



Submitted Electronically to: www.regulations.gov

March 22, 2022

U.S. Food and Drug Administration
Dockets Management Staff
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: FDA Draft Guidance: Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (86 Fed. Reg. 72973, December 23, 2021), Docket # FDA-2021-D-1118; & FDA Draft Guidance: Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (86 Fed. Reg. 72978, December 23, 2021), Docket # FA-2021-D-1149

Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Center for Devices and Radiological Health's (CDRH) draft Guidance documents (1) "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" ("Enforcement Guidance"), and (2) "Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" ("EUA Guidance").

AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare/home medical equipment (HME) community. Our members who are HME/respiratory suppliers provide medically necessary DMEPOS items and services to patients in their homes. Many of our members provide respiratory devices to consumers in their homes, and some of these devices, such as ventilators and CPAP devices, are those that fall within Food and Drug Administration's (FDA's) enforcement and/or EUA policies issued during the COVID-19 PHE.

FDA Draft Transition Guidance Documents

The purpose of the FDA Draft Transition Guidance documents is to provide manufacturers, health care facilities, providers, patients, and consumers with information regarding how devices approved during the COVID-PHE can transition to post-COVID-19 normal operations. Due to the COVID-19 PHE, the demand for certain medical devices has exceeded available supply. In response, the FDA issued guidance

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documents to facilitate the availability of certain devices intended to diagnose, treat and prevent COVID-19 and associated conditions. These guidance documents remain in effect only for the duration of the COVID-19 PHE. The draft Guidance documents are designed to facilitate “an orderly and transparent transition back to normal operations.”ⁱ

In March 2020, the FDA issued guidance on its enforcement policy for ventilators and accessories, and other respiratory devices, during the PHE.ⁱⁱ Many of these devices are life-supporting or life-sustaining. AAHomecare members, and the larger HME/respiratory provider community, have distributed and provided some of these devices to patients in their homes. In addition, HME providers likely have provided ongoing supply replacements that are necessary for the appropriate use of these devices, such as masks and tubing.

The FDA Draft Transition Enforcement Guidance describes a three-part phased approach which begins with the manufacturer of affected devices making a decision to either (1) not distribute the device after the PHE, or (2) continue distribution of the device after the PHE. That decision will then trigger a series of required actions, including notification of that decision to the FDA.

Recommendations to Publicize Transition Process Milestones

AAHomecare generally supports the draft Guidance documents recommended procedures, to achieve an orderly transition to normal operations. We appreciate the FDA’s recognition that it will take time for all – providers, manufacturers, clinicians, and patients alike, to adjust from PHE era polices to normal operations, and support the proposed 180-day transition period. The first and most critical step in the transition process will be the manufacturers of affected devices submission of information to the FDA regarding whether or not the manufacturer intends to submit a marketing submission to continue distributing their product after the EUA termination date.

One the PHE ends, our members will likely be servicing patients who may be using ventilators, CPAP and other respiratory devices that have been subject to one of the FDA EUA enforcement policies or that have been issued EUAs. Most likely, our members will be providing ongoing supply replacements to be used with these respiratory devices. Our members will therefore be directly impacted by (1) the manufacturer’s decision about whether it intends to continue distribution or not after the PHE, and (2) the FDA’s decision to approve or not the manufacturer’s application, assuming the manufacturer intends to continue distribution after the PHE. Particularly since many of these respiratory devices are life-supporting or life-sustaining, it will be critically important for HME/respiratory providers, and their patients and the clinical team, to be kept apprised of the various milestones and decisions, beginning with the manufacturer’s intent, and ending with the FDA’s decision. In the event the FDA does not approve a manufacturer’s marketing application, stakeholders will also need to know the manufacturer’s plans for disposition of already-distributed product, or if the manufacturer proposes to leave already distributed product in place, what the manufacturer’s plan will be. If the result is that a particular device can no longer be used, patients, HME/respiratory providers, and the patient’s physician will need to be notified as soon as possible to develop a plan to obtain an alternative device.

We therefore strongly recommend that the FDA make public (e.g., on its web site, through its list serves, etc.), the following information for manufacturers of a respiratory device that falls with the FDA’s

enforcement policies issued during the COVID-19 PHE. The information should be made publicly available on a timely basis. ***We recommend that the FDA make public within one week of the FDA's receipt of information from the manufacturer; and for FDA decisions, within one week of those decisions.***

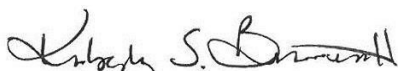
Information that FDA Should Publicize

1. Date of submission detailing the manufacturer plans to submit a marketing submission, (e.g., manufacturer's "Notification of Intent")
2. Date of submission detailing the manufacturer's plan to not submit a marketing submission to continue distribution after the EUA termination date,
 - a. Include the manufacturer's decision to either (a) restore the device to the previously cleared or approved version, or (b) have publicly available copy of labeling that accurately describes the product features and regulatory status (i.e., that the product lacks FDA clearance or approval)
3. Date of FDA positive decision on a manufacturer's marketing application to continue distribution after the PHE,
 - a. Include any changes or updates to the device and/or its labeling compared to the product that has been distributed under the EUA
 - b. Including the manufacturer's process for notifying patients, consumers, healthcare providers and distributors of the device's regulatory status
 - c. Process and timeline for providing to users of previously distributed devices updated labeling or components that reflect any changes made to the cleared or approved device
4. Date of FDA negative decision on a manufacturer's marketing application to continue distribution after the PHE
 - a. Include manufacturer's plan to manage devices already distributed, explanation of the manufacturer's risk-benefit-based plan for disposition of already distributed product
 - b. If manufacturer intends to leave already distributed product in place, the manufacturer's rationale for doing so and relevant considerations (e.g., plan for notifying healthcare providers, HME/respiratory suppliers, patients and distributors)

Conclusion

AAHomecare appreciates the opportunity to comment. If you have any questions, or would like further information, please contact me at kimb@aahomecare.org.

Sincerely,



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ⁱ See Draft Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency p. 4

ⁱⁱ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus>