WINSTON & STRAWN LLP

CLIENT ALERT

FDA Issues New Temporary Policy on Prescription Drug Samples in Light of the COVID-19 Public Health Emergency

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On June 8, 2020, in response to the declared COVID-19 public health emergency, the Food and Drug Administration (FDA or the Agency) issued new guidance (the Guidance) outlining FDA's temporary policy regarding certain requirements under the Prescription Drug Marketing Act (PDMA) for distribution of drug samples during the public health emergency (PHE). The Guidance also addresses part 203, related to the collection of physical signatures upon delivery of drug samples and the ability of licensed health care providers to request that drug samples be delivered to various locations during the public health emergency.

The PDMA and attendant regulations establish requirements related to the distribution of prescription drug samples by mail or common carrier.[1] PDMA requires, in part, that licensed practitioners[2] who request drug samples do so in writing, and mandates storage, handling, and recordkeeping requirements for drug samples.[3]

FDA's Guidance indicates that the Agency does not intend to take enforcement action against a manufacturer or authorized distributor that forgoes signature and accepts alternate ways of verifying delivery and receipt of drug samples, provided the manufacturer or authorized distributor complies with all other receipt requirements under the law. Likewise, the FDA announced a temporary policy relaxing the requirement that drug samples be sent either to the requesting health care practitioner licensed to prescribe the drug, or to a designee at the pharmacy of a hospital or other health care entity. Given the PHE and the reality that practitioners are not always meeting face-to-face with their patients at this time, the FDA explains that where certain requirements are met, drug samples may be sent directly to patients' homes or delivered to the requesting licensed practitioner at home (as opposed to his or her usual health care facility). The policy outlined in this Guidance is intended to remain in effect only throughout the COVID-19 PHE.

See Temporary Policy on PDMA Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency (June 2020), *available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-prescription-drug-marketing-act-requirements-distribution-drug-samples-during-covid*.

PHYSICAL COLLECTION OF SIGNATURES UPON RECEIPT OF DRUG SAMPLES

Under the PDMA, drug samples may be distributed by a manufacturer or its authorized distributor of record[4] to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity,[5] by mail or common carrier, provided that certain conditions are met.[6] Among other conditions, before such drug samples can be delivered, a licensed practitioner must submit a written request for drug samples to the manufacturer or authorized distributor of record that contains the name, address, professional title, and signature of the practitioner making the request.[7] Upon delivery, the recipient of a prescription drug sample must both acknowledge the sample's acceptance with the carrier (usually via signature) and execute a written receipt to be returned to the manufacturer or authorized distributor from which the sample was received.[8,9]

In the interest of employee and patient safety during the COVID-19 PHE, and as manufacturers increasingly rely on mail and common carriers to deliver samples, FDA's Guidance explains the Agency 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,[10] 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).

PLACE OF DELIVERY OF PRESCRIPTION DRUG SAMPLES

In response to state or local stay-at-home orders and social distancing recommendations that have impacted how licensed practitioners are providing care and consultation, the FDA also announced a temporary policy regarding its enforcement of the requirement for drug samples to be sent to the requesting health care practitioner licensed to prescribe the drug, or to a designee at the pharmacy of a hospital or other health care entity.[11]

Delivery to Patient's Home

The FDA understands that during the PHE, many licensed practitioners are not meeting face-to-face with patients. Accordingly, the FDA does not intend to take action against a manufacturer or authorized distributor of record that delivers drug samples by mail or common carrier directly to the identified patient's home during the COVID-19 PHE, provided that: (i) the written request executed by the licensed practitioner in accordance with 21 CFR 203.30(a)(1), in addition to information required by the regulation, is for an identified patient of that licensed practitioner who has been designated to accept the delivery of the drug samples as the licensed practitioner's designee; (ii) the receipt of the drug samples is documented in accordance with 21 CFR 203.30(a)(3) and (4); and (iii) the recordkeeping and other applicable requirements under PDMA and FDA regulations under part 203 are met by the manufacturer or authorized distributor of record.

Delivery to Licensed Practitioner's Home

Similarly, the FDA understands that during the PHE, licensed practitioners may be practicing telemedicine from their homes. The FDA notes that neither PDMA nor part 203 prohibits the delivery of drug samples to the licensed practitioner's home, provided that the licensed practitioner executes and submits a written request to the manufacturer or authorized distributor of record for the delivery of the drug samples to their home being used as an office, and all other applicable provisions in part 203 are met. This interpretation of PDMA and part 203 reflects the FDA's current thinking and is not anticipated to change following termination of the COVID-19 PHE.

Delivery to Pharmacies

Under the PDMA, drug samples cannot be distributed to a retail pharmacy.[12] There are no changes in policy regarding these requirements during the COVID-19 PHE. Under 21 CFR 203.30, a drug sample may be distributed to a pharmacy of a hospital or other health care entity at the written request of a licensed practitioner.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

All entities should consult legal counsel for compliance issues and questions related to rapidly evolving COVID-19 legislation and policy.

For further information or questions on the new Guidance regarding the temporary policy on the Prescription Drug Marketing Act, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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[1] *See* FD&C Act § 503(d) (21 U.S.C. 353(d)); 21 CFR part 203, subpart D.

[2] *Licensed practitioner* is defined in 21 CFR 203.3(r) to mean any person licensed or authorized by State law to prescribe drugs.

[3] FD&C Act § 503(d) (21 U.S.C. 353(d)); *see also* 21 CFR part 203, subpart D.

[4] *Authorized distributor of record* is defined in section 503(d)(4) of the FD&C Act (21 U.S.C. 353(d)(4)) and in 21 CFR 203.3(b) to mean a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

[5] *See* 21 CFR 203.3(q).

[6] *See* FD&C Act § 503(d)(2)(A) (21 U.S.C. 353(d)(2)(A)); 21 CFR 203.30(a).

[7] *See* 21 CFR 203.30(a), (b).

[8] *See id*. § 203.30(a)(3), (4).

[9] PDMA also regulates the content of the receipt. *See id*. § 203.30(a), (c); *id*. § 203.30(c)(1); *id*. § 203.30(c)(2).

[10] *Compare id* § 203.30(c)(1); *id*. § 203.30(c)(2).

[11] *See id*. § 203.30.

[12] *See* FD&C Act 503(d)(1), (2)(A) (21 U.S.C. 353(d)(1)); *see also* 21 CFR 203.30(a). Pursuant to 21 CFR 203.30(a), a manufacturer or authorized distributor of record may distribute a drug sample to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity. *Health care entity* is defined in 21 CFR 203.3(q) to mean any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor.

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