

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 730.000: THE DISTRIBUTION OF BIOLOGIC PRODUCTS

- (A) Subjects to the provisions of 105 CMR 730.000, boards of health in cities and towns are the responsible agencies in their respective communities for procurement, proper storage and issue of biologic products used in the control of diseases dangerous to the public health.
- (B) Biologic distribution stations shall be established by local boards of health in cities and towns of 10,000 population or over.
- (C) Cities and towns of less than 10,000 population may establish biologic distribution stations, when the need has been established, subject to the approval of the Department.
- (D) A board of health not equipped to act as a distribution station may designate a hospital or drug store as its agent, but may not designate more than one agency.
- (E) A board of health may maintain more than one distribution station but products will be delivered by the Department to only one agency in each town or city, except when needed for emergency use.
- (F) Distribution stations must be under the charge of a qualified person, familiar with the principles of care and handling of biologic products, and must supply and use adequate refrigerating facilities. They must observe such special requirements for the storage, handling or issue of products, as may from time to time be communicated to them by the Department or its agents.
- (G) The location, responsible personnel, equipment and operation of all distribution stations are subjected to the approval of the Department. Biologic stations may be discontinued by the Department when the need no longer exists and/or when the products are being improperly stored, handled, or distributed.
- (H) District health officers or their authorized representatives will inspect biologic products on hand at distribution stations at least once a year, and their findings will be reported to the Superintendent, Institute of Laboratories.
- (I) The delivery of diphtheria and scarlet fever antitoxins, smallpox vaccine, typhoid-paratyphoid vaccine, Schick outfits, diphtheria toxoid, tuberculin, immune serum globulin, silver nitrate solution, and such other products as the Superintendent, Institute of Laboratories may designate is limited to boards of health, except as noted below.
- (J) Biologic products as specified in 105 CMR 730.000(I) may be delivered directly to physicians or hospitals located in cities or towns of less than 10,000 population which do not maintain a biologic station.
- (K) Distribution of citrated whole blood, normal human plasma, or their fractions (except immune serum globulin) is limited to physicians, hospitals or their qualified agents. These products must be obtained by calling at the laboratory except when their shipment is authorized by the Superintendent, Institute of Laboratories.
- (L) Physicians, hospitals, boards of health, and other responsible agencies, or their qualified agents, may obtain all biologic products by calling at the laboratory, subject to the provisions noted below.
- (M) Any product, or any part of a specific request for products, may, where adequate cause exists, be withheld from delivery or distribution, upon the decision of the Superintendent, Institute of Laboratories. The Superintendent may, for valid reasons, authorize exceptions to any of the regulations stated below.

REGULATORY AUTHORITY

105 CMR 730.000: M.G.L. c. 111, § 5.

NON-TEXT PAGE