

## CDRH Learn: MDUFA IV Introduction

Elias Mallis

### Slide 1

Hi, I'm Elias Mallis, Director of the Division of Industry and Consumer Education at FDA's Center for Devices and Radiological Health. Thanks for joining us. In this CDRH Learn module, I'll provide you with an Introduction to the Medical Device User Fee Amendments of 2017, or as I'll refer to them: MDUFA IV.

### Slide 2

In this presentation, we'll review the background of the user fee legislation for medical devices. We'll review the user fees themselves in more detail and discuss the performance goals established as a result. And finally, we'll devote the bulk of this presentation to highlighting the program areas addressed with the passage of MDUFA IV.

### Slide 3

Let's get started with some background to frame the discussion.

### Slide 4

The general premise for user fees is relatively straightforward: the regulated medical device industry agrees to provide funds – or user fees – to CDRH. The Center, in response, applies those funds to increase resources, in the form of staffing and other internal support, with the goal of making premarket review decisions more timely, predictable, and transparent to sponsors.

User fees represent a shared commitment between CDRH and Industry, which ultimately advances the Center's vision that patients in the U.S. have access to high-quality, safe and effective medical devices of public health importance, first in the world.

### Slide 5

This table highlights the prior history of user fees at CDRH. Moving across this table from left to right, you'll see the User Fee Law implemented, the years under which it was effect, and some key provisions. The first user fee program was the Medical Device User Fee and Modernization Act of 2002, or MDUFMA. This was established for a period of 5 years, starting with Fiscal Year 2003 through FY 2007. MDUFMA authorized user fees for the review of certain medical device submissions.

MDUFA II and III each ran for 5 fiscal years and continued to grow the user fee program and further foster timeliness, predictability, and transparency to sponsors for various premarket submissions.

### Slide 6

As you can imagine, it takes a lot of time and effort to reach a negotiated user fee program. This slide shows the timeline for the development of MDUFA IV, which started back in July 2015 with the first public meeting to solicit input related to the user fee program. Over the next year, CDRH and industry worked tirelessly, and with input from patient and consumer advocacy groups, to develop a user fee proposal. FDA submitted the final agreed upon proposal to Congress in early January 2017 for consideration. And finally, on August 18, 2017, the President signed the FDA Reauthorization Act of 2017, or FDARA, which includes the reauthorization of the medical device user fees and what we call MDUFA IV.

### Slide 7

On this slide, I include links to section of FDARA that pertains to MDUFA IV, as well as the Federal Register Notice that FDA published to announce the medical device user fee rates for Fiscal Year 2018.

### Slide 8

Now let's get into some more detail about the user fees themselves.

### Slide 9

The medical device user fees apply to: premarket notifications, or 510(k)s, except for those submitted by Third Parties. They apply to the family of Class III medical device applications, including premarket approval applications, or PMAs, product development protocols, or PDPs, premarket reports, or PMRs, applicable biologics license applications, or BLAs – both originals, supplements, and annual reports.

Requests for classification, or 513(g)s, and establishment registration are subject to user fees. And, starting with MDUFA IV, De Novos are subject to user fees.

Note that all of these fees, except for the establishment registration fee, are eligible for a small business discount, so I encourage all eligible firms to submit an application to be certified as a small business and obtain the reduction in applicable user fees. Please note that you need to be certified as a small business prior to submitting your user fee-requiring submission, so please plan ahead.

### Slide 10

MDUFA IV runs from Fiscal Year 2018 through 2022, which means it begins on October 1, 2017 and runs through September 30, 2022. The user fees are estimated for the 5-year cycle of MDUFA IV, but will be adjusted for inflation each year to meet the revenue target. Approximately 60 days before the start of the next fiscal year, we'll announce the next fiscal year's user fees in the Federal Register.

The website listed here shows the actual user fees for the fiscal year once they are calculated and published.

Ultimately, MDUFA IV will allow the Center to hire 217 full time equivalent, or FTEs, to our staffing to support the functions and goals outlined in MDUFA IV.

### Slide 11

So what are those performance goals? Let's take a closer look in the next two slides.

### Slide 12

This first slide outlines the Shared Outcome Goals, expressed as the "total time to decision", which means from the time the submission is received by FDA to when a final decision is reached. This shared goal applies to 510(k)s and PMAs and is expressed here in total days.

As you can see, the decision time for 510(k)s starts with 124 days in FY18 and drops down to 108 days in FY22. The PMA total time to decision goal is stratified over a 3 year period: for FY16 through 18, we have 320 days, and by FY20 through 22, it drops to 290 days.

### Slide 13

The table here outlines the overall performance goals. Working from left to right, we start with the submission type, the regulatory action to be taken, the FDA review days, and the percent of submission to meet the FDA Days over the course of the 5 year program of MDUFA IV.

Highlighted in yellow on this table are the performance goals that are new or otherwise updated from MDUFA III. As highlighted here, the performance goals for a De Novo are all new. The Pre-Submission Program and CLIA Waiver by Applications also see some changes in performance goals.

### Slide 14

For the remainder of this presentation, we'll review some of the program highlights and activities that will take place under MDUFA IV.

### Slide 15

Here are the nine program areas we'll review next.

### Slide 16

As many of you already know, the Pre-Submission Program can be a very important resource to allow a sponsor to better understand the regulatory expectations CDRH will have for a premarket submission. I encourage you to view the CDRH Learn Module on the Pre-Submission Program for more information. Under MDUFA IV, the Pre-Submission Process will feature specific actions and deadlines for each step, with the goal of FDA providing feedback by Day 70 upon the request. Note that FDA plans to publish a guidance on the new Pre-Submission Process that includes an acceptance checklist to help provide clarity on FDA's expectations on what should go into a request for Pre-Submission feedback.

### Slide 17

Turning to the De Novo program, this program actually saw significant improvements under MDUFA III with respect to reduced timelines, even though the number of submissions increased during this period.

The additional resources made available under MDUFA IV, which includes the new fees collected for De Novos, will be used to help FDA meet the commitment of the new performance goals for De Novos, further advancing the timeliness, predictability, and transparency of this program.

### Slide 18

MDUFA IV will allow FDA to invest resources to address a number of IT needs. Some of these will help FDA Reviewers conduct their review work more efficiently, such as the development of smart review templates. But other enhancements will be directly visible and useful to industry. Of note, FDA will work toward development of an electronic submission template that will guide the preparation of a premarket submission and one that is complete. FDA will also develop an electronic dashboard that will allow an applicant to track the status of their submission. On the right side of this slide you'll see a prototype of an industry dashboard.

### Slide 19

MDUFA IV sees FDA's continued commitment to patients, and specifically, to the incorporation of patient-specific information and feedback into regulatory decision-making. Of note, the new Law commits FDA to develop in-house expertise for the review of patient preference information, or PPI, and

patient-reported outcomes, or PROs. FDA anticipates holding publish workshops on this topic and to work toward the goal of improving the regulatory predictability of PROs.

#### Slide 20

Another initiative begun under the time period of MDUFA III continues further under MDUFA IV, that is, the use of real world evidence.

MDUFA IV supports the continued development and support of the National Evaluation System for health Technologies, or NEST. The goal of NEST is to generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence to permit the FDA to strike the right balance between assuring safety and fostering device innovation and patient access. This initiative will help FDA determine usability of real world evidence for new product approvals or expanded indications for legally marketed devices, or for improved malfunction reporting.

In addition, FDA will streamline its medical device reporting, with the goal of moving toward a quarterly summary reporting of malfunctions for most, if not all, product codes.

#### Slide 21

The space of digital health has seen major advances over the past few years and MDUFA IV recognizes the importance of this field. FDA will establish a central digital health unit that will assist the Center in its premarket review of the variety of digital health technologies. In addition, FDA will explore various premarket pathways for software as a medical device and software in a medical device, and will leverage real world evidence and international harmonization efforts to advance the Center's policies on digital health.

#### Slide 22

Standards are a very common and prolific resource with respect to premarket submissions. Under MDUFA IV, FDA will establish an accreditation scheme for conformity assessment of FDA-recognized consensus standards. In this scheme, an accrediting body will accredit test labs according to specific FDA-recognized consensus standards and FDA will rely on testing conducted by those accredited labs.

#### Slide 23

MDUFA IV sees some focus on the Third Party Review Program. One goal will be to establish a plan to eliminate the routine re-review by FDA of submissions previously reviewed and submitted by Third Party Reviewers. FDA will enhance training and support provided to Third Parties, including granting access to redacted FDA review memos and communication with respect to changes in regulatory expectations for device types. And finally, FDA will issue a guidance on third party accreditation: to include accreditation, but also reaccreditation, suspension, and withdrawal of accreditation of a third party reviewer.

#### Slide 24

And finally, MDUFA IV calls for FDA to establish a dedicated Quality Management Unit whose goal will be to foster greater quality, consistency, and effectiveness in premarket review processes. The QM Unit will perform routine program audits to facilitate process improvements for the Center.

As you can see, the program areas impacted by MDUFA IV are varied and diverse, but ultimately serve to improve the quality and efficiency of the regulatory programs at FDA to provide safe and effective medical devices to U.S. patients first in the world.

Slide 25

Let's recap what we reviewed in this module. First, we reviewed the history of user fees for medical devices, including the timeline leading up to the MDUFA IV. We learned what types of submissions and activities are subject to medical device user fees. We reviewed the user fee performance goals and highlighted what's new in MDUFA IV. And finally, we summarized the key program areas addressed by MDUFA IV.

Slide 26

Thank you for your attention to this CDRH Learn Module on the Introduction to the Medical Device User Fee Amendments of 2017, or MDUFA IV. We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Of note, for comprehensive regulatory information, please contact CDRH's Division of Industry and Consumer Education. We look forward to helping you.

Thanks for watching this program and we'll see you next time.

\*\*\*\*\*