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Department of Public Health  
Bureau of Health Professions Licensure  
Drug Control Program

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## Drug Stewardship Program

### Frequently Asked Questions

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**Q: Who must file a Drug Stewardship Plan with the MA Department of Public Health?**

A: Any manufacturer of benzodiazepines or Schedule II or III opioids, where those products are sold or distributed to consumers in the Commonwealth of Massachusetts, either directly or indirectly.

**Q: If a pharmaceutical drug manufacturer sells their products to a wholesaler (the wholesaler now owns the products and decides to sell the product in any state of their choice) and the wholesaler distributes the product to the Commonwealth of Massachusetts, does the manufacturer still need to file a plan to operate a Drug Stewardship Program with the Commonwealth of Massachusetts Department of Public Health? Is the responsibility to file a plan for the drug stewardship program still applicable to the drug manufacturer?**

A: Yes. If the manufacturer's covered products are sold or distributed to Massachusetts consumers, directly or indirectly, the manufacturer must file a plan to operate a Drug Stewardship Program. It doesn't matter whether the manufacturer sells or distributes directly to Massachusetts consumers, or whether its products travel to Massachusetts consumers indirectly through a wholesaler or other intermediary. The law states that if a manufacturer's covered products are sold or distributed to consumers in Massachusetts, the manufacturer must file a plan to operate a Drug Stewardship Program. If the manufacturer's covered products do not make it to the Massachusetts market in any way, no stewardship plan need be filed.

**Q: We are a virtual manufacturer and we do not physically manufacture any product. Instead, we contract with contract manufacturing organizations to produce our products. Do both the virtual manufacturer and the contract manufacturer need to file Drug Stewardship Program plans?**

A: No. Only the virtual manufacturer, which is ultimately responsible for the drug products, must comply with the Drug Stewardship Program.

**Q: Will the Department confirm whether the Drug Stewardship Program applies or doesn't apply to a pharmaceutical drug manufacturer?**

A: No, it is the responsibility of each manufacturer to determine if the Drug Stewardship Program applies to it or not. A manufacturer that believes it is not required to file a Drug Stewardship Program plan may fill out the Drug Stewardship Non-Participation Form and file it with the Department, which will consider the request.

**Q: Does the Department provide a template available for manufacturers to use in their efforts to create a Drug Stewardship Program?**

A: No, at this time the Department does not provide a template for drug manufacturers to use to create their own Drug Stewardship Programs. Please refer to the statute (M.G.L. c. 94H) and Department guidance (<http://www.mass.gov/eohhs/docs/dph/quality/boards/drug-stewardship-letter.pdf>), which outline the process and requirements.

**Q: We are a small manufacturer of covered drugs that are sold or distributed in the commonwealth. How can we comply with the plan requirement until the Department has a template?**

A: A manufacturer can meet the plan requirement in several ways:

1. It can create its own individual plan;
2. It can find one or more other manufacturers and join them to create a joint plan; or
3. It can request to be connected with a group that has already filed a plan. Whether it will be permitted to join, and the conditions of joining, are up to the filing group.

**Q: Will the Drug Stewardship Program be discussed or become a rulemaking?**

A: The regulations, with respect to enforcement and appeals, will be drafted and open to public comment in the future.