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NEWSLETTER FROM **DELPHI CONSULTING GROUP** (**DCG**)
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Delphi Consulting Group (DCG), *provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs*

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US FDA unveils online resource center for biocompatibility assessment

Questions? Request more information from our specialists
CONTACT US
Mar 24, 2021

The US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) published its new Biocompatibility Assessment Resource Center this month to help companies navigate requirements relating to ISO 10993-1. Users of the website are advised to read the agency's guidance document on evaluating and testing biocompatibility for medical devices, which was finalized in September 2020, in full. After this is complete, they are presented with a list of recommended steps along with the online resources to facilitate them. Rather than comprising a collection of all existing FDA resources on biocompatibility, the resource center provides a generalized procedural guide intended to be suitable for most companies.

Resource center provides procedural guide to biocompatibility evaluation

The steps and corresponding web pages given in the resource document are as follows:

1st **Biocompatibility Basics**. This step features links to a guide on when biocompatibility information is needed, what the FDA assesses or evaluates, and how it does so, along with biocompatibility factors of interest to the FDA. Additionally featured here is a glossary of biocompatibility terms.

2nd **Evaluation Endpoints**. Biological endpoints tables for use in evaluation are provided here by device category as well as by contact duration period.

3rd **Test Articles**. This links to a page providing examples of how to document the comparison of test articles with the final proposed forms of medical devices. The content here is derived from Attachment F of the guidance document.

4th **Test Report**. This links to a guide to the preparation of the test report for biocompatibility testing, explaining what information is needed to meet FDA expectations. This content is derived from Attachment E of the biocompatibility guidance. The page also includes links to further resources on the appropriate use of consensus standards and accreditation of testing laboratories.

The resource center concludes with the advice to utilize the FDA's Q-Submission program for device-specific questions about biocompatibility evaluation.

We must protect the right to repair medical devices

As a volunteer at a hospital, I have witnessed medical devices malfunction and need repair before being used again on patients. During the pandemic, I have learned that the technicians and engineers who could perform these repairs often don't have access to the tools, information or replacement parts they need. In fact, U.S. PIRG (a federation of public interest research groups) found that 76% of medical repair professionals surveyed have been denied access to repair information and parts by the manufacturer.

The increased demand for ventilators during the pandemic led to hospitals pulling the machines out of storage, but many had to wait for a representative from the manufacturer to come out for routine software tests or repairs. I wouldn't want my loved ones to have to wait for a breathing machine while they're struggling to fight COVID-19.

Hospitals need the right to repair their medical equipment. The right to repair movement is calling on manufacturers to provide repair information and sell replacement parts at a reasonable price, so everyone from independent repair businesses to hospital technicians can fix equipment themselves. Sen. Elder Vogel Jr. is planning to introduce legislation for the right to repair in our state. I encourage Sen. Judy Schwank to co-sponsor it.

We cannot afford to wait for these changes, especially during the pandemic when we are relying on medical professionals and their equipment to save lives.

Sara Tabakha

The following is an option from Delphi Consulting Group. Sounds like just the right thing to do, ---- WRONG, the lawyers are waiting to take the medical device manufactures down when anything allegedly goes wrong. The people repairing will not have the documentation, jigs, test equipment etc., to ensure the device is working properly. **All medical device documentation should contain legal language protecting the manufacture from unauthorized repair.**

CMS delays breakthrough device Medicare coverage

March 19, 2021 By Nancy Crotti Leave a Comment

Medicare coverage for FDA-designated breakthrough medical devices will have to wait, despite broad support.

The Centers for Medicare and Medicaid Services (CMS) issued a final rule in January granting coverage for breakthrough devices the same day as their FDA approvals. The rule was supposed to take effect March 12, but CMS has postponed the Medicare Coverage of Innovative Technology (MCIT) final rule by 60 days to give the public more opportunities to comment, the agency said in a Federal Register notice.

Immediately upon taking office, the Biden administration asked federal agencies to consider delaying the effective date of rules

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published in the Federal Register so it could review questions of fact, law and policy the rules may raise. CMS officials decided that further review was warranted.

The pause is mystifying to officials of the medtech trade group AdvaMed, according to its president and CEO. Scott Whitaker told ***Medical Design & Outsourcing*** that the final rule, which has broad bipartisan support, has been the subject of plenty of deliberation within and outside the government.

"It feels like a long and deliberate process, which again underscores why some of us are a little confused that at the last minute they would suggest that it wasn't moving forward," Whitaker said. "We are all trying to better understand it and we are all speculating a little bit.

"It may be one of two things," he added. "There is some sense that the agency just wasn't ready to implement it, whether they weren't able to get the work done in time, or because there are open policy questions that they needed further answer to. We're hopeful that that is the reason. There are some that suggest that the underlying policy is something that the new administration might not be supportive of. I'm not sure why that would be… We're trying to square those two things as best we can and we're hopeful that once they dig into this rule — the new administration — they'll realize the value it provides for innovation and for patients who are impacted by it."

If the Biden administration does not support the underlying concept of the proposed rule, the medtech industry is willing to talk about it, according to Whitaker.

"I'm not sure from a policy perspective who'd be opposed to speeding up the process for Medicare beneficiaries to get access to these breakthrough products," he said. "Not a large number have been cleared and it's not a simple definition that's wide open to interpretation. It's very clear from statute to regulation. there shouldn't be a lot of ambiguity, that and it underscores why we're a little bit concerned and confused."

Mark Leahey, president & CEO of the Medical Device Manufacturers Association, told ***MDO*** that MDMA is sure the rule will go into effect.

"While we are disappointed in the delay of the MCIT program, we remain confident that it will be enacted due to the strong ongoing support of physician and patient groups, as well as the bipartisan support in Congress," Leahey said in an email. "MDMA will continue to work with CMS to advance the MCIT program, and to help ensure that patients get timely access to medical technology innovation."

If the proposed rule goes into effect without changes on May 15, 2021, the coverage would last for four years, during which CMS would specify what additional data, if any, would be needed to maintain coverage after the four-year coverage period expires.

CMS officials said in a news release in January that they believe four years of Medicare coverage will encourage manufacturers to voluntarily develop evidence to show these treatments improve the health of Medicare patients. When MCIT coverage sunsets, manufacturers will have all current coverage options available such as a national coverage determination (NCD), one or more local coverage determinations (LCD), and claim-by-claim decisions.

Workshop Summaries

How to Use Consensus Standards in Premarket Submissions:

The use of FDA-recognized consensus standards promotes predictability, advances regulatory science, and supports a least burdensome approach to medical device review. The first session of the CDRH Industry Basics Workshop will discuss how to use and reference standards in your device submissions.

The ASCA Pilot: Streamlining Conformity Assessment in Device Submissions: The second session introduces the Accreditation Scheme for Conformity Assessment (ASCA) Pilot, which is intended to improve the efficiency of conformity assessment in device review. This session will share strategies for successful participation in the ASCA Pilot.

Each session will feature a presentation followed by a moderated question and answer session with a panel of knowledgeable FDA staff. Audience participants will have the opportunity to send in questions to be answered during each session.

There is no fee to attend and registration is not required.

You may choose to participate in one or both sessions. Each session will begin at the scheduled time:

- 1:00-2:00 p.m. ET: How to Use Consensus Standards in Premarket Submissions
- 2:00-3:00 p.m. ET: The ASCA Pilot: Streamlining Conformity Assessment in Device Submissions

Target Audience: All medical device industry, testing laboratories and accreditation bodies.

- **How to Join the Workshop:**

On April 13, go to this page to join the workshop: CDRH Industry Basics Workshop: Consensus Standards and the Accreditation Scheme for Conformity Assessment (ASCA) PilotExternal Link Disclaimer

The CDRH Industry Basics Workshop is a general educational forum. Prior to the workshop we encourage you to review the Standards Modules in CDRH Learn.

For questions about this program, please contact the Division of Industry and Consumer Education (DICE) in the Center for Devices at dice@fda.hhs.gov, or via phone at 1-800-638-2041, or 301-796-7100.

Microsoft tackles the bandwidth problem for remote workers using Teams

Microsoft is closing another gap on Zoom by ensuring that if you can't be seen, you are at least heard over a poor connection. SIC – 35% of Americans do not have high speed net.

By Liam Tung | March 10, 2021 -- 11:59 GMT (03:59 PST) | Topic: Microsoft

Microsoft's Teams group is addressing bandwidth problems for people who are using the collaboration platform to work from home.

"Whether you want to preserve data or are in a location with a poor or limited network connection, sometimes it's helpful to limit the amount of data you're using during a video call," Microsoft explains in an update to its roadmap.

"A new low data mode allows users to cap the amount of data that will be used during Teams video calls, as well as to establish different settings based on network availability."

It's like Google and Bing search engines, so far ZOOM has won the day.