**mHealth Regulatory Coalition**

# Issue Brief

## Software Modularization— FDA Falling Behind on the Regulation of Reusable Software

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Adoption of Modular-Based Software Development. Although new to health technology, software modularization is not a novel concept. Sophisticated software often consists of independent modules that function separately and as part of overall software programs. In fact, the Federal Aviation Administration (FAA) currently approves reusable software modules or reusable software components (RSC), allowing for reuse of a GPS software module, for example. The FAA has used this approach in all types of aviation systems, including those in the highest risk classification. According to the FAA, if properly planned and packaged, software life cycle data (including software code) can be reused from one project to the next, with minimal rework. Mobile applications similarly are made up of distinct modules from a variety of sources.

In addition, the European Commission recently distinguished between modules that have a medical purpose and those that do not and acknowledged that non-medical device modules are not subject to the medical devices requirements. The guidance requires the manufacturer to identify the boundaries between the medical and non-medical use modules based on the module's intended use.

Historical FDA Policy. The FDA regulates medical device software programs or apps as a single product. It views software as one system and applies the highest applicable regulatory classification to all modules included in software.

The Challenge: The current regulatory approach does not stratify functionality within a software app based on the risk associated with specific functional modules. This creates a significant regulatory burden and restricts the implementation of reusable modules in innovative software designs.

For example, a software application could include a module to facilitate the download of information from a medical device (e.g. blood pressure cuff or blood glucose monitor). The application could also include a module to generate graphical reports to show the data received over time and a database module to store the information. The software application could also incorporate a calendar module, allowing the user to add reminders for appointments, when tests were taken, etc. From a software design perspective, the modules can be designed with logical separation to compartmentalize risks within each module; only communication linkages are exposed to the other modules. The design establishes confidence that the risks are mitigated for information shared between modules.

Under the current regulatory framework, if one of the modules in the example of the blood glucose app is classified as Class II, the other modules such as the calendar might also be classified as Class II. In our opinion, that's overkill. It means that any time the developer of that calendar module wants to update it, for example to make it work with Facebook, they would need to get FDA clearance.

MRC Recommendation: FDA should recognize the use of standard software design principles and limit its regulatory oversight to medical use modules only.
To achieve this,

- FDA should develop classification regulations for mHealth software to ensure the appropriate level of regulatory oversight for software modules in mHealth.
    - FDA should publish a guidance document clarifying the use of these classification regulations in mHealth and their applicability in modular software designs. Specifically, the guidance should state that manufacturers are required to identify the boundaries between the medical and non-medical use modules based on the module's intended use and conduct appropriate testing of the complete software program when modules are re-used. For example, the calendar module in our example would not need to meet FDA medical device software requirements if the medical software developer follows the guidance.

***The MRC proposal streamlines the development cycle and minimizes the regulatory burdens for mHealth products through adoption of standard software design principles.***