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ALERT

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Closer to Normalcy: FDA Finalizes Transition Plans for Medical Devices Marketed Under COVID-19 Emergency Policies

Attorneys
Greg Levine
Josh Oyster
Michael Purcell

On March 27, 2023, FDA issued two final guidance documents providing transition plans for medical devices that FDA allowed to be marketed during the COVID-19 pandemic: the "Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)" ("EUA Transition Plan") and the "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" ("Enforcement Policy Transition Plan"). Both plans are intended to help prepare manufacturers of relevant devices for the transition to "normal operations" and to foster compliance with relevant FDA requirements as the COVID-19 public health emergency winds down.

FDA issued drafts of both transition plans in December 2021, as summarized in a prior Ropes & Gray Alert. The final transition plans maintain many of the key elements of the draft versions, but FDA has revised the documents to provide additional clarity based on industry comments and to ensure the approach described is "least burdensome" on FDA and industry stakeholders. This Alert highlights the key changes made in the final transition plans and provides key takeaways and next steps for manufacturers and distributors of devices covered by COVID-19 EUAs or enforcement discretion policies.

Background

Throughout the COVID-19 pandemic, FDA has undertaken various efforts to facilitate the availability of medical devices necessary to assist in the diagnosis, treatment, and prevention of COVID-19 and associated conditions, as well as to alleviate the supply chain issues caused by the pandemic. Among other things, FDA issued EUAs for certain unapproved or uncleared devices or unapproved uses of otherwise legally marketed devices. Additionally, FDA issued numerous guidance documents outlining enforcement discretion policies that recognize FDA's "non-objection" to the distribution of certain unapproved or otherwise non-compliant devices. Many of these policies expressly state that they are intended to be in effect only for the duration of the COVID-19 Public Health Emergency ("PHE").

In January 2023, the Biden Administration announced that it would allow the declaration of the COVID-19 PHE to expire on May 11, 2023, as explained in a prior Ropes & Gray Alert. The imminent expiration of the PHE no doubt prompted FDA to issue the final Enforcement Policy Transition Plan, given that the applicable policies will no longer be in effect. Additionally, while EUAs issued by FDA are not directly affected by the end of the PHE, the end of the PHE presumably makes it more likely that HHS and FDA will at least consider whether to terminate EUA declarations in the near term. Thus, the issuance of the final EUA Transition Plan enables industry to start planning ahead for such terminations.

EUA Transition Plan – Key Updates

As in the draft version, the final EUA Transition Plan anticipates a 180-day timeline for transition, triggered by publication in the *Federal Register* of a 180-day advanced notice of termination of a particular EUA declaration. Because HHS has published several EUA declarations covering different categories of devices, particular attention will need to be paid to the scope of any advance notice of termination to understand whether the transition period is triggered for a particular device subject to an EUA.

Generally, if a manufacturer wants to continue to market a product after the termination of the relevant EUA declaration, it will need to have submitted a marketing authorization application to FDA and have it accepted for review by the time the EUA declaration is terminated. Under the EUA Transition Plan, so long as the application has been accepted for

review before the EUA termination date, the manufacturer can continue to distribute the device until such time as FDA has made a decision on the application.

The final EUA Transition Plan includes a few key differences from the draft version, including:

- Elimination of Interim Labeling Updates: Whereas the draft contemplated that manufacturers make interim labeling updates while a marketing authorization submission is under review by FDA, the final EUA Transition Plan has removed this language. The final EUA Transition Plan expects that manufacturers that intend to continue to distribute their devices will update their product labeling only *after* FDA issues its final decision on the marketing submission.
- COVID-19 Laboratory Developed Tests ("LDTs"): The final EUA Transition Plan explains that, while FDA generally exercises enforcement discretion with respect to LDTs, it has not applied this enforcement discretion to LDTs used for public health emergencies, such as the COVID-19 pandemic. FDA states that "following termination of the EUA declaration for COVID-19 IVDs, FDA intends to have the same enforcement approach for COVID-19 LDTs as it does for other LDTs." In other words, once there is no applicable EUA declaration, FDA will exercise enforcement discretion with respect to COVID-19 LDTs in the same manner as any other LDT. This statement is the latest in a long history of shifting FDA and HHS policies with respect to COVID-19 LDTs, as discussed in a prior Ropes & Gray Alert.
- Clinical Laboratory Improvement Amendments ("CLIA") Categorization of COVID-19 IVDs: FDA explains that, for IVDs authorized under an EUA for use in CLIA-waived patient care settings, FDA will accept marketing submissions under the "Dual 510(k) and CLIA Waiver by Application" or "Dual De Novo and CLIA Waiver" pathways. FDA recommends that any marketing submission that may necessitate a CLIA categorization decision be submitted as soon as possible prior to the termination of the EUA declaration to reduce the potential for disruption in distribution due to the need for CLIA categorization.

Key Updates Specific to the Enforcement Policy Transition Plan

Similar to the EUA Transition Plan, the Enforcement Policy Transition Plan also describes a 180-day transition period. However, the start date contemplated in the Enforcement Policy Transition Plan is clearer than for the EUA Transition Plan, as the transition period for the Enforcement Policy Transition Plan will begin when the PHE Declaration expires—currently anticipated to be May 11, 2023. The Enforcement Policy Transition Plan describes a phased approach for the application of FDA requirements. Assuming the PHE Declaration expires as anticipated, Phase 1 would begin on May 11, 2023; Phase 2 would begin 90 days later (August 9, 2023); and Phase 3 would begin 90 days after that (November 7, 2023).

The Enforcement Policy Transition Plan explains that manufacturers of devices that fall within the scope of the covered enforcement policies should begin complying with adverse event and device malfunction reporting requirements under 21 C.F.R. Part 803 immediately upon the start of Phase 1, if not before. Additionally, manufacturers of covered devices that intend to continue to distribute their devices should also register their establishments and list their devices before the start of Phase 2. By the start of Phase 2, manufacturers should also be complying with 21 C.F.R. Part 806 relating to reports of corrections and removals to FDA. Finally, all manufacturers that intend to continue distribution should begin preparation of any required marketing submission as soon as possible, as FDA expects that such submissions will be submitted to FDA and accepted for review prior to the start of Phase 3.

The final Enforcement Policy Transition Plan includes a revised list of relevant enforcement policies issued during the PHE that are subject to the plan. FDA added two guidance documents to the list: the Enforcement Policy for Viral Transport Media During the COVID-19 PHE (Revised) and the Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the COVID-19 PHE. FDA also removed from the draft list its guidances related to quality

standards of the Mammography Quality Standards Act; non-invasive remote monitoring devices used to support patient monitoring; face masks and barrier face coverings; and clinical electronic thermometers. FDA explained that these guidances were removed because either (a) FDA determined that the policy should not continue in effect beyond the expiration of the COVID-19 PHE at all, or (b) FDA intends to retain the policy with appropriate changes.

Key Updates Common to Both Transition Plans

Both the EUA Transition Plan and the Enforcement Policy Transition Plan retain a number of fundamental elements outlined in their draft versions. For example, both transition plans reiterate the recommendation that manufacturers intending to continue marketing their devices submit transition implementation plans to FDA along with their marketing submissions. Additionally, both transition plans maintain the expectation that manufacturers of certain specified categories of life-sustaining, life-supporting ("LSLS") devices will notify FDA of whether they intend to submit a marketing submission and continue distributing their product after the relevant transition period ends.

Changes from the draft transition plans that are common to both the EUA Transition Plan and Enforcement Policy Transition Plan include:

- Disposition of Devices Already Distributed: For manufacturers that do not intend to continue distribution of devices after the relevant EUA declaration terminates or enforcement policy transition period ends, the transition plans provide additional clarity regarding when FDA does not intend to object to the disposition and use of already distributed devices (i.e., FDA does not intend to request market removals of devices that had already been distributed). To be considered "already distributed," devices must have been distributed either prior to the end of Phase 2 of the Enforcement Policy Transition Plan or the termination of the relevant EUA declaration. FDA's approach for specific categories of devices is as follows:

    - *For single-use, non-LSLS devices, including IVDs*, market removal is not expected so long as such devices are used by the end user prior to the product expiration date. For IVDs authorized under EUAs, FDA does not intend to object to the continued use of such tests prior to the product expiration date in a manner consistent with the EUA that was in effect.

    - *For reusable, non-LSLS devices*, market removal is not expected so long as the device is used by the end user and either (a) is restored by the manufacturer to an FDA-cleared or -approved version of the device; or (b) has a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status (e.g., that the product lacks FDA clearance, approval, or authorization).

    - *For reusable LSLS devices*, market removal is not expected so long as the device is restored to an FDA-cleared or -approved version of the device so that it may be used by the end user. If the devices are not restored, a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status should be provided, and such devices are not to be used.

- Provision of Updated Labeling: FDA will allow for the continued use of certain devices so long as manufacturers have or provide "a physical and/or electronic copy of updated labeling." The transition plans provide additional clarity on what this means. The transition plans explains that manufacturers of reusable non-LSLS devices should provide updated labeling to the original purchaser and collaborate with the original purchaser to ensure that labeling is distributed to other relevant stakeholders, including distributors, healthcare facilities, providers, patients, and consumers. Manufacturers of reusable LSLS devices should take additional steps to ensure that stakeholders have the opportunity to request a physical copy of the labeling without cost.

- Case-by-Case Flexibility: FDA added language throughout both final transition plans emphasizing its authority to make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type.

Next Steps and Implications for Manufacturers

FDA's EUA Transition Plan and Enforcement Policy Transition Plan provide helpful clarity to medical device manufacturers as they begin to transition away from the FDA authorizations and policies unique to the COVID-19 pandemic. Manufacturers of devices marketed under enforcement discretion policies should begin preparing their transition implementation plans, as well as any necessary marketing authorization submissions, as soon as possible to ensure that they are prepared to meet FDA's expectations once the transition periods begin. Similarly, manufacturers of devices marketed under COVID-19 EUAs should assess how they will respond if FDA announces a termination of relevant EUAs, including whether they will pursue traditional marketing authorization.

FDA plans to hold a webinar to discuss the EUA Transition Plan and Enforcement Policy Transition Plan on April 18, 2023. Ropes & Gray will continue to monitor developments in this area. If you have any questions about this Alert, please contact any member of our FDA regulatory practice or your usual Ropes & Gray advisor.