AGENDA

DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

December 10, 2015
Immediately Following the Board Meeting

Residence Inn Tallahassee Universities at the Capitol
600 West Gaines Street
Tallahassee, FL
(850) 329-9080

Committee Members
Jeffrey J. Mesaros, PharmD, Chair
Jeenu Philip, BPharm
Lee Fallon, BPharm
Goar Alvarez, PharmD

Board Staff
Allison Dudley, J.D., Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

Board Counsel
Lawrence Harris, Assistant Attorney General
David Flynn, Assistant Attorney General

PARTICIPANTS IN THIS PUBLIC MEETING SHOULD BE AWARE THAT THESE PROCEEDINGS ARE BEING RECORDED.

Thursday, December 10, 2015 – Immediately following the Full Board meeting

1. Roll Call
2. Rules
    - 64B16-26.1001 – Examination and Application Fees
    - 64B16-28.1081 – Regulation of Daily Operating Hours
    - 64B16-28.2021 – Change of Ownership
3. New Business
    - 64B16-26.300 – Consultant Pharmacists
    - 64B16-26.303 – Nuclear Pharmacists
4. Repeal
    - 64B16-26.603

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-26.1001 Examination and Application Fees
PURPOSE AND EFFECT: The Board proposes the rule amendment to provide notice to pharmacy interns that no fee is required to accompany the Immunization Administration Certification Application and Information form DH-MQA 1125.
SUMMARY: Notice will be provided to pharmacy interns that no fee is required to accompany the Immunization Administration Certification Application and Information form DH-MQA 1125.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 465.005, 465.009 FS.
LAW IMPLEMENTED: 456.025(7), 465.007, 465.0075, 465.009, 465.014 FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Allison Dudley, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-26.1001 Examination and Application Fees.

(1) through (3) No change.

(4) The non-refundable application fee for the ~~Influenza~~ Immunization Administration Certification shall be $55 for pharmacists and no fee for pharmacy interns, payable to the Board.

(5) No change.

Rulemaking Authority 465.005, 465.009, 456.025 FS. Law Implemented 456.025(7), 465.007, 465.0075, 465.009, 465.014, 465.189 FS. History–New 1-11-05, Amended 10-30-07, 11-15-09, 7-7-10, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 12, 2015
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: September 25, 2015

PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law Bureau

Lawrence D. Harris
Assistant Attorney General
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3771 Fax (850) 922-6425
Lawrence.Harris@myfloridalegal.com

November 25, 2015

Ms. Marjorie C. Holladay
Chief Attorney
Joint Administrative Procedures Committee
Room 680, Pepper Building
111 W. Madison Street
Tallahassee, Florida 32399-1400

Re: Department of Health, Board of Pharmacy
Rule 64B16-26.1001, F.A.C.

Dear Ms. Holladay:

I am writing in response to your correspondence of October 23, 2015, regarding the above referenced rule. You make several substantive comments, which will require decisions by the Board. Currently, the Board is scheduled to meet December 10th - 11th, and I will place this matter on the meeting agenda for the Board's consideration. I will promptly update you on the Board's decisions thereafter.

As always, thank you for your comments and assistance regarding the Board's proposed rule amendments. Please let me know if you have any questions or further concerns.

Sincerely,

Lawrence D. Harris
Assistant Attorney General
Counsel to the Florida Board of Pharmacy

cc: Allison Dudley, Executive Director
Angela Southwell, Paralegal Specialist

ANDY GARDINER
President

STEVE CRISAFULLI
Speaker

THE FLORIDA LEGISLATURE

JOINT ADMINISTRATIVE PROCEDURES COMMITTEE

Representative W. Travis Cummings, Chair
Senator Denise Grimsley, Vice Chair
Senator Aaron Bean
Senator Dwight Bullard
Senator Nancy C. Detert
Senator Geraldine F. "Geri" Thompson
Representative Matt Hudson
Representative Lake Ray
Representative Hazelle P. "Hazel" Rogers
Representative Barbara Watson

KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
111 W. Madison Street
Tallahassee, Florida 32399-1400
Telephone (850) 488-9110
Fax (850) 922-6934
www.japc.state.fl.us
joint.admin.procedures@leg.state.fl.us

October 23, 2015

Mr. David Flynn
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1001, F.A.C.

Dear Mr. Flynn:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on October 13, 2015. I have the following comments.

Rulemaking Authority: It appears that sections 465.007(1)(a), 465.0075(1), and 465.014(2) should be added as rulemaking authority.

64B16-26.1001(1): Please explain the board's authority to charge a nonrefundable examination fee for licensure by examination. Section 465.007(1)(a), which authorizes this fee, does not state that the application fee shall be nonrefundable. *Cf.* §§ 465.0075(1), Fla. Stat. (stating specifically that an application for licensure by endorsement is nonrefundable); 465.014(2), Fla. Stat. (stating that an application to register as a pharmacy technician is nonrefundable); *see also* Op. Att'y Gen. Fla. 75-293 (1975) (concluding that fees should be refundable if no action has been taken upon the application).

64B16-26.1001(3): Please explain the board's authority to charge a nonrefundable application fee for a continuing education provider. Section 456.025(7), which authorizes this fee, does not state that the application fee shall be nonrefundable. See comment to 64B16-26.1001(1), above.

64B16-26.1001(4): Please explain the board's authority to charge a nonrefundable application fee for the Immunization Administration Certification. See comment to 64B16-26.1001(1), above.

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward Tellechea, Bureau Chief

MCH:SA WORD/MARJORIE/64B16_26.1001LS102315_159390

MEETING MINUTES

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING
October 6, 2015
Immediately Following the Board Meeting

Tampa Marriott Westshore
1001 N. West Shore Boulevard
Tampa, Florida 33607
(813) 287-2555

Committee Members:
Jeffrey J. Mesaros, PharmD, Tampa, Chair
Jeenu Philip, BPharm
Lee Fallon, BPharm
Goar Alvarez, PharmD

Board Staff:
Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

Board Counsel:
David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General (Lead counsel and contact attorney for this committee meeting)

Participants in this public meeting should be aware that these proceedings are being recorded.

Tuesday, October 6, 2015 – Immediately following Full Board meeting

Dr. Mesaros called the meeting to order at 9:11 am.

All members were present.

Ms. Norr stated two letters from JAPC have been received with comments regarding Rule 64B16-26.1031 and 64B16-26.1032. Ms. Norr then asked the committee to address the comments.

Some issue's brought up in the JAPC letters were the incorporation of various documents that were referenced during the last committee meeting on DH 1997 and DH-MQA 1125.

JAPC has recommended the specific documents be incorporated into the rule; the SHOTS form, adult immunization schedule and the travel recommendation list.

Ms. Dudley said the SHOTS form is a DOH rule and should not be referenced in the Board of Pharmacy rule. She said references to SHOTS should be removed from the application. Board staff will add a link to SHOTS information on the Board website, FloridasPharmacy.gov.

Ms. Norr stated she decided not to incorporate the CDC schedule in the rule. She then stated there is no available pdf form of the adult travel immunizations, only a website.

Dr. Weizer stated the 2016 Online Yellow Book is a very effective website to use when looking for travel recommendation list. Mr. Philip stated the Yellow Book has a list of just travel vaccines under appendix B.
CDC.gov/travel/yellowbook
http://wwwnc.cdc.gov/travel/yellowbook/2016/appendices/appendix-b-travel-vaccine-summary-table

Motion: by Dr. Mesaros, to write back to JAPC and advise we are not going to incorporate the CDC guidelines by reference because it's in the statute.

TAB 1. Rule 64B16-28.2021 Change of Ownership.

Dr. Weizer stated we have been dealing with the change of ownership issue for years. Pharmacies sell 100 percent of stock and keep the corporation open through Sunbiz (Florida Department of State Division of Corporations) therefore the Board office is not notified of the change. Dr. Weizer stated this is an opportunity to create a new application process.

Ms. Norr asked the committee to review rule 64B16-28.2021 to ensure the rule allows efficient changes of pharmacy ownership without negatively impacting patient health and safety – specifically review stock transfer sales and propose new language.

Mr. Flynn stated with the new process the new owner needed to be fingerprinted.

Dr. Weizer's solution to the committee was to create a stock transfer permit application for any transfer of 5 percent or more. We would require an inspection to be done within 90 days. The permit number would not change and the application would serve as notification to the Board.

After further discussion the committee asked Ms. Norr to work on rule language for notification.

During Wednesday morning committee reports Dr. Mesaros stated Rule 64B16-28.2021, Change of Ownership has been tabled until the December Board meeting.

TAB 2. Rule 64B16-28.702(6)(b)4. Modified Class II Institutional Pharmacies.

Ms. Norr stated a minor but substantive change may have been considered previously by the Committee and the Board, but we have not been able to verify any action through our review of the minutes. Therefore, it is here before you today to formally consider the proposed change.

The proposed change to subparagraph (6)(b)4. replaces a colon with a semi-colon. This changes the meaning from –

> Requiring a perpetual inventory system of all controlled substances only as required by the Pharmacy Services Committee
>
> to –
>
> Requiring a perpetual inventory of all controlled substances, period, while injectables and other medicinal drugs require a perpetual inventory system only as required by the Pharmacy Services Committee.

Ms. Norr proposed Rule 64B16-28.702(6)(b)(4), Modified Class ll Institutional Pharmacies be broken down into two parts therefore creating a new #4,#5, #6 and adding a #7.

Motion: by Dr. Weizer, to accept proposed edits. Motion carried.

Motion: by Dr. Weizer, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Fallon, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Break 10:55-11:21

TAB 3. Rule 64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

Ms. Norr asked the committee to review rule 64B16-28.450 and consider amendments to reflect current practice, clarify the allowance of electronic record keeping to align with other laws and rules, and to avoid duplication with section 465.0265, F.S. and to specifically review 64B16-28.450(4)(a)1. To allow an electronic record keeping alternative to indicate CENTRAL FILL or that the prescription was filled via centralized prescription filling. Specifically for non-controlled substances. She then asked the committee review whether 64B16-28.450(4) or other sections have duplicate language for controlled substances vs. 21 CFR 1306. If so, consider whether that section of rule 64B16-28.450 can be deleted and also to review whether to amend 64B16-28.450(4) to allow any or all pharmacies involved in the centralized prescription filling process to be on the label in order to avoid patient confusion while ensuring the rule contains appropriate safeguards that the pharmacies involved in the process are available to the patient as required by section 465.0265 F.S.

Tim Koch with Wal-Mart suggested the language in (4)(a) mirrors CFR 1306.27. He stated it might be best to break up the recordkeeping requirements and call out the following for NON-CONTROLLED substances and then refer to 1306.27 for how to handle controlled substances. The reason being, that if (when) DEA updates the rules for controlled substances, you don't have to open up the rule and change the language again.

The changes he requested for non-controlled substances are as follows:

* (4)(a)1. Electronically record in the pharmacy recordkeeping (operating) system or document on the face of the original prescription that the prescription has been filled at a central fill pharmacy[added for those pharmacies without a means for recording electronically] ….

* (4)(a)5. Keep an electronic or paper record of receipt…

Mr. Flynn stated we do not want to limit ourselves in what changes we make. Dr. Mesaros stated we are trying to clean up the rule for the practitioners and align with record keeping requirements; we do not want to create unnecessary restrictions.

Dr. Mesaros read the proposed language changes to Rule 64B16-28.450, Centralized Prescription Filling, Delivering and Returning and stated the change should coincide with any Federal requirements.

The existing rule language is:

(4) The central fill and originating pharmacy shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating

pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:
(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:
1. Write the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number if a controlled substance of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal;

The proposed language change to 28.450(4)(a)(1) would be:

(4) The central fill and originating pharmacy shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:
(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:
1. Electronically record in the pharmacy record keeping system or document on the face of the original prescription that the prescription has been filled at a central fill pharmacy. If a controlled substance, [w]rite the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number if a controlled substance of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal;

Motion: by Dr. Alvarez, to accept proposed edits. Motion carried.

Motion: by Mr. Philip, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Fallon, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

There was discussion regarding patients being confused with multiple pharmacies being listed on the prescription label.

Dr. Mesaros stated he would confer with Lynette Norr to come up with clarification for the December Rules committee meeting.

Lunch Break 12:17-1:47

TAB 4. Rule 64B16-28.1081 Regulation of Daily Operating Hours.

Ms. Norr asked the committee to review rule 64B16-28.1081 to determine the current benefit to patients' safety and/or health to requiring a pharmacy to be open a minimum of 40 hours per week and whether the rule needs additional safeguards to ensure patient access when a pharmacy is open less than 40 hours per week.

The current rule language is as follows:

64B16-28.1081 Regulation of Daily Operating Hours.

Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment shall keep the prescription department of the establishment open for a minimum of forty (40) hours per week. The Board hereby approves exceptions to the requirements noted above and permits closing of the prescription department for the following holidays: New Year's Day, Memorial Day, Fourth of July (Independence Day), Labor Day, Veterans' Day, Thanksgiving, Christmas and any bona fide religious holiday provided that notice of such closing is given in a sign as set forth herein. A sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. The prescription department manager may petition the Board in writing to operate the prescription department for less than forty (40) hours per week, but no less than twenty (20) hours per week. Prior to approving reduced hours, the Board may require the prescription department manager to appear before the Board to explain in detail the services that will be performed. Any pharmacy open less than 40 hours shall have a policy and procedure that provides a mechanism for access to a pharmacist during the time the pharmacy is not open for the remainder of the forty hour week. Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access. Any pharmacy open less than 40 hours shall also have a policy and procedure for transferring a prescription pursuant to Rule 64B16-27.105, F.A.C., or receiving an emergency dose pursuant to Section 465.0275, F.S. during the time the pharmacy is open less than 40 hours.

After discussion, the committee requested Ms. Norr draft the proposed language and bring to full board.

Motion: by Dr. Fallon, to move to full board for discussion. Motion carried.

Ms. Norr presented the following proposed language during Wednesday's board meeting.

Proposed language is as follows:

64B16-28.1081 Regulation of Daily Operating Hours.

Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment shall keep the prescription department of the establishment open for a minimum of forty (40) hours per week. The Board hereby approves exceptions to the requirements noted above and permits closing of the prescription department for the following holidays: New Year's Day, Memorial Day, Fourth of July (Independence Day), Labor Day, Veterans' Day, Thanksgiving, Christmas and any bona fide religious holiday provided that notice of such closing is given in a sign as set forth herein. A post a sign in block letters not less than one inch in height stating the hours the prescription department is open each day. The sign shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. The prescription department manager may petition the Board in writing to operate the prescription department for less than forty (40) hours per week, but no less than twenty (20) hours per week. Prior to approving reduced hours, the Board may require the prescription department manager to appear before the Board to explain in detail the services that will be performed. Any pharmacy open less than 40 hours shall have a policy and procedure that provides a mechanism for access to a pharmacist during the time the pharmacy is not open for the remainder of the forty hour week. Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access. Any pharmacy open less than 40 hours shall also have a policy and procedure for transferring a prescription pursuant to Rule 64B16-27.105, F.A.C., or receiving an emergency dose pursuant to Section 465.0275, F.S. during the time the pharmacy is open less than 40 hours.

Motion: by Mr. Philip, that there is not an adverse economic impact on small business and that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Dr. Weizer stated the holiday section has been deleted but does not think that was the intention. She then stated the proposed edit didn't delineate the holidays, so now we just required people to work holidays.

Dr. Mesaros stated Rule64B16-28.1081, Regulation of Daily Operating Hours, will be tabled until December Board meeting.

Motion: by Dr. Fallon, to table Rule 64B16-28.1081 until December Board meeting. Motion carried.

New Business: Discussion of rules to be placed on the next Rules Committee Agenda, and similar issues, if any.

Ms. Dudley requested the pharmacy technical training rule be placed on an upcoming rules committee agenda.

Dr. Alvarez suggested discussion around physician dispensing. Dr. Mesaros suggested we discuss during normal board comment and then see if the rule needs to be addressed. He then recommended Dr. Alvarez speak to Mr. Flynn and considering placing it on the December agenda.

Ms. Glass requested discussion regarding intern licenses that do not expire. Ms. Dudley did not think we had the power to create a rule and suggested Ms. Glass confer with Mr. Flynn.

Dr. Mikhael suggested discussion regarding how many hours a Prescription Department Manager must spend in a pharmacy.

Motion: by Dr. Fallon, to ADJOURN at 2:54 pm. Motion carried.

64B16-26.300 Consultant Pharmacist Licensure.

(1) No person shall serve as consultant pharmacist as defined in Section 465.003(3), F.S., unless that person holds a license as a consultant pharmacist.

(2) Application for consultant pharmacist licensure shall be made on form DOH-MQA 1109, (Rev. 12/15) ~~02/09~~, Consultant Pharmacist Application and Information, which is hereby incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-01636 and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at http://floridaspharmacy.gov/Applications/app-consultant-pharmacist.pdf. ~~Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at www.doh.state.fl.us/mqa/pharmacy.~~ The application shall be accompanied by a non-refundable application fee.

(3) In order to be licensed as a consultant pharmacist, a person must meet the following requirements:

(a) Hold a license as a pharmacist which is active and in good standing,

(b) Successfully complete a consultant pharmacist course of no fewer than twelve (12) hours, sponsored by an accredited college of pharmacy located within the State of Florida, and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

(c) Successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b) above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit. The training shall include:

Minimum Skills Required	Percent of Time	Minimum Hours
Minimum of 40 Hours in Maximum of Three Months		
1. Regimen review, documentation and communication. a. Demonstrate ability to carry out process and understand documentation functions. b. Understand and perform drug regimen review. Communicate findings to appropriate individuals or groups. c. The applicant is responsible for learning other skills needed to perform in his/her type of facility where he/she is or will be the consultant Pharmacist of Record.	60%	24
2. Facility review. Demonstrate areas that should be evaluated, documentation, and reporting procedures.	20%	8
3. Committee and Reports. Review quarterly Quality of Care Committee minutes and preparation and delivery of pharmacist quarterly report.	5%	2
4. Policy and Procedures. Preparation, review, updating Policy and Methods.	5%	2
5. Principles of formulary management. Demonstrate ability to manage formulary.	5%	2
6. Professional Relationships. Knowledge and interaction of facility administration and professional staff.	5%	2

(4) In order to act as a preceptor, a person shall:

(a) Be a consultant pharmacist of record at an institutional pharmacy which is required to have a consultant pharmacist under the provisions of Chapter 465, F.S., and these rules.

(b) Have a minimum of one (1) year of experience as a consultant pharmacist of record.

(c) Maintain all pharmacist licenses in good standing with the Board.

(d) Not act as a preceptor to more than two (2) applicants at the same time.

(5) Upon completion of the requirements set forth above, the applicant's preceptor shall confirm that the applicant's assessment and evaluation have met the requirements and that the applicant has successfully completed all required assignments under the preceptor's guidance and supervision.

(6) After licensure a consultant pharmacist's license shall be renewed biennially upon payment of the fee set forth in Rule 64B16-26.1003, F.A.C., and upon completing twenty-four (24) hours of board approved continuing education based upon the provisions of Rule 64B16-26.302, F.A.C.

(7) The number of hours earned in recertification programs by a consultant pharmacist, if applied to the twenty-four (24) hours required for consultant pharmacist license renewal, may not be used toward the thirty (30) hours of continued professional pharmaceutical education credits as set forth in Rule 64B16-26.103, F.A.C.

(8) An applicant who applies for a consultant pharmacist license after the effective date of this rule shall be required to complete the assessment and evaluation required in paragraph (3)(c) prior to being licensed as a consultant pharmacist.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 5-19-72, Revised 4-19-74, Repromulgated 12-18-74, Amended 10-17-79, 4-8-80, 7-29-81, 7-1-83, 4-10-84, 4-30-85, Formerly 21S-1.26, 21S-1.026, Amended 7-31-91, 10-14-91, Formerly 21S-26.300, 61F10-26.300, Amended 9-19-94, 3-28-95, 3-10-96, Formerly 59X-26.300, Amended 5-22-01, 5-5-05, 11-29-06, 3-29-10,_____.

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

CONSULTANT PHARMACIST APPLICATION AND INFORMATION

December 2015

DH-MQA 1109, 12/15
Rule 64B16-26.300, F.A.C.

Dear Florida Consultant Pharmacist Applicant,

Thank you for applying for licensure as a Consultant Pharmacist in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

You should use the enclosed checklist to ensure that all sections of the application are complete and that the required documentation is submitted. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. You can now follow the progress of your application through our website at: http://ww2.doh.state.fl.us/mqaservices/login.asp.You will receive a letter, which provides your user id and password, acknowledging receipt of your application. The staff will notify you within 7-14 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at info@floridaspharmacy.gov, or you may at call us at (850) 245-4292. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

General Information

Requirements for Florida Consultant Pharmacist Licensure

To become licensed as a Consultant Pharmacist, an applicant must meet the following requirements.

1) Must hold a Florida pharmacist license that is active and in good standing.

2) Must successfully complete a board approved consultant pharmacist course of no fewer than 12 hours, sponsored by an accredited college of pharmacy, located within the State of Florida.

3) Must successfully complete a period of assessment and evaluation of 40 hours over no more than three (3) consecutive months within one year of completion of the course, pursuant to Rule 64B16-26.300(3)(c), Florida Administrative Code.

Application Processing

Please read all application instructions before completing your application.

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application and your status. If your application is complete, you will be issued a license within 7-14 days. If your application is incomplete, you will be notified in writing of the missing documents required to complete your application.

APPLICATION REQUIREMENTS FOR FLORIDA CONSULTANT PHARMACIST LICENSURE

Please submit the following to the Florida Board of Pharmacy:
P.O. Box 6320, Tallahassee, FL 32314-6320

ITEM #1 – Social Security Form: Under the Federal Privacy Act, disclosure of Social Security Numbers is voluntary unless specifically required by federal statute. **In this instance, Social Security Numbers are mandatory pursuant to Title 42 United States Code, Sections 653 and 654; and Sections 456.013(12), 409.2577, and 409.2598, Florida Statutes (F.S.)**. 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, Section 317. **Please attach to Item #2 (Consultant Pharmacist Application).**

ITEM #2 – Consultant Pharmacist Application: All sections must be completed in full. If an item is not applicable, indicate with N/A. N/A is not an acceptable answer for yes or no questions and could result in a delay of processing. Failure to submit a complete application will result in a processing delay. If you provide false information, the board *may* deny your application for licensure. **Please attach a check payable to THE FLORIDA DEPARTMENT OF HEALTH in the amount of $55.00.**

ITEM #3 – Preceptor Evaluation Form: Upon completion of the period of assessment and evaluation of 40 hours, the preceptor who supervised you must complete and sign this form, affirming that you have met the requirement.

APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation to the board, will result in an incomplete application. **Final approval cannot be granted until the application is complete**. Faxed applications will not be accepted.

_____ **Social Security Form (Item #1) – Attach to Item #2**

_____ **Consultant Pharmacist Application (Item #2)**

_____ **Check made payable to the FLORIDA DEPARTMENT OF HEALTH in the amount of $55.00.**

_____ **Preceptor Evaluation Form (Item #3)**

_____ **Proof of Eligibility** – Copy of initial course certificate for the consultant pharmacist course.

CONFIDENTIAL AND EXEMPT FROM PUBLIC RECORDS DISCLOSURE*

Florida Department of Health
Board of Pharmacy

Name: _____
Last **First** **Middle**

Social Security Number: _____

* This page is exempt from public records disclosure. The Department of Health is required and authorized to collect Social Security Numbers relating to applications for professional licensure pursuant to Title 42 USCS § 666 (a)(13). For all professions regulated under Chapter 456, Florida Statutes, the collection of Social Security Numbers is required by section 456.013 (1)(a), Florida Statutes.

4052 Bald Cypress Way, Bin # C04
Tallahassee, Florida 32399-3254
Phone: (850) 245-4292 Fax: (850) 413-6982
Website: www.floridaspharmacy.gov

DH-MQA 1109, 12/15
Rule 64B16-26.300, F.A.C.

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.floridaspharmacy.gov

ITEM #2 – CONSULTANT PHARMACIST APPLICATION
FEE: $55.00

Section 465.019(5), *Florida Statutes*, requires that all Institutional Pharmacies shall be under the professional supervision of a Consultant Pharmacist. All Consultant Pharmacist licenses must be obtained in accordance with *Florida Statutes* and the provisions of Rule 64B16-26.300, Florida Administrative Code.

Please print or type legibly.

1. Biographical Data			
Last Name	**First Name**	**Middle Name**	
Mailing Address	**City**	**State**	**Zip**
Home Phone Number	**Business Phone Number**	**Date of Birth**	

CORRESPONDENCE VIA E-MAIL? YES_____ NO_____ By checking "yes", you agree to allow the board office to contact you with information regarding your application via e-mail. Under Florida law, e-mail addresses are public records. If you do not want your e-mail address released in response to a public records request, do not send electronic mail to this entity. Instead, contact this office by phone or in writing.

E-MAIL ADDRESS: **Please print legibly.**

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☐ Female
RACE: ☐ Caucasian ☐ Black ☐Hispanic ☐ Asian ☐ Native American ☐ Other

3. Do you have a Florida Pharmacist (PS) license active and in good standing? If yes, what is the license number?

Yes _____ No _____ Florida License Number: PS_____

4. Have you ever held a Consultant License in Florida? If yes, what was the license number?

Yes _____ No _____ Florida License Number: PU_____

The information contained herein is true and correct to the best of my knowledge, and am aware that my Pharmacist Consultant registration certificate may be suspended or revoked if I violate any pharmacy law, rule or regulation, and the Florida Board of Pharmacy Code of Conduct, and hereby affix my signature as acknowledgement and agreement of such terms.

_____ _____
Applicant Signature Date

64B16-26.303 Nuclear Pharmacist Licensure.

(1) A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be actively licensed as a nuclear pharmacist.

(2) A pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy the following:

(a) An application for nuclear pharmacist licensure, form DOH-MQA 104, (Rev. 12/15), Nuclear Pharmacist Application and Information, which is hereby incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-01636 and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at http://floridaspharmacy.gov/Applications/app-nuclear-pharmacist-2013.pdf;

(b) A non-refundable application fee as specified by Rule 64B16-26.1002(3), F.A.C.;

(c) A course outline and certificate of training which document successful completion of the didactic training in complance with susection (3), below;

(d) Documentation of sucessful completion of on-the-job training and experience in compliance with subsection (5), below.

(3) All applicants must complete a minimum of 200 clock hours of formal didatic training from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy as specified by subsection (4), below. ~~(a program comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists), and a certificate of training which provides a minimum of 200 clock hours of formal didactic training, which includes:~~ All such formal traning must include, at a minimum:

(a) Radiation physics and instrumentation (85 hours).

(b) Radiation protection (45 hours).

(c) Mathematics pertaining to the use and measurement of radioactivity (20 hours).

(d) Radiation biology (20 hours).

(e) Radiopharmaceutical chemistry (30 hours).

(4)~~(3)~~ Programs recognized by the Department and Board shall be determined to be comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists Such academic training programs will be submitted to the Board of Pharmacy for approval by an accredited educational institution which operates under the auspices of or in conjunction with an accredited college of pharmacy.

(5)~~(4)~~ The minimum on-the-job training which shall be included in a radiopharmacy internship is 500 hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include but shall not be limited to the following:

(a) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys.

(b) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.

(c) Calculating, preparing and verifying patient doses, including the proper use of radiation shields.

(d) Following appropriate internal control procedures to prevent mislabeling.

(e) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys.

(f) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(g) Clinical practice concepts.

(6)~~(5)~~ If the didactic and experiential training required in this section have not been completed within the last seven (7) years, the applicant must have been engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven (7) years.

Specific Authority 465.005, 465.0126 FS. Law Implemented 465.0126 FS. History–New 1-18-05, _____.

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

NUCLEAR PHARMACIST APPLICATION AND INFORMATION

December 2015

DH-MQA 104, 12/15
Rule 64B16-26.303, F.A.C

Dear Florida Nuclear Pharmacist Applicant,

Thank you for applying for licensure as a nuclear pharmacist in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

You should use the enclosed checklist to ensure that all sections of the application are complete and that the required forms are submitted. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. You can now follow the progress of your application through our website at: http://ww2.doh.state.fl.us/mqaservices/login.asp.You will receive a letter, which provides your user id and password, acknowledging receipt of your application. The staff will notify you within 7-14 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at info@floridaspharmacy.gov, or you may at call us at (850) 245-4292. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Florida Board of Pharmacy

General Information

Requirements for Florida Nuclear Pharmacist Licensure

To become licensed as a nuclear pharmacist, an applicant must meet the following requirements.

1) Must hold a Florida pharmacist license that is active and in good standing.

2) Certification by a university or other approved program provider of your completion of a minimum of 200 clock hours of formal didactic training as set forth in Rule 64B16-26.303(2), Florida Administrative Code (F.A.C.).

3) Certification by your supervising pharmacist of the minimum 500 hours of training and experience as set forth in Rule 64B16-26.303(4), F.A.C.

4) If the didactic and experiential training required in this section have not been completed within the last seven (7) years, you must have engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven (7) years.

Application Processing

Please read all application instructions before completing your application.

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If your application is complete, you will receive a license within 7 days. If your application is incomplete, you will be notified in writing of the missing documents required to complete your application.

APPLICATION REQUIREMENTS FOR FLORIDA NUCLEAR PHARMACIST LICENSURE

Please submit the following to the Florida Board of Pharmacy:
P.O. Box 6320, Tallahassee, FL 32314-6320

ITEM #1 – Social Security Form: Under the Federal Privacy Act, disclosure of Social Security Numbers is voluntary unless specifically required by federal statute. **In this instance, Social Security Numbers are mandatory pursuant to Title 42 United States Code, Sections 653 and 654; and Sections 456.013(12), 409.2577, and 409.2598, Florida Statutes (F.S.)**. 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, Section 317. **Please attach to Item #2 (Nuclear Pharmacist Application).**

ITEM #2 – Nuclear Pharmacist Application: All sections must be completed in full. If an item is not applicable, indicate with N/A. N/A is not an acceptable answer for yes or no questions and could result in a delay of processing. Failure to submit a complete application will result in a processing delay. If you provide false information, the board *may* deny your application for licensure. **Please attach a check payable to THE FLORIDA DEPARTMENT OF HEALTH in the amount of $55.00.**

ITEM #3 - Certificate of Training and Experience: Upon completion of the 500 hours of training and experience as set forth in Rule 64B16-28.903(4), F.A.C., the nuclear pharmacist who supervised you must complete and sign this form, affirming that you have met the requirements.

If the didactic and experiential training required in this section have not been completed within the last seven (7) years, you must have engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven (7) years.

APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation to the board, will result in an incomplete application. **Final approval cannot be granted until the application is complete**. Faxed applications will not be accepted.

_____ **Social Security Form (Item #1) – Attach to Item #2**

_____ **Nuclear Pharmacist Application (Item #2)**

_____ **Check made payable to the FLORIDA DEPARTMENT OF HEALTH in the amount of $55.00 attached.**

_____ **Certificate of Training and Experience (Item #3)**

_____ Certification by your supervising pharmacist of the 500 hours of training and experience as set forth in Rule 64B16-26.03(2), F.A.C

_____ **Proof of Eligibility**

_____ Certification by a university or other approved program provider of your completion of 200 clock hours of formal didactic training as set forth in Rule 64B16-28.303(4), Florida Administrative Code (F.A.C.).

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Phone: (850) 245-4292
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CONFIDENTIAL AND EXEMPT FROM PUBLIC RECORDS DISCLOSURE

Name: _____
Last **First** **Middle**

Social Security Number: _____

This page is exempt from public records disclosure. The Department of Health is required and authorized to collect Social Security Numbers relating to applications for professional licensure pursuant to Title 42 USCS § 666 (a)(13). For all professions regulated under chapter 456, Florida Statutes, the collection of Social Security Numbers is required by section 456.013 (1)(a), Florida Statutes.

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ITEM #2 – NUCLEAR PHARMACIST APPLICATION
FEE: $55.00

All Nuclear Pharmacist licenses must be obtained in accordance with Section 465.0126, *Florida Statutes* and the provisions of Rule 64B16-26.303, *Florida Administrative Code*.

Please print or type legibly.

1. Biographical Data			
Last Name	**First Name**	**Middle Name**	
Mailing Address	**City**	**State**	**Zip**
Home Phone Number	**Business Phone Number**	**Date of Birth**	**E-Mail Address**

CORRESPONDENCE VIA E-MAIL? YES_____ NO_____ By checking "yes", you agree to allow the board office to contact you with information regarding your application via e-mail. Under Florida law, e-mail addresses are public records. If you do not want your e-mail address released in response to a public records request, do not send electronic mail to this entity. Instead, contact this office by phone or in writing.

E-mail Address: **Please print legibly.**

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☐ Female
RACE: ☐ Caucasian ☐ Black ☐Hispanic ☐ Asian ☐ Native American ☐ Other

3. Do you have a Florida Pharmacist (PS) license active and in good standing? If yes, what is the license number?

Yes _____ Florida License Number: PS_____
No _____

4. Have you ever held a Nuclear Pharmacist License in Florida? If yes, what was the license number?

Yes _____ Florida License Number: NP_____
No _____

The information contained herein is true and correct to the best of my knowledge, and I am aware that my Nuclear Pharmacist registration certificate may be suspended or revoked if I violate any pharmacy law, rule or regulation, or the Florida Board of Pharmacy Code of Conduct. I hereby affix my signature as acknowledgement and agreement of such terms.

_____ _____
Applicant Signature Date

FLORIDA BOARD OF PHARMACY
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Phone: (850) 245-4292
www.floridaspharmacy.gov

ITEM #3 – CERTIFICATE OF TRAINING AND EXPERIENCE

Please print or type legibly.

1. Applicant Information			
Last Name	**First Name**	**Middle Name**	
Mailing Address	**City**	**State**	**Zip**
Home Phone	**Work Phone**		

2. Nuclear Pharmacist (Supervisor) Name			
Last Name	**First Name**	**Middle Name**	
Mailing Address	**City**	**State**	**Zip**
Home Phone	**8. Work Phone**		

3. Supervisor's Florida License Numbers
Pharmacist License: PS_____
Nuclear Pharmacist License: NP_____

4. Certification of Assessment and Evaluation

I certify that the applicant above completed either a minimum of 500 hours of training and experience, or 1080 hours of lawful practice of nuclear pharmacy, including the handling of unsealed radioactive material, in another jurisdiction within the last 7 years. This training and experience or lawful practice occurred under my supervision from ___/___/___ to ___/___/___. If I am certifying training and experience, I further certify the training included the following as mandated by Rule 64BF16-26.303, Florida Administrative Code.

1) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys;
2) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment;
3) Calculating, preparing and verifying patient doses, including the proper use of radiation shields;
4) Following appropriate internal control procedures to prevent mislabeling;
5) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys;
6) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and technetium-99m labeled radiopharmaceuticals; and
7) Clinical practice concepts.

Supervisor Name _____ Date _____

Supervisor Signature

Supervisor License Number

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Phone: (850) 245-4292
www.floridaspharmacy.gov

ITEM #3 – PRECEPTOR EVALUATION FORM

Please print or type legibly.

1. Applicant Information			
Last Name	**First Name**	**Middle Initial**	
Mailing Address	**City**	**State**	**Zip Code**
Home Phone Number	**Business Phone Number**		

2. Consultant Pharmacist (Preceptor) Information			
Last Name	**First Name**	**Middle Initial**	
Mailing Address	**City**	**State**	**Zip**
Home Phone	**Work Phone**		

3.Preceptor's Florida License Numbers
Pharmacist License: PS_____
Consultant Pharmacist License: PU_____

4. Certification of Assessment and Evaluation

The applicant above completed a minimum of 40 hours of assessment and evaluation under my supervision, which began on ___/___/___ and ended on ___/___/___ and the training included the following as mandated by Rule 64B16-26.300(3)(c), Florida Administrative Code.

1) Regimen review, documentation, and communication (24 hours).
2) Facility review (8 hours).
3) Committees and Reports (2 hours).
4) Policy and Procedures (2 hours).
5) Principles of Formulary Management (2 hours).
6) Professional relationships (2 hours)

_____ _____
Preceptor Name (Printed) Date

_____
Preceptor Signature

_____
Preceptor License Number

64B16-26.603 Continuing Education Records Requirements.

Each pharmacist shall retain documentation of participation in continuing education programs required for license renewal for not less than two years after the license is renewed for audit purposes if and when such audit is undertaken by the Department of Health and the Board of Pharmacy. Such documentation shall consist of statements of credit for lecture attendance, certification forms from instructors, or course completion slips from correspondence courses.

Specific Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Formerly 21S-13.04, Amended 5-10-89, Formerly 21S-13.004, 21S-26.603, 61F10-26.603, 59X-26.603, Amended 1-11-05.