

MAURA T. HEALEY Governor KIMBERLEY DRISCOLL Lieutenant Governor The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health 250 Washington Street, Boston, MA 02108-4619

> KATHLEEN E. WALSH Secretary ROBERT GOLDSTEIN, MD, PhD Commissioner

> > Tel: 617-624-6000 www.mass.gov/dph

To:	Massachusetts Registered Manufacturers, Distributors and Practitioners
From:	David E. Johnson, Director, Massachusetts Drug Control Program
Date:	April 16, 2025
Re:	Delivery of Controlled Substance Samples to Massachusetts Licensed Practitioners.

ADVISORY

The purpose of this advisory is to clarify the physical locations in the Commonwealth where a manufacturer or distributor may deliver samples of controlled substances to a registered practitioner.

Pursuant to M.G.L. c. 94C, § 10 and 105 CMR 700.004(F) all persons required to register must have a separate registration for each place of business or professional practice where they manufacture, distribute or dispense controlled substances. Confusion has arisen among manufacturers and distributors regarding whether these requirements limit the physical address in the Commonwealth where they may deliver controlled substance samples for registered practitioner.

M.G.L. c. 94C, § 10 and 105 CMR 700.004(F) do not limit the delivery of controlled substance samples only to the address shown on a practitioner's Massachusetts Controlled Substance Registration (MCSR). Samples of controlled substances may be delivered to any address where a registered practitioner engages in professional practice, which may include other addresses in addition to that shown on their MCSR.

A registered practitioner is permitted to engage in professional practice at sites other than those indicated on their MCSR. For example, if a practitioner sees patients at a site, and engages in prescriptive practice with those patients, but does not order controlled substance inventory for the site, the practitioner is not required to maintain a MCSR with the address of that site, so long as the practitioner is registered at another location. *See*, 105 MR 700.004(F)(1)(c).

A practitioner who receives controlled substance samples is personally responsible for such controlled substances and is required to maintain effective physical security controls and records regarding them.¹ Therefore, a manufacturer or distributor may deliver controlled substance samples to a practitioner at any address where the practitioner engages in professional practice, including but not limited to the address on their MCSR.

Additional Resources

<u>Accountability for manufacturers' samples | Mass.gov</u> <u>Labeling guidelines for sample prescription drugs | Mass.gov</u> 105 CMR 700.010: *Dispensing and Labeling of Sample Medications by Practitioners*

Contact Information

Please direct any questions or concerns to the Drug Control Program: dcp.dph@mass.gov

¹¹ <u>Accountability for manufacturers' samples | Mass.gov</u>