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To: Third Party Logistics Providers, Virtual Manufacturers and Virtual Distributors

From: James Lavery, Director, Bureau of Health Professions Licensure
David Johnson, Director, Drug Control Program

Date: April 21, 2023

Subject: Massachusetts Controlled Substance Registrations (MCSRs) for
Third Party Logistics Providers, Virtual Manufacturers and Virtual Distributors

This Circular Letter is issued by the Drug Control Program (DCP), which is part of the Bureau of Health Professions Licensure, regarding registration of Third Party Logistics Providers (3PLs), Virtual Manufacturers and Virtual Distributors. The purpose is to assist registrants who conduct these kinds of operations to understand which of the three MCSRs available for virtual activities best meets the needs of their business.

I. Selecting the Appropriate MCSR Category

A **Virtual Manufacturer** is a person/entity with a principal place of business in the Commonwealth of Massachusetts but which never takes physical possession of controlled substances in the Commonwealth.¹ An example of a Virtual Manufacturer could be a person/entity with a principal office in Massachusetts, while its manufacturing operations are located in another state. Manufacturing operations are managed or directed in Massachusetts, but no controlled substances are manufactured or stored in Massachusetts. An MCSR for virtual manufacturing would also authorize the person/entity to conduct virtual distribution of its own controlled substance products.

A **Virtual Distributor** is a person/entity with a principal place of business in Massachusetts but which never take physical possession of controlled substances in Massachusetts.² An example of a Virtual Distributor could be a person/entity with a principal office in Massachusetts, while its distribution centers, warehouses, trucking operations, etc. are all located in other states. Distribution operations are managed or directed in the Massachusetts, but no controlled substances are received or stored in Massachusetts.

¹ M.G.L. c. 94C, §7(i); 105 CMR 700.001 (Definitions).

² M.G.L. c. 94C, §7(i); 105 CMR 700.001 (Definitions).

A **3PL** is an entity that provides or coordinates warehousing, or other logistics services, of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product. 3PLs are federally regulated under 21 U.S.C. § 360eee-3. A 3PL may choose to conduct purely virtual activities in Massachusetts, where it directs or manages from Massachusetts but does not receive or store controlled substance here. However, under current federal law, a 3PL may also employ a business model where it takes custody of controlled substances as part of the logistical arrangements being made. An example of this might be that a 3PL chooses to store controlled substances in its warehouse or distribution center located in Massachusetts as part of its operations.

The primary difference between Virtual Manufacturers/Distributors and 3PLs is that Virtual Manufacturers and Distributors never take possession of any controlled substance in Massachusetts, while a 3PL may choose to do so.

II. Pre-Registration Inspections

Virtual Manufacturers and Distributors register with the Commonwealth of Massachusetts primarily because regulators in other states require that they be registered in their “home” state to conduct operations in the other state. For these registrants, no physical inspection of their premises in Massachusetts will be conducted, unless requested. If, at any point, a Virtual Manufacturer or Distributor plans to have controlled substances on site, it must register with DCP for an appropriate MCSR (e.g. manufacturer or distributor) and complete an inspection.

Federal law requires that a 3PL be registered with any state where the 3PL distributes a controlled substance to or from such state.³ Federal law also bars states from licensing/registering 3PLs as wholesale distributors.⁴ Therefore, the Drug Control Program is making a 3PL MCSR available for this kind of business. To register, a 3PL will need to certify on its initial application and any subsequent renewal applications whether it will be taking custody of controlled substances in Massachusetts. If it is taking custody in Massachusetts, an inspection will be conducted of the necessary premises. If it is registering here for purely virtual activities, no inspection will be conducted, unless requested.

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

³ 21 U.S.C. § 360eee-3(a).

⁴ 21 U.S. Code § 360eee-4(b)(2).