

**FDA Webinar:
Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st
Century Cures Act: Final Guidance**

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by for today's conference. All participants will be in listen-only mode until the question-and-answer session. At that time to ask a question, please press Star 1. Today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello. And welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On September 27, 2019, the FDA issued the final guidance titled Changes to Existing Medical Software Policy resulting from Section 3060 of the 21st Century Cures Act. This guidance provides FDA's current thinking regarding the amended revised definitions and the resulting effect the amended definition has on FDA's guidances related to medical device software.

Today, Bakul Patel, Director of Digital Health and Matthew Diamond in the same division both here at CDRH will present an overview of the final guidance document. Following the presentation, we will open the line for your

questions related to the information provided during the presentation. Additionally, there are other center subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now I give you Bakul.

Bakul Patel: Thank you, Irene. And welcome everybody to the webinar. Hopefully we can cover today the topic of the five guidances that we published on September 27. But before we do that, let me just walk you through sort of the background and then hand it over to Matthew to dive into details about the 3060 guidance and the nuances and the details that went into modifying our existing policies that we had laid out prior to the 21st Century Cures.

So let me just start with this picture of this page approach to regulating and overseeing software and digital health products. As we think about (unintelligible), I think we need to think about how do we focus narrowly our approach and overseeing so that we are focusing our efforts on things that matter the most. At the same time, we are focusing on those functionalities that enable these products to be medical devices and in a way that gives us independence from the platform changes and innovation that's happening. And allows us to not only promote responsible innovation but also promote patient engagement where patients are the center of the discussion where we are having in this world of digital health.

We also want to highlight that this approach has been - is what we've been taking for the last almost 10 years in developing a method and a way to think about patients and the safety of the patients for these products. But keeping all these actors in balance is really what our policies are developing, and we've developed over the last many years.

Today, we are finalizing our interpretation of 21st Century Cures because really look at how FDA had already thought about (unintelligible) digital health produces where the Cures Act fundamentally codifies our policies which is in line with our least burdensome approach to device regulation. Just to give you a really high level overview on the 21st Century Cures Act, the Section 36D of the Cures Act basically amended the device definition and removed certain software functions that we had previously said would be under what we coined enforcement discretion which basically mean our enforcement priorities would not lie to those lower risk products. This final guidance is making that interpretation final, modifying our current policies so that we are aligned and we're implementing the Cures Act.

Just to highlight and remind people what the Cures Act sort of outlined, it basically said administrative support functions of that exists in any product or any system that is highlighted in the work we did in the FDASIA health IT effort is now getting codified to 21st Century Cures. The only wellness products we said certain products are lower risk and we would not be enforcing a requirement. Electronic patient records which are also part of the discussion of the (FDASIA) health IT discussion and health management functionality are also now something that we have basically said is not part of the device definition.

And then medical device data systems which we promulgated and regulations call MDDS. That function and the functionality of those kind of products are also no longer considered medical devices. The Act also talked about clinical systems support. We use the term clinical decision support in the short form for that last provision which talks about, you know, how (FDASIA) health IT report identified both function in the health management functionality.

Today we are going to focus only on the top four parts of the Act and not about the part E which is clinical Decision Support. We discussed that in the previous webinar, that particular topic of clinical Decision support. So we will focus our conversation today and the discussion today on the top four and how it sort is reflected in the guidance that we published and the interpretation. And the effect of that interpretation on our existing policy.

With that, I want to turn it over to Matthew to help us talk through the details about what was explained in the guidance and finally open up for questions. Matthew?

Matthew Diamond: Thank you very much, Bakul and Irene. It's good to be here speaking with you today about the changes to existing medical software policy resulting from Section 3060 of the 21st Century Cures Act guidance which we can just call the 3060 guidance for short. And let's take a moment and review the objectives for today's webinar.

Number 1, we're presenting what software functions were excluded from the device definition by the 21st Century Cure's Act. Which we can simply refer to as the Cure's Act. And Bakul has already introduced this. And Number 2 will explain how a number of FDA's existing software guidances have been updated to reflect that change to the device definition. To be clear, if a software function is excluded from the device definition that means that we do not consider it to be a medical device function. And as Bakul alluded to, we've adopted a function-based approach to digital health regulations and that's why we're speaking here in terms of functions.

So let's talk a little bit more about the software provisions of Section 3060 of the Cure's Act. And there's a lot of words on this slide but it's worth going over the most important points. And first and as we've already mentioned,

Section 3060 defines some set of software functions that are not devices. Bakul already showed on the previous slide the different categories, A through E of the FD&C Act 520(o)1 of software functions excluded from the device definition, and we'll revisit them again in more detail soon.

Second, it states that the FDA shall not regulate non-device functions of a product with multiple functions, but can consider the impact of non-device functions on the device functions. Next, there is a process by which FDA can regulate software functions that are excluded from the device definition by the Cures Act if the agency finds that it would be reasonably likely to have serious adverse health consequences. And additionally, software used in the manufacture and transfusion of blood and blood components for humans are not excluded from the device definition by the Cure's Act even if they would otherwise be.

So here is a list of the final guidances that were updated based on the Cures Act. In other words all of these guidances were published previously and have now been updated, or in one case withdrawn, with the publication of the 3060 guidance. They include the mobile medical app guidance which is now called the policy for device software functions and mobile medical applications. The general wellness policy for low-risk devices, medical device data systems, medical image storage devices, and medical image communication devices or MDDS, off-the-shelf software used in medical devices, and guidance for the submission of premarket notification for medical image management devices which is actually being withdrawn.

So we're now going to walk through some of the changes to the 3060 guidance, software category by software category. And the way we'll do this is that we'll first discuss if there were any changes to the 3060 guidance from draft to final. And then for areas where there is another affected guidance, we'll discuss the highlights from that affected guidance.

We'll start with the changes to the 3060 guidance related to the types of software functions described in 520(o)1A of the Food, Drug and Cosmetic Act and then we'll make our way down the Act from A to D.

And so here we see the first set of software functions excluded from the device definition in Section 3060. They are intended for administrative support of a healthcare facility. These functions include maintenance of financial records, information about patient population, and laboratory workflow. This slide highlights changes from what was written in the draft 3060 guidance in the left column to what is now the final 3060 guidance in the right column. So in the final guidance in this area, we did not make any changes in FDA policy. But we did clarify, however, that certain laboratory information systems include software functions that remain devices.

An important note here is that FDA generally did not consider these administrative support software functions to be devices even prior to the Cures Act.

The next slide summarizes the second set of software functions to be excluded by the Cures Act described in 520(o)1B. They are intended for a purpose related to general wellness and are described in detail in the general wellness guidance. We won't spend too much time on this slide because we have unpacked the info of general wellness into the next few slides. The main point to take away from this slide is that there is no change in policy for the low risk, general wellness products from the draft 3060 guidance to the final 3060 guidance. To summarize, there are changes to the general wellness guidance as a result of the Cures Act. But there are no policy changes related to general wellness in the final 3060 guidance compared with the draft 3060 guidance.

So let's go ahead and get into more detail on some of the main point of the updated general wellness guidance. The general wellness guidance describes two categories of general wellness intended uses. And this should be a review. It's not new to this guidance update. Category 1 has an intended use that relates to maintaining or encouraging a general state of health or a healthy activity. Category 2 has an intended use that relates to the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions when it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

So what's the regulatory status of these two categories of wellness products? Let's start with what we just called Category 1 general wellness software functions. The software functions for maintaining or encouraging a healthy lifestyle are now excluded from the device definition by the Cures Act that is as long as the software function is unrelated to the diagnosis, cure, mitigation, prevention or treatment of a disease or condition.

Prior to cures, and as described in the previous general wellness guidance, the software functions have been under enforcement discretion. Meaning that based on the agency's understanding of the risks of these devices they did not intend to enforce compliance with applicable device requirements, as Bakul mentioned earlier.

As opposed to software, hardware for general wellness intended uses that meet the device definition remain devices. But these remain under enforcement discretion.

Okay so we've covered general wellness Category 1, how about Category 2 general wellness software functions? If the intended use relates the role of a

healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition then the product is not excluded from the definition of the term device. We encourage you to refer to the general wellness guidance for more information for current policy on these devices.

Okay, so we've discussed some ramifications of 520(o)1A and 520(o)1B of the FD&C Act that was modified by Section 3060 of the Cures Act. Now let's discuss 520(o)1C. The third category of software functions excluded from the device definition are electronic patient records. For the record to be excluded from the device definition, it must be created or reviewed by healthcare providers. It must be certified under the ONC health IT certification program. And it must not be intended for interpretation or analysis for the purpose of diagnosis, cure, mitigation, prevention or treatment of a disease or condition.

In the draft 3060 guidance, FDA explained that we do not intend to enforce the requirements for records that are not certified under the ONC health IT certification program. We also noted that personal health records, those that are not created or reviewed by healthcare professionals, are not devices. This distinction is separate from the exclusion of the cure's act.

In the final guidance, we did not change any of the policies. We created sections to better describe each of the exclusion criteria and we added examples as requested by the comments on the draft guidance.

Okay, let's move on to 520(o)1D, the fourth set of software functions excluded from the device definition by the Cure's Act. The fourth category of software functions excluded from the device definition are those intended to transfer, store, convert, format or display device data and results. These

functions echo functions described in the medical device data system or MDDS regulation. These functions were under enforcement description according to the 2015 MDDS guidance we described earlier. That guidance did not distinguish between hardware and software functions, neither does the regulation.

In the final guidance, we clarified that the Cure's Act only excluded software and MDDS functions from the device definition, and the MDDS hardware remains devices. However, FDA does not intend to enforce the requirement under the FD&C Act for hardware products, provided the hardware function is limited to performing the excluded MDDS software functions.

We also state that general purpose IT products that are not intended for a device function, for example all-purpose computer monitors or routers, are not device functions. In the draft 3060 guidance, we included a reference to a policy for alarms, alerts, and flags because the MDDS regulation refers to active patient monitoring. In the final 3060 guidance we refer the discussion of alarms, alerts and flags to the clinical decision support or CDS guidance, since comments noted that these types of functions may be excluded from the device definition according to Section 520(o)1E, which is discussed in the CDS guidance and not in the 3060 guidance. In the CDS guidance we describe these functions as device functions because they analyze medical device data, so they are not excluded from the device definition. There is a lot here on this slide and you can refer to it as a reference but let's review this information in a little bit less compressed format on the next few slides.

So software functions that are solely intended to transfer, store, convert formats and display medical device data or results are now excluded from the device definition by the Cures Act and considered non-device MDDS. Note that the non-device software functions may or may not be intended for active patient monitoring. Software functions intended to interpret or analyze clinical laboratory test or other device data, results, or findings are not considered

MDDS, and are not excluded from the device definition. In other words, while these non-device MDDS software functions are transferring, storing, converting or displaying medical device data, they are not modifying it or interpreting or analyzing it.

And one other thing I'd like to highlight about these non-device MDDS software focuses is that they do not control the functions or parameters of a connected medical device. Now we just said that non-device MDDS software functions may or may not be intended for active patient monitoring. But note, that software functions intended to generate alarms or alerts or prioritize patient-related information on multi-patient displays are generally considered device software functions because these functions involve analysis or interpretation of laboratory tests or other device data and results.

So it is the analyzing/ interpreting feature of alarms and alerts that would make them not be excluded from the device definition, in other words that would make them devices, not the fact that they are intended for active patient monitoring.

Okay, we've discussed software MDDS which is non-device MDDS. Let's move on to hardware MDDS. Hardware products that are solely intended to transfer, store, convert, format and display medical device data results are considered device MDDS. But FDA does not intend to enforce compliance with the regulatory controls for such devices. They are under enforcement discretion, that is provided that the hardware function, as I mentioned, is limited to assisting MDDS software functions, in other words the electronic transfer, storage, conversion, format or display of medical device data.

An important note here is that specialized medical display hardware devices, for example digital mammography, radiology, pathology and ophthalmology

have not been considered device MDDS and are not excluded from the device definition by the Cure's Act. So were distinguishing here between hardware that is intended for what you could call a general MDDS functionality, which are under enforcement discretion. And hardware that is intended for a specialized medical display function, which are not.

And on the next slide we will summarize hardware that is not specifically intended for medical purposes either general or specialized, in other words, hardware that is not intended by the manufacturer for a medical device function.

So general purpose products --IT infrastructure like network routers, network storage equipment, general purpose computer monitors, or PDF software -- not intended for a medical purpose do not meet the definition of a device for either the software or hardware function and therefore are not regulated as devices.

Okay, that was the last slide on MDDS. Let's move on to the last few guidances. The mobile medical app guidance now called policy for device software functions and mobile medical application has a few changes including the terminology used to reflect a focus on using the term software function as opposed to mobile application. Also in the guided several examples have been revised as some have been moved from Appendix B to Appendix A because some software that was previously under enforcement discretion has now been excluded from device definition by the Cure's Act, like general wellness Category 1 software functions which we discussed.

Okay, moving on to the next guidance. The next guidance we'll briefly mention briefly is the off-the-shelf software guidance, notably the section that

is specific to laboratory information systems and laboratory information management system has been removed.

Okay, we have one guidance left to discuss. And that is the medical image management devices guidance. This guidance was withdrawn because some software functions described in the guidance no longer meet the definition of device as amended. Rather, for the limited subset of medical image medical devices that continue to meet the definition of a device, CDRH encourages manufacturers to reference the most recent FDA recognized versions of relevant voluntary consensus standards.

And the last thing I want to say about the series of guidances released in September is that we are asking for your feedback on the one guidance that was released in draft format that was the clinical decision support software guidance. But this is not the subject of today's webinar.

I would like to take this opportunity again to please ask for your feedback. The docket is open to comment until December 26 and we need all of your comments and suggestions, which we'll take into account as we update the guidance.

And here again is a list of the guidance documents that we did discuss in this webinar. And also there's an opportunity to sign up for digital health email updates.

If you have additional questions, you can email FDA's division of digital health directly at digitalhealth@fda.hhs.gov. You can also contact FDA's division of industry and consumer education or DICE. This live presentation, transcript and webinar recording will be available at the link at the bottom of the slide.

Thank you very much and we're going to open up this webinar now for questions.

Bakul Patel: Thank you, Matthew. And thank you, everybody.

Irene Aihie: We'll now take questions.

Coordinator: Thank you and at this time to ask your question, please press Star 1. Please unmute your phone and record your name clearly at the prompt. To withdraw your request, please press Star 2. Once again, at this time to ask a question, please press Star 1.

Bakul Patel: Great, while we're waiting for comments, questions thank you Matthew for that wonderful overview on all the guidances. I'm sure people have a lot of questions. I do want to take a minute to highlight some of the nuances that we have done for in the guidance itself. And I would underscore a couple of points especially on the mobile medical apps guidance that we are taking the exact same approach that we have taken on mobile medical apps and applied to all software functions and this is true to what we have said all along in mobile medical apps guidance. But now in this particular change that we've done to the title of the guidance it reflects our policies applied to any software regardless of the platform. So it's going back to the foundational framework that I started talking about in the beginning of this webinar.

We'll take some questions now. Operator, when you're ready.

Coordinator: Thank you, one moment please. Our first question is from (Mike Beneke). Your like is open, sir.

(Mike Beneke): Hi, Bakul and Matt. Thank you for your webinar. It was great. Could you comment on how do you regulate things that are kind of like hybrid apps? Like telemedicine apps or something like that like where a patient would transmit an image, you know, maybe a selfie to diagnose acne to a physician, how would you regulate that?

Bakul Patel: Actually, that's a great question and if you look at the mobile medical apps guidance, that is exactly one of the examples we have sort of highlighted and said that is not a medical device anymore. Because it's just enabling communications to, between a patient and a provider. So those, you know, typically messaging or a video or a taxpaying or a picture transmitter over to a provider is not something that we are regulating.

(Mike Beneke): Thank you.

Coordinator: Our next question is from (Lauren Zigler). Your line is open.

(Lauren Zigler): Okay, thank you. If this software recommends that a patient see a healthcare professional for a diagnoses and treatment and that is not based on the output functionality of the test within the app. Is that still a regulated medical device?

Bakul Patel: So this may, just so that I'm clear and then Matthew see if you want to chime in here and provide your thoughts. When we're talking about navigating or identifying a healthcare provider as an administrative function, that's definitely not a device. And when you are trying to identify a condition and then identification of that condition as a result, the action you want the user to take is go with it, a specialist or not a specialist. It would be a different. It will be considered differently.

Some of - and I think this is where the nuances are, and I'll encourage you to look at the guidance and the example we have taken time to put into the document. It might be really helpful for you to take a look at that. But those are the nuances that matter. And it becomes important to not just think about what it is doing but also how and where and what's the effect of that recommendation or suggestion to the user that's going to be and what impact of that is.

(Lauren Zigler): Yes, thank you.

Coordinator: And once again to ask a question at this time, please press Star 1 and provide your name. Our next question is from (Ralph Crogue). Your line is open.

(Ralph Crogue): Hello, thank you for the webinar. My question is about, I have a product that we're - that's under development that would annotate electronic health records. So if electronic health records are not a medical device, would something that annotates it be a medical device? And then the next question that follows that is what if it makes - it analyzes the medical record and makes suggestions about how to annotate the medical record?

Bakul Patel: Yes, so the medical record functionality as far as the 21st Century Cures Act goes, the function of creating a record or appending a record itself is something not regulated by FDA. I mean think about the paper records and the explanation that we are given in the guidance in 3060, you can see sort of, how and what rationale you should think about for the functionalities that may exist on top of the records itself.

And I think it's important to sort of, highlight some of those points that you're raising. In addition to just, you know, annotating a record and there may be other functions that may happen as part of your provider entry system that

exists inpatient setting. I think those are the things that we consider as electronic health record systems. And that is specifically - and if it's certified by Office of National Coordinator, that is not necessarily able to be considered medical device.

Matthew, did you want to add anything?

Matthew Diamond: Yes, and just to add that, you know, I think annotating is a fairly broad term and, you know, as Bakul mentioned, a simple annotation would seem to fall under the category of electronic patient records. But if the software had additional functionality that included analysis and as you mentioned specific recommendations, we would have to look at the specifics of that case.

(Ralph Crogue): Okay, thank you.

Coordinator: Next question is from (Resa Sherte). Your line is open.

(Resa Sherte): Good morning and thank you for a very informative session. I'm thinking as - there's two parts to this question. One is what's the Office of Strategic Partnership supposed to do? And how they can help us startups to be able to compete with the big companies from the point of view of - actually this question is more related to the 2019 and (unintelligible) company was forming or helping the regulatory definitions for the software and also for the decision making by the software.

And the second question is if there is new method for analyzing data that we captured in our trial, should we provide all the data and how that's normally get transferred to a CA? Can we, let's say if we are running with the accredited institute, should be we get all the data or how we should think about the keeping a good record when we want to go for FDA?

Bakul Patel: Your question is actually very interesting and intriguing at the same time. I would highly recommend, I think, and would reach out to what Matthew referred to as, you know, the Division of Industry and Consumer Education. And if you have specific questions, I think you started off with, you know, what is - how FDA is looking at a new paradigm and the pre-certification program. I encourage you to write to the precertification inbox as well as our, you can write to (unintelligible) health inbox and on the screen you're seeing right now.

They field general questions about, you know, do you have certain data and how do you want to discuss that with FDA. We have several programs in the center starting from queue submission program which basically, you know, you can share what you're trying to do in detail, and we can take that conversation in that very specific discussion.

Today I think we are talking specifically about policy we laid out to encourage people online to start - to highlight some of the things that we shared today and see if there's any clarification in the documents we published that would be helpful for us to address today.

(Resa Sherte): So which division you mentioned at the beginning? Sorry, I wasn't (unintelligible) so I couldn't hear exactly.

Bakul Patel: Yes, so the slides if you're not seeing the slides, it's the Division of Industry and Consumer Education. It's the email address is dice@ ...

((Crosstalk))

(Resa Sherte): Is this the one on the slides right now?

Bakul Patel: Yes.

(Resa Sherte): Okay, Division of Industry and Consumer Education. Okay, I got it. Thank you, thank you for your response.

Bakul Patel: You're welcome.

Coordinator: Our next question from (Tucker Tomlinson). Your line is open.

(Tucker Tomlinson): Thank you. I was hoping to get a little clarification on a note that you had earlier in the slides about the option to regulate MDDS systems if there's sufficient risks around the use. And what the thresholds for that decision might be. When you would choose to regulate a system that would otherwise be classified as a non-device. Do you have any additional guidance about how that decision would be made?

Bakul Patel: Yes, I think at this time, I would recommend that our policy and the last basically says that the current set of information that we have from a public health perspective, patient safety perspective, FDA has very clearly laid out in these final guidances what is that. And this final guidance that they're not devices. However, on an ongoing basis as part of the law, we have been asked by Congress to continuously observe in this space that are not devices. And if there is any public health impact, we would be engaging in a very broad public dialogue and before we make any changes to these policies.

(Tucker Tomlinson): So would there be reports or monitoring that would need to be supplied to the FDA for these non-devices as part of that ongoing monitoring/

Bakul Patel: No, it is a responsibility that FDA will publish. And engage in a draft and final as the policies or notices that will help make people aware if we are changing the policies than what we published today.

(Tucker Tomlinson): Okay, and then a second question is for an MDDS, does the consumer of the data make a difference? So if the consumer is clinician versus another medical device, if you had a Class 3 device that's consuming data from a MDDS, does that impact how you would regulate the MDDS?

Bakul Patel: So the way the, and you'll see we have a draft guidance on multiple functionality which addresses exactly the point you're raising which we are in the process of finalizing. But to share what is highlighted in that guidance, it talks about it's not about regulated the non-device functions. It's about understanding the Class 3 device impact on the Class 3 device from that non-device function. And that analysis of risk needs to be conducted on the Class 3 device or device of any other class.

(Tucker Tomlinson): Okay, thank you.

Coordinator: We are showing no further questions. We'll turn it back to Irene Aihie for closing remarks.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH learn webpage at www.fda.gov/chrhlearn by Friday, November 22. If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback. Following the conclusion of today's live webinar, please complete a short 13-question survey about your FDA CDRH webinar experience. This survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live webinar.

Again, thank you for participating. This concludes today's webinar.

Coordinator: Thank you. That does conclude today's conference. We do appreciate you attending. You may disconnect at this time.

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