

AGENDA

DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

February 9, 2016
Immediately Following the Board Meeting

Hyatt Regency Jacksonville Riverfront
225 East Coastline Drive
Jacksonville, Florida 32202
(904) 588-1234

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.

1. Roll Call

2. February Monthly Rules Report

3. Old Business

- 64B16-26.1031

4. New Business

- 64B16-27.104
- 64B16-26.600
- 64B16-28.2021
- 64B16-28.1081
- 64B16-28.451
- 64B16-26.203
- 64B16-26.2031

**BOARD OF PHARMACY
RULES REPORT
FEBRUARY 2016**

Rule Number	Rule Title	Date Rule Language Approved by Board	Date Sent to OFARR	Rule Development Published	Notice Published	Adopted	Effective
64B16-26.1001	Examination and Application Fees.	08/12/15	09/16/15(RD/RN) NOC(01/07/16)	09/25/15	10/13/15 JAPC LTR 10/23/15 JAPC RESPONSE 11/25/15 JAPC RESPONSE 12/21/15 NOTICE OF CHANGE 01/15/16		
64B16-26.1031	Vaccine Certification Program.	08/12/15	04/29/15 (RD) 09/16/15(RN)	05/06/15	09/25/15 JAPC LTR 10/01/15 JAPC LTR 12/03/15 RULE TOLLED 12/03/15 JAPC RESPONSE 12/08/15 JAPC RESPONSE 12/28/15 JAPC LTR 01/05/16		
64B16-26.1032	Immunization Administration Certification Application and Information.	08/12/15	07/21/15 (RD) 09/16/15(RN) 01/15/16(NOC)	07/23/15	09/25/15 JAPC LTR 10/01/15 JAPC LTR 12/03/15 RULE TOLLED 12/03/15 JAPC RESPONSE 12/08/15 JAPC RESPONSE 12/28/15 NOTICE OF CHANGE 01/22/16 (anticipated)		
64B16-26.300	Consultant Pharmacist Licensure.	12/11/15	01/07/16(RD/RN)	01/11/16			
64B16-26.303	Nuclear Pharmacist Licensure.	12/11/15	01/07/16(RD/RN)	01/11/16			
64B16-26.603	Continuing Education Records Requirements.	12/11/15	01/07/16(RN)	n/a (repeal)	01/11/16		
64B16-27.700	Definition of Compounding.		07/30/15 (RD)	08/03/15			
64B16-28.100	Pharmacy Permits – Applications and Permitting.	02/10/15	03/04/15(RD/RN)	10/31/14	03/06/15 JAPC LTR 03/20/15 JAPC LTR 04/17/15 JAPC LTR 05/11/15 RULE TOLLED 05/11/15 JAPC RESPONSE 05/12/15 JAPC LTR 12/14/15		

**BOARD OF PHARMACY
RULES REPORT
FEBRUARY 2016**

Rule Number	Rule Title	Date Rule Language Approved by Board	Date Sent to OFARR	Rule Development Published	Notice Published	Adopted	Effective
64B16-28.450	Centralized Prescription Filling, Delivering and Returning.	10/07/15	12/07/15(RD/RN)	12/08/15	01/19/16		
64B16-28.608	Automated Filling Systems within a Pharmacy.		04/29/15 (RD)	05/06/15			
64B16-28.702	Modified Class II Institutional Pharmacies.	10/07/15	12/07/15(RD/RN)	12/08/15	01/19/16		
64B16-28.905	Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities.	02/10/15 08/12/15	03/04/15(RD/RN) 09/28/15(NOC)	10/31/14	03/06/15 JAPC LTR 03/20/15 JAPC LTR 04/17/15 JAPC LTR 05/11/15 RULE TOLLED 05/11/15 JAPC RESPONSE 05/12/15 NOTICE OF CHANGE 10/07/15 JAPC LTR 10/13/15 JAPC RESPONSE 11/05/15 JAPC LTR 11/09/15 JAPC RESPONSE 12/02/15	12/04/15	12/24/15

64B16-26.1001 Examination and Application Fees.

(1) The ~~non-refundable~~ examination fee for licensure by examination shall be \$100, payable to the Board. Examination fees for the National Practice Examination and jurisprudence examination are payable to the examination vendor.

(2) No change.

(3) The ~~non-refundable~~ application fee for a continuing education provider seeking approved provider status shall be \$150, payable to the Board.

(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, _____.

ANDY GARDINER
President

STEVE CRISAFULLI
Speaker



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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.

Mr. David Flynn
October 23, 2015
Page 2

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,

A handwritten signature in cursive script, reading "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward Tellechea, Bureau Chief

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



PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

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Administrative Law Bureau

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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



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Lawrence.Harris@myfloridalegal.com

December 21, 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 to supplement my November 25, 2015, correspondence regarding the above referenced rule. As indicated, the Board of Pharmacy did meet on December 10 - 11, and considered this rule, including your comments, as an agenda item. The Board determined that it agreed with your comments, and directed that a Notice of Change be published to resolve your concerns.

Attached is a copy of the Agenda for the December 10, 2015, Rules Committee meeting, which documents that the rule was on the agenda for consideration. In addition, this Public Hearing was noticed on November 10, 2015, in Volume 41, Number 219 of the Florida Administrative Register. 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

enclosure

64B16-26.1031 Vaccine Certification Program.

(1) All applications for vaccine certification programs shall be made on board approved form DH-MQA 1234, "Board of Pharmacy Immunization Certification Program Provider Application," dated 08/15, "Vaccine Immunization Certification Program Application," effective 01/13, which is hereby incorporated by reference. To obtain an application go to <http://www.flrules.org/Gateway/reference.asp?No=Ref-02897> or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850) 488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) The Board shall approve for initial certification of pharmacist and pharmacy intern administration of vaccines, programs of study not less than 20 hours that include coursework covering all of the following;

(a) through (b) No change.

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry through ~~enrollment application DH Form 1997 (effective 10/07) herein incorporated by reference and may be obtained from the Board office by writing to the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or by telephoning 1(877)888-7468;~~

(d) through (k) No change.

(l) Administration of epinephrine using an autoinjector delivery system;:-

(m) The immunization and vaccine guidelines in the February 1, 2015, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – 2015; The current influenza, pneumococcal and shingles vaccine guidelines and recommendations of the United States Department of Health Centers for Disease Control and Prevention, which are entitled "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) – United States, 2012-13 Influenza Season," dated August 17, 2012, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02898>; "Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)," dated September 3, 2010, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02899>; "Prevention of Pneumococcal Disease Among Infants and Children – Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine," dated December 10, 2010, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02900>; "Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," dated June 6, 2008, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02901>; which are hereby incorporated by reference and published at <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>;

(n) The immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015;

(o) State of emergency administration of immunizations or vaccines;

(p)(~~n~~) No change.

(q)(~~e~~) Cardiopulmonary Resuscitation (CPR) training.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History—New 3-20-08, Amended 8-30-10, 7-29-13,

ANDY GARDINER
President

STEVE CRISAFULLI
Speaker



THE FLORIDA LEGISLATURE
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October 1, 2015

Ms. Lynette Norr
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1031, F.A.C.**

Dear Ms. Norr:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on September 25, 2015. I have the following comments.

64B16-26.1031(2)(c): This rule is being amended to remove the reference to Form DH 1997, effective 10/07.

Rule 64B16-26.1032 incorporates by reference form DH-MQA 1125, entitled Immunization Administration Certification Application and Information, dated 08/2015. Page 4 of that application advises pharmacists how to register for access to the state registry of immunization information, referred to as "Florida SHOTS." In order to register with Florida SHOTS, the pharmacist must obtain Form DH 1997, entitled Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking System), from www.flshots.com. This reference to Form DH 1997 does not include an effective date of the form.

It appears that form DH 1997 should be incorporated by reference into the appropriate rule. *See* § 120.55(1)(a)4., Fla. Stat. Please either incorporate this form by reference in this rule or explain in which rule Form DH 1997 is incorporated by reference.

Also, please provide a copy of form DH 1997 to the committee for review.

64B16-26.1031(2)(m): This paragraph refers to the February 1, 2015, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – 2015." Please include a quotation mark following "2015."

As the board is requiring programs of study seeking approval for initial certification to include coursework covering this immunization schedule, it appears that it is part of the rule and therefore should be specifically incorporated by reference into the rule text. Further, the rule text does not explain where this document may be found. Please explain why this document is not incorporated by reference. *See Fla. Admin. Code R. 1-1.013.*

Please provide a copy of this immunization schedule to the committee for review.

64B16-26.1031(2)(n): This paragraph refers to the immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. A program seeking approval is required to cover these recommended immunizations or vaccines.

Please explain how programs seeking approval may locate a list of these CDC recommended immunizations or vaccines. If the recommended immunizations or vaccines are included in a document, it appears that document should be incorporated by reference into the rule text. *See Fla. Admin. Code R. 1-1.013.* Also, please provide a copy of any such document containing these recommendations to the committee for review.

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

Sincerely,



Marjorie C. Holladay
Chief Attorney

cc: Mr. David Flynn, Assistant Attorney General
Mr. Edward Tellechea, Bureau Chief

ANDY GARDINER
President



Senator Denise Grimsley, Chair
Representative W. Travis Cummings, Vice Chair
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STEVE CRISAFULLI
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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

December 3, 2015

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

**Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1031, F.A.C.**

Dear Mr. Harris:

The letter dated October 1, 2015, outlining substantive problems with the above-referenced rule may be considered notice that the committee is considering an objection to this rule. It is my understanding that the board plans to toll the time for filing this rule pursuant to section 120.54(3)(e)6., Florida Statutes, as of December 3, 2015. If so, please confirm this decision in writing.

If you have any questions, please do not hesitate to call me.

Sincerely,

A handwritten signature in cursive script that reads "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney

cc: Mr. David Flynn, Assistant Attorney General
Mr. Edward Tellechea, Bureau Chief



PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

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December 8, 2015

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

Re: Department of Health,
Board of Pharmacy
Rule 64B16-26 1031, F.A.C.

Dear Ms. Holladay:

Pursuant to your letter dated December 3, 2015, which states that the Joint Administrative Procedures Committee is considering an objection to the rule, the Board elects to toll the 90 day deadline for adoption of the rule pursuant to Section 120.54(3)(e)6, F S effective December 3, 2015

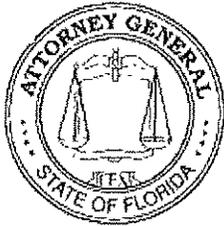
Thank you for your attention to this matter.

Sincerely yours,

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

Copy to. Edward A Tellechea, Bureau Chief
Allison Dudley, Executive Director
Angela Southwell, Paralegal Specialist

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December 28, 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 64B16-26.1031, F.A.C.

Dear Ms. Holladay:

I am writing in response to your correspondence of October 1, 2015, to Ms. Lynette Norr, regarding the above referenced rule, wherein you make three comments, which I will address in turn.

26.1031(2)(c) In sum, you comment that reference to Form DH 1997 is being deleted; Form DH-MQA 1125 advises pharmacists how to register for the Florida SHOTS program, including use of Form DH 1997; and therefore, Form DH 1997 should be incorporated by reference in this (or some other) rule, and a copy provided to the Committee for review. As I will more fully address in my response to your correspondence regarding rule 64B16-26.1032, F.A.C., the Board considered your comment, and in response, voted to remove the requirement for registration with the Florida SHOTS program from both rules. Since this reference will be removed from Form DH-MQA-1125, your concern regarding incorporation of Form DH 1197 is resolved.

Your remaining two comments are substantially the same: you comment that the rule requires programs of study seeking to be approved for purposes of initial certification of Pharmacists and Pharmacist Interns to include coursework regarding the Adult Immunization Schedule [26.1031(2)(m)] and the vaccines recommended by the US CDC for international travel [26.1031(2)(n)] as part of the curriculum; therefore, these documents should be incorporated by reference and copies provided to the Committee for review.

In response, the Board notes that section 465.189(1), F.S., the law implemented, specifically states:

(1) In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist, or a registered intern under the supervision of a pharmacist who is certified under subsection (6), **may administer the following vaccines to an adult** within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:

(a) Immunizations or vaccines listed in the Adult Immunization Schedule as of February 1, 2015, by the United States Centers for Disease Control and Prevention. The board may authorize, by rule, additional immunizations or vaccines as they are added to the Adult Immunization Schedule.

(b) Immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. The board may authorize, by rule, additional immunizations or vaccines as they are recommended by the United States Centers for Disease Control and Prevention for international travel. (emphasis added)

Subsection 465.189(6), F.S. then goes on to require:

(6) Any pharmacist or registered intern seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board and the registered intern complete at least 20 hours of coursework approved by the board. **The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines**, including, but not limited to, potential allergic reactions to such vaccines. (emphasis added)

Accordingly, it is the Board's position that the implemented statute itself identifies these two documents, and requires that certification programs must include training on these documents in the course of study. Because these documents are specifically identified and required by the implemented statute, the Board does not believe these two documents are required to be incorporated by reference in the current rule, and declines to do so.

As always, thank you for your comments and assistance regarding the Board's proposed rule amendments. It is my belief that this written correspondence fully responds to your comments, and accordingly, that the Committee will so certify such that the rule may proceed towards adoption. Please do not hesitate to contact me if you have any questions

Ms. Marjorie C. Holladay
RE: Rule 64B16-26.1031, F.A.C.
Page 3 of 3

or further concerns.

Sincerely,



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

cc: Allison Dudley, Executive Director
✓ David Flynn, Assistant Attorney General
Angela Southwell, Paralegal Specialist

ANDY GARDINER
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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

January 5, 2016

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

**Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1031, F.A.C.**

Dear Mr. Harris:

Thank you for your letter of December 28, 2015, regarding the above-referenced proposed rule. I have the following comments.

64B16-26.1031(2)(m): This paragraph refers to the February 1, 2015, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – 2015."

As stated in my letter of October 1, 2015, the rule text does not explain where this document may be found. Also, as requested in my letter of October 1st, please provide a copy of this document to the committee for review in order to determine whether this document must be incorporated by reference in the rule text.

64B16-26.1031(2)(n): This paragraph refers to the immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. As requested in my October 1st letter, please explain how programs seeking approval may locate a list of these CDC recommended immunizations or vaccines. In order to know whether a list of these immunizations or vaccines must be incorporated in the rule text, please provide a copy of any document containing these recommendations to the committee for review.

Mr. Lawrence Harris

January 5, 2016

Page 2

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

Sincerely,

A handwritten signature in cursive script that reads "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney

cc: Mr. David Flynn, Assistant Attorney General
Mr. Edward Tellechea, Bureau Chief

MCH:SA WORD/MARJORIE/64B16_26.1031LS010516_159221

64B16-26.1032 Immunization Administration Certification Application and Information.

All applications for immunization certification shall be made on board approved form DH-MQA 1125, "Immunization Administration Certification Application and Information," dated 12-2015 ~~effective October 2012~~, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the Department of Health's website at <http://www.doh.state.fl.us/mqa/pharmacy> or at <http://www.flrules.org/Gateway/reference.asp?No=Ref-03063>. The application must be accompanied with a non-refundable application fee, if applicable, as set forth in Rule 64B16-26.1001, F.A.C.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History--New 9-21-10, Amended 8-13-13, _____.

ANDY GARDINER
President

STEVE CRISAFULLI
Speaker



THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
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October 1, 2015

Ms. Lynette Norr
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1032, F.A.C.**

Dear Ms. Norr:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on September 25, 2015. I have the following comment.

64B16-26.1032: This rule incorporates by reference form DH-MQA 1125, entitled Immunization Administration Certification Application and Information, dated 08/2015.

Page 4 of this application advises pharmacists how to register for access to the state registry of immunization information, referred to as "Florida SHOTS." In order to register with Florida SHOTS, the pharmacist must obtain Form DH 1997, entitled Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking System), from www.flshots.com. This reference to Form DH 1997 does not include an effective date of the form.

Rule 64B16-26.1031 incorporated this form by reference, but proposed rule 64B16-26.1031, as noticed on September 25, 2015, is being amended to remove the reference to the form. The version of the form that was incorporated in rule 64B16-26.1031 was effective October 2007.

It appears that form DH 1997 should be incorporated by reference into the appropriate rule. See § 120.55(1)(a)4., Fla. Stat. Please either incorporate

Ms. Lynette Norr
October 1, 2015
Page 2

this form by reference in this rule or explain in which rule Form DH 1997 is incorporated by reference.

Also, please provide a copy of form DH 1997 to the committee for review.

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

Sincerely,

A handwritten signature in cursive script that reads "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney

cc: Mr. David Flynn, Assistant Attorney General
Mr. Edward Tellechea, Bureau Chief

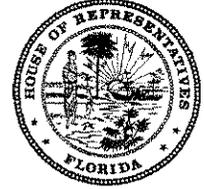
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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

December 3, 2015

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

**Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1032, F.A.C.**

Dear Mr. Harris:

The letter dated October 1, 2015, outlining substantive problems with the above-referenced rule may be considered notice that the committee is considering an objection to this rule. It is my understanding that the board plans to toll the time for filing this rule pursuant to section 120.54(3)(e)6., Florida Statutes, as of December 3, 2015. If so, please confirm this decision in writing.

If you have any questions, please do not hesitate to call me.

Sincerely,

A handwritten signature in cursive script that reads "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney

cc: Mr. David Flynn, Assistant Attorney General
Mr. Edward Tellechea, Bureau Chief



PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Lawrence D Harris
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December 8, 2015

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

Re: Department of Health,
Board of Pharmacy
Rule 64B16-26.1032, F.A.C.

Dear Ms Holladay:

Pursuant to your letter dated December 3, 2015, which states that the Joint Administrative Procedures Committee is considering an objection to the rule, the Board elects to toll the 90 day deadline for adoption of the rule pursuant to Section 120 54(3)(e)6., F S effective December 3, 2015.

Thank you for your attention to this matter.

Sincerely yours,

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

Copy to: Edward A Tellechea, Bureau Chief
Allison Dudley, Executive Director
Angela Southwell, Paralegal Specialist

RECEIVED
2015 DEC -8 PM 2:53
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PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
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December 28, 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 64B16-26.1032, F.A.C.

Dear Ms. Holladay:

I am writing in response to your correspondence of October 1, 2015, to Ms. Lynette Norr, regarding the above referenced rule. The Board considered your comments at a public meeting, and in response submits the following.

In sum, you comment that the incorporated Form DH-MQA 1125 advises pharmacists how to register for the Florida SHOTS program, including use of Department of Health Form DH 1997. You note that Form DH 1997 was incorporated by reference in Rule 64B16-26.1031, but the Board's proposed amendments to that rule remove the reference to Form DH 1997. You further comment that because use of Form DH 1197 is required by Form DH-MQA 1125, that DH 1997 should be incorporated through some rule of the Board. You conclude by asking that the Board either incorporate Form DH 1197 through this rule, or identify the rule that does incorporate the form.

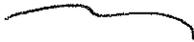
As a preliminary matter, the Board wishes to point out that the Florida SHOTS program is administered by the Department of Health, and not the Board of Pharmacy; furthermore, Form DH 1197 is a Department of Health form. The Board's references to the Florida SHOTS program, including reference to use of the 1197 form to register for that program, were included in the Board's rules as an aid to licensees. However, because registration with and use of the Florida SHOTS program is a Department requirement, the Board has determined that removal of the references to Florida SHOTS from rules 64B16-26.1031 and 64B16-26.1032 would be appropriate.

Accordingly, the Board will revise Form DH-MQA-1125, to delete the references to the Florida SHOTS program, including reference to Form DH 1197. A Notice of Change will be promptly prepared and published to incorporate the revised form.

Ms. Marjorie C. Holladay
RE: Rule 64B16-26.1032, F.A.C
Page 2 of 2

As always, thank you for your comments and assistance regarding the Board's proposed rule amendments. It is my belief that after review of the Notice of Change, revised Form DH-MQA-1125, and this written correspondence, you will determine the Board has fully responded to your comments, and will accordingly so certify. Please do not hesitate to contact me 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
David Flynn, Assistant Attorney General
Angela Southwell, Paralegal Specialist

64B16-26.300 Consultant Pharmacist Licensure.

(1) No change.

(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-> 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) through (b) No change.

(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:

<u>Minimum Skills Required</u>	<u>Percent of Time</u>	<u>Minimum Hours</u>
Minimum of 40 Hours in Maximum of Three Months		

1. through 6 No change.

(4) through (8) No change.

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, _____.

64B16-26.303 Nuclear Pharmacist Licensure.

(1) No change.

(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-> 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) An 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 compliance with subsection (3), below;

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

~~(2) A pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy a course outline from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy (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:~~

(3) All applicants must complete a minimum of 200 clock hours of formal didactic 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. All such formal training 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) through (6)(5) No change.

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

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.~~

Rulemaking 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, Repealed _____.

64B16-27.700 Definition of Compounding.

“Compounding” is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner’s agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term “commercially available products,” as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

- (a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
- (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.

(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer’s guidelines is permissible without notice to the practitioner.

(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy, except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

(3) Office use compounding, “Office use” means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner’s office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner’s office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner’s practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(d) The pharmacy and the practitioner enter into a written agreement. The agreement shall specifically provide:

1. That the compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity;

2. That the practitioner shall include on the patient’s chart, medication order, or medication administration record the lot number and the beyond-use-date of any compounded drug administered to the patient that was provided by the pharmacy;

3. That the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded drugs.

(e) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of four (4) years and shall include:

1. The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;

2. The name, strength, and quantity of the compounded drug provided, including the number of containers and quantity in each;

3. The date the drug was compounded;

4. The date the compounded drug was provided to the practitioner;

5. The lot number and beyond use date.

(f) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:

1. The name, address, and phone number of the compounding pharmacy;

2. The name and strength of the preparation of a list of active ingredients and strengths;

3. The pharmacy’s lot number and beyond-use-date;

4. The quantity or amount in the container;
5. The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and
6. The statement “For Institutional or Office Use Only – Not for Resale,” or if the drug is provided to a veterinarian the statement “Compounded Drug.”

(g) In the case of compounded sterile products intended for human use, the pharmacy must be in full compliance with 21 U.S.C. § 353b, including being registered as an Outsourcing Facility. 21 U.S.C. § 353b (eff. Nov. 27, 2013) is hereby adopted and incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-04180>.

Rulemaking Authority 465.005 FS. Law Implemented 465.003, 465.0155, 465.0265 FS. History—New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08, 3-21-13, 6-22-14.

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at <http://www.doh.state.fl.us/mqa/pharmacy> or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595. Inquiries regarding the status of the application or license verification may be obtained at <http://www.FLHealthsource.com>. The application must be accompanied with a \$250 initial permit fee, payable to the Board.

(1) through (8) No change.

(9) Nonresident Sterile Compounding Permit: This permit is required before an Outsourcing Facility or a Nonresident Pharmacy ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida.

(a) Outsourcing Facility applicants for this permit shall submit an application using Form DH5004-MQA-2/15, Nonresident Sterile Compounding Permit Application for Outsourcing Facilities, that is hereby incorporated by reference. The Form is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-> or <http://floridaspharmacy.gov>. Applicants must comply with all requirements found in section 465.0158, F.S.

(b) Nonresident Pharmacy applicants for this permit shall submit an application using Form DH5003-MQA-2/15, Nonresident Sterile Compounding Permit Application for Nonresident Pharmacies, that is hereby incorporated by reference. The Form is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-> or <http://floridaspharmacy.gov>. Applicants must comply with all requirements found in section 465.0158, F.S.

(c) Once a Nonresident Sterile Compounding Permit is issued, the permit holder must notify the board within 10 days of any change in the prescription department manager or pharmacist in charge or the supervising pharmacist on Form DH5005-MQA-2/15, Nonresident Sterile Compounding Permit Change in Pharmacist, that is hereby incorporated by reference. The Form is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-> or <http://floridaspharmacy.gov>.

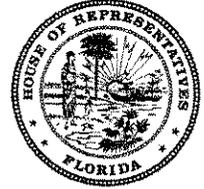
Rulemaking Authority 465.005, 465.0158, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.0158, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History—New 2-21-13, Amended 9-23-13,_____.

ANDY GARDINER
President

STEVE CRISAFULLI
Speaker



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March 20, 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 64B16-28.100, F.A.C.**

Dear Mr. Flynn:

I have conducted a preliminary review of the above-referenced proposed rule, which was advertised in the Florida Administrative Register on March 6, 2015. I have the following comments.

**Rulemaking
Authority and**

Law Implemented: Please properly code section 465.0158, which has been added as rulemaking authority and as a law implemented.

64B16-28.100(9)(a): This paragraph incorporates by reference Form DH5004-MQA-2/15, Nonresident Sterile Compounding Permit Application for Outsourcing Facilities.

Form DH5004-MQA-2/15:

Page 1: Number 2.b. states in part that, "The current inspection must demonstrate compliance with section 465.015, *Florida Statutes* and compliance with Federal Current Good Manufacturing Practices." First, it appears the citation should be to section 465.0158, *Florida Statutes*. Next, it appears that the reference to "compliance with Federal Current Good Manufacturing Practices" should instead be to "current good manufacturing practices for an outsourcing facility," to conform to the requirements of section 465.0158(3)(d). *See* § 120.52(8)(c), Fla. Stat. Also, it appears that the reference to current good manufacturing practices

should either refer to rule 64B16-27.797(3) or reiterate the definition of current good manufacturing practices as defined in that rule. *See* § 120.52(8)(d), Fla. Stat.

It appears that number 2.c. should refer to current good manufacturing practices for an outsourcing facility instead of “Federal Current Good Manufacturing Practices.”

Page 2: Please explain why the fee for a new establishment is \$255. Section 465.022(14)(a) authorizes an initial permit fee in the amount of \$250. If the board is relying on the special fee of \$5 per licensee to fund efforts to combat unlicensed activity pursuant to section 456.065(3), that statute should be cited as a law implemented.

Please provide statutory authority for the change of ownership fee for an outsourcing facility in the amount of \$255.

Page 3: Number 10. asks whether the inspection was structured to ensure compliance with current good manufacturing practices. It appears that the reference to Good Manufacturing Practices should either refer to rule 64B16-27.797(3) or reiterate the definition of current good manufacturing practices as defined in that rule.

Pages 4-5: Please explain why questions 13. through 20., which are asked pursuant to section 456.0635(2), are asked if the applicant is an outsourcing facility that is not a pharmacy. *See* § 465.0158(3)(b), Fla. Stat.

Page 8: Please provide statutory authority for requiring the applicant to sign under penalties of perjury. Specific statutory authority is required if a rule establishes a penalty. *See* Art. I, § 18, Fla. Const.; § 120.54(1)(e), Fla. Stat. In the absence of such authority, if appropriate, the board may consider adapting the language contained in section 456.067 for use in the application.

Please explain why this page requires the signature of the supervising pharmacist. Section 465.0158(3)(c) requires the applicant’s prescription department manager or pharmacist in charge to sign the attestation. It does not appear that chapter 465 uses the term “supervising pharmacist.” *See* § 120.52(8)(c), Fla. Stat.

64B16-28.100(9)(b): This paragraph incorporates by reference Form DH5003-MQA-2/15, Nonresident Sterile Compounding Permit Application for Nonresident Pharmacies.

DH5003-MQA-2/15:

It does not appear that this application includes the submission of a set of fingerprints of the enumerated persons listed in section 465.022(3)(a). Please add this to the application or explain why it is not required.

Page 5: See comments regarding the New Establishment Fee in Form DH5004-MQA-2/15.

Please provide statutory authority for the change of location fee in the amount of \$100. See § 465.0156(3), Fla. Stat.

Page 10: See comment regarding requiring the applicant to sign under penalties of perjury in Form DH5004-MQA-2/15.

64B16-28.100(9)(c): This paragraph incorporates by reference Form DH5005-MQA-2/15, Nonresident Sterile Compounding Permit Change in Pharmacist.

DH5005-MQA-2/15:

The citation to "Rule 64B16-28.100 (9), (c), F.A.C." should be corrected to "Rule 64B16-28.100(9)(c), F.A.C."

Please provide statutory authority for requiring this form to be completed by a "pharmacist in charge" for a nonresident pharmacy. It appears, instead, that this form should refer to the prescription department manager or consultant pharmacist of record. See § 465.022(10), Fla. Stat.

Please explain why this page requires the signatures of the incoming and out-going supervising pharmacists. Section 465.022(10) requires a permittee to provide notification of any change in prescription department manager or the consultant pharmacist of record. It does not appear that chapter 465 uses the term "supervising pharmacist." See § 120.52(8)(c), Fla. Stat.

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

Sincerely,



Marjorie C. Holladay
Chief Attorney

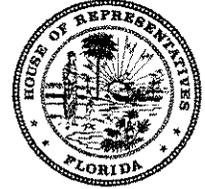
cc: Mr. Lawrence Harris
Assistant Attorney General

ANDY GARDINER
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THE FLORIDA LEGISLATURE
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April 17, 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 64B16-28.100, F.A.C.**

Dear Mr. Flynn:

This is a follow-up to my letter dated March 20, 2015. Please advise me of the status of this rule as soon as possible.

Thank you for your attention to this matter, and I look forward to your response.

Sincerely,

A handwritten signature in cursive script that reads "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney

ANDY GARDINER
President

STEVE CRISAFULLI
Speaker



THE FLORIDA LEGISLATURE
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Representative Lake Ray
Representative Hazelle P. "Hazel" Rogers
Representative Barbara Watson

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May 11, 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 64B16-28.100, F.A.C.**

Dear Mr. Flynn:

The letter dated March 20, 2015, outlining substantive problems with the above-referenced rule may be considered notice that the committee is considering an objection to this rule. It is my understanding that the board plans to toll the time for filing this rule pursuant to section 120.54(3)(e)6., Florida Statutes, as of May 11, 2015. If so, please confirm this decision in writing.

If you have any questions, please do not hesitate to call me.

Sincerely,

A handwritten signature in cursive script that reads "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney



PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

David D. Flynn
Assistant Attorney General
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
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May 12, 2015

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

Re. Department of Health,
Board of Pharmacy
Rule 64B16-28.100, F.A.C.

Dear Ms. Holladay:

Pursuant to your letter dated May 11, 2015, which states that the Joint Administrative Procedures Committee is considering an objection to the rule, the Board elects to toll the 90 day deadline for adoption of the rule pursuant to Section 120.54(3)(e)6., F.S. effective May 11, 2015

Thank you for your attention to this matter.

Sincerely yours,

David D. Flynn
Assistant Attorney General
Counsel to the Board of Pharmacy

Copy to. Edward A. Tellechea, Bureau Chief
Allison Dudley, Executive Director
Angela Southwell, Paralegal Specialist

RECEIVED
2015 MAY 12 PM 2:37
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PROCEDURES COMMITTEE

ANDY GARDINER
President

STEVE CRISAFULLI
Speaker



THE FLORIDA LEGISLATURE
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December 14, 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 64B16-28.100, F.A.C.**

Dear Mr. Flynn:

This rule was tolled as of May 11, 2015. Please let me know what the board is doing to continue to work on this rule, and provide me the status of the rule as soon as possible.

Thank you for your attention to this matter, and I look forward to your response.

Sincerely,

A handwritten signature in cursive script that reads "Marjorie C. Holladay".

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward Tellechea, Bureau Chief
Mr. Lawrence Harris, Assistant Attorney General

MCH:SA WORD/MARJORIE/64B16_28.100LS121415_157896

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

(1) through (3) No change.

(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, write the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number 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;

2. through 5. No change.

(b) No change.

(5) through (7) No change.

Rulemaking Authority 465.005, 465.0155, 465.0265 FS. Law Implemented 465.003(16), 465.019, 465.022, 465.0265 FS. History—New 9-23-03, Amended 7-27-04, 4-28-08, 2-5-14, 8-27-15, _____.

64B16-28.608 Automated Filling Systems within a Pharmacy.

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(a) "Automated filling system" means an automated system used within a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems, or systems governed by Rule 64B16-28.606 or 64B16-28.607, F.A.C.

(b) "Electronic verification process" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system.

(c) "Manufacturer Unit of Use Package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

(d) "Repackager" means a repackager registered with the United States Food and Drug Administration (FDA), as defined by Section 499.003(50), F.S.

(e) "Prepacked" means any drug that has been removed from the original packaging of the manufacturer or an FDA Repackager and is placed in a container for use in an automated filling system, as referenced by Section 499.003(42), F.S.

(f) "Load" means assigning new medications for new NDC numbers to the system, which must be completed by an onsite pharmacist.

(2) Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or restocked by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are defined by subsection 64B16-27.1001(7), F.A.C.

(3) Medication Loading. System must be loaded by an onsite pharmacist.

(4) Verification. Except as provided herein, a licensed pharmacist must verify the accuracy of the final contents of any medication filled or packaged by a system, and any label affixed thereto, prior to dispensing, as defined by subsection 64B16-27.1001(3), F.A.C.

(5) The pharmacist verification requirements of subsection (4) shall be deemed satisfied if:

(a) The pharmacy establishes and follows a policy and procedure manual that complies with subsection (6) of this rule;

(b) The system is fully automated from the time the medication is loaded into the machine until a completed, labeled and sealed prescription is produced by the system that is ready for dispensing to the patient. No manual intervention with the medication may occur after the medication is loaded into the system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(c) A pharmacist must perform a prospective drug review and verify the accuracy of the prescription information used by or entered into the system for a specific patient prior to initiation of the automatic fill process. The name, initials or identification codes(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing, or longer if required by applicable law;

(d) All medication Prepacked by the pharmacy must be verified by a pharmacist pursuant to subsection 64B16-27.1001(3), F.A.C.

(e) A pharmacist verifies the correct medication, either the Manufacturer Unit of Use Package, Repacked, or Prepacked container, was properly stocked, filled and loaded in the system. Alternatively, an electronic verification process may be used to verify a manufacturer unit of use package, repackaged, or prepacked containers;

(f) The medication to be dispensed is selected, filled, labeled, or sealed in the prescription container by the system or dispensed by the system in a manufacturer's unit of use package, repacked, or prepacked container;

(g) An electronic verification process is used to verify the proper prescription label has been affixed to the correct medication, prepackaged medication or manufacturer unit of use package for the correct patient; and

(h) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintain for four (4) years.

(6) Policies and Procedures. Pharmacies verifying prescriptions pursuant to subsection (5) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the prescription department manager or consultant pharmacist of record and shall be maintained in the

pharmacy's records for a minimum of four (4) years. The required annual review shall be documented in the pharmacy's records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for:

- (a) Maintaining the system and any accompanying electronic verification system in good working order;
- (b) Ensuring accurate filling, loading, and stocking of the system;
- (c) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;
- (d) Testing the accuracy of the system and any accompanying electronic verification system. At a minimum, the system and electronic verification process shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification process that changes or alters the filling or electronic verification process;
- (e) Training persons authorized to access, stock, restock, or load the system in equipment use and operations;
- (f) Conducting routine and preventive maintenance and, if applicable, calibration;
- (g) Removing expired, adulterated, misbranded or recalled drugs;
- (h) Preventing unauthorized access to the system, including assigning, discontinuing or changing security access;
- (i) Identifying and recording persons responsible for stocking, loading and filling the system;
- (j) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;
- (k) Maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification process to ensure proper and accurate functioning, including tracking and documenting of automated filling system errors that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for four (4) years and produced to the Board upon request.

(7) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of four (4) years, or longer if required under applicable law. If the verification requirements of paragraph (5)(d) of this rule are completed by a pharmacist, the name, initials or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing. Records shall be made available for inspection and produced to the Board or the Board's authorized designee upon request.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(17), 465.0155 FS. History—New 3-24-14.

64B16-28.702 Modified Class II Institutional Pharmacies.

(1) through (5) No change.

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A" and Type "B" as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A" and Type "B" Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) No change.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:

1. through 3. No change.

4. Provisions for the utilization of a perpetual inventory system for all controlled substances, ~~injectables and other medicinal drugs as required by the Pharmacy Services Committee.~~

5. Provisions for the utilization of an inventory system for injectables and other medicinal drugs as required by the Pharmacy Services Committee.

~~6.5.~~ No change.

~~7.6.~~ No change.

(c) No change.

(7) through (8) No change.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c), 465.022 FS. History--New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01, 7-14-14, _____.

64B16-28.905 Nonresident Sterile Compounding Permit Inspections: Approved Inspection Entities.

All applicants for a nonresident sterile compounding permit must have and present a current and satisfactory inspection report, and all nonresident sterile compounding permit holders seeking biennial renewal of the permit must have and present a current and satisfactory inspection report, as mandated by section 465.0158, F.S.

(1) Current and Satisfactory Inspection Report: An inspection report is current if the inspection report establishes that the inspection took place within the time frames established in section 465.0158(3)(e), F.S. An inspection report will be deemed satisfactory when the report reflects that the applicant or permit holder compounds all sterile products in compliance with minimum practice and quality standards (minimum standards). The minimum standards are different for those who are only registered as a nonresident pharmacy pursuant to section 465.0156, F.S., and for those who are registered as an outsourcing facility pursuant to section 21 U.S.C. 353b.

(2) Minimum Standards: Applicants for an initial permit or applicants for biennial renewal that are both a registered nonresident pharmacy and a registered outsourcing facility must meet the minimum standards applicable to a registered outsourcing facility.

(a) Registered Outsourcing Facility: The minimum standards for a registered outsourcing facility are the Current Good Manufacturing Practices (cGMP) that are adopted and incorporated by reference in rule 64B16-27.797(3), F.A.C.

(b) Registered Nonresident Pharmacies: The minimum standards for a registered nonresident pharmacy are chapters 797, 71, 85, and 731 of the United States Pharmacopeia that are adopted and incorporated by reference in rule 6416-27.797(1), F.A.C.

(3) Mandatory State Inspection Report: The current and satisfactory inspection report must be generated from an inspection that is performed by the regulatory or licensing authority of the state, territory, or district (hereinafter "state") where the applicant is geographically located, unless the applicant meets the acceptable circumstances established herein. The board hereby deems the following as acceptable circumstances for the department's acceptance of a current and satisfactory inspection report performed pursuant to section 465.0158(3)(e)1.-3., in lieu of the state inspection report:

(a) In the event that state or federal law prohibits the submission of the state inspection report;

(b) In the event that the state refuses to perform the inspection or generates an inspection report after completion of the inspection;

(c) In the event that the state is unable to perform an inspection within a reasonable time period from the date requested. Reasonable time period means within 180 days from the date that the applicant requested an inspection be performed. A failure by the applicant to request an inspection within 180 days from the date of permit renewal is deemed not to be an acceptable circumstance.

(d) In the event that the state inspection report documents that the applicant fails to meet the minimum standards adopted in this rule or when the inspection report merely lists an overall pass or fail and does not have the minimum standards enumerated within the inspection report with an appropriate indication of pass, fail, or not applicable, next to each enumerated standard.

(e) In the event the state inspection report would not be admissible in an administrative proceeding pursuant to the provisions of Chapter 120, F.S., or when state or federal inspectors advise they will not testify to the contents, results thereof, or authentication of the state inspection report.

(f) In the event that the applicant is able to submit a current inspection report from the United States Food and Drug Administration that concludes or establishes the applicant is in compliance with cGMP.

(4) Approved Inspection Entities for Registered Nonresident Pharmacies: This section is not applicable to inspection reports for registered outsourcing facilities. The board must approve entities for which the department will accept a current and satisfactory inspection report in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory authority of the state, territory, or district where the applicant is located. An entity that wants to be approved as an inspection entity must submit an Approval Request with attached documentation to the board office. The Approval Request, and attached documentation, shall demonstrate compliance with the following requirements:

(a) The entity must be a legally recognizable business entity that possesses a separate existence for tax purposes. An Approval Request must be submitted with business formation documents that establish compliance with this paragraph.

(b) The entity is formed, established, or created to avoid a reoccurring conflict of interest between the entity and those whom the entity will be inspecting. A conflict of interest is a real or seeming incompatibility between the entity's private interests and the entity's duty to conduct an impartial inspection.

(c) The entity will not conduct any inspection in which the entity or an employed inspector of the entity has a conflict of interest.

(d) The entity must have a customized inspection report. The inspection report must enumerate all minimum standards of each of the chapters of the United States Pharmacopeia that are listed in subparagraph (2)(b) of this rule. Each enumerated minimum standard must have a place for the inspector to mark compliant or yes; non-compliant, deficient or no; and not applicable. Each enumerated minimum standard must also have room for the inspector to document observations or comments. An Approval Request must be submitted with a copy of the customized inspection report.

(e) The entity must submit any completed inspection report with digital photography capturing each enumerated minimum standard if the enumerated minimum standard is subject to being captured by photography.

(f) With the Approval Request, the entity must submit an inspection history report. The inspection history report must reflect that the applicant has experience performing inspections for compliance with the required minimum standards. To be approved, an entity must have a minimum of 2 years' experience performing inspections and must have performed a minimum of 20 inspections. The required inspection experience may be demonstrated through the experience of the employed inspectors, if the entity has not been in existence for 2 years prior to submitting an Approval Request.

(g) The entity must agree in writing that the entity will not make a recommendation for the granting, denial, or discipline of a permit.

(h) The entity shall have a written policies and procedures manual. The policies and procedures shall at a minimum address the timely completion and proper performance of inspections and must establish protocols and procedures to ensure compliance with this rule. The policy and procedures manual must be submitted with the Approval Request. The policies and procedures shall require the inspections to be unannounced and that the costs of any inspection shall not be based on or differ in the amount based on the results of the inspection.

(i) The entity must agree in writing that it will testify to the contents of the inspection report in any civil, criminal, or administrative proceeding and that the entity agrees that it and any employed inspectors will not request an expert witness fee (s.92.231) for the testimony of the inspector who performed the inspection.

(j) The entity shall maintain all inspection reports and related records for a period of no less than 4 years from the date inspection was concluded.

(k) The entity shall, within 60 days prior to closing, notify the department or the board when it will close or cease performing inspection services and make arrangements with the department for preserving inspections records that are still within the 4 year retention requirement.

(5) Employed Inspectors: The entities' employed inspectors must meet the following criteria:

(a) Any employed inspector must hold an active license to practice pharmacy in any state, territory or district of the United States. Proof of the license shall be submitted with the Approval Request. The employed inspectors may not have any disciplinary history related to the practice of a health profession within 5 years prior to the Approval Request and may have never been disciplined for an offense related to compounding. This provision shall not prohibit the entity from retaining or employing any person that does not hold a pharmacy license for the purposes of assisting the inspectors. For example, it is acceptable to hire a microbiologist or chemist to assist the inspectors in completing the inspection and inspection report.

(b) Any employed inspector must have a minimum of 4 years' experience in the practice of sterile compounding. At least 2 of the 4 years of experience must be obtained through the active practice of compounding sterile products in all risk categories (low, medium, and high risk sterile compounding). The other 2 years may be obtained by one or more of the following: 1) Being employed by a state or federal agency to perform inspections of pharmacies or pharmaceutical manufacturers to determine compliance with minimum sterile compounding standards or current good manufacturing practices standards; 2) Being employed as a full-time instructor at an accredited university for the purpose of instructing students in didactic and clinical instruction on sterile compounding; 3) Being employed to conduct research related to sterile compounding; or 4) Being published in a peer review journal when the article is related to sterile compounding. Three months of credit will be awarded for each published article related to sterile compounding.

(c) At least one of the employed inspectors must have a minimum of 1 year, of the 4 years required, supervisory experience related to the practice of sterile compounding. Supervisory experience is being employed as a supervisor of other pharmacists, not just technicians, in a pharmacy setting that engaged in sterile compounding.

(d) Those employed inspectors which do not have at least 6 months of experience in performing inspections related to sterile compounding must first attend 2 inspections, as a subordinate inspector in training, before being allowed to perform an inspection independently.

(e) The entity must submit a copy of each inspector's employment history and a copy of the each inspector's curriculum vitae (CV) with the Approval Request. The CV must demonstrate that the inspectors are compliant with the experience requirements of this rule.

(f) During the period of employment as an inspector for the entity, the inspectors must have documented training related to sterile compounding and performing sterile compounding inspections. At a minimum, the training must consist of at least 10 clock hours of training annually. The training documentation shall be made available to the Board upon written request.

(6) Once an entity is approved by the Board, the applicant will be required to maintain compliance with the provisions of this rule or the approval is subject to revocation in compliance with the provisions of Chapter 120, F.S. The department will randomly require documentation of each approved entity to ensure continued compliance with the provision of this rule.

(7) All approved entities shall be listed on the Department's website.

Rulemaking Authority 465.0158 FS. Law Implemented 465.0158 FS. History--New, _____.

ANDY GARDINER
President



Representative W. Travis Cummings, Chair
Senator Denise Grimsley, Vice Chair
Senator Aaron Bean
Senator Dwight Bullard
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STEVE CRISAFULLI
Speaker



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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

October 1, 2015

Ms. Lynette Norr
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1031, F.A.C.**

Dear Ms. Norr:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on September 25, 2015. I have the following comments.

64B16-26.1031(2)(c): This rule is being amended to remove the reference to Form DH 1997, effective 10/07.

Rule 64B16-26.1032 incorporates by reference form DH-MQA 1125, entitled Immunization Administration Certification Application and Information, dated 08/2015. Page 4 of that application advises pharmacists how to register for access to the state registry of immunization information, referred to as "Florida SHOTS." In order to register with Florida SHOTS, the pharmacist must obtain Form DH 1997, entitled Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking System), from www.flshots.com. This reference to Form DH 1997 does not include an effective date of the form.

It appears that form DH 1997 should be incorporated by reference into the appropriate rule. *See* § 120.55(1)(a)4., Fla. Stat. Please either incorporate this form by reference in this rule or explain in which rule Form DH 1997 is incorporated by reference.

Also, please provide a copy of form DH 1997 to the committee for review.

64B16-26.1031(2)(m): This paragraph refers to the February 1, 2015, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled “Recommended Adult Immunization Schedule – United States – 2015.” Please include a quotation mark following “2015.”

As the board is requiring programs of study seeking approval for initial certification to include coursework covering this immunization schedule, it appears that it is part of the rule and therefore should be specifically incorporated by reference into the rule text. Further, the rule text does not explain where this document may be found. Please explain why this document is not incorporated by reference. *See Fla. Admin. Code R. 1-1.013.*

Please provide a copy of this immunization schedule to the committee for review.

64B16-26.1031(2)(n): This paragraph refers to the immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. A program seeking approval is required to cover these recommended immunizations or vaccines.

Please explain how programs seeking approval may locate a list of these CDC recommended immunizations or vaccines. If the recommended immunizations or vaccines are included in a document, it appears that document should be incorporated by reference into the rule text. *See Fla. Admin. Code R. 1-1.013.* Also, please provide a copy of any such document containing these recommendations to the committee for review.

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

Sincerely,



Marjorie C. Holladay
Chief Attorney

cc: Mr. David Flynn, Assistant Attorney General
Mr. Edward Tellechea, Bureau Chief

ANDY GARDINER
President



Senator Denise Grimsley, Chair
Representative W. Travis Cummings, Vice Chair
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STEVE CRISAFULLI
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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

January 5, 2016

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

**Re: Department of Health: Board of Pharmacy
Rule 64B16-26.1031, F.A.C.**

Dear Mr. Harris:

Thank you for your letter of December 28, 2015, regarding the above-referenced proposed rule. I have the following comments.

64B16-26.1031(2)(m): This paragraph refers to the February 1, 2015, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – 2015."

As stated in my letter of October 1, 2015, the rule text does not explain where this document may be found. Also, as requested in my letter of October 1st, please provide a copy of this document to the committee for review in order to determine whether this document must be incorporated by reference in the rule text.

64B16-26.1031(2)(n): This paragraph refers to the immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. As requested in my October 1st letter, please explain how programs seeking approval may locate a list of these CDC recommended immunizations or vaccines. In order to know whether a list of these immunizations or vaccines must be incorporated in the rule text, please provide a copy of any document containing these recommendations to the committee for review.

Mr. Lawrence Harris

January 5, 2016

Page 2

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

Sincerely,

A handwritten signature in blue ink that reads "Marjorie C. Holladay". The signature is written in a cursive style with a large initial 'M' and a long, sweeping tail on the 'y'.

Marjorie C. Holladay
Chief Attorney

cc: Mr. David Flynn, Assistant Attorney General
Mr. Edward Tellechea, Bureau Chief

MCH:SA WORD/MARJORIE/64B16_26.1031LS010516_159221



PAM BONDI
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December 28, 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 64B16-26.1031, F.A.C.

Dear Ms. Holladay:

I am writing in response to your correspondence of October 1, 2015, to Ms. Lynette Norr, regarding the above referenced rule, wherein you make three comments, which I will address in turn.

26.1031(2)(c) In sum, you comment that reference to Form DH 1997 is being deleted; Form DH-MQA 1125 advises pharmacists how to register for the Florida SHOTS program, including use of Form DH 1997; and therefore, Form DH 1997 should be incorporated by reference in this (or some other) rule, and a copy provided to the Committee for review. As I will more fully address in my response to your correspondence regarding rule 64B16-26.1032, F.A.C., the Board considered your comment, and in response, voted to remove the requirement for registration with the Florida SHOTS program from both rules. Since this reference will be removed from Form DH-MQA-1125, your concern regarding incorporation of Form DH 1197 is resolved.

Your remaining two comments are substantially the same: you comment that the rule requires programs of study seeking to be approved for purposes of initial certification of Pharmacists and Pharmacist Interns to include coursework regarding the Adult Immunization Schedule [26.1031(2)(m)] and the vaccines recommended by the US CDC for international travel [26.1031(2)(n)] as part of the curriculum; therefore, these documents should be incorporated by reference and copies provided to the Committee for review.

In response, the Board notes that section 465.189(1), F.S., the law implemented, specifically states:

(1) **In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine**, a pharmacist, or a registered intern under the supervision of a pharmacist who is certified under subsection (6), **may administer the following vaccines to an adult** within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:

(a) **Immunizations or vaccines listed in the Adult Immunization Schedule as of February 1, 2015, by the United States Centers for Disease Control and Prevention.** The board may authorize, by rule, additional immunizations or vaccines as they are added to the Adult Immunization Schedule.

(b) **Immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015.** The board may authorize, by rule, additional immunizations or vaccines as they are recommended by the United States Centers for Disease Control and Prevention for international travel. (emphasis added)

Subsection 465.189(6), F.S. then goes on to require:

(6) **Any pharmacist or registered intern seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy** in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board and the registered intern complete at least 20 hours of coursework approved by the board. **The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines**, including, but not limited to, potential allergic reactions to such vaccines. (emphasis added)

Accordingly, it is the Board's position that the implemented statute itself identifies these two documents, and requires that certification programs must include training on these documents in the course of study. Because these documents are specifically identified and required by the implemented statute, the Board does not believe these two documents are required to be incorporated by reference in the current rule, and declines to do so.

As always, thank you for your comments and assistance regarding the Board's proposed rule amendments. It is my belief that this written correspondence fully responds to your comments, and accordingly, that the Committee will so certify such that the rule may proceed towards adoption. Please do not hesitate to contact me if you have any questions

Ms. Marjorie C. Holladay
RE: Rule 64B16-26.1031, F.A.C.
Page 3 of 3

or further concerns.

Sincerely,

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

cc: Allison Dudley, Executive Director
David Flynn, Assistant Attorney General
Angela Southwell, Paralegal Specialist

64B16-26.1031 Vaccine Certification Program.

(1) All applications for vaccine certification programs shall be made on board approved form DH-MQA 1234, "Board of Pharmacy Immunization Certification Program Provider Application," dated 08/15, which is hereby incorporated by reference. To obtain an application go to <http://www.flrules.org/Gateway/reference.asp?No=Ref-02897> or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850) 488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) The Board shall approve for initial certification of pharmacist and pharmacy intern administration of vaccines, programs of study not less than 20 hours that include coursework covering all of the following;

(a) through (b) No change.

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry

(d) through (k) No change.

(l) Administration of epinephrine using an autoinjector delivery system;-

(m) The immunization and vaccine guidelines in the February 1, 2015, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – 2015 which is hereby incorporated by reference. The Schedule may be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref> and the Board office at the address in subsection (1);

(n) The immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015, which may be found in the CDC Health Information for International Travel (2014 Edition), which is incorporated herein by reference. The material incorporated is copyrighted material that is available for public inspection and examination, but may not be copied, at the Department of State, Administrative Code and Register Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250, and at the Board office at the address in subsection (1);

(o) State of emergency administration of immunizations or vaccines;

(p) No change.

(q) No change.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 3-20-08, Amended 8-30-10, 7-29-13,

_____.

Board Counsel's suggested language to add PDM responsibilities.

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees; Prescription Department Managers.

(1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.

(2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.

(3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.

(4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.

(5) Prescription Department Managers. Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager.

(a) Registration as prescription department manager. ~~responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy.~~ The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

(b) Responsibilities of the prescription department manager. Prescription department managers are responsible for ensuring the pharmacy permittee's compliance with all statutes and rules governing the practice of the profession of pharmacy, including maintenance of all drug records and ensuring the security of the prescription department, and shall competently and diligently exercise their responsibilities as a prescription department manager. Prescription Department Managers shall spend such time in the prescription department as is necessary to exercise these responsibilities by, at a minimum:

1. Within seven (7) days of being designated as the prescription department manager of a pharmacy, the pharmacist so designated shall conduct an on-site visit of the pharmacy. During this on-site visit, the prescription department manager shall verify that the pharmacy is in compliance with all statutes and rules, and shall also perform the tasks identified in subparagraph (b)2. below.

2. Following the initial on-site visit, the prescription department manager shall, no less than semi-annually, perform the following tasks:

a. Conduct a self-audit of the prescription department's drug records, inventory logs, COI committee minutes, and other required documentation;

b. Conduct a full inspection of the pharmacy's drug stocks and inventory;

3. Prescription Department Managers shall maintain documentation of the activities required by paragraph (5)(b), above, and shall provide such documents to the Board or Department upon request.

Specific Authority 465.005, 465.0155, 465.018, 465.022 FS. Law Implemented 465.018, 465.022, 465.024 FS. History—New 10-20-81, Formerly 21S-1.20, 21S-1.020, Amended 7-30-91, Formerly 21S-27.104, 61F10-27.104, 59X-27.104, Amended 11-18-07.

Board Counsel's suggested language to add the Controlled Substances CE course.

64B16-26.600 Tripartite Continuing Education Committee.

(1) The Tripartite Continuing Education Committee will be composed of equal representation from the Board of Pharmacy, each College or School of Pharmacy in the State, and practicing pharmacists within the State. The members of the Committee shall be selected by the Board of Pharmacy and shall serve for a period of two years. The ~~C~~ehair~~man~~ of the committee shall be selected by the Chair of the Board.

(2) The Tripartite Continuing Education Committee shall perform the following duties pursuant to Rule 64B16-26.601, F.A.C.:

(a) Review continuing education providers and make recommendations to the Board;

(b) Approve the following continuing education courses or programs to be offered by ~~for~~ approved providers or individuals that are non-approved providers ~~for the following~~:

1. General;
2. Initial Consultant Pharmacist Certification;
3. Consultant Recertification;
4. Nuclear Recertification;
5. Medication Errors;
6. HIV/AIDS;
7. Laboratory Tests;
8. Laws and Rules;
9. Quality Related Events;-
10. Validation of Prescriptions for Controlled Substances.

(3) The Tripartite Continuing Education Committee shall perform auditing and monitoring activities pursuant to Rule 64B16-26.601, F.A.C. The Tripartite Committee shall perform an audit on each approved continuing education provider 90 days prior to the end of the biennium. The approved provider shall submit the following information for one program of the provider's choosing and one program selected by the Board:

- (a) Title, date and location of the program;
 - (b) Program Number;
 - (c) Any ~~c~~o-sponsors;
 - (d) Total number of pharmacists attending;
 - (e) Rosters of attendees with appropriate license numbers;
 - (f) Brochures of program announcement;
 - (g) CV's of each speaker;
 - (h) Handouts, ~~c~~opy of CE Credit statement, educational materials distributed as part of the program; and
 - (i) Summary report of program evaluations.
- (4) The Committee shall hold meetings as may be convened at the call of the Chair~~man~~ of the Committee.

Rulemaking Authority 465.005, 465.009(5) FS. Law Implemented 465.009 FS. History—New 10-18-79, Amended 7-29-81, Formerly 21S-13.01, 21S-13.001, 21S-26.600, 61F10-26.600, 59X-26.600, Amended 10-15-01, 3-10-05, 6-11-09,_____.

Board Counsel's suggested language to add language regarding stock transfers / continuing business entity.

64B16-28.2021 Change of Ownership.

(1) A pharmacy permit is not transferable. ~~If u~~Upon the sale of an existing pharmacy, there is any change in the identity of the natural person, partnership, or business entity which holds the permit, a new application must be filed and a new permit obtained.

(2) Permits held by business entities with no change in identity. In those cases where the permit is held by a business entity (e.g. a corporation, limited liability company, limited partnership, etc.) which entity continues to hold the permit without change in identity, a corporation—the transfer of the ownership interests all the stock of said business entity corporation to another business person or entity does not constitute a change of ownership (requiring application for and issuance of a new pharmacy permit) provided that the initial corporation holding the permit continues to exist. Upon transfer of the ownership interests in the business entity, the following steps shall be taken:

(a) Within fifteen (15) days of closing the transfer, the permittee shall notify the Board office of the transfer of ownership interests; and

(b) As specified in section 465.022(3), F.S., all persons, members, partners, officers, directors, and agents having an ownership or other financial interest of greater than five percent (5%), and all persons who directly or indirectly manage, oversee, or control the operation of the business entity, must file with the board a set of fingerprints as specified in Rule 64B16-28.100(1)(c), F.A.C.

(3) If a criminal history check identifies any person listed in paragraph (2)(b) above as meeting any of the provisions of section 465.022(4), (5), or (6), F.S., the Board staff shall immediately refer the matter to the Department for investigation and possible prosecution as provided in section 465.023, F.S.

~~(4)(2)~~ A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an “opening inventory” for DEA purposes. Both the new permit and the old permit must keep appropriate records for four (4) years for the transfer of legend drugs and controlled substances.

~~(5)(3)~~ A change in the company or person who leases the building where the permit is housed or a change in the management company which contracts with the owner of the permit for the operation of the permit does not constitute a change in ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022, 465.023, FS. History—New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05, 7-14-14,_____.

64B16-28.1081 Regulation of Daily Operating Hours; commencement of operations.

(1) 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 ~~twenty (20)~~ 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) "Commences to Operate" means the compounding, dispensing, storage, or sale of medicinal drugs or the filling or dispensing of prescriptions.

(b) The Board recognizes that a delay may exist between the time a pharmacy receives a Florida pharmacy permit and commences to operate. Accordingly, upon receipt of a Florida pharmacy permit, a community pharmacy may delay commencement of operations in compliance with the following:

1. Within seven (7) days of receipt of the Florida pharmacy permit, the permittee shall notify the Board office, in writing, of the permittee's election to delay commencement of operations and the reason(s) therefore;

2. The permittee shall display a sign in block letters not less than one inch in height at the main entrance of the establishment the the pharmacy is not yet open for business and that medicinal drugs may not be dispensed nor sold nor prescriptions filled or dispensed;

3. No later than fourteen (14) days prior to commencement of operations, the permittee shall notify the Board office in writing that the permittee intends to commence to operate and the date of commencement.

(c) Any pharmacy permittee that does not commence to operate within six (6) months of the date of receipt of the Florida pharmacy permit shall provide a written statement to the Board office, which shall include the reason(s) the pharmacy has not yet commenced operations, the efforts the pharmacy has made to commence to operate, and the date the pharmacy expects to commence to operate.

(2) At the time a pharmacy commences to operate, 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, which sign must include: 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 written 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.

Rulemaking Authority 465.005, 465.022(1) FS. Law Implemented 465.022(4) FS. History—New 4-10-05, Amended 2-1-12,_____.

64B16-28.451 Pharmacy Common Database; Exceptions for prescription drug processing only pharmacies.

(1) A pharmacy licensed under this chapter may perform prescription drug processing for other pharmacies, provided that all pharmacies are under common ownership, utilize a common database, and are properly licensed, permitted or registered in this state or another state. Nothing in this subsection shall prohibit a pharmacist employee of said pharmacies who is licensed in Florida or in another state from remotely accessing the pharmacy's electronic database from outside the pharmacy in order to process prescriptions, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(2) Prescription drug processing shall include the following:

- (a) Receiving, interpreting, or clarifying a prescription;
- (b) Entering prescription data into the pharmacy's record;
- (c) Verifying or validating a prescription;
- (d) Performing prospective drug review as defined by the Board;
- (e) Obtaining refill and substitution authorizations;
- (f) Interpreting or acting on clinical data;
- (g) Performing therapeutic interventions;
- (h) Providing drug information concerning a patient's prescription; and
- (i) Providing patient counseling.

(3) Each pharmacist that performs a specific function within the prescription drug processing process via use of a common database shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(4) Each pharmacy performing prescription drug processing pursuant to this section must maintain a policy and procedure manual, which shall be made available to the Board or its agent upon request. The policy and procedures manual shall include the following information:

- (a) A description for how each pharmacy will comply with federal and state laws, rules and regulations;
- (b) The procedure for maintaining appropriate records to identify the pharmacies and pharmacists responsible for the prescription drug processing and dispensing of the prescription;
- (c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and
- (d) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(5) The prescription drug processing of a prescription by one pharmacy for another pursuant to this section shall not be construed as the transferring of a prescription as set forth in Section 465.026, F.S.

(6) In addition to all record requirements of Rule 64B16-28.140, F.A.C., all pharmacies participating in prescription drug processing, shall maintain appropriate records which identify, by prescription, the name(s), initials, or identification code(s) of each pharmacist or registered pharmacy technician who performs a processing function for a prescription. Such records shall be maintained:

- (a) Separately by each pharmacy and pharmacist; or
- (b) In a common electronic file, as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy, pharmacist, registered pharmacy intern and registered pharmacy technician.

(7) Prescription drug processing only pharmacies. A pharmacy permittee which solely performs prescription drug processing for other pharmacies pursuant to this rule, and at which medicinal drugs are not compounded, dispensed, stored or sold, nor are prescriptions filled or dispensed, and which notifies the Board that its pharmacy practice is limited solely to prescription drug processing shall be exempt from the following rules:

- (a) Rule 64B16-28.102, Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment;
- (b) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;
- (c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours; and
- (d) Rule 64B16-28.109(1), F.A.C., relating to signage.

**Amendments to update incorporated form DH-MQA 101
February 2016**

64B16-26.203 Pharmacist Licensure by Examination (U.S. Graduates); Application.

Applicants who are at least eighteen (18) years of age and a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Department Office of Education may apply to take the licensure examination.

(1) All applications for licensure by examination must be made on board approved form DOH-~~MQA~~-101, Pharmacist Examination Application for U.S. ~~and Puerto Rico~~ Graduates and Instructions, (Rev ~~02/16~~ ~~9/09~~), which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-> , the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or the Board's website at <http://floridaspharmacy.gov/Applications/app-pharmacist-exam-us-pr-grad.pdf> the Board of Pharmacy, 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 <http://www.doh.state.fl.us/mqa/pharmacy>. The application must be accompanied with an non-refundable examination fee and an initial license fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) In addition to the requirements of subsection (1), ~~t~~The applicant must submit proof of having met the following requirements:

(a) Completion of an internship program provided by either an accredited school or college of pharmacy or a state board of pharmacy or jointly by both, provided that the program meets the requirements of Rule 64B16-26.2032, F.A.C.; and

(b) Completion of a board approved course not less than two (2) hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For those applicants who apply within one (1) year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than two (2) contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety, as evidenced by a letter attesting to subject matter covered from the Dean of the University.

(3) An applicant must reapply if all requirements for licensure are not met within one (1) year of the receipt of the application.

(4) Passing examination scores may be used upon reapplication only if the examination was completed within three (3) years of the reapplication.

Rulemaking Authority ~~456.033~~, 465.005 FS. Law Implemented 456.013(1), (7), 456.025(3), ~~456.033~~, 465.007, ~~465.022~~ FS. History—New 10-17-79, Formerly 21S-12.04, 21S-12.004, Amended 7-31-91, 10-14-91, Formerly 21S-26.203, 61F10-26.203, Amended 7-1-97, Formerly 59X-26.203, Amended 8-17-99, 10-15-01, 1-2-02, 1-12-03, 1-11-05, 2-18-08, 5-26-09, 5-11-10, _____.

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



**PHARMACIST EXAMINATION APPLICATION
FOR U.S. GRADUATES AND INSTRUCTIONS**

February 2016

General Information

Requirements for Florida Pharmacist Examination

In order to be licensed as a pharmacist in the State of Florida, you must apply to the Florida Board of Pharmacy (the board), and have passing scores on the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®) (also referred to as the “Florida law exam”). Both parts of the exam are computerized and can be taken in your state. Exams are offered everyday of the year with the exception of holidays and Sundays. Please refer to the NAPLEX®/MPJE® Registration Bulletin for testing locations in your state. The NAPLEX®/MPJE® Registration Bulletin is available on the National Association of Boards of Pharmacy’s (NABP®) website at www.nabp.net.

The board is a participant in the NAPLEX® Score Transfer Program. If you elect to transfer your NAPLEX® score to Florida, the score is good for three (3) years from the date you took the examination and you will have to fulfill all other requirements for licensure in Florida which includes passing the MPJE®. Please review the requirements for the NAPLEX® Score Transfer Program in the NAPLEX®/MPJE® Registration Bulletin.

***If you are licensed as a pharmacist in another state and have passed the NAPLEX® examination, please visit our website at www.floridaspharmacy.gov and review the requirements for licensure by endorsement to see if you qualify by this method. If you would like to apply by endorsement, please visit our website at www.floridaspharmacy.gov/resources to download an endorsement application.**

Application Processing

Please read all application instructions before completing your application.

IF YOU ARE A FOREIGN GRADUATE YOU HAVE DOWNLOADED THIS APPLICATION IN ERROR. PLEASE VISIT OUR WEBSITE AT <http://www.floridaspharmacy.gov/resources> TO DOWNLOAD THE LICENSURE BY EXAMINATION FOR FOREIGN GRADUATES APPLICATION.

ALL REQUIREMENTS FOR LICENSURE MUST BE MET WITHIN ONE (1) YEAR OF THE RECEIPT OF YOUR APPLICATION OR THE APPLICATION WILL EXPIRE AND YOU WILL HAVE TO REAPPLY.

Following receipt of the application and fees the board office will acknowledge the receipt of your application and notify you of any missing documentation or information. You can follow the progress of your application through our website at <http://ww2.doh.state.fl.us/mqaservices/login.asp> once we have issued you a username and password. Once your application is complete and you have registered for the NAPLEX® and MPJE® as required, you should receive an Authorization to Test (ATT) from NABP® within 7 days via email. Please make sure the email address you use when registering for the exam(s) is

DH-MQA 101, 02/16

Rule 64B16-26.203, F.A.C.

valid. The board office must be notified in writing of anything which changes or affects a response given in your application (e.g., change of name, address, telephone number, arrests or convictions, licensure status or disciplinary action in another state, or an incorrect answer to a question). If you move, you must notify the board, as state mail is not forwarded. **Please download a copy of the laws and rules from the board website at <http://www.floridaspharmacy.gov/resources> for study purposes.**

Prevention of Medication Errors

All applicants must complete a Florida Board approved course on the prevention of medication errors prior to licensure. The course shall be no less than two (2) contact hours and shall cover the subjects listed in subsection 64B16-26.103(1)(c), Florida Administrative Code (F.A.C.). **Please refer to CE Broker's website at www.CEBroker.com and click the Florida Course Search quick link for a list of approved courses. Submit Item #6- Prevention of Medication errors continuing education affirmation.**

Grade Reports

Your examination results will be available online at <http://flhealthsource.com>, in the "Provider Services" section under "Check Exam Results" within 7-10 days of your test date. You will need the last 4 digits of your social security number and your date of birth in order to access your scores online. Please do not telephone the board office for the results of your examination; we cannot give your results over the phone for any reason.

Board Licensure Procedure

Once you have passed the exam(s), submitted all required documents, and met all licensure requirements, you will receive the license in approximately seven (7) days. **You may lookup your license number on our website at <http://flhealthsource.gov> under "Verify a License". You may begin practicing pharmacy on your licensure date.**

Withdrawals

If you are unable to continue with the licensure process and wish to withdraw your application, you may submit a written request to the board office requesting a refund of the \$195.00 initial licensure/unlicensed activity fee. The request must be received prior to the board's granting of licensure. The board reserves the right to deny your request to withdraw your application.

Special Testing Assistance

All testing accommodation requests will be evaluated by the National Association of Boards of Pharmacy (NABP). Please visit <http://www.nabp.net/programs/examination/naplex/testing-accommodations> for information regarding testing accommodations.

Please note, if the board has questions or concerns about the information contained in your application you may be required to appear before the board prior to the granting of licensure.

IMPORTANT NOTICE:

Effective July 1, 2012, section 456.0635, Florida Statutes, provides that health care boards or the department **shall refuse** to issue a license, certificate or registration and **shall refuse** to admit a candidate for examination if the applicant:

1. Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S., (relating to social and economic assistance), Chapter 817, F.S., (relating to fraudulent practices), Chapter 893, F.S., (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed.

Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration, unless the sentence and any subsequent period of probation for such conviction or plea ended:

- For the felonies of the first or second degree, more than 15 years from the date of the plea, sentence and completion of any subsequent probation;
 - For the felonies of the third degree, more than 10 years from the date of the plea, sentence and completion of any subsequent probation;
 - For the felonies of the third degree under section 893.13(6)(a), F.S., more than five years from the date of the plea, sentence and completion of any subsequent probation;
2. Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues), unless the sentence and any subsequent period of probation for such conviction or pleas ended more than 15 years prior to the date of the application;
 3. Has been terminated for cause from the Florida Medicaid program pursuant to section 409.913, F.S., unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent five years;
 4. Has been terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program, unless the candidate or applicant has been in good standing with a state Medicaid program for the most recent five years and the termination occurred at least 20 years before the date of the application;
 5. Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

NOTE: This section **does not apply** to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

REQUIREMENTS FOR FLORIDA PHARMACIST LICENSURE BY EXAMINATION

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 are 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 this form to Item #2 (Pharmacist Examination Application).**

ITEM #2 – Pharmacist Examination Application for U.S. Graduates: All candidates must complete this application. If you answer “yes” to any question in 15-27 on the application, please submit certified official court copies of any supporting documents for the board to review. Supporting documents relative to criminal history consist of:

- Certified official court documents relative to your criminal record, showing the dates and circumstances surrounding your arrest/conviction,
- Section of the law violated,
- Disposition of the case.

Supporting documents relative to disciplinary history consist of:

- Certified copies of documents relative to any disciplinary action taken against any license. The documents must come from the agency that took the action and must be certified by that agency.

Applicants who have listed offenses on the application must submit a letter in their own words describing the circumstances of the offense and a thorough description of the rehabilitative changes in your lifestyle since the time of the offense or disciplinary action which would enable you to avoid future occurrences. All sections must be completed in full. If an item is not applicable, indicate with N/A. 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 \$295.00.

**Please submit the following to the Florida Board of Pharmacy:
4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399-3254**

ITEM #3 – Certificate of Pharmacy Education (Form A): Complete only **Part I**, then forward to the College of Pharmacy for the completion of **Part II**. **The College of Pharmacy must mail or email the form back to the board office or it will not be accepted. Official transcripts from your College of Pharmacy are also acceptable.**

ITEM #4 – Internship or Work Experience Form (Form B)

GRADUATES WITH A PHARM.D. DEGREE EARNED AFTER JANUARY 1, 2001: You are only required to submit a Certification of Graduation (Form A) or official transcript.

GRADUATES WITH A B.S. or PHARM.D. DEGREE EARNED PRIOR TO JANUARY 1, 2001: You are required to submit Form A or an official transcript to certify your graduation, and document the completion of 2080 hours of intern or work experience by submitting an Internship or Work Experience Form (Form B) to the board office. **PLEASE BE ADVISED ALL INTERNS MUST HOLD A LICENSE OR PERMIT BY THE STATE IN WHICH THEY ARE PRACTICING IN ORDER TO COUNT THE HOURS AS INTERNSHIP HOURS.** These hours may be sent in by **one or all** of the following:

- From the College of Pharmacy from which you received your degree (Form A).
- From the state board of pharmacy in the state you completed your internship (Form B).
- From your Employer. These may be additional hours that the school or state board of pharmacy will not certify (Form B).

If you have worked as a licensed pharmacist in another state for one (1) year or more, you only have to show your work experience to satisfy the 2080 hour requirement. Please have your employer complete the enclosed Internship or Work Experience Form (Form B).

If you are self-employed as a pharmacist, please submit a statement with your Form B certifying your ownership of the pharmacy.

ITEM #5 – Licensure Verification Form: If you have been licensed in any other state, then you must submit a written verification of the current status of your license. **Online verifications are acceptable if they are current and show disciplinary history status.** If an online verification is not submitted with your application, then each state board where you hold a license must submit a written verification of the current status of your license. It is the applicant's responsibility to contact each state in which they have held or currently hold a license to request licensure verification. The verification should be received directly from the state board of pharmacy. The state board of pharmacy does not have to use the form included in this packet, they may submit their own. **This information is required even if you are no longer licensed in the state.**

ITEM #6- Prevention of Medication Errors Continuing Education: All applicants must complete a course on prevention of medication errors prior to licensure. The course shall be no less than two (2) contact hours and shall cover the subjects listed in subsection 64B16-26.103(1)(c), Florida Administrative Code (F.A.C.). Please refer to CE Broker's website at www.CEBroker.com and click the Florida Course Search quick link for a list of approved courses.

APPLICATION CHECKLIST

Keep a copy of the completed application documents 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 sent 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)**
- _____ **Pharmacist Examination Application for U.S. Graduates (Item #2)**
- _____ **Check made payable to the FLORIDA DEPARTMENT OF HEALTH in the amount of \$295.00 attached.**
- _____ **Certificate of Pharmacy Education – Form A (Item #3) – send to College of Pharmacy Dean for completion. (College of Pharmacy must submit the Certificate directly to the Board of Pharmacy or it will not be accepted.) Official transcripts from your College of Pharmacy are acceptable.**
- _____ **Internship or Work Experience Form – Form B (Item #4) – a separate form must be completed by each employer.**
- _____ **Licensure Verification Form (Item #5) – An online verification or a form completed by the board office must be completed for each U.S. jurisdiction in which you are licensed or have held a license.**
- _____ **NAPLEX®/MPJE® (law exam) Registration - You must go online to NABP®'s website at www.nabp.net to register and pay for the exams.**
- _____ **Prevention of Medication Errors Course Affirmation (Item #6) - All applicants must complete a course on the prevention medication errors prior to licensure. The course shall be no less than two (2) contact hours and shall cover the subjects listed in subsection 64B16-26.103(1)(c), F.A.C. Please refer to CE Broker's website at www.CEBroker.com and click the Florida Course Search quick link for a list of approved courses.**
- _____ **CRIMINAL HISTORY: “Yes” responses to questions in this section require the following documentation:**
 - _____ **Final Dispositions/Arrest Records:** The applicant must obtain and submit arrest and final disposition records for all offenses listed from the Clerk of the Court in the arresting jurisdiction. If the records are not available, you must have a letter on court letterhead sent from the Clerk of the Court attesting to their unavailability.
 - _____ **Self-Report:** Applicants who have listed offenses on the application must submit a letter in your own words describing the circumstances of the offense.

APPLICATION CHECKLIST (continued)

_____ **HEALTH HISTORY:** “Yes” responses to questions in this section require the following documentation:

_____ Supporting documentation must include a letter from the applicant explaining the medical condition(s) or occurrence(s) and current status; letter(s) from licensed professional summarizing diagnosis, treatment and prognosis; or any other official documentation as it relates to any “yes” answer. Documentation should be current within the last year.

Keep a copy of the completed application documents for your records.



FLORIDA BOARD OF PHARMACY
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www.floridaspharmacy.gov

**Item #1-SOCIAL SECURITY FORM
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 –PHARMACIST EXAMINATION APPLICATION
 FOR U.S. GRADUATES
 FEE: \$295.00 (1010)**

Please print or type legibly.

1. Biographical data						
Last name		First name		Middle name		
Street address (ML – Mailing Address)			City		State	Zip
Work address (PL – Practice Location)			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.						
Email 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: <input type="checkbox"/> Male <input type="checkbox"/> Female						
RACE: <input type="checkbox"/> Caucasian <input type="checkbox"/> Black <input type="checkbox"/> Hispanic <input type="checkbox"/> Asian <input type="checkbox"/> Native American <input type="checkbox"/> Other						
3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. Use a separate sheet, if necessary.						
Yes _____			No _____			
Name				Date		
4. Name of University, College or School of Pharmacy attended						
5. Date of graduation		6. Type of degree earned		7. Have you ever been licensed as an intern in Florida?		
				Yes _____ No _____		
				Intern License number: _____		

8. Are you planning to transfer your NAPLEX® score to Florida? If yes, please indicate approximate date of transfer.

Yes _____ Date of transfer: _____
 No _____

9. Did you transfer your NAPLEX® score to Florida within the past three (3) years?

Yes _____ Date of exam: _____
 No _____

10. Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?

Yes _____ No _____

11. Have you ever applied to take the Florida Pharmacist Examination? If yes, please indicate the date.

Yes _____ No _____ Date _____

12. List all experience earned as an intern. If you have been a registered pharmacist for at least one (1) year, list only your pharmacist experience. If you graduated after January 1, 2001 with a Pharm.D. Degree, it is not necessary to complete this section. **Note: you must submit one (1) Internship or Work Experience Form - Form B (Item #4) for each employer listed below. Use a separate sheet, if necessary.**

Dates	Employer	Location	Intern or pharmacy experience	Total hours

13. List all state(s) in which you have held or currently hold a pharmacist license. **Note: you must submit one (1) Licensure Verification Form (Item #5) for each state listed below. Use a separate sheet, if necessary.**

State	License number	Date issued

14. Special testing accommodations – Please indicate if you require special testing accommodations due to a disability, or if you have a religious conflict with the scheduled examination date. All testing accommodation requests candidates will be evaluated by the National Association of Boards of Pharmacy (NABP). Please visit <http://www.nabp.net/programs/examination/naplex/testing-accommodations> for information regarding testing accommodations.

Yes _____ No _____

15. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes _____ No _____

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is **NOT** a minor traffic offense for the purposes of this question.)

CONFIDENTIAL AND EXEMPT FROM PUBLIC RECORDS DISCLOSURE

16. In the last five (5) years, have you been enrolled in, required to enter into, or participated in any drug or alcohol recovery program or impaired practitioner program for treatment of drug or alcohol abuse that occurred within the past five years?

Yes _____ No _____

17. In the last five (5) years, have you been admitted or referred to a hospital, facility or impaired practitioner program for treatment of a diagnosed mental disorder or impairment?

Yes _____ No _____

18. In the last five (5) years, were you admitted or directed into a program for the treatment of a diagnosed substance-related (alcohol/drug) disorder or, if you were previously in such a program, did you suffer a relapse within the last five (5) years?

Yes _____ No _____

19. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes _____ No _____
20. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No _____
21. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No _____
22. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If no, go to question #24.)
Yes _____ No _____
23. If "yes" to 22, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
23a. If "yes" to 22, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6) (a), Florida Statutes).
Yes _____ No _____
23b. If "yes" to 22, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
23c. If "yes" to 22, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No _____
24. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes _____ No _____
24a. If "yes" to 24, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes _____ No _____

25. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 26.)
Yes _____ No _____
26. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____
27. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 27a and 27b.)
Yes _____ No _____
27a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
27b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
28. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes _____ No _____ (If yes, provide supporting documentation)
29. If "yes" to any of the questions 22 through 29 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes _____ No _____
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 15-28, explain on a separate sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Applicant Signature

Date

NOTE: Please check to be sure that you have answered all of the questions above.



FLORIDA BOARD OF PHARMACY
 4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
 Phone: (850) 245-4292 • www.floridaspharmacy.gov

ITEM #3 - CERTIFICATE OF PHARMACY EDUCATION (FORM A)

Please print or type legibly.

Part I. – To be completed by applicant and forwarded to the College of Pharmacy for completion of Part II below.			
Last name	First name	Middle name	
Maiden name/surname		Date of graduation	
Mailing address	City	State	Zip

Part II. – To be completed by College of Pharmacy Dean			
Name of School/College of Pharmacy			
Mailing address	City	State	Zip
Type of degree awarded	Date degree awarded	Dates of attendance	
		From: ___/___/___ To: ___/___/___	

The information recorded above is true and correct according to the official records of this institution. Failure to include the school seal may result in a delay in processing the applicant's application.

_____	_____	(SCHOOL SEAL)
Print Name	Signature	
_____	_____	
Title	Date	

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

**FLORIDA BOARD OF PHARMACY
 4052 BALD CYPRESS WAY
 BIN #C-04
 TALLAHASSEE, FL 32399-3254**



FLORIDA BOARD OF PHARMACY
 4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
 Phone: (850) 245-4292 • www.floridaspharmacy.gov

ITEM #5 - LICENSURE VERIFICATION FORM

To be completed by applicant licensed as registered pharmacist. Please print or type legibly.

1. Biographical information			
Applicant name		Date of birth	Social Security Number
Street address	City	State	Zip
2. License number		3. Date issued	

To be completed by state board office:

The individual listed above has applied for licensure in the State of Florida as a registered pharmacist. Before further consideration is given to this application, we would appreciate your assistance in completing the information requested below. (Upon completion of this form, please return same to the address below.)

4. Licensure verification provided by state of:		5. Applicant's name	
6. Type of license issued	7. Date license issued	8. License number	
9. Current status of license			
<input type="checkbox"/> Active <input type="checkbox"/> In-active <input type="checkbox"/> Other (explain) _____			
10. License obtained by			
Examination _____ Reciprocity/Endorsement _____			
11. Has applicant been found guilty of any violations for which disciplinary action was taken?			
Yes _____ No _____			
Note: if disciplinary action has been taken against this licensee, please provide this office with any documentation regarding this action.			

 Print name

 Signature

 Title

 Date

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

**FLORIDA BOARD OF PHARMACY
 4052 BALD CYPRESS WAY
 BIN #C-04
 TALLAHASSEE, FL 32399-3254**

(BOARD SEAL)



Item #6- Prevention of Medication Errors Course Affirmation

To: Florida Board of Pharmacy
4052 Bald Cypress Way
Bin #C-04
Tallahassee, FL 32399

From: _____
(Please type or print)

I have completed a board approved educational course on the "Prevention of Medication Errors", as required by Florida Statutes.

I understand that these statements are true and correct. I further understand and acknowledge that providing false information may result in the denial of my application, disciplinary and/or criminal penalties as provided in Florida Statutes 456.072, 456.067.

Course Title

Ce Broker Course Number

Date Course Completed

Signature (Required)

Date (of signature)

**Amendments to update incorporated form DH-MQA 103
February 2016**

64B16-26.2031 Licensure by Examination; (Foreign Pharmacy Graduates); Application.

In order for a foreign pharmacy graduate to be admitted to the professional licensure examination, the applicant must be a graduate of a four year undergraduate pharmacy program at a school or college outside the United States and have completed an internship program approved by the Board.

(1) All applications for licensure by examination must be made on form DH-MQA 103 (Rev. ~~02/16 09/09~~), Pharmacist Examination Application For Foreign Graduates and Instructions, which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref->, the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or the Board's website at <http://floridaspharmacy.gov/Applications/app-pharmacist-exam-foreign-grad.pdf> ~~Contact the Board of Pharmacy, 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 <http://www.doh.state.fl.us/mqa/pharmacy>.~~ The application must be accompanied with an non-refundable examination fee and an initial license fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) In addition to the requirements of subsection (1), ~~t~~The applicant must submit proof of having met the following requirements:

(a) ~~For applications received at the Board of Pharmacy on or before June 30, 2009, the applicant must:~~
~~1. Successfully pass the foreign pharmacy graduate equivalency examination which is given by the Foreign Pharmacy Graduate Equivalency Commission with a minimum score of 75%.~~

~~2. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is administered by the Educational Testing Service, Inc., with a score of at least 500 for the pencil and paper test or 173 for the computer version and by passing the Test of Spoken English (TSE) with a score of 45 on the recalibrated TSE; or~~

~~3. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language Internet based test (TOEFL ibt) with scores of: Listening – 18; Reading – 21; Speaking – 26; and Writing – 24.~~

(b) ~~For applications received at the Board of Pharmacy on or after July 1, 2009, the applicant must:~~
~~1. Successfully pass the foreign pharmacy graduate equivalency examination, which is given by the Foreign Pharmacy Graduate Equivalency Commission, with a minimum score of 75%;~~

~~1. 2. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is administered by the Educational Testing Service, Inc., with a score of at least 550 for the pencil and paper test or 213 for the computer version and by passing the Test of Spoken English (TSE) with a score of 50 on the recalibrated TSE; or~~

~~2. 3. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language Internet-based test (TOEFL ibt) with scores of: Listening – 18; Reading – 21; Speaking – 26; and Writing – 24;~~

(c) ~~2. Complete 2080 hours of supervised work activity, of which a minimum of 500 hours must be completed within the State of Florida. Such experience must be equivalent to that required in the internship program as set forth in Rule 64B16-26.2032, F.A.C. The work experience program, including both the preceptor and the permittee, must be approved by the Board of Pharmacy. The work experience shall be documented on form DH-MQA 1153 (Rev. ~~02/16 04/10~~), Foreign Graduate Intern Work Activity Manual, which is hereby incorporated by reference and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref->; the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254; or the Board's website at <http://floridaspharmacy.gov/Applications/info-foreign-grad-reg-intern-manual.pdf> ~~Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399 3254 or (850) 488 0595 to request a manual or download the manual from the Board's website at <http://www.doh.state.fl.us/mqa/pharmacy>. Further, n~~No program of supervised work activity shall be approved for any applicant until said applicant has obtained the specified passing scores on the Foreign Pharmacy Graduate Equivalency Examination; and~~

(d) ~~3. Completion of a Board approved course of not less than two (2) hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For applicants who apply within one (1) year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than two (2) contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety as evidence by a letter attesting to subject matter covered from the Dean~~

of the University.

Rulemaking Authority 465.005, ~~465.007~~ FS. Law Implemented 456.013(1), (7), 456.025(3), 465.007(1) FS. History—New 1-11-05, Amended 8-8-07, 6-10-09, 5-27-10,_____.

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



**PHARMACIST EXAMINATION APPLICATION FOR FOREIGN
GRADUATES AND INSTRUCTIONS**

February 2016

General Information

Requirements for Florida Pharmacist Examination for Foreign Graduates

In order to be licensed in the State of Florida, you must apply to the Florida Board of Pharmacy (the board), and have passing scores on the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®) (also referred to as the “Florida law exam”). Both parts of the exam are computerized and can be taken in your state. Exams are offered everyday of the year with the exception of holidays and Sundays. Please refer to the NAPLEX®/MPJE® Registration Bulletin for testing locations in your state. The NAPLEX®/MPJE® Registration Bulletin is available on the National Association of Boards of Pharmacy’s (NABP®) website at www.nabp.net.

The board is a participant in the NAPLEX® Score Transfer Program. If you elect to transfer your NAPLEX® score to Florida, the score is good for three (3) years from the date you took the examination and you will have to fulfill all other requirements for licensure in Florida which includes passing the MPJE®. Please review the requirements for the NAPLEX® Score Transfer Program in the NAPLEX®/MPJE® Registration Bulletin.

***If you passed the NAPLEX® examination, please visit our website at www.floridaspharmacy.gov/licensing and review the requirements for licensure by endorsement for foreign graduates to see if you qualify by this method. If you would like to apply by endorsement, please visit our website at www.floridaspharmacy.gov/lresources to download an endorsement application.**

Foreign graduate applicants (graduates of non-Accreditation Council of Pharmacy Education (ACPE) accredited programs) must meet the following requirements to be deemed eligible to sit for the Florida Pharmacist Examination:

- 1) Meet the qualifications for licensure in Section 465.007(1)(b) and (c), F.S:
 - a. Submit satisfactory proof that the applicant is not less than 18 years of age.
 - b. Submit evidence that the applicant is a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States.
 - c. Has obtained passing scores on the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE), or the TOEFL iBT.

Passing Scores:

TOEFL:

213 (computer based test)
550 (paper and pencil test)

TSE:

50

TOEFL iBT:

Listening – 18
OR Reading – 21
Speaking – 26
Writing - 24

- d. Has completed 2080 internship hours in a program that has been approved by the board. (Per Rule 64B16-26.2031(2)(c), Florida Administrative Code (F.A.C.) a minimum of 500 hours of 2080 hour requirement must be completed in a supervised work activity program in the State of Florida under the supervision of a pharmacist licensed by the State of Florida.)
- e. Has obtained a passing score on the Foreign Pharmacy Graduate Equivalency Examination (FPGEE®). To obtain information about this examination, please contact the Foreign Pharmacy Graduate Equivalency Commission (FPGEC®) at 1600 Feehanville Drive, Mount Prospect, IL 60056, or call (847) 391-4406.

Application Processing

Please read all application instructions before completing your application.

ALL REQUIREMENTS FOR LICENSURE MUST BE MET WITHIN ONE (1) YEAR OF THE RECEIPT OF YOUR APPLICATION OR THE APPLICATION WILL EXPIRE AND YOU WILL HAVE TO REAPPLY.

Following receipt of the application and fees the board office will acknowledge the receipt of your application and notify you of any missing documentation or information. You can follow the progress of your application through our website at <http://ww2.doh.state.fl.us/mqaservices/login.asp> once we have issued you a username and password. Once your application is complete and you have registered for the NAPLEX® and MPJE® as required, you should receive an Authorization to Test (ATT) from NABP® within 7 days via email. Please make sure the email address you use when registering for the exam(s) is valid. The board office must be notified in writing of anything which changes or affects a response given in your application (e.g., change of name, address, telephone number, arrests or convictions, licensure status or disciplinary action in another state, or an incorrect answer to a question). If you move, you must notify the board, as state mail is not forwarded. **Please download a copy of the laws and rules from the board website at <http://www.floridaspharmacy.gov/resources> for study purposes.**

Prevention of Medication Errors

All applicants must complete a Florida Board approved course on the prevention of medication errors prior to licensure. The course shall be no less than two (2) contact hours and shall cover the subjects listed in subsection 64B16-26.103(1)(c), Florida Administrative Code (F.A.C.). **Please refer to CE Broker's website at www.CEBroker.com and click the Florida Course Search quick link for a list of approved courses. Submit Item #6- Prevention of Medication errors continuing education affirmation.**

Grade Reports

Your examination results will be available online at <http://flhealthsource.com>, in the "Provider Services" section under "Check Exam Results" within 7-10 days of your test date. You will need the last 4 digits of your social security number and your date of birth in order to access your scores online. Please do not telephone the board office for the results of your examination; we cannot give your results over the phone for any reason.

Board Licensure Procedure

Once you have passed the exam(s), submitted all required documents, and met all licensure requirements, you will receive the license in approximately seven (7) days. **You may lookup your license number on our website at <http://flhealthsource.com> under "Verify a License." You may begin practicing pharmacy on your licensure date.**

Withdrawals

If you are unable to continue with the licensure process and wish to withdraw your application, you may submit a written request to the board office requesting a refund of the \$195.00 initial licensure/unlicensed activity fee. The request must be received prior to the board's granting of licensure. The board reserves the right to deny your withdrawal request.

Special Testing Assistance

All testing accommodation requests will be evaluated by the National Association of Boards of Pharmacy (NABP). Please visit <http://www.nabp.net/programs/examination/naplex/testing-accommodations> for information regarding testing accommodations.

Please note, if the board has questions or concerns about the information contained in your application, you may be required to appear before the board prior to the granting of licensure.

IMPORTANT NOTICE:

Effective July 1, 2012, section 456.0635, Florida Statutes, provides that health care boards or the department **shall refuse** to issue a license, certificate or registration and **shall refuse** to admit a candidate for examination if the applicant:

1. Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S., (relating to social and economic assistance), Chapter 817, F.S., (relating to fraudulent practices), Chapter 893, F.S., (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed.

Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration, unless the sentence and any subsequent period of probation for such conviction or plea ended:

- For the felonies of the first or second degree, more than 15 years from the date of the plea, sentence and completion of any subsequent probation;
 - For the felonies of the third degree, more than 10 years from the date of the plea, sentence and completion of any subsequent probation;
 - For the felonies of the third degree under section 893.13(6)(a), F.S., more than five years from the date of the plea, sentence and completion of any subsequent probation;
2. Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues), unless the sentence and any subsequent period of probation for such conviction or pleas ended more than 15 years prior to the date of the application;
 3. Has been terminated for cause from the Florida Medicaid program pursuant to section 409.913, F.S., unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent five years;
 4. Has been terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program, unless the candidate or applicant has been in good standing with a state Medicaid program for the most recent five years and the termination occurred at least 20 years before the date of the application;
 5. Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

NOTE: This section **does not apply** to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

REQUIREMENTS FOR FOREIGN GRADUATE PHARMACIST LICENSURE BY EXAMINATION

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 (Pharmacist Examination Application for Foreign Graduates).**

ITEM #2 – Pharmacist Examination Application for Foreign Graduates: All candidates must complete this application. If you answer “yes” to any question in 15-27 on the application, please submit certified official court copies of any supporting documents for the board to review. Supporting documents relative to criminal history consist of:

- Certified official court documents relative to your criminal record, showing the dates and circumstances surrounding your arrest/conviction,
- Section of the law violated,
- Disposition of the case.

Supporting documents relative to disciplinary history consist of:

- Certified copies of documents relative to any disciplinary action taken against any license. The documents must come from the agency that took the action and must be certified by that agency.

Applicants who have listed offenses on the application must submit a letter in their own words describing the circumstances of the offense and a thorough description of the rehabilitative changes in your lifestyle since the time of the offense or disciplinary action which would enable you to avoid future occurrences. All sections must be completed in full. If an item is not applicable, indicate with N/A. 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 \$295.00.

**Please submit the following to the Florida Board of Pharmacy:
4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399-3254**

ITEM #3 – Internship or Work Experience Form (Form B)

Foreign Graduate licensure by examination applicants must complete 2080 internship hours, 500 of which must be completed in Florida. 1580 hours must be documented on the Internship or Work Experience Form (Form B), and the 500 hours completed in Florida must be documented on page 22 of the Foreign Graduate Work Activity Manual.

ITEM #4 – Licensure Verification Form: If you have been licensed in any other state, then you must submit a written verification of the current status of your license. **Online verifications are acceptable if they are current and show disciplinary history status.** If an online verification is not submitted with your application, then each state board where you hold a license must submit a written verification of the current status of your license. It is the applicant's responsibility to contact each state in which they have held or currently hold a license to request licensure verification. The verification should be received directly from the state board of pharmacy. The state board of pharmacy does not have to use the form included in this packet, they may submit their own. **This information is required even if you are no longer licensed in the state.**

ITEM #5- Prevention of Medication Errors Continuing Education: All applicants must complete a course on the prevention of medication errors prior to licensure. The course shall be no less than two (2) contact hours and shall cover the subjects listed in subsection 64B16-26.103(1) (c), Florida Administrative Code (F.A.C.). Please refer to CE Broker's website at www.CEBroker.com and click the Florida Course Search quick link for a list of approved courses.

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 sent 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)**
- _____ **Pharmacist Examination Application for Foreign Graduates (Item #2)**
- _____ **Check made payable to the FLORIDA DEPARTMENT OF HEALTH in the amount of \$295.00 attached.**
- _____ **Copy of Passing Test Scores**
- _____ **FPGEE®**
- _____ **TOEFL AND _____ TSE; OR _____ TOEFL iBT**
- _____ **Internship or Work Experience Form (Form B - Item #3) – a separate form must be completed by each employer.**
- _____ **Licensure Verification Form (Item #4) – An online verification or a form completed by the board office must be completed for each U.S. jurisdiction in which you are licensed or have held a license.**
- _____ **NAPLEX®/ MPJE® (law exam) Registration - You may go online to NABP®'s website at www.nabp.net to register and pay for the exams.**
- _____ **Prevention of Medication Errors Course Affirmation (Item #5) - All applicants must complete a course on the prevention of medication errors prior to licensure. The course shall be no less than two (2) contact hours and shall cover the subjects listed in subsection 64B16-26.103(1) (c), F.A.C. Please refer to CE Broker's website at www.CEBroker.com and click the Florida Course Search quick link for a list of approved courses.**
- _____ **Foreign Graduate Activity Manual - The assignments and Certification of Completion (page 22) of the manual must be sent with your application if you have not already mailed this information to the board office. You will not be approved for the examination until all work assignments have been received and approved by the Board.**
- _____ **CRIMINAL HISTORY: "Yes" responses to questions in this section require the following documentation:**
 - _____ **Final Dispositions/Arrest Records:** The applicant must obtain and submit arrest and final disposition records for all offenses listed from the Clerk of the Court in the arresting jurisdiction. If the records are not available, you must have a letter on court letterhead sent from the Clerk of the Court attesting to their unavailability.
 - _____ **Self-Report:** Applicants who have listed offenses on the application must submit a letter in your own words describing the circumstances of the offense.

APPLICATION CHECKLIST (continued)

_____ **HEALTH HISTORY:** “Yes” responses to questions in this section require the following:

___ Supporting documentation must include a letter from the applicant explaining the medical condition(s) or occurrence(s) and current status; letter(s) from licensed professional summarizing diagnosis, treatment and prognosis; or any other official documentation as it relates to any “yes” answer. Documentation should be current within the last year.

Keep a copy of the completed application documents for your records.



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

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 – PHARMACIST EXAMINATION APPLICATION
 FOR FOREIGN GRADUATES
 FEE: \$295.00 (1012)**

Please print or type legibly.

1. Biographical Data			
Last Name	First Name	Middle Name	
Street Address (ML – Mailing Address)	City	State	Zip
Work Address (PL – Practice Location)	City	State	Zip
Home Phone Number	Business Phone Number	Date of Birth	
<p>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.</p>			
E-mail Address			
<p>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.</p>			
SEX: <input type="checkbox"/> Male <input type="checkbox"/> Female			
RACE: <input type="checkbox"/> Caucasian <input type="checkbox"/> Black <input type="checkbox"/> Hispanic <input type="checkbox"/> Asian <input type="checkbox"/> Native American <input type="checkbox"/> Other			
<p>3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. Use a separate sheet, if necessary.</p>			
Yes _____ No _____			
Name		Date	
4. Name of University, College or School of Pharmacy attended			
5. Date of graduation	6. Type of degree earned	7. Country in which degree was received	

8. Are you planning to transfer your NAPLEX® score to Florida? If yes, please indicate approximate date of transfer.	9. Did you transfer your NAPLEX® score to Florida within the past three (3) years?			
Yes _____ Date of transfer: _____ No _____	Yes _____ Date of exam: _____ No _____			
10. Have you ever applied to take the Florida Pharmacist Examination? If yes, please indicate the date.	11. Have you ever been licensed as a Foreign Graduate intern in Florida? (If no you are not eligible for the exam)			
Yes _____ Date: _____ No _____	Yes _____ No _____ Intern License Number: _____			
11. Please answer the following questions: Date you took and passed the Test of English as a Foreign Language (TOEFL) or TOEFL iBT? _____ Date _____ Score _____ b. Date you took and passed the Test of Spoken English (TSE)? _____ Date _____ Score _____ c. Date you took and passed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE)? _____ Date _____ Score _____				
12. Date you completed your 500 intern hours in the State of Florida.				
Date: _____				
13. Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?				
Yes _____ No _____				
14. List all experience earned as an intern. <u>Note: you must submit one (1) Internship or Work Experience Form - Form B (Item #3) for each employer listed below. Use a separate sheet, if necessary.</u>				
Dates	Employer	Location	Intern or pharmacy experience	Total hours
15. List all state(s) in which you have held or currently hold a pharmacist license. <u>Note: you must submit one (1) Licensure Verification Form (Item #4) for each state listed below. Use a separate sheet, if necessary.</u>				
State	License Number	Date Issued		
16. Special testing accommodations – Please indicate if you require special testing accommodations due to a disability, or if you have a religious conflict with the scheduled examination date. All testing accommodation requests candidates will be evaluated by National Association of Boards of Pharmacy (NABP). Please visit http://www.nabp.net/programs/examination/naplex/testing-accommodations for information regarding testing accommodations.				
Yes _____ No _____				
17. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense? (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is <u>NOT</u> a minor traffic offense for the purposes of this question.)				
Yes _____ No _____				

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18. In the last five (5) years, have you been enrolled in, required to enter into, or participated in any drug or alcohol recovery program or impaired practitioner program for treatment of drug or alcohol abuse that occurred within the past five years?

Yes _____ No _____

19. In the last five (5) years, have you been admitted or referred to a hospital, facility or impaired practitioner program for treatment of a diagnosed mental disorder or impairment?

Yes _____ No _____

20. In the last five (5) years, were you admitted or directed into a program for the treatment of a diagnosed substance-related (alcohol/drug) disorder or, if you were previously in such a program, did you suffer a relapse within the last five (5) years?

Yes _____ No _____

21. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes _____ No _____
22. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No _____
23. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No _____
24. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If no, do not answer 26 a-c.)
Yes _____ No _____
25. If "yes" to 24, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
25a. If "yes" to 24, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6) (a), Florida Statutes).
Yes _____ No _____
25b. If "yes" to 24, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
25c. If "yes" to 24, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No _____
26. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes _____ No _____
26a. If "yes" to 26, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes _____ No _____
27. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 27a.)
Yes _____ No _____

27a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____
28. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 29a and 29b.)
Yes _____ No _____
28a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
28b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
29. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes _____ No _____ (If yes, provide supporting documentation)
30. If "yes" to any of the questions 25 through 29 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes _____ No _____
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 16-30, explain on a separate sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in section 465.016(1)(a), F.S.

Applicant Signature

Date

NOTE: Please check to be sure that you have answered all of the questions above.



FLORIDA BOARD OF PHARMACY

4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254

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

ITEM #3 – INTERNSHIP OR WORK EXPERIENCE FORM (FORM B)

Please print or type legibly.

1. Biographical Information			
Applicant Name		Intern/Pharmacist License Number	
Street Address		City	
		State	Zip
2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.			
Yes _____ No _____ Date _____			

I HEREBY APPLY FOR INTERNSHIP OR WORK EXPERIENCE CREDIT AS OUTLINED BELOW UNDER THE SUPERVISION OF:

3. Pharmacy Information			
Supervising Pharmacist's Name			License Number
Pharmacy Name			Permit Number
Street Address		City	
		State	Zip
Phone Number		4. Dates Of Experience	
		From: ___/___/___ To: ___/___/___	
5. Average number of hours per week		6. Total hours of experience	
(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)			

Applicant's Signature

Date

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and are available for inspection by the Board of Pharmacy.

Preceptor/Supervisor's Signature

Date

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

**FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254**



FLORIDA BOARD OF PHARMACY

4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254

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

ITEM #4 - LICENSURE VERIFICATION FORM

To be completed by applicant licensed as registered pharmacist. Please print or type legibly.

1. Biographical Information			
Applicant Name		Date Of Birth	Social Security Number
Street Address	City	State	Zip
2. License Number		3. Date Issued	

To be completed by state board office:

The individual listed above has applied for licensure in the State of Florida as a registered pharmacist. Before further consideration is given to this application, we would appreciate your assistance in completing the information requested below. (Upon completion of this form, please return same to the address below.)

4. Licensure verification provided by state of:		5. Applicant's Name	
6. Type of license issued	7. Date License Issued	8. License Number	
9. Current status of license			
<input type="checkbox"/> Active <input type="checkbox"/> In-active <input type="checkbox"/> Other (explain) _____			
10. License Obtained By			
Examination _____ Reciprocity/Endorsement _____			
11. Has applicant been found guilty of any violations for which disciplinary action was taken?			
Yes _____ No _____			
Note: if disciplinary action has been taken against this licensee, please provide this office with any documentation regarding this action.			

Print name

Signature

Title

Date

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

**FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254**

(BOARD SEAL)



Item #5- Prevention of Medication Errors Course Affirmation

**To: Florida Board of Pharmacy
4052 Bald Cypress Way
Bin #C-04
Tallahassee, FL 32399**

From: _____
(Please type or print)

I have completed a board approved educational course on the "Prevention of Medication Errors", as required by Florida Statutes.

I understand that these statements are true and correct. I further understand and acknowledge that providing false information may result in the denial of my application, disciplinary and/or criminal penalties as provided in Florida Statutes 456.072, 456.067.

Course Title

Ce Broker Course Number

Date Course Completed

Signature (Required)

Date (of signature)