Pharmaceutical Marketing FAQs

Q. What is DCP's definition of a "Gift"?

A. A gift is anything that has monetary value that you obtain for less than "market value." A gift may be tangible or intangible and includes both objects (such as pens, t-shirts, and meals) and services (such as transportation, travel, and lodging). If you are uncertain whether something constitutes a gift for purposes of this statute Public Act 23-171, you may choose to err on the side of caution and assume that it does, or consult with an attorney for legal advice.

Q. In the "Names of all Sales Reps" tab, does the "Gift Value ($) (No samples drugs)" field represent the total sum of materials and gifts given by the sales representative to the specific healthcare provider over the reporting period, or does it encompass the total provided to all healthcare providers and office staff during a particular single event (e.g., lunch)?

A. The "Gift Value ($) (No samples drugs)" includes the total value of gifts provided over the reporting period for the representative listed in the row.

Q. Do only samples need to be reported? Rather than including in-office meals or similar items for example.

A. Only samples need to be reported in the worksheet, "Fill Drug Sample Info". Items that are not samples, such as gifts, are to be reported in the worksheet titled, "Name of all Sales Reps."

Q. Are <u>all</u> manufacturers of pharmaceutical products required to complete the annual registration regardless of whether there are any manufacturing or other operations occurring in the state of Connecticut and regardless of the type of pharmaceutical product manufactured?

A. Any pharmaceutical manufacturer within or outside the boundaries of the state of Connecticut that uses pharmaceutical representatives to market, promote or provide information regarding a legend drug for human use to a prescribing practitioner MUST register with the Department.

"Pharmaceutical manufacturer" is defined in Section 3 of Public Act 23-171.

"Pharmaceutical representative" is defined in Section 3 of Public Act 23-171.

Q. Is a Marketing Firm Registration required for manufacturers who outsource their sales force?

A. Yes. "Pharmaceutical representative" means any person, including, but not limited to, a sales representative, who markets, promotes or provides information regarding a legend drug for human use to a prescribing practitioner and is employed or compensated by a pharmaceutical manufacturer. This includes BOTH contracted and outsourced sales forces.

Q. Does a non-resident virtual manufacturer have to obtain the Pharmaceutical Marketing Firm Registration?

A. Yes. If the rep is marketing, promoting or providing information regarding a legend drug for human use to a prescribing practitioner virtually or physically in the state of Connecticut, then the employing pharmaceutical manufacturer must obtain a Pharmaceutical Marketing Firm Registration pursuant to Public Act 23-171.

Q. Is hemp considered a pharmaceutical?

A. No.

Q. Does this regulation apply to over the counter (OTC) drug or OTC medical device sales representatives?

A. Public Act 23-171 applies to legend drugs ONLY.

Q. Do the reporting and registration requirements pertain to Rx drug wholesalers?

A. The requirements are applicable to anyone meeting the definition of a pharmaceutical manufacturer, including virtual manufacturers.

Q. Does this registration and reporting include Rx device virtual manufacturers/wholesalers?

A. Yes, this rule applies to virtual manufacturers.

Q. Does this reporting requirement include manufacturers who have pharmaceutical sales representatives physically working in the state of CT only?

A. No. It includes any pharmaceutical manufacturer within or without the boundaries of state of Connecticut whose representatives works physically or virtually to market, promote or provides information regarding legend drugs for human use to a prescribing practitioner in the state of Connecticut.

Q. Does the new licensing requirement apply to prescription devices?

A. Yes. The requirement applies to pharmaceutical manufacturers of legend drugs. “Legend drug” has the same meaning as provided in section 20-571(16) of the general statutes.

Q. Is there a fee for registration for the pharmaceutical manufacturer registration?

A. There is a $150 application fee and a $150 renewal fee.

Q. Is there a fee to update contact information such as address or business name?

A. There is no fee for updating contact information for the registration. For instructions on how to update contact information using the eLicense online system, go to https://portal.ct.gov/dcp/license-services-division/all-license-applications/change-of-address.

Q. What are the record keeping requirements for a pharmaceutical manufacturer?

A. Pharmaceutical manufacturers are subject to all applicable state and federal laws and regulations, including those related to record keeping. Please review Chapter 417 of the Connecticut General Statutes, specifically Section 21a-70e, as well as all relevant state and federal laws.

Q. How long does it take to obtain a registration for a pharmaceutical manufacturer?

A. There is no specified time frame for application approval by the Department. To expedite the process, please be sure to submit a complete application with all required information and pay the application fee in full.

Q. Is there a fee for submitting change of ownership documentation?

A. No.

Q. What should I do if my firm no longer employs a sales representative?

A. A pharmaceutical marketing firm shall notify the Department of anyone who is no longer employed as a pharmaceutical sales representative within two weeks of the individual leaving their position. This can be done using the eLicense online system through the License Maintenance feature.

Q. Do the new pharmaceutical representative disclosure requirements replace the APRN disclosure requirements

A. Both disclosures are required. The reporting requirements set forth in Public Act 23-171 are not related to or in lieu of any other reporting, disclosure or other requirement of licensed practitioners.

Q. Who should I contact if I have any questions about the pharmaceutical manufacturer registration?

A. Questions should be sent via email to DCP.DrugManufacturers@ct.gov.