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Policy 2023-03: COVID-19 Control Measures

The Massachusetts Department of Public Health (“DPH”), through the Board of Registration in Pharmacy (“Board”), Drug Control Program (“DCP”), and Bureau of Infectious Disease and Laboratory Sciences (“BIDLS”) authorizes the dispensing or dispensing by administration of certain COVID-19 control measures to populations approved or otherwise authorized by the Food and Drug Administration (“FDA”) in accordance with this policy.

COVID-19 control measures are defined by M.G.L. c. 94C, §19E as a COVID-19 drug, COVID-19 test, or other COVID-19 diagnostic device approved or otherwise authorized by the federal Food and Drug Administration.

I. General Requirements

Pursuant to a standing order, pharmacists and pharmacy interns may dispense or dispense by administration COVID-19 control measures when the following criteria are met:

- A. complete an ACPE-approved training program on COVID-19 drugs that includes evaluation of the patient’s medical history, relevant records including recent kidney and liver laboratory values, contraindications with commonly prescribed medications, recommendations for clinical monitoring, and appropriate recommendations for follow up with a medical practitioner;
- B. provide a confidential report on the doses, tests or devices dispensed, upon request;
- C. for the purposes of health insurance billing and cost-sharing, treat the transaction as the dispensing of a prescription to the person purchasing the COVID-19 control measure in accordance with the standing order. Unless the purchaser requests to pay out-of-pocket, a reasonable effort must be made to identify the purchaser’s insurance coverage and submit a claim; and
- D. pharmacists and pharmacies must establish appropriate facility provisions (e.g., segregated area, drive through, etc.) and precautions (i.e., [donning appropriate](#)

[personal protective equipment](#)) for consulting with COVID-19 positive patients in order to reduce the risk of transmission.

II. Criteria for Dispensing by Administration (“Administer”)

Pharmacists and pharmacy interns may administer COVID-19 control measures when the following criteria are met:

- A. the control measure may only be administered subcutaneously or intramuscularly and only in accordance with the FDA approval or authorization;
- B. compliance with any state or federal requirements, including recordkeeping, adverse event reporting, and informing the patient’s primary-care provider when available;
- C. compliance with any applicable conditions of use (e.g., pregnancy screening);
- D. appropriate private space (e.g., counseling / immunization room) based on the nature of administration (e.g., gluteal injection);
- E. clinical monitoring and observation (e.g., 1 hour) of individuals after administration in accordance with manufacturer’s instructions;
- F. administration training requirements as outlined in [Policy 2023-02: Vaccine Administration](#) to include competency in intramuscular gluteal administration (as applicable); and
- G. any additional training as required by the FDA approval or authorization.

III. COVID-19 Tests

Pharmacists and pharmacy interns may administer, process, read, and report the results of FDA-authorized COVID-19 tests pursuant to a prescription or standing order provided the following requirements are satisfied:

- A. Pharmacists and pharmacy interns may administer, process, read, and report test results to patients but may not engage in interpretation of any test results.
- B. Policies and procedures must be in place to notify the patient of the results, in accordance with DPH guidance:
<https://www.mass.gov/info-details/covid-19-testing-guidance#testing-guidelines>
- C. Any reporting requirements of DPH must be completed. For guidance and a reporting template, please request via email:
ISIS-ImmediateDiseaseReporting@mass.gov
- D. Any reporting requirements of the local Board of Health must also be completed.
- E. Board-licensed pharmacies planning to engage in the administering, processing, reading, and reporting of COVID-19 tests must have an active CLIA certificate. Review the DPH Clinical Laboratory Program website for any additional requirements that may apply:
<https://www.mass.gov/clinical-laboratory-program>

- F. No aspects of testing (including machine-processing of specimens), may be conducted within a pharmacy's licensed prescription area, including the service counter.
- G. Any testing locations must comply with local Board of Health requirements. Please review the following helpful links:
 - <https://www.mass.gov/doc/space-on-clinic-premises-for-covid-19-testing/download>
 - <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>
- H. Pharmacy licensees must institute risk mitigation strategies, including utilizing proper personal protective equipment ("PPE"), to minimize the spread of disease in accordance with the Centers for Disease Control and Prevention ("CDC"), Occupational Safety and Health Administration ("OSHA"), and / or local Board of Health requirements.
 - <https://www.mass.gov/doc/update-to-defining-aerosol-generating-procedures-and-recommended-ppe/download>

Please direct any questions to: Pharmacy.Admin@mass.gov