



Massachusetts Department of Public Health
Pharmaceutical and Medical Device Manufacturer
Marketing Code of Conduct
**Initial Registration Compliance Filing Form for
Manufacturers in Accordance with M.G.L. Chapter 111N**

(This form should be used by manufacturers who have not previously registered in regards to this regulation. Manufacturers seeking to renew their registration should consult the program's web site for registration renewal instructions)

Section 1: Contact Info

Manufacturer Name: _____
City, State, Zip Code: _____
Contact Name: _____
Phone: _____
Email: _____
Compliance Officer Name: _____
Phone: _____
Email: _____
Address: _____

Section 2: Attestation and Signature

Attest to ALL of the following statements by checking the box next to the statement

- Our company has a marketing code of conduct in compliance with 105 C.M.R. 970.000.
- Our company has adopted a program to routinely train appropriate employees, including, without limitation, all sales and marketing staff regarding the marketing code of conduct, as described in 105 C.M.R. 970.000. A copy of the training program is available to the Department of Public Health on request (DO NOT SEND COPIES).
- Our company has policies and procedures in place for conducting investigations into any and all non-compliance with 105 C.M.R. 970.000, taking corrective actions in response to all non-compliance, and reporting instances of non-compliance to the appropriate state authority. A copy of these policies and procedures is available to the Department of Public Health on request (DO NOT SEND COPIES).

Our company expects that it will be required to conduct annual audits to ensure compliance with 105 C.M.R. 970.000. The Manufacturer will be required to certify completion of annual audits during annual registration renewal, which takes place July through August, annually.

Our company expects that it will be required to submit annually to the Department of Public Health a disclosure report detailing all payments made to 'covered recipients.' The disclosure report includes activity for an entire calendar year, and is required to be submitted to the department by July 1st of the following year. Details on this reporting requirement can be found in 105 C.M.R. 970.009 and on the program's web site at www.mass.gov/dph/pharmamed.

Our company expects that it will be required to renew its registration annually, during the registration renewal period, held annually July through August of a given year. Registration renewal will also require the payment of an annual registration fee of \$2000.

An annual fee of \$2000 is included with this form. Please make checks payable to the Commonwealth of Massachusetts.

Year company first became subject to regulation: _____

(105 CMR 970.000 went into effect in 2009. If your company was doing business with Massachusetts providers in that year, enter 2009. Otherwise, enter the year your company began doing business with Massachusetts providers)

I hereby certify to the Massachusetts Department of Public Health to the best of the company's knowledge, information, and belief that _____

(Manufacturer's Name)

is in compliance with 105 C.M.R. 970.000.

Signed under the pains and penalties of perjury:

Signature of Compliance Officer _____

Date _____

Section 3: Payment and Submission

Please submit this completed registration form, along with a check for the registration fee of \$2000 (checks made payable to the Commonwealth of Massachusetts), to the following contact:

Pharmaceutical Code of Conduct Program
MA Bureau of Health Professions Licensure
239 Causeway St., 5th floor – Suite 500
Boston, MA 02114

For questions, please submit an email to pharmamedreg@massmail.state.ma.us