



Department of Health

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Executive Deputy Commissioner

August 10, 2016

Dear Manufacturers and Distributors of Controlled Substances:

Subject: Recently Adopted New York State (NYS) Regulations

This letter is to advise currently-licensed manufacturers and distributors that Title 10 NYCRR Part 80, Section 80.11 – *Additional Requirements for Manufacturers and Distributors* has been amended. These regulations are effective August 10, 2016.

The following is a brief summary of the relevant changes:

- Section 80.11 language is amended to ensure consistency with Correction Law Article 23-A's balancing test that is used when reviewing application forms for applicants and existing providers who have criminal convictions.
- Section 80.11 language is updated to clarify when a chemist and/or pharmacist is required to be employed, on-site, or in a supervisory position.
- Section 80.11 language is updated to provide consistency with the State Education Department's Board of Pharmacy registration requirements.

New York Codes, Rules and Regulations, Title 10 may be viewed at:

http://www.health.ny.gov/regulations/nycrr/title_10/

- Select the "Search Title 10" link,
- Enter "80.11" in the "Search for" box, and
- Select the "Section 80.11 – Additional requirements for manufacturers and distributors".

Recently adopted regulations, including the above, may be viewed at:

http://www.health.ny.gov/regulations/recently_adopted/

Should you have any questions, please contact the NYS Department of Health's Bureau of Narcotic Enforcement, Regulatory Compliance Section, at narcotic@health.ny.gov.

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