FDA Issues Guidance on Prescription Drug Sample Distribution During COVID-19

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On June 8, 2020, the Food and Drug Administration (FDA or Agency) issued temporary guidance to address concerns related to distribution of drug samples during the COVID-19 public health emergency.[1] Under an exercise of enforcement discretion, the FDA has declared it will not enforce certain requirements of the Prescription Drug Marketing Act of 1987 (PDMA) and its implementing regulations during the pandemic with respect to the distribution of drug samples by mail or common carrier. Specifically, the FDA has expressed a willingness to allow drug samples to be shipped directly to patients' homes and to allow for alternative forms of receipt and verification.

Manufacturers' Distribution Challenges During Pandemic

The PDMA was enacted to ensure that drug products purchased by consumers are safe and effective, and to avoid the risk to consumers from counterfeit, adulterated, misbranded, subpotent or expired drugs. Among other things, the PDMA and its implementing regulations established requirements for the distribution of drug samples by company representatives and by mail or common carrier. Although the specific requirements in 21 CFR Part 203 for each method of delivery differ in some respects, they share certain basic features:

- A licensed practitioner must first request the samples in writing;
- The samples must be delivered to the licensed practitioner, or to a pharmacy at a hospital or other health care entity at the written request of the practitioner; and
- The recipient must execute a written receipt when the samples are delivered.

Stay-at-home orders and social distancing practices associated with COVID-19 have led to shifts in the practice of medicine, with practitioners reducing face-to-face interactions with patients and increasing available telemedicine services. This shift in care also has impacted how pharmaceutical manufacturers handle drug sampling. Pharmaceutical sales representatives are no longer delivering drug samples to a licensed practitioner's office, meaning many manufacturers now are relying solely on mail and common carriers to deliver drug samples, if they are doing so at all. Due to COVID-19, however, many licensed practitioners are not at their offices to receive mail deliveries, and the safety concerns associated with personal interaction at any location are in tension with the goal of procuring receipts in real time when samples are delivered.

[1] Guidance for Industry, "Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency" (June 2020).

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FDA's Temporary Solution

In light of these challenges, the FDA's guidance attempts to relieve pressure — at least for the moment — on two fronts: the location where samples can be delivered and the method of verifying receipt when the drug samples are delivered by mail or common carrier.

Places of Delivery of Prescription Drug Samples

With respect to place of delivery, the FDA announced that it does not intend to take action against pharmaceutical manufacturers or authorized distributors of record that deliver drug samples by mail or common carrier directly to a patient's home, provided that:

- A written request for the drug samples is executed by the licensed practitioner in accordance with 21 CFR 203.30(a)(1) and is for an identified patient of that licensed practitioner who has been designated to accept the delivery of drug samples;
- The receipt of drug samples is documented in accordance with 21 CFR 203.30(a)(3) and (4); and
- Record keeping and other applicable requirements are met by the manufacturer or authorized distributor of record.

The guidance also permits samples to be shipped to the licensed practitioner's home; the FDA explains this practice is allowed under current law provided that the practitioner submits a written request for the delivery of samples to their home if being used as an office, and other applicable requirements are met. Notably, however, the guidance offers no reprieve with respect to pharmacies, reinforcing the FDA's long-standing position that drug samples cannot be distributed to a retail pharmacy.

Physical Collection of Signatures Upon Receipt of Drug Samples

With respect to receipts, the guidance also acknowledges the need for mail or common carriers to identify alternate ways of verifying deliveries that normally require an adult signature. Therefore, for the duration of the public health emergency, "FDA does not intend to take action against a manufacturer or authorized distributor of record that accepts alternate ways of verifying delivery and receipt of drug samples instead of obtaining the signature of the person acknowledging delivery, provided, however, the receipt obtained by the manufacturer or authorized distributor of record complies with all other receipt requirements in PDMA and 21 CFR 203.30(c)."

Analysis

The guidance is welcome news for all stakeholders in the drug delivery system, especially manufacturers and authorized distributors that are struggling to meet bona fide requests for drug samples in a manner that both complies with applicable law and safeguards the well-being of stakeholders. By allowing common carriers to deliver drug samples directly to patients, the FDA is obviating the need for additional visits to practitioner's homes and offices, which protects the safety of both the patient and practitioner.

The guidance offers little advice, however, on alternative ways to verify delivery and receipt of drug samples — an activity that has long been a key feature of the regulated distribution system. The FDA's skepticism in the early 2000s about the ability of common carriers to meet PDMA requirements with handheld devices highlights that the Agency takes these obligations very seriously. In our view, it thus would be misguided to interpret the FDA's willingness to accept alternatives as permission to relax efforts to ensure compliance with PDMA. The burden here is on those seeking the alternative, and those pursing new methods must not lose sight of the basic objectives of the regulation: Ensuring the samples ordered are the ones received, and that discrepancies do not create the opportunity for theft or diversion. To that end, the guidance states that all other requirements of the PDMA will continue to apply. As manufacturers and their authorized distributors develop new approaches to verification, they should be mindful of their current procedures and processes, implemented under 21 CFR 203.34, to ensure reconciliation of requests and receipts. We also urge manufacturers to document the new procedures, even if temporary, under their applicable compliance and quality systems.

Finally, manufacturers and others involved with drug sample distribution should follow developments closely. The guidance, which is in effect only for the duration of the public health emergency, represents the Agency's current thinking and does not establish any legally enforceable rights or responsibilities. The FDA has issued scores of COVID-19-related materials, including approximately 50 guidance documents, in the months since the crisis began in a laudable effort to address public health and regulatory exigencies. The FDA also has shown a willingness to revisit these policies when they have produced unintended outcomes. For example, the FDA has twice revised its "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" guidance document, including removing prior recommendations regarding emergency use authorizations for decontamination of face masks and filtering facepiece respirators. Against this backdrop — and given the agency's past concerns about sample diversion — it is essential that those acting under the guidance stay tuned for further developments.

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