

Candidate Information Booklet for the Certified Designated Representative Laws and Rules Examination



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Statement of Nondiscriminatory Policy

The Department of Business and Professional Regulation does not discriminate among candidates on the basis of age, sex, race, religion, national origin, handicap, or marital status.

Please save this document for future reference.

Visit our website at:

<http://www.MyFloridaLicense.com/DBPR>

I. Introduction

This Candidate Information Booklet (CIB) is designed to introduce Computer Based Testing and provide candidate information for this examination. The Department of Business and Professional Regulation has retained the services of Pearson VUE to schedule, administer, score and report the results for computer based testing. Pearson VUE is a leading provider of assessment services to regulatory agencies and national associations and offers licensing and credentialing support services to associations, state agencies, and private industry.

Your examination(s) will be administered on an electronic testing system. The testing system eliminates the use of paper, pencil and answer sheets. Candidates input their responses by entering the answer of their choice (A, B, C or D). Before you begin the examination, you will have an opportunity to go through a tutorial on the computer. The computer is very simple to operate; it should only take you a few minutes to learn to use it.

The screen features a variety of function buttons to help candidates navigate through the examination. The function buttons are located in the same position throughout the test. Candidates can mark a question for review, move forward or backward one question at a time, or move to a specific question. The summary screen, which can be accessed at any time during the examination, shows candidates the following:

- Number of questions answered
- Number of questions unanswered and/or skipped
- Time remaining for the examination

II. Testing Locations and Reservations

To locate a Pearson VUE Test Center near you, as well as to check that site's availability, use this link to view the vendor web site for more details: <https://home.pearsonvue.com/fl/dbpr>.

Making your Test Reservations

Candidates that already know their candidate identification number are reminded that they do not have to wait for a "Confirmation"/ "Authorization" letter to make their reservation.

Telephone or Internet Reservations

Call 1.888.204.6230 and a Pearson VUE Customer Care Associate will help you to select a convenient examination date and location and answer any questions you may have. The best times to call for a reservation are: Monday – Friday (8am – 11pm), Saturday (8am – 5pm), and Sunday (10am – 4pm). You may register as far in advance as you would like to test based on seat availability. However, it is strongly recommended you call at least five (5) business days before the examination date desired since reservations are made on a first-come, first-served basis.

Candidates may register via the Internet. You may submit a request via the Internet to Pearson VUE website at <http://www.PearsonVUE.com> twenty-four (24) hours a day, seven (7) days a week, provided you include a credit card number, electronic check or voucher, and valid email address. A reservation confirmation will be returned to you via email. Examination reservations may be canceled or changed via the Internet.

Please have the following information when you call to make an examination reservation:

- Your authorization notice
- Candidate identification number listed on your authorization notice

- Your full name, address and a daytime telephone number
- The location of the test center you desire
- The name of the examination you will be taking
- Credit card number, check, or voucher

III. The Examination

Content Overview

This is a closed book examination. Reference materials and/or the Candidate Information Booklet will not be allowed in the test room at the time of the examination. No written material other than that issued at the time of testing will be permitted.

Candidates must submit an application and fee to the Department to be authorized to sit for the examination. You will be given ninety (90) minutes (1½ hours) to complete the examination. This time does not include the thirty (30) minutes for the tutorial. The examination consists of forty (40) scored multiple-choice questions.

Content Outline

Content Area	Percentage of Exam
Product Integrity: A. General B. Storage C. Recalls D. Quarantine E. Returns F. Security	27.5%
Records	25%
Inspections	12.5%
Authorized Recipients	10%
Lawful/Unlawful Products	10%
Permits and Renewals	10%
CDR Requirements	5%

References

- I. **Chapter 499 Florida Statutes** - All sections relating to prescription drugs
[Chapter 499 Florida Drug and Cosmetic Act](#)
- II. **Chapter 61N-1, Florida Administrative Code** - All sections relating to prescription drugs
[Rule Chapter: 61N-1 Regulations for Drugs, Devices and Cosmetics](#)
- III. **Code of Federal Regulations (CFR)**
[Title 21 Code of Federal Regulations \(CFR\) Food and Drug](#)
 - A. Part 205.2
 - B. Part 205.3
 - C. Part 205.4
 - D. Part 205.50

- E. Part 205.6
- F. Part 205.8
- G. Part 1301.71 and 72

IV. United States Code (USC)

Title 21 United States Code Food and Drugs

- A. Chapter 9 Subchapter II Section 321
- B. Chapter 9 Subchapter III Section 331
- C. Chapter 9 Subchapter III Section 333
- D. Chapter 9 Subchapter V Section 351
- E. Chapter 9 Subchapter V Section 352
- F. Chapter 9 Subchapter V Section 353
- G. Chapter 9 Subchapter V Sections 360eee – 360eee-2

Content Description

Product Integrity

Please be familiar with the definitions found in section 499.003, Florida Statute (hereinafter FS), storage, handling and recordkeeping in section 499.0121, FS and adulterated and misbranded drugs or devices in sections 499.006 through 499.007, FS. In addition, prohibited acts in section 499.005, FS, will be seen on the exam. Review the application requirements for residences in section 499.012, FS. Please be familiar with drugs samples and its permissibility in section 499.028, FS. How records are maintained from Rule 61N-1.012, Florida Administrative Code (hereinafter FAC) will be seen. Questions regarding the receipt, storage and security of prescription drugs in Rule 61N-1.013, FAC will be seen. Be familiar with the definitions and wholesale distributor requirements of product tracking and tracing in Rules 61N-1.028 and 61N-1.030, FAC. Finally, parts of Rules 61N-1.023, FAC and 61N-1.0301, FAC, and Title 21 CFR 205.50 will be tested.

Records

Candidates should be aware of the definitions covered under Rule 61N-1.001, FAC. Records of drugs, cosmetics and devices from Rule 61N-1.012, FAC will be covered under this section, as well as the appropriate time to notify the Department of a security threat as found in Rule 61N-1.013, FAC. Candidates will find the different prohibited acts from sections 499.005, FS, inspections and investigations from section 499.0051, FS, record-keeping, prescription drug purchase list, and written policies and procedures under section 499.0121, FS, will also be found. Inspections and investigations from section 499.051, FS, should be expected. Parts of 21 CFR 205.50 will also be found. Finally, the definitions and wholesale distributor requirements for product tracking and tracing will be seen as covered in Rules 61N-1.028 and 61N-1.030, FAC and 21 CFR Part 360eee.

Inspections

Inspections and investigations as well as imminent dangers from sections 499.051, FS and 499.065, FS, and Rule 61N-1.019, FAC will be covered under this section. Candidates should also expect to see questions that cover compliance with federal, state and local law in section 499.0121, FS. Be familiar with the Department’s role in enforcing and administering parts of section 499.002, FS. Finally, review Rule 61N-1.015, FAC and section 499.012, FS.

Authorized Recipients

Candidates will find this section covers definitions from section 499.003, FS, and Rule 61N-1.001, FAC. Prohibited acts such as the sale or transfer of a prescription drugs to unauthorized person in section 499.005, FS, will be seen. Candidates should be familiar with the differing types of permits in section 499.01, FS. The possession of certain drugs without lawful prescriptions and its exemptions and exceptions from section 499.03, FS, will be seen on the exam. Expect to see exceptions and specific distributions authorized for wholesale distri-

bution of prescription drugs in Rule 61N-1.011, FAC. Permits for restricted prescription drug distributor permits and its special provisions in Rule 61N-1.023, FAC will be seen on the exam. Finally, parts of sections 499.0121 and 499.055, FS and Rules 61N-1.012, 61N-1.015, 61N-1.028 and 61N-1.031, FAC, should be reviewed.

Lawful and Unlawful Products

The areas covered under this section will include definitions under section 499.003, FS, prohibited acts under section 499.005, FS, and adulterated and misbranded drugs or devices in sections 499.006 through 499.007, FS. Expect to see items covering the sale, manufacture, repackaging and distribution of new drugs in section 499.023, FS. In addition, ephedrine from sections 499.033, FS, the seizure and condemnation of drugs, devices, or cosmetics under section 499.062, FS, and the imminent danger arising from inspections under section 499.065, FS will be seen on the exam. Finally, be aware of the penalties associated with selling or purchasing contraband prescription drugs under section 499.0051, FS.

Permits and Renewals

Candidates should be aware of the definitions covered under section 499.003, FS, and Rule 61N-1.001, FAC. In addition, permits and its application requirements will be found on the exam in sections 499.01 and 499.012, FS, and Rule 61N-1.015, FAC. Finally, parts of sections 499.005, 499.028 and 499.067, FS, should be expected on the exam.

CDR Requirements

This section will cover permit application requirements in section 499.012, FS, and cease and desist orders and the removal of certain persons in section 499.0661, FS. Finally, definitions and licensing, application, and permitting requirements from Rules 61N-1.001 and 61N-1.015, FAC will be covered.

Sample Questions

(The correct answers are bold and italicized.)

1. Which activity is not authorized under a prescription drug wholesale distributor permit?

- A. *distribution of complimentary drug samples*
- B. selling to a licensed ship captain
- C. selling to a permitted charitable organization
- D. sending returns to a wholesale supplier

2. The safety of a drug returned to a prescription drug wholesale distributor is doubted by the certified designated representative. Which option is NOT available to the certified designated representative?

- A. destroy the drug
- B. *return the drug to stock*
- C. return the product to its manufacturer
- D. test the product

3. What type of agreement must a purchasing wholesale drug distributor and a selling wholesale drug distributor enter into before a wholesale transaction occurs?

- A. confidentiality
- B. cooperative
- C. fixed-price
- D. *indemnity*

4. Why must the outside perimeter of an establishment used for wholesale drug distribution be well-lighted?
- A. for the protection of personnel working at the establishment
 - B. in case the establishment takes delivery of prescription drugs after dark
 - C. to aid local law enforcement officials
 - D. *to help secure the establishment from unauthorized entry***

Pilot Testing

The Examination may contain a small number of experimental or “pilot test” questions. The purpose of including pilot test questions within the examination is to expand and improve the bank of questions from which future examinations will be drawn. This is a common practice used by many national and state examination programs and is a critical step in ensuring the continued reliability and validity of these examinations.

In the event that pilot test questions are included within the examination, these questions will NOT be counted when computing scores. Additional time will be given for answering the pilot test questions. The time allowed for testing has been evaluated to ensure there is adequate time for completing test questions and pilot questions.

Pilot questions are NOT identified. If the pilot questions were identified, many of the candidates would skip them, and the results would not be valid. The development of a good examination requires accurate candidate response information for the pilot questions.

Test Taking Advice

The advice offered here is presented primarily to help you demonstrate knowledge and maximize your chances of passing the examination.

- Read all instructions carefully.
- For best results, pace yourself by periodically checking your progress. This will allow you to make any necessary adjustments.
- Be sure to record an answer for each question, even the items about which you are not completely sure. You can note the questions you wish to reconsider on the computer testing system and return to them later.
- Alert a Proctor or Test Center Manager to any problems that may occur during the examination. Do not wait until the examination is over to inform someone about a problem.

Supplies

It is expressly understood by each candidate that the State of Florida, and/or the Department of Business and Professional Regulation, and the Department’s staff hereby assume absolutely no liability of any nature whatsoever for any items of the candidate’s personal property which may have been brought to, left at, or left outside the examination site.

It is further understood that the candidate’s admission to the examination shall hereby constitute the candidate’s full, knowing, and complete waiver of any and all such claims against the State of Florida, and/or the Department of Business and Professional Regulation, and the Department’s staff.

What to Bring

All candidates will be required to bring the following items to the testing center on the day of the examination:

- Personal items are not permitted in the examination room. Any personal items such as toiletries, snacks, etc must be encased in a clear plastic bag, no larger than 8" X 11" in size and kept in the locker provided by the vendor.
- Two forms of valid signature identification, one of which is government issued: driver's license, state identification card, passport or military identification card. **Student or employment I.D. cards and photo bearing credit cards are not acceptable as picture bearing identification.** Candidates will not be admitted without showing proper identification. Your name and address must match what was submitted on your application.
- Calculators are permitted if they are silent, hand-held, battery-operated, non-printing, and without an alphabetic keypad. Solar calculators are not recommended
- To better serve our "English as a second language" candidates, the Bureau of Education and Testing is permitting the use of foreign language translation dictionaries during the examination. Translation dictionaries shall contain word-for-word or phrase translations ONLY. Dictionaries that contain definitions of words, explanations of words, or handwritten notes may NOT be used.
- Electronic translation dictionaries are NOT recommended as most will have more than word-for-word or phrase translations, an alphabetic keypad, have mathematical formulas and stored memory capabilities. Should these electronic translation devices have these capabilities; these devices WILL be rejected by the Proctor or Test Center Manager in NOT being suitable for the test site environment.
- Testing Center staff will inspect and approve each dictionary before it can be used during the examination. In order to maintain security and to ensure fairness to all candidates, candidates are limited to the use of a single dictionary.
- If you have any questions concerning acceptable translation dictionaries, please contact the Bureau of Education and Testing at 850.487.1395

What not to Bring

Unauthorized supplies, those not listed in this Candidate Information Booklet, will be subject to removal by the Department's representative at the examination site.

The following items are NOT allowed in the examination room:

- Cameras, tape recorders, or computers
- Pagers, electronic transmitting devices, or telephones (watches with alarms or beepers should be set so that they will NOT sound or go off during the examination administration)
- Any bound or loose leaf reference materials and notes
- Dictionary, thesaurus, or other spelling aids

- Canisters of mace, pepper spray, or other personal defense items
- Purses, briefcases, portfolios, fanny packs, or backpacks

IV. Administrative Policies

Change and Cancellation Policies

If you wish to cancel your exam, you must contact Pearson VUE **2 DAYS** prior to your scheduled appointment. Cancelling an exam less than **2 DAYS** prior to your appointment or missing your exam may result in forfeiting your exam fees.

Absence Policy

If you are unable to attend the examination for which you were scheduled, you may be excused for the following reasons:

- Your illness or that of an immediate family member
- Death in the immediate family
- Disabling traffic accident
- Court appearance or jury duty
- Military duty

All candidates seeking excused absences must submit written verification and supporting documentation of the situation to Pearson VUE no later than four days after the original examination date. Documentation of medical absences must have the original signature of the medical practitioner. Stamped signatures will NOT be accepted. **You will be required to pay your examination in full, and possibly reapply to DBPR, if you do not show up for your exam appointment.**

Admission to the Examination

When registering at the test center, you will be required to have the following items:

- Two forms of valid signature identification, one of which is government issued: driver's license, state identification card, passport or military identification card. **Student or employment I.D. cards and photo bearing credit cards are not acceptable as picture bearing identification.** Candidates will not be admitted without showing proper identification. Your name and address must match what was submitted on your application.

Admission Procedures

- Please report to the test center thirty (30) minutes prior to your scheduled examination. As part of the checking-in process, a photo will be taken of the candidate prior to taking the exam. This photo will be visible on the candidate's exam result report. The Test Center Manager will assign you a seat and assist you with the computer. You may take up to fifteen (15) minutes to complete the tutorial and the Test Center Manager will answer any questions you may have about the computer testing unit at this time.
- The time you spend on the tutorial will NOT reduce the time allotted for taking your examination. When you feel comfortable with the computer testing unit, you may begin your examination. The time of the examination begins the moment you look at the first question on your examination.

- Your specific reporting time will be given to you when you make your examination reservation. Please allow yourself sufficient time to find the test center. Make sure you have all necessary documentation before you report for registration.
- At the completion of the examination, your score report will provide instructions on the next step of the licensure process.

Late Arrivals

Test Center Managers will review the daily schedule for that day to determine if the candidate can be accommodated due to tardiness. If the tardiness was caused by an emergency (i.e., car trouble, traffic accident, etc) the candidate must provide documentation of the event. If the candidate cannot be accommodated due to unexcused tardiness, they will be liable for the test fee for that day in addition to the new test fee and classified as a “No Show.”

Rules for the Examination

- The examination materials, documents, or memoranda of any kind are not to be taken from the examination room.
- Listen carefully to the instructions given by the Test Center Manager and read all directions thoroughly. Test Center Managers are NOT qualified or authorized to answer questions concerning examination content. However, if you have any procedural questions, they will do their best to assist you.
- If you have a concern about the content of an examination question, please request a “Candidate Comment Form.”
- You must have the Test Center Manager’s permission to leave the examination room. You will NOT be allowed additional time to make up for time lost.
- Smoking will not be permitted in an examination room or in the restrooms, based on the October 1985 Florida Clean Indoor Air Act.
- Do not bring food into an examination room. If applicable, a lunch break will be provided. Drinks are allowed in spill proof containers. Children and visitors are NOT allowed in the test center.
- You are NOT permitted to take personal belongings such as briefcases, large bags, study materials, extra books, or papers into the testing room. Any such materials brought into the testing room will be collected and returned to you when you have completed the test. Pearson VUE and the Department are NOT responsible for lost or misplaced items.
- Under NO circumstances will you be permitted to work beyond the time allotted for the examination. Time limits are generous; you should have ample time to answer all questions and check all work.

Apparel

Please dress comfortably, but appropriately, for the examination. The examination room is usually climate controlled. However, it is not always possible to maintain a temperature suitable to each candidate, and from time to time there are maintenance problems beyond the Department’s or Pearson VUE’s control. It is suggested that you bring a sweater or jacket in case the temperature is cooler than your individual preference.

Change of Address

If an address change occurs after your examination administration, please make corrections at <http://www.My-FloridaLicense.com> or by completing the change of address form provided at the end of this booklet.

Change or Correction of Name

If you have a name change or correction, please send a copy of notarized legal documentation to the Central Intake Unit-License Maintenance immediately.

Special Testing Accommodations

The Department of Business and Professional Regulation certifies that it will comply with the provisions of the Americans with Disabilities Act (42 USC Section 12101, et seq.) and Title VII of the Civil Rights Act, as amended (42 U.S.C.2000e, et seq.), in accommodating candidates who, because of a disability, need special arrangements to enable them to take an examination.

All applicants for an examination or a reexamination who desire special testing accommodations due to a disability must submit an application to the Special Testing Coordinator prior to each exam. The application can be found at: http://www.myfloridalicense.com/dbpr/servop/testing/documents/ada_applic.pdf?x40199.

The application for accommodation must be completed and returned to the Bureau of Education and Testing at:

*Department of Business and Professional Regulation
Bureau of Education and Testing
Special Testing Coordinator
2601 Blair Stone Road
Tallahassee, Florida 32399-0791*

For more information regarding special testing accommodations, please our visit webpage at: <http://www.myfloridalicense.com/DBPR/examination-information/special-testing-accommodations/>.

V. Scoring Information and Grade Notification

Scoring Procedures

All questions are equally weighted. Examination scores are reported as percentage scores. The minimum percentage score needed to pass has been set at seventy-five percent (75%).

Notification of Results

All candidates will receive an official photo-bearing exam result report immediately following completion of their examination. Please verify that all information is correct on your exam result report prior to leaving the test center.

Examination Review and Fees

Candidates who fail an examination are entitled to review the questions they answered incorrectly, under such terms and conditions as may be prescribed by the Department of Business and Professional Regulation. Candidates are entitled to review only their most recent examination. The candidate shall be permitted to review only

those questions the candidate answered incorrectly.

The request to review must be made within 21 days from the date of the examination and can be scheduled by going online to: <http://www.PearsonVUE.com> or by calling 1.888.204.6230. The same security requirements observed at the examination will be followed during the review session. Reviews will be held at a Pearson VUE testing center.

The fees associated with reviewing a Computer Based Testing examination are included in the following link: http://www.myfloridalicense.com/dbpr/servop/testing/documents/cbt_exam_admin_Fee_2016.pdf.

Review Session

The review session is considered to be an extension of the examination administration. Only the candidate may attend the review session. Proper identification is required to obtain entry. There will be no talking or note taking of any kind. Candidates are usually given one-half of the exam administration time. For example, a 2 hour and 30 minute examination will only receive 1 hour and 15 minutes to review. Candidate will not be able to see their original exam book since it is not retained, after the exam.

Challenge Process

Written challenges are accepted for DBPR developed examinations. Candidates are given an opportunity during the review session to note in writing, on the computer, any objections they have to questions answered incorrectly. The challenges are forwarded to the Bureau of Education and Testing for review by a Psychometrician and subject matter experts to determine if there is any merit to the candidate's objection.

The response time to challenges, on average, is approximately 21 days. Due to the confidential nature of the examinations, the only response you will receive is "credit" or "no credit" for each challenged question. Credit will only apply to the candidate who reviewed and challenged. Per Rule 61-11.017(g) the candidate's challenges must be submitted in writing during the scheduled review. Any challenges or supporting documentation submitted after the candidate has left the review room shall not be accepted.

For informal review and formal hearing procedures visit: <http://www.myfloridalicense.com/DBPR/examination-information/examination-reviews-and-hearings/>.

Reexamination Information

Beginning in April, a candidate who fails to achieve the required passing score on the examination must wait 30 days before retaking the examination. A candidate will have 18 months, from the date they are authorized to test, to pass the examination. After 18 months the candidate must reapply to the Department. Pertinent reexamination information is provided to all affected candidates along with the original grade report.

VI. Appendix

Points of Contact

Please contact the appropriate office for questions regarding the following:

Application Policies and Fees

Customer Contact Center
2601 Blair Stone Road
Tallahassee, Florida 32399-0791
850.487.1395

Scheduling, Grade Notification, and Reviews

Pearson VUE, Inc.
Customer Care at 1.888.204.6230
Website: www.PearsonVUE.com
Fax-Back System at 1.800.274.8920

Formal Hearings

Department of Business and Professional Regulation
Bureau of Education and Testing
2601 Blair Stone Road
Tallahassee, Florida 32399-0791
850.487.1395

Requests for Special Testing Accommodations

Department of Business and Professional Regulation
Bureau of Education and Testing
Special Testing Coordinator
2601 Blair Stone Road
Tallahassee, Florida 32399-0791
BETSpecialTesting@myfloridalicense.com

For information regarding hotels or directions to the examination site, contact the chamber of commerce in the city where your examination has been scheduled.

**Visit our website at:
<http://www.MyFloridaLicense.com/DBPR>**

Please fill out the change of address form below and return to:

Florida Department of Business and Professional Regulation
Central Intake Unit – License Maintenance
2601 Blair Stone Road
Tallahassee, Florida 32399-0791
Fax: 850.487.9529

Address Change Form

Please type or print in the appropriate spaces below if you have a change of address correction.

NAME: _____

*SOCIAL SECURITY #: _____

EXAMINATION DATE: _____

CANDIDATE NUMBER: _____

PHONE NUMBERS: _____

Area Code/Home Number

Area Code/Work Number

OLD ADDRESS: _____

NEW ADDRESS: _____

SIGNATURE: _____

NOTE: If your name has changed, please use your prior name on this form and contact the Central Intake Unit for name change information.

*Under the Federal Privacy Act, disclosure of Social Security Numbers is voluntary, unless specifically required by Federal Statutes. In this instance, Social Security Numbers are mandatory pursuant to Title 42, United States Code, Sections 653 and 654; and Sections 455.203(9), 409.2577, and 409.2598, Florida Statutes. Social Security Numbers are used to allow efficient screening of applicants and licensees by a Title IV-D child support agency to assure compliance with child support obligations. Social Security Numbers must also be recorded on all professional and occupational license applications, and will be used for licensee identification pursuant to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Welfare Reform Act), 104 Pub.L. 193, Sec. 317.

Common Abbreviations and Definitions

Abbreviations	Definitions
DBPR	Department of Business and Professional Regulation
F.S.	Florida Statute
F.A.C.	Florida Administrative Code
BET	Bureau of Education & Testing
ADA	Americans with Disability Act
CBT	Computer Based Testing
CE	Continuing Education
CIB	Candidate Information Booklet
BCAIB	Building Code Administrators and Inspectors Board
ICC	International Code Council
FBC	Florida Building Commission
CILB	Construction Industry Licensing Board
ECLB	Electrical Contractors' Licensing Board
FAQ	Frequently Asked Questions