

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES AND COSMETICS
2601 Blair Stone Road, Tallahassee, FL 32399-1047
850-717-1800

Health Care Clinic Establishment Survey

DDC TRANSACTION CODE: 2017

HEALTH CARE CLINIC ESTABLISHMENT PERMIT NUMBER 60: _____

Please provide your Health Care Clinic Establishment Permit Number above for processing.



Completing the Survey Instructions:

Once you open the document, you will see “Fill & Sign Tool” on the right hand side of the screen. You can click on these tools to assist with filling out the survey. To add a check to the “yes” or “no” responses, you first click on the “Add Checkmark” tool to the right of the survey, then position the cursor over the box where you want the check mark and then click. The check mark will fill the appropriate box.

To add text to the boxes click on the add text tool and place your mouse in the box and type your response.

If you prefer to print out the survey and respond in writing you can return the survey by any of the following methods below.

Email: hcceinspection@myfloridalicense.com

Fax: 850-414-8240

Mail:

Division of Drugs, Devices & Cosmetics
Department of Business and Professional Regulations
2601 Blair Stone Road
Tallahassee, FL 32399-1047
850.717.1800- Telephone

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION DRUGS, DEVICES AND COSMETICS 2016 HEALTH CARE CLINIC ESTABLISHMENTS (PERMIT 60)

1. SELF-INSPECTION REPORT FOR HEALTH CARE CLINIC ESTABLISHMENTS (PERMIT 60)

The self-inspection document that follows should be completed by the health care clinic establishment's owner and designated qualifying practitioner; questions 65 thorough 76 should be completed by the designated qualifying practitioner only.

THE SELF-INSPECTION MUST BE COMPLETED AND RETURNED TO THE DIVISION OF DRUGS, DEVICES AND COSMETICS WITH ANY REQUIRED SUPPORTING DOCUMENTS WITHIN 60 DAYS OF RECEIPT BY EMAIL OR 60 DAYS OF DATE MAILED IF YOU RECEIVED THE SELF-INSPECTION BY MAIL.

If additional space is required to complete a response you may complete the response on a separate sheet of paper and provide the response to the Division of Drugs, Devices and Cosmetics as directed below. Your response must reference the **QUESTION NUMBER** you are responding to and **MUST INCLUDE YOUR PERMIT NUMBER AND YOUR PERMITTED NAME**. You may send as many additional sheets of paper as necessary to provide responses.

Some responses may require you to send information to the Division of Drugs, Devices and Cosmetics. If you are required to send information, please **INCLUDE YOUR PERMIT NUMBER AND YOUR PERMITTED NAME ON THE INFORMATION**. You may send information via mail, facsimile or by email. Please send the information to:

**ATTENTION:
DIVISION OF DRUGS, DEVICES AND COSMETICS
2601 BLAIR STONE ROAD
BUILDING B
TALLAHASSEE, FLORIDA 32399-1047
Facsimile: 850.414.8240
Email: hcceinspection@myfloridalicense.com**

The goal of the self-inspection is to identify areas where education is needed and provide guidance to the industry to assist with compliance with state and federal laws and rules.

The failure to complete the self-inspection report will increase the probability of an in-person inspection by the Division of Drug, Devices and Cosmetics.

When answering questions 1-64, unless otherwise noted, the "you" refers to the Health Care Clinic Establishment.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION DRUGS, DEVICES AND COSMETICS 2016 HEALTH CARE CLINIC ESTABLISHMENTS (PERMIT 60)

2. ESTABLISHMENT'S INFORMATION

- * 1. What is the permitted name of the Health Care Clinic Establishment? What is the establishment's physical address?

- * 2. Has there been a change of ownership since the initial issuance of this Health Care Clinic Establishment's permit number?

☐ Yes

☐ No

- * 3. If you answered yes to Question 2, in space below please provide a detailed explanation including, supporting documentation of the change of ownership to the Division of Drugs, Devices and Cosmetics (e.g., bill of sale, stock transfer or merger documents).

NOTE: If information related to your change of ownership has been provided to the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, please indicate such as well as the date that the information was provided in the space below.

☐ answer to Question 2 was no

☐ Other (please specify)

- * 4. What is the firm's federal employer ID (FEID) number?

3. ESTABLISHMENT'S INFORMATION CONTINUED

- * 5. Do you currently operate at least 10 hours per week, Monday through Friday, between 8:00 a.m. and 5:00 p.m., Eastern Standard Time, and at least 2 consecutive hours on at least 1 day?

☐ Yes

☐ No

- * 6. Please state this establishment's business hours below.

- * 7. Do you comply with the temperature monitoring and recording requirements for prescription drugs set forth in 61N-1.013 Florida Administrative Code (FAC)?

☐ yes

☐ no

- * 8. Is your facility equipped with an alarm system?

☐ yes

☐ no

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4. INFORMATION ON OTHER LICENSES OR PERMITS

- * 9. Do you have DEA registration in the firm's business name?

☐ yes

☐ no

- * 10. Do you have a current active pharmacy license under Ch. 465, Florida Statutes (F.S.) ?

☐ yes

☐ no

* 11. If your answer to Question 10 was yes, please list below the license number, PH _____ and the pharmacy type (e. g., community, modified Class II institutional pharmacy, etc.).

☐ answer to Question 10 was no

☐ Other (please specify)

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5. INFORMATION ON FIRM'S PRESCRIPTION DRUG PURCHASES

* 12. Does the Health Care Clinic Establishment purchase prescription drugs in the business's name?

☐ yes

☐ no

* 13. Is the name in which you purchase prescription drugs the same name as the firm's permitted name under the firm's Health Care Clinic Establishment permit? If your response is no, please state the name that is used to purchase prescription drugs for this establishment and the name that is reflected on this establishments' prescription drug purchase invoices in the comment field below.

☐ yes

☐ no-name(s) used:

* 14. Do you currently employ a designated qualifying practitioner ("DQP")?

☐ yes

☐ no

- * 15. If your answer to Question 14 was yes, please indicate below the full name of this person (DQP) and when (month and year) this person began serving as the DQP in the space provided below.
If you answered no to Question 14, indicate the date (month and year) you last employed a DQP in the space provided below.

- * 16. Has this Health Care Clinic Establishment employed a DQP without interruption since receiving a permit?

☐ yes

☐ no

- * 17. If your response was no to Question 16, please describe and include specific details, names, and dates.

☐ answer to Question 16 was yes

☐ Other (please specify)

- * 18. What is the state board license number of your designated qualifying practitioner (DQP)?

- * 19. Is the qualifying practitioner (DQP) currently authorized under the appropriate practice act to prescribe and administer prescription drugs?

☐ yes

☐ no

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6. INFORMATION ON FIRM'S PRESCRIPTION DRUG PURCHASES CONTINUED

* 20. Does the Health Care Clinic Establishment purchase and/or receive all prescription drugs from establishments that are authorized or permitted under s. 499.01, F.S., to distribute to this Health Care Clinic Establishment?

☐ yes

☐ no

* 21. If your response to Question 20 was no, please list the name(s) and address(es) of the establishment(s) not permitted and provide to the Division of Drugs, Devices and Cosmetics the most recent 5 and oldest 5 purchase invoices, corresponding vendor's packing list or shipping document, and firm's corresponding payment documentation from those establishments not permitted. See instruction page for directions on how to send information to the Division of Drugs, Devices and Cosmetics.

☐ answer to Question 20 was yes

☐ Other (please specify)

* 22. If your response to Question 20 was no, please explain below why this Health Care Clinic Establishment did not purchase prescription drugs from a permitted source.

☐ answer to Question 20 was yes

☐ Explanation

* 23. How long do you maintain records related to the purchase and/or receipt of prescription drugs?

* 24. Are prescription drug business records readily available, as required under s. 499.0121(6)(f), Florida Statutes, for inspection for the required six (6) years?

☐ yes

☐ no

* 25. If you receive human prescription drugs that are defined as products under 21 USC 360eee(13), are you receiving Transaction Information, Transaction Histories and Transaction Statements as required in 21 USC 360eee-1(d). If your answer is no, please explain in the comment field below?

☐ yes

☐ no

☐ Explanation for answer of no:

* 26. For expired, damaged, unwanted or otherwise unusable prescription drugs, do you employ the services of only those entities authorized to arrange for the credit or the destruction of prescription drugs, or a facility that destroys prescription drugs immediately upon receipt?

☐ yes

☐ no

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7. PRESCRIPTION DRUG SAMPLE ACTIVITIES

* 27. Do healthcare practitioner(s) at the Health Care Clinic Establishment receive prescription drug samples? Drug sample or complimentary drug for the purpose of this question means a human prescription drug that is labeled "sample," "not to be sold," "complimentary," or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug. (see s. 499.028(1)(a), F.S.)

☐ yes

☐ no

* 28. If your answer to Question 27 was yes, for each receipt (a) was the manufacturer or distributor provided with a written request that contains the practitioner's name/address/professional designation; name/strength/dosage form/quantity of the prescription drug sample requested; manufacturer's or distributor's name; request date; and practitioner's signature AND (b) made under a system that requires the recipient/practitioner to execute a written receipt to the complimentary drug distributor?

☐ yes

☐ no

☐ Answer to Question 27 was no.

* 29. Are expired prescription drug samples returned to the manufacturers or distributor as required by section 499.028(9), Florida Statutes?

☐ yes

☐ no

* 30. If you answered yes to Question 29, does the health care practitioner provide an inventory listing of the prescription drug samples returned with the following elements to the recipient: return date; name; dosage form; and quantity of the prescription drug by lot number; the source's or sender's name/address/permit number; and the recipient's name/address/license or permit number?

☐ yes

☐ no

☐ Answered no to Question 29

☐ Other (please specify)

* 31. If expired prescription drug samples are not returned to the manufacturer, please describe how they are disposed.

☐ Drug samples are only returned to the manufacturer

☐ Expired samples are disposed as follows:

* 32. Did the healthcare practitioner receive the prescription drug samples from permitted complimentary drug distributors or their sales representatives acting on their behalf?

☐ yes

☐ no

* 33. If your answer to Question 32 was no, please describe where the healthcare practitioner received the prescription drug samples from.

☐ Answered yes to Question 32

☐ Describe where the samples received from:

* 34. Does the healthcare practitioner donate prescription drug samples you receive?

☐ yes

☐ no

* 35. If you answered yes to Question 34, other than to charitable organizations, to whom are prescription drug samples donated/distributed?

☐ Answered no to Question 34

☐ Donated/distributed to:

* 36. Do you donate any expired or out-of-date prescription drug sample(s)?

☐ yes

☐ no

☐ answered no to Question 34

* 37. If the answer to Question 34 was yes, does the donation record provided to the recipient and maintained by donor include the donor's name/address/telephone number and the practitioner's state license number, and DEA number if a controlled substance is donated; the name of the manufacturer; brand name/strength/dosage form / quantity by lot number / expiration date of the prescription drug; donation date; and name/address/state license number that authorizes the possession of prescription drugs by the charitable organization if applicable – and – within 48 hours of receipt, the recipient charitable institution must provide a written receipt to the donor acknowledging receipt of the donated prescription drugs?

- ☐ Yes the required information is maintained
- ☐ Answered no to Question 34
- ☐ The required information is not maintained, see explanation below

explanation:

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8. BACKGROUND

* 38. Has the Health Care Clinic Establishment been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapters 455, 456, 458, 459, 465, 474, 499, or 893, F.S., related to distribution, possession, purchase, administration, or dispensing of prescription drugs that has not been disclosed to the Division of Drugs, Devices and Cosmetics?

- ☐ yes
- ☐ no

* 39. If the answer to Question 38 was yes, provide a detailed explanation below and supporting documentation to the Division of Drugs, Devices and Cosmetics including, the letter and/or notice of violation from that regulatory agency. See instructions for directions as to how to provide this information to the Division of Drugs, Devices and Cosmetics.

☐ answer to Question 38 was no

☐ Other (please specify)

* 40. Has the Health Care Clinic Establishment entered a plea to, been convicted or found guilty of, any felony under a federal, state (including Florida), or local law related to the distribution, purchase, possession, administration or dispensing of prescription drugs that was not disclosed to the Division of Drugs, Devices and Cosmetics? (Include as part of your response all pleas where a plea of guilty, nolo contendere or no contest was entered, whether or not adjudication was withheld.)

☐ yes

☐ no

* 41. If your answer was yes to Question 40, provide a detailed explanation below and supporting documentation to the Division of Drugs, Devices and Cosmetics including, case description and all case(s) number(s) where a guilty, nolo contendere or no contest plea was entered, whether or not adjudication was withheld and all supporting legal documents. See instructions for directions as to how to provide the requested information.

☐ answer to Question 40 is no

☐ Other (please specify)

* 42. Has the Health Care Clinic Establishment had any current or previous permit or license suspended or revoked which was issued by a federal, state or local government agency relating to the purchase, manufacturing, distribution, prescribing, dispensing, or administration of prescription drugs?

☐ yes

☐ no

* 43. If your answer was yes to Question 42, provide a detailed explanation below and provide supporting documentation to the Division of Drugs, Devices and Cosmetics. See instructions for directions as to how to provide the requested information.

☐ answer to Question 42 is no

☐ Other (please specify)

* 44. Has the Health Care Clinic Establishment been denied a permit or license in any state (including Florida) related to any activity regulated under Chapters 455, 456, 465, 474, 458, 459, 499, or 893, Florida Statute?

☐ yes

☐ no

* 45. If your answer to Question 44 was yes, provide a detailed explanation below and provide supporting documentation to the Division of Drugs, Devices and Cosmetics. See instructions for directions as to how to provide the requested information.

☐ answer to Question 44 is no

☐ Other (please specify)

* 46. Has the DQP been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapters 455, 456, 458, 459, 465, 474, 499, or 893, F.S., related to distribution, possession, purchase, administration, or dispensing of prescription drugs?

☐ yes

☐ no

* 47. If the answer to Question 46 was yes, provide a detailed explanation below and supporting documentation to the Division of Drugs, Devices and Cosmetics including, the letter and/or notice of violation from that regulatory agency. See instructions for directions as to how to provide the requested information.

☐ answer to Question 46 is no

☐ Other (please specify)

* 48. Has the DQP, since the initial permitting or renewal of the Healthcare Clinic Establishment permit (whichever occurred most recently), entered a plea to, been convicted or found guilty of, any felony under a federal, state (including Florida), or local law related to the distribution, purchase, possession, administration or dispensing of prescription drugs? (Include as part of your response all pleas where a plea of guilty, nolo contendere or no contest was entered, whether or not adjudication was withheld.)

☐ yes

☐ no

* 49. If your answer was yes to Question 48, provide a detailed explanation below and supporting documentation to the Division of Drugs, Devices and Cosmetics, including case description and all case(s) number(s) where a guilty, nolo contender or no contest plea was entered, whether or not adjudication was withheld and all supporting legal documents. See instructions for directions as to how to provide the requested information.

☐ answer to Question 48 is no

☐ Other (please specify)

* 50. Has the DQP had any current or previous permit or license suspended or revoked which was issued by a federal, state or local government agency relating to the purchase, manufacturing, distribution, prescribing, dispensing, or administration of prescription drugs that was not disclosed to the Division of Drugs, Devices and Cosmetics?

☐ yes

☐ no

* 51. If your answer was yes to Question 50, provide a detailed explanation below and provide supporting documentation to the Division of Drugs, Devices and Cosmetics. Please see instructions for directions as to how to provide documentations to the Division of Drugs, Devices and Cosmetics.

☐ answer to Question 50 is no

☐ Other (please specify)

* 52. Has the DQP been denied a permit or license in any state (including Florida) related to any activity regulated under Chapters 455, 456, 465, 474, 458, 459, 499, or 893, Florida Statute that has not been disclosed to the Division of Drugs, Devices and Cosmetics?

☐ yes

☐ no

* 53. If your answer to Question 52 was yes, provide a detailed explanation below and provide supporting documentation to the Division of Drugs, Devices and Cosmetics. Please see instructions as to how to provide documentation to the Division of Drugs, Devices and Cosmetics.

☐ answer to Question 52 is no

☐ Other (please specify)

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION DRUGS, DEVICES AND COSMETICS 2016 HEALTH CARE CLINIC ESTABLISHMENTS (PERMIT 60)

9. OTHER INFORMATION AND INQUIRIES

* 54. As a Health Care Clinic Establishment are you aware that you must notify the department within 10 days of any change in status of the designated qualifying practitioner (DQP) on a form furnished by the department?

☐ yes

☐ no

* 55. Do you have a current copy of Chapter 499, Florida Statutes?

☐ yes

☐ no

* 56. Have you reviewed Chapter 499, Florida Statutes, and the rules adopted under Chapter 499, Florida Statutes, specifically rule 61N-1, Florida Administrative Code?

☐ yes

☐ no

* 57. Do you have written policy and procedures for the receipt of prescription drugs?

☐ yes

☐ no-If your answer is no, please review subsection 499.01(2)(r) and 499.0121(4), Florida Statutes as to the requirements for the receipt of prescription drugs.

* 58. Do you have written policy and procedures for the inventory of prescription drugs?

☐ yes

☐ no-If your answer is no, please review subsection 499.01(2)(r) and 499.0121(6)(d), Florida Statutes.

* 59. Do you have written policy and procedures for the storage of prescription drugs?

☐ yes

☐ no-If your answer is no, please review subsection 499.01(2)(r) and 499.0121(3), Florida Statutes.

* 60. Do you have written policy and procedures for recordkeeping?

☐ yes

☐ no-If your answer is no, please review subsection 499.01(2)(r) and 499.0121(6), Florida Statutes.

* 61. Do you have written policy and procedures for the recall of prescription drugs?

☐ yes

☐ no-If your answer is no, please review subsection 499.01(2)(r) and 499.0121(5), Florida Statutes.

* 62. Do you have written policy and procedures for the security of prescription drugs?

☐ yes

☐ no-If your answer was no, please review subsection 499.01(2)(r) and subsection 499.0121(1), Florida Statutes.

* 63. Are there controlled substances at the Health Care Clinic Establishment?

☐ yes

☐ no

- * 64. If there are controlled substances at the Health Care Clinic Establishment, are inventories conducted and appropriate security measurements in place as required by federal law?

- ☐ yes
- ☐ no-If you answered no, please review Title 21, Part 1300-1321, Code of Federal Regulation.
- ☐ I answered no to Question 63.

**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION DRUGS, DEVICES AND
COSMETICS 2016 HEALTH CARE CLINIC ESTABLISHMENTS (PERMIT 60)**

10. DESIGNATED QUALIFIED PRACTITIONER

THIS SECTION MUST BE ANSWERED BY THE DESIGNATED QUALIFIED PRACTITIONER ONLY

- * 65. What is your name as it appears on your license as a practitioner?

- * 66. What was the first date that you started as this establishment's designated qualifying practitioner?

- * 67. What is your emergency contact telephone number?

- * 68. What is your business e-mail address (email with the company you serve as designated qualifying practitioner)?

- * 69. What is your emergency email address?

* 70. As the designated qualifying practitioner, are you aware that you are responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of prescription drugs?

☐ yes

☐ no

* 71. As the designated qualifying practitioner, are you aware that you must be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the Health Care Clinic Establishment?

☐ yes

☐ no

* 72. As the designated qualifying practitioner, are you aware that you must notify the department on a form furnished by the department within 10 days of your departure from employment with the Health Care Clinic Establishment?

☐ yes

☐ no

* 73. As the designated qualifying practitioner, are you aware that violations of Chapter 499, Florida Statutes or Rule 61N Florida Administrative Code by the Health Care Clinic Establishment or designated qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the practitioner's regulatory board?

☐ yes

☐ no

* 74. Do you understand that pursuant to s. 499.051, Florida Statutes ANY application for a permit or renewal of a permit constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations?

☐ yes

☐ no

* 75. Do you as the Designated Qualifying Practitioner, certify that you are the QUALIFYING PRACTITIONER and that you are empowered to execute this self- inspection form on behalf on the Health Care Clinic Establishment. That you understand that your submission of this self-inspection document has the same legal effect as if made under oath. To the best of your knowledge, all information contained in this document is true and correct. You understand the falsification of any information in this form may result in administrative action, including a fine, suspension, or revocation of the Health Care Clinic Establishment permit and a referral to the professional license board as applicable.

- ☐ yes
- ☐ no

* 76. What is your Health Care Clinic Establishment Permit Number?

Please remember to enter your Health Care Clinic Establishment Permit Number on the first page of survey.