

Ken Lawson, Secretary

Rick Scott, Governor

MEMORANDUM

To: Interested Parties

From: Reginald D. Dixon, Director
Division of Drugs Devices and Cosmetics

Date: December 21, 2016

Re: Health Care Clinic Establishments

Pursuant to the provisions of chapter 499, F.S., our division permits and regulates Health Care Clinic Establishments (HCCEs). The HCCE permit is issued to a place of business at one general physical location, that provides health care or veterinary services and which employs a qualifying practitioner who is either a health care practitioner as defined in s. 456.001, F.S., or a veterinarian licensed under chapter 474, F.S. The purpose of the HCCE permit is to allow the business to purchase prescription drugs in the name of the business for use by the practitioners of the business instead of having each practitioner within the business purchase the prescription drugs under his/her individual license for use on his/her patients. The qualifying practitioner is the person that is legally responsible for the HCCE's compliance with legal and regulatory requirements related to the purchase, recordkeeping, storage and handling of the prescription drugs.

There are currently 4,193 permitted HCCEs falling under the jurisdiction of the division. As part of the division's risk-based inspection program, the division will be implementing a self-inspection process whereby the division will be asking these HCCEs to answer a survey pertaining to their compliance with chapter 499, F.S.; these self-inspections are in lieu of the division conducting in-person inspections of each HCCE. The division will be sending out the surveys to approximately 600 HCCEs, each quarter, over the next two years. The first set of surveys was sent out via electronic mail on August 1, 2016. The next set will be sent out **January 3, 2017**.

The department's goal is to license efficiently and to regulate fairly. The division's mission is to protect Floridians from injury due to the use of contaminated, adulterated or misbranded drugs, devices and cosmetics. We believe that the self-inspection strikes a balance by allowing the division to ensure compliance and protect the public while minimizing as much as possible any disruptions to normal business operations.

These HCCE's employ professionals that are permitted by the professional regulatory boards housed within the Departments of Health and Business and Professional Regulation. Many of these professionals are also members of their professional associations. The division is asking that you share this communication with your licensees and professional members to give them a "heads up" to expect the survey and to ease any tension or anxiety that may accompany the receipt of the survey. It is the division's hope that the survey will cause HCCEs to take a moment to reflect on their business practices and to do a self-assessment as to where they are and where they need to be with respect to their compliance with the laws and rules governing their practices.