagnostics (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA issued a policy to phase out, over the course of four years, its general enforcement discretion approach for LDTs. The agency also issued targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories."

When marketing a product where FDA has decided to exercise enforcement discretion, innovators should keep in mind that they may still be subject to requirements of other regulatory authorities such as the Federal Trade Commission, the HIPPA Rules within the Office for Civil Rights, and the Office of the National Coordinator for Health Information Technology.

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