

From: [OPLC: Pharmacy Compliance](#)
To: [Home, Christine](#)
Subject: FW: HCPs Shipping Prescription Drug Samples to Patients Question
Date: Tuesday, October 4, 2022 1:27:58 PM
Attachments: [image001.png](#)
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[image010.png](#)
Importance: High

Chris,

This should go to the Board. I believe we have already gotten inquiries about this before but I don't know what their response was (if there was one).

Thank you,
Kaitlyn

From: OPLC: Pharmacy <Pharmacy@oplcnh.gov>
Sent: Tuesday, October 4, 2022 12:54 PM
To: OPLC: Pharmacy Compliance <Pharmacy.Compliance@oplcnh.gov>
Subject: FW: HCPs Shipping Prescription Drug Samples to Patients Question
Importance: High

This email came into licensing, we do not know how to answer this, can someone reach out to them?

Thank you

If you have any questions or need additional assistance, please go to our website www.oplc.nh.gov or call 603-271-2152 to speak with one of our customer support representatives. Our office hours are Monday thru Friday, 8am-4pm (excluding holidays).

Thank you,

Licensing Bureau (or Customer Support)

NH Office of Professional Licensure and Certification
7 Eagle Square, Suite 300, Concord, NH 03301, 603.271.2152

STATEMENT REGARDING LEGAL INTERPRETATION OR ADVICE

*If you need assistance with interpretation of advice regarding the statutes and rules established, **please seek assistance from your personal or corporate legal counsel.** The statutes and rules established for OPLC and your specific profession are located at www.oplc.nh.gov.*

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From: Lopez, Michelle <Michelle.Lopez@knipper.com>
Sent: Tuesday, October 4, 2022 12:26 PM
To: OPLC: Pharmacy <pharmacy.licensing@opl.nh.gov>
Cc: Lopez, Michelle <Michelle.Lopez@knipper.com>
Subject: HCPs Shipping Prescription Drug Samples to Patients Question

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Good morning,

On June 8, 2020, the Food and Drug Administration ("FDA") issued a guidance document (see below link to document) entitled "Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency" ("Guidance"). The Guidance states that the FDA does not intend to take action against a manufacturer that delivers drug samples directly to a patient's home. It requires that the request for samples must be made in writing by the patient's prescriber, and must indicate that the patient is designated to accept the delivery.

<https://www.fda.gov/media/138697/download>

1. Delivery to Patient's Home

FDA understands that during the COVID-19 PHE, many licensed practitioners are not meeting face-to-face with patients, and these licensed practitioners would like to be able to request that a manufacturer or authorized distributor of record send drug samples directly to the identified patient's home. We understand that this is due to social distancing and for the protection of patients and healthcare providers during the COVID-19 PHE. At this time, 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: (1) 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; (2) the receipt of the drug samples is documented in accordance with 21 CFR 203.30(a)(3) and (4); and (3) the recordkeeping and other applicable requirements under PDMA and FDA regulations under part 203 are met by the manufacturer or authorized distributor of record.

Can you please advise whether your state is still following this FDA Guidance and permitting the distribution of samples directly to patients at the physician's request in accordance with this Guidance? Samples would be delivered by the sample fulfillment vendor that would normally ship the samples to the physician's office.

Thank you,

Michelle Lopez

Compliance Analyst, Regulatory Compliance



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