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NEWSLETTER FROM DELPHI CONSULTING GROUP (DCG)
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The ORACLE is a free newsletter of recent medical device regulatory & computer information that is of interest to designers, and device manufactures.

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

Have a Good 2020

Medical device tax is permanently repealed

December 23, 2019 By Chris Newmarker Leave a Comment

President Donald Trump has signed into law the 2020 federal spending package, which includes a provision to permanently repeal the 2.3% medical device excise tax.

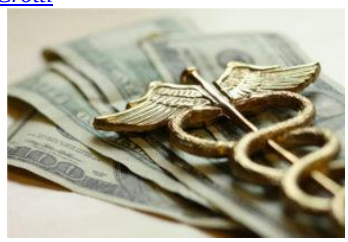
Trump signed off on the spending bills on Dec. 20, providing the medical device industry a win that it has sought for nearly a decade. The tax was part of the Affordable Care Act of 2010 and was one of a number of funding mechanisms meant to help pay for the health reform. But the medtech industry argued that the tax limited jobs and innovation

Device companies over the years achieved temporary suspensions of the tax through Congress — but never an outright repeal, until now.

"The medical device tax is officially history. With the end of this burdensome tax, the U.S. medtech industry can do what it does better than anyone else in the world: develop life-changing innovations that save and improve patients' lives, and create high-paying, high-tech jobs to keep the American economy booming," AdvaMed CEO Scott Whitaker said in a statement. "We thank President Trump and his administration for their strong support of medical innovation and for their leadership as we worked with Congress to repeal this onerous tax," Whitaker said.

FDA publishes final list of 510(k)-exempt devices

December 30, 2019 By Nancy Crotti



The FDA today published a list of Class I and Class II medical devices that it now considers exempt from premarket notification, in accordance with the 21st Century Cures Act.

Sponsors of these devices will no longer have to apply for 510(k) clearance from the FDA. The agency said this action, published today in the Federal Register, decreases the regulatory burden on the medtech industry and eliminates private costs and expenditures required to comply with certain federal regulations.

Sponsors of devices covered by exemption stand to save some money. User fees for devices covered by 510(k) regulations went up nearly 6% from fiscal year 2019 to FY2020, from 10,953 to $11,594.

Included in the exempt list are:

- Clinical chemistry test systems.

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- Clinical laboratory instruments.
- Clinical toxicology test systems.
- Hematology and pathology devices.
- Immunology and microbiology devices.
- Ophthalmic devices.
- Radiology devices.

Devices now exempt from the 510(k) to determine their reasonable safety and effectiveness are still subject to other statutory and regulatory requirements, the agency said. The exemptions go into effect today.
To review complete FDA ruling and list of devices click here. http://www.delphiconsulting.com/Exemptions%2012%202019.pdf

FDA issues a Final Rule to Require Medical Device Submissions in Electronic Format.

The U.S. Food and Drug Administration (FDA) issued a final rule, Medical Device Submissions: Amending Premarket Regulations that Require Multiple Copies and Specify Paper Copies to be Required in Electronic Format. The new rule requires medical device premarket submissions to be sent in electronic format, eliminating the need for multiple pa-per submissions. We are taking this action to improve the efficiency of FDA's premarket submission program for medical devices.

The FDA is also publishing a revised eCopy Guidance "eCopy Program for Medical Device Submissions; Guidance for Industry and Food and Drug Administration Staff." The update to the eCopy guidance reflects the amendments to the regulations.
Additional Guidance's

Several additional guidance's are being updated to conform to changes made in the final rule:

- Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)
- Real-Time Premarket Approval Application (PMA) Supplements
- 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75- Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes
- Annual Reports for Approved Premarket Approval Applications (PMA)
- FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act

Questions?
If you have any questions, contact the Division of Industry and Consumer Education (DICE).
Copy of Guidance click here. http://www.delphiconsulting.com/0181%20iDoc%20ecopy-program-guidance.pdf

Focusing on social media.

A conforming social media program includes not only establishing a policy that addresses the latest FDA requirements for staff to follow, but also accounts for periodic auditing and on-going monitoring of company social media activity.

A growing trend.

Sophisticated drug and device makers have finally jumped on the social media bandwagon. Leading manufacturers now have campaigns designed to educate consumers, promote products, engage health care professionals (HCPs), and raise awareness of new therapies. Marketers love social media because it facilitates patient engagement via short, focused and attention-grabbing posts, health-related questionnaires, and the provision of "real-time" information. It's also relatively inexpensive and easy to use. Paid advertising and search engine optimization (SEO) are often used in tandem with social media to drive awareness of new therapies. For example, targeted Facebook ads direct users to links where they can find out if they may be a candidate for a therapy and even find an HCP.

Social media questions to consider:

- Do I have to share safety information in my product posts on Twitter?
- Do I have to share safety information on Facebook, YouTube, LinkedIn, and Instagram?
- Can I retweet live conference posts?
- Can I share an article or event posted by an HCP customer?
- What should I do when a 3rd-party posts information on my social media page that is off-label?
- Can I "like" off-label" posts?
- Can I encourage off-label conversations?
- Do I have to report product complaints that I find on social media sites?
- Can I force someone to take down a post?
- Can I delete posts I don't like?
- Can anyone in the company post product information?
- Can I share news about customers to help them generate more business?
- Can I help promote my customer's practice?

Common pitfalls.

Use of social media in the highly regulated drug and device industry is much more challenging than some may think. Despite the upside, social media use can put drug and device makers in legal jeopardy if FDA requirements are not followed. Avoiding a warning letter, or some other legal action, requires forethought and planning—which often comes as an unwelcome surprise to marketers.

Rules and issues to consider:

- Social media does not offer a pass to the provision of safety information.
- The "most significant" warnings or precautions must be communicated, among other things.
- Responding to an off-label question or request on social media *may* be okay if FDA recommendations are followed but speculating about and promoting unapproved uses is NOT allowed.

- Promoting unapproved/uncleared investigational products is barred per Parts 312.7 and 812.7.
- Cherry-picking posts to "like" and/or delete presents risk.
- Unsupervised forums may be an option, but they also present risks. Such platforms require careful planning.
- Allowing staff to post can be acceptable but only under certain conditions outlined in written company policy and subject to copy review. Social media training is advised.
- Drug (and biologics) manufacturers must follow special rules for submitting post-marketing social media communications to the FDA's Office of Prescription Drug Promotion (OPDP).
- Misinformation may be corrected as prescribed by FDA under certain circumstances.
- Driving patients to particular customers raises serious kickback concerns as we recently shared in our September Regulatory Alert.
- 3rd party users and manufacturers who post patient information may run afoul of HIPAA if patient permission is not gained before posting.
- Consider how a plaintiff's lawyer may use social media and internet campaigns against the company.
- Consider what you would do if an unfriendly party bad mouthed the company on a social media platform.

FDA guidance.

FDA guidance documents and warning letters provide the basis of a "social media road map." Best practice for creating a tailored road map for an organization entails considering what risks and obstacles are faced before the first post is ever made. Consider ascertaining: What is our risk profile? Do we have a written policy on social media use? What is allowed and what is prohibited? Who reviews posts before they are made? What special FDA rules apply to us?

FDA has issued four (4) guidance documents related to social media in an effort to provide clarity on various topics. These include:

- Communicating risk and benefit information when there is a character or space limitation
- Correcting misinformation posted by a 3rd party
- Responding to unsolicited requests for off-label information
- Post-market FDA submissions of interactive promotional materials

FDA Warning Letters.

FDA warning letters also provide additional insight into current Agency thinking. FDA has issued many warning letters to companies for activities such as: liking or responding to a 3rd party comment in an inappropriate way, using metatags that misbrand a product, and failing to adequately disclose safety information.

For example, Kim Kardashian was famously warned by the FDA through her employer, Duchesnay, Inc., a drug maker, for a false or misleading post that presented efficacy claims for DICLEGIS®, an FDA-approved morning sickness medication, but failed to communicate any risk information associated with the use of the drug. The Agency also claimed that the post omitted material facts. Thus, FDA claimed that the social media post misbranded DICLEGIS® within the meaning of the Federal Food, Drug, and Cosmetic Act.

Microsoft's first Office app arrives on Linux – *outstanding*

Microsoft is bringing its first Office app to Linux today. The software maker is releasing Microsoft Teams into a public preview, with the app available in native Linux packages in .deb and .rpm formats. "The Microsoft Teams client is the first Office app that is coming to Linux desktops, and will support all of Teams' core capabilities," explains Marissa Salazar, a product marketing manager at Microsoft.

The app looks identical to what is available on Windows and macOS, and it's entering public preview before Microsoft finalizes it. Microsoft is bringing Teams to Linux as part of a bigger push to align Teams as its hub for Office and teamwork, alongside supporting mixed environments that rely on Linux. Microsoft has been gradually improving the Teams feature set as it battles rivals like Slack.

Related

Microsoft: Slack doesn't have the 'breadth and depth' to reinvent work

"I'm really excited about the availability of Microsoft Teams for Linux," says Jim Zemlin, executive director at The Linux Foundation. "With this announcement, Microsoft is bringing its hub for teamwork to Linux. I'm thrilled to see Microsoft's recognition of how companies and educational institutions alike are using Linux to transform their work culture."

It's significant to see Microsoft invest in desktop Linux, especially an Office app. Microsoft has never embraced Linux with its own Office apps before, and this Teams launch appears to be a way for the company to address that gap. It's unlikely we'll see full versions of Word, Excel, and PowerPoint anytime soon, but this Teams launch could act as a bridge to improved Progressive Web App versions of Office.

Microsoft is also developing its new Fluid Framework, which takes the idea of documents and turns them into a cloud app that multiple people can contribute to with graphs, tables, text, and more. Microsoft revealed recently that Teams will act like the "scaffolding" to combine old experiences like Word and new ones like Fluid into a single hub.

DCG wishes all a very good and safe 2020.