

**Legislative & Rule Committee
Conference Call
February 19, 2007
10:00 A.M.
1-888-808-6959, Conference Code 5642037**

Board Members:

Jennifer Lalani, R.Ph., Chair
Jim Powers, R.Ph., Tallahassee
Amy Jones, J.D., Consumer, Tallahassee
Albert Garcia, R.Ph., Miami

Board Staff:

Reginald Dixon, Assistant Attorney General
Rebecca Poston, R.Ph., Executive Director
Maxine Wenzinger, Administrative Assistant II

- Call to Order: Jennifer Lalani, R.Ph., Chair
- TAB 1: Approval of Minutes from November 21, 2006, Meeting
- TAB 2: 64B16-25 - Organization and Purpose
1. 64B16-25.170 Probable Cause Panel
 2. 64B16-25.340 Meetings and Workshops
- TAB 3: 64B16-26 – Pharmacist Licensure
1. 64H16-26.203 Licensure by Examination; Application
 2. 64B16-26.2031 Licensure by Examination: Foreign Pharmacy Graduates
 3. 64B16-25.204 Licensure by Endorsement
- TAB 4: 64B16-27 – Pharmacy Practice
1. 64B16-27.430 Responsibilities of the Pharmacist
- TAB 5: 64B16-30 – Disciplinary Guidelines
1. 64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.
 2. 64B16-30.002 Minor Violations
 3. 64B16-30.003 Citations
 4. 64B16-30.0035 Mediation

**DEPARTMENT OF HEALTH
BOARD OF PHARMACY
LEGISLATIVE AND RULE COMMITTEE
MINUTES
NOVEMBER 21, 2006, 9:00 A.M.**

Board Members:

Jennifer Lalani, R.Ph., Chair
Jim Powers, R.Ph., Tallahassee
Amy Jones, J.D., Consumer, Tallahassee
Albert Garcia, R.Ph., Miami

Board Staff:

Reginald Dixon, Assistant Attorney General
Rebecca Poston, R.Ph., Executive Director
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Tuesday, November 21, 2006 - 9:00 a.m.

Ms. Lalani, Chair, called the meeting to order at 9:13 a.m.

64B16-26.103 Continued Education Credits; Licensure Renewal

MOTION: by Powers to accept amended rule as presented and proceed with rule development and present to full board, second by Jones. Motion carried unanimously.

MOTION: by Garcia to require five (5) of the 30 hours to be live in Rule 64B16-26.103(1), second by Powers. Motion carried unanimously.

MOTION: by Powers, second by Garcia to adjourn.

Meeting adjourned at 9:30 a.m.

64B16-26.103 Continuing Education Credits; License Renewal; Consultant Pharmacist License Renewal; Nuclear Pharmacist License Renewal.

(1) No change.

(a) The initial renewal of a license will not require completion of courses of continued professional pharmaceutical education hours if the license was issued less than 12 months prior to the expiration date of the license. If the initial renewal occurs 12 months or more after the initial licensure, then 15 hours of the continued professional pharmaceutical education hours shall be completed prior to the renewal of the license but no earlier than the date of initial licensure. At least five (5) of the required fifteen (15) hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

(b) Prior to a licensee's first renewal, a licensee must complete, within the 24 month period prior to the expiration date of the license, a one-hour continuing education course approved in advance by the Board on HIV/AIDS that covers the topics contained in Rule 64B16-26.6011, F.A.C. In lieu of completing an HIV/AIDS course, the licensee may complete a course in end-of-life care and palliative health care, ~~so long as the licensee completed an approved HIV/AIDS course in the immediately preceding biennium.~~ Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(c) through (l) No change.

(2) No change.

(3) No change.

AUTHORITY: Specific Authority 456.033, 465.009, 456.033(1) FS.
Law Implemented 456.013(7), (9), 456.033, 465.009 FS.

HISTORY

New 3-19-79, Formerly 21S-6.07, Amended 1-7-87, Formerly 21S-6.007, Amended 7-31-91, 10-14-91, Formerly 21S-26.103, 61F10-26.103, Amended 7-1-97, Formerly 59X-26.103, Amended 7-11-00, 10-15-01, 1-2-02, 1-12-03, 4-12-05, _____.

64B16 BOARD OF PHARMACY
CHAPTER 64B16-25 ORGANIZATION AND PURPOSE

- 64B16-25.130 Executive Director.
- 64B16-25.150 General Information. (Repealed)
- 64B16-25.160 Statutory Chapters and Rules. (Repealed)
- 64B16-25.170 Probable Cause Panel.
- 64B16-25.180 Investigators; Criteria for Selection. (Repealed)
- 64B16-25.320 Workshops. (Repealed)
- 64B16-25.330 Emergency Meetings. (Repealed)
- 64B16-25.340 Meetings and Workshops.

64B16-25.130 Executive Director.

The Executive Director is hereby designated as the agent of the Board for the service of legal process upon the Board.

Specific Authority 465.005 FS. Law Implemented 48.111(2), 456.004, 456.009 FS. History—New 10-17-79, Formerly 21S-8.04, 21S-8.004, Amended 7-30-91, Formerly 21S-25.130, 61F10-25.130, 59X-25.130, Amended 10-29-97, 11-2-03.

64B16-25.170 Probable Cause Panel.

(1) The determination as to whether probable cause exists to believe that a violation of Chapter 456, Part II, 465, 499, or 893, F.S., or of the rules promulgated thereunder, has occurred shall be made by the ~~probably~~ probable cause panel. The panel shall meet as necessary.

(2) The probable cause panel shall be composed of two (2) members of the Board appointed by the chairman of the Board. No more than one (1) member of the panel may be a lay member ~~of the Board~~ ~~member~~. An affirmative vote of both members of the panel shall be required to find probable cause.

Specific Authority 465.015 FS. Law Implemented 456.073, 465.013 FS. History—New 10-17-79, Formerly 21S-8.08, 21S-8.008, 21S-25.170, 61F10-25.170, 59X-25.170.

64B16-25.340 Meetings and Workshops.

The following are considered to be official meetings of the Board:

- (1) Board Meetings.
- (2) Examination Committee Meetings.
- (3) Tripartite Continuing Education Committee Meeting.
- (4) Meetings of committees set out in the official minutes of the Board where statutory authority is given by the practice act.
- (5) Meetings of a Board member with Department staff or contractors of the Department at the Department's or Board's request. Any participation or meeting of members noticed or unnoticed will be on file in the Board office.
- (6) Where a Board member has been requested by the Secretary of the Department to participate in a meeting.
- (7) Probable Cause Panel meetings.
- (8) All activity of Board members, if authorized by the Board, when grading, proctoring or reviewing examinations given by the Department.
- (9) All participation in Board authorized meetings with professional associations of which the Board is a member or invitee.

This would include all meetings of ~~national~~ ~~National~~ ~~associations~~ ~~Association~~ of Boards of Pharmacy of which the Board is a member as well as Board authorized participation in meetings of national or professional associations or organizations involved in educating, regulating and reviewing the profession over which the Board has statutory authority.

(10) Any and all other activities which are Board approved and which are necessary for Board members to attend in order to further protect the public health, safety and welfare, through the regulation of which the Board has statutory authority.

Specific Authority 456.011(4) FS. Law Implemented 456.011(4) FS. History—New 9-30-81, Amended 11-13-81, 12-31-81, Formerly 21S-10.05, 21S-10.005, Amended 7-30-91, Formerly 21S-25.340, 61F10-25.340, 59X-25.340.

1 **64B16-26.203 Licensure by Examination; Application**

2
3 Applicants who are at least 18 ears of age and a recipient of a degree form a school or
4 college of pharmacy accredited by an accrediting agency recognized and approved by
5 the United Sate Offices of Education may apply to take the licensure examination.

6 (1) No Change

7 (2) The applicant must submit proof of having met the following requirements:

8 (a) No change

9 ~~—(b) Completion of an HIV/AIDS course of no less than 3 contract hours coverin~~
10 ~~the subject listed in Rule 64B16-26.602, F.A.C. For those applicants who apply~~
11 ~~within one year following receipt of their degree, completed academic course~~
12 ~~work on HIV/AIDS will be accepted by the Board as an educational course under~~
13 ~~this section, provided such course work is no less than 3 contact hours and that it~~
14 ~~covers the subjects listed in Rule 64B16-26.601, F.A.C., as evidenced by a letter~~
15 ~~attesting to subject matter covered for the Dean of the University.~~

16 (c) No change

17
18 (3) No Change

19 (a) No Change

20 (b) No Change

21 (4) No Change

22
23
24

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

In order for a foreign pharmacy graduate to be admitted to the professional licensure examination, the applicant must:

(1) No change.

(2) Be certified by the Foreign Pharmacy Graduate Examination Committee to have passed the FPGEE, the Test of English as a Foreign Language, and the Test of Spoken English. Successfully pass the foreign pharmacy graduate equivalency examination which is given by the Foreign Pharmacy Graduate Equivalency Commission.

(3) Complete a minimum of 500 hours of supervised work activity 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. Further, no program of work activity will be approved for any applicant until said applicant has been certified by FPGEE. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL) which is given 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.

(4) Demonstrate proficiency in the use of spoken English by passing the Test of Spoken English (TSE) with a score of at least 200 or an equivalent score of 45 on the recalibrated TSE.

(5) Complete a minimum of 500 hours of supervised work activity 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. Further, no program of work activity will be approved for any applicant until said applicant has successfully completed the examination as set forth in subsections (2) and (3) above.

Specific Authority 465.005, 465.007 FS. Law Implemented 465.007 FS. History-New 1-11-05,_____.

1 **64B16-26.204 Licensure By Endorsement**

2
3 An applicant for licensure by endorsement must be at least 18 years of age and a
4 recipient of a degree from a school or college of pharmacy accredited by an accrediting
5 agency recognized and approved by the United State Office of Education.

6 (1) No Change

7 (2) No Change

8 (3) The applicant must submit satisfactory proof of completion of the following:

9 ~~(a) A Board approved course of no less than three (3) contact hours on~~

10 ~~HIV/AIDS covering the subjects set forth in Rule 64B16-26.6011,~~

11 ~~F.A.C. The course shall be completed no earlier than 12 months prior~~
12 ~~to application.~~

13 (b) No Change

14
15 (4) – (8) No Change

1 **64B16-27.430 Responsibilities of the Pharmacist.**

2
3 The delegation of any duties, tasks or functions to licensed interns and pharmacy
4 technicians must be performed subject to a continuing review and ultimate supervision
5 of the Florida licensed pharmacist who instigated the specific task, so that a continuity
6 of supervised activity is present between one pharmacist and one pharmacy technician.
7 In every pharmacy, the licensed pharmacist shall retain the professional and personal
8 responsibility for any delegated act performed by licensed interns and pharmacy
9 technicians in his employ and under his supervision.

10 Specific Authority 465.005 F.S. Law Implemented 465.014 FS. History—New 2-14-77,
11 Formerly 21S-4.03, Amended 9-1-87, Formerly 21S-4.003, 21S-27.430, 61F10-27.430,
12 59X-27.430.

1 **64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating**
2 **Circumstances.**

3 (1) The board sets forth below a range of disciplinary guidelines from which disciplinary
4 penalties will be imposed upon practitioners guilty of violating Chapter 465, F.S. The purpose of
5 the disciplinary guidelines is to give notice to licensees of the range of penalties which will
6 normally be imposed upon violations of particular provisions of Chapter 465, F.S. The minimum
7 penalty range is based upon a first time single count violation of each provision listed. The
8 maximum penalty range is based upon repeated violations of the same provision of Chapter
9 465, F.S., or the rules promulgated thereto. All penalties at the upper range of the sanctions set
10 forth in the guidelines, i.e., suspension, revocation, etc., include lesser penalties, i.e., fine,
11 probation or reprimand which may be included in the final penalty at the board's discretion.
12 Probation may be subject to conditions, including restriction from practice in certain settings,
13 restricting the licensee to working only under designated conditions or in certain settings,
14 requiring continuing or remedial education, or any other restriction found to be necessary for the
15 protection of the public health, safety and welfare. In addition to any other discipline imposed
16 under these guidelines, the board shall assess costs relating to the investigation and
17 prosecution of the case.

18 (2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary
19 penalties upon licensees and permittees for violation of the below mentioned statutes and rules:

20 **PENALTY RANGE**

21 VIOLATION	MINIMUM	MAXIMUM
22 (a) Obtaining a license or 23 permit by misrepresentation 24 fraud or error 25 (Section 465.016(1)(a), F.S.) 26 (Section 465.023(1)(a), F.S.)		27 Revocation
28 (b) Procuring a license or 29 permit through false 30 representation 31 (Section 465.016(1)(b), F.S.) 32 (Section 465.023(1)(b), F.S.)		Revocation
33 (c) Permitting unlicensed persons to practice pharmacy	\$2,500 fine	\$5,000 and one (1) year suspension

34	(Section 465.016(1)(c), F.S.)		
35	(d) Being unfit or		Revocation or, at the
36	incompetent to practice		licensee's discretion,
37	pharmacy		voluntarily relinquishment
38	(Section 465.016(1)(d), (m), F.S.)		with reinstatement under
39			the terms and conditions
40			approved by the board
41	(e) Violating laws		
42	governing the practice of		
43	pharmacy		
44	(Section 465.016(1)(e), F.S.)		
45	(Section 465.023(1)(c), F.S.)		
46	1. Chapter 465, F.S.:		
47	a. Failure to supervise	\$1,500 fine and	\$5,000 and one (1) year
48	pharmacy technician	one (1) year	suspension
49	(Section 465.014, F.S.)	probation	
50	b. Operating a pharmacy	\$500 per month	Revocation (if no permit
51	without a permit	to maximum of	exists, refer to State's
52	(Section 465.015(1)(a), F.S.)	\$5,000 (penalty	Attorney)
53		will require	
54		permittee to	
55		renew permit or	
56		cease practice)	
57	c. Operating a pharmacy	\$5,000 fine and	\$5,000 and one (1) year
58	where an unlicensed and	one (1) year probation	suspension
59	unsupervised person		
60	practices pharmacy		
61	(Section 465.015(1)(b), F.S.)		
62	d. Making a false or		Revocation
63	fraudulent statement to the		

68	(Section 465.015(2)(b), F.S.)		inactive; \$200/month or
69			\$5,000 maximum (penalty
70			Will require licensee to renew
71			License or cease practice)
72	f. Selling or dispensing		
73	drugs without a prescription		
74	(Section 465.015(2)(c), F.S.)		
75	(i) Non-scheduled legend	\$1,500 fine	\$5,000 and one (1) year
76	drugs		suspension
77	(ii) Scheduled (controlled	\$5,000 fine and	Revocation
78	substances) legend drugs	one (1) year probation	
79	g. Selling samples or		Same as violation of
80	complimentary drugs		465.015(2)(c), F.S.
81	(Section 465.015(2)(d), F.S.)		(see sub-subparagraph
82			64B16-30.001, F.A.C.
83			(2)(e)1.f., F.A.C., above)
84	h. Failure to notify the		
85	board of or not to have a		
86	prescription department		
87	manager or consultant		
88	pharmacist		
89	(Section 465.022(4), F.S.)		
90	(i) Failure to notif		Fine based on length of time
91			prior to notifying board.
92			\$200 a month to \$5,000
93			maximum (penalty requires
94			notification or ceasing practice)
95	(ii) Failure to have	\$2,5000 fine and	Revocation of permit
96	prescription department	one (1) year probation	
97	manager or consultant		
98	pharmacist		
99	i. Failure to comply with	\$1,000 fine	\$2,500 fine
100	required substitution of		
101	legend drug requirements		

102	(Section 465.025, F.S.)		
103	j. Failure to follow negative	Reprimand	\$2,500 fine and one (1) year
104	formulary requirements		probation
105	(Section 465.025(6), F.S.)		
106	64B16-27.500, F.A.C.		
107	k. Failure to follow	\$500 fine	\$1,000 fine and one (1) year
108	emergency prescription		probation
109	requirements		
110	(Section 465.0275, F.S.)		
111	l. Engage in prohibited	\$1,500 fine	\$5,000 fine and one (1) year
112	rebate scheme		probation
113	(Section 465.185, F.S.)		
114	m. Failure to comply with		
115	pharmacist dispensing		
116	requirements		
117	(Section 465.186, F.S.)		
118	(i) Failure to follow	Reprimand	\$1,000 fine, and (1) year
119	procedure, but dispense		probation and suspension
120	drug appearing on		of right to dispense
121	formulary		
122	(Section 465.186(3), F.S.)		
123	64B16-27.210, F.A.C.		
124	(ii) Dispensing drug not on		Same as violation of
125	the formulary		465.015(2)(c), F.S.
126	(Section 465.186(2), F.S.)		(see sub-subparagraph
127	64B16-27.220, F.A.C.		64B16-30.001(2)(e)1.f., F.A.C.,
128	64B16-27.230, F.A.C.		above)
129	2. Chapter 499, F.S.		
130	a. Adulteration of a drug	\$2,000 fine and one (1)	Revocation
131	(Section 499.005(2), (3), F.S.)	year probation	
132	(Section 499.006, F.S.)		
133	b. Misbranding a drug		
134	(Section 499.005(2), (3), F.S.)		
135	(Section 499.007, F.S.)		

136	(i) Incomplete or inaccurate	\$1,000 fine	\$2,500 fine and one (1)
137	labeling		year probation
138	(Section 499.007, F.S.)		
139	64B16-28.108, F.A.C.		
140	(ii) Fraudulent misbranding	One (1) year	Revocation
141	of legend drugs	suspension	
142	(499.007, F.S.)		
143	3. Chapter 893, F.S.		
144	(Controlled substances)		
145	a. Filling a prescription not	\$1,500 fine	\$5,000 fine and one (1)
146	appropriately signed		year suspension
147	(Section 893.04(1)(b), F.S.)		
148	b. Filling an improper	\$1,500 fine	\$5,000 fine and one (1)
149	prescription (other		year probation
150	64B16-30.001(2)(e)3., F.A.C.		
151	above) (893.04(1)(b), (c),		
152	F.S.)		
153	c. Failing to retain	\$1,000 fine	\$2,500 fine and one (1)
154	prescription records for two		year probation
155	(2) years		
156	(Section 893.04(1)(d), F.S.)		
157	d. Failing to appropriately	\$500 fine	\$1,000 fine and one (1)
158	label		year probation
159	(Section 893.04(1)(e), F.S.)		
160	e. Dispensing a Schedule II	\$2,500 fine	\$5,000 fine and one (1)
161	drug inappropriately with a		year probation (for
162	non-written prescription		dispensing without a
163	(Section 893.04(1)(f), F.S.)		without a prescription see
164			sub-subparagraph
165			64B16-30.001, F.A.C.
166			(2)(e)1.f., F.A.C., above)
167	f. Inappropriate refilling of	\$1,750 fine and	One (1) year suspension
168	Schedule III, IV, or V drugs	one (1) year	
169	(Section 893.04(1)(g), F.S.)	probation	

170	g. Receiving controlled	\$1,500 fine	\$5,000 fine and one (1)
171	substances without an		year probation
172	appropriate order form		
173	(Section 893.06(1), F.S.)		
174	h. Unlawful possession of	\$2,500 fine and	Revocation
175	controlled substances	one (1) year	
176	(893.06(2), F.S.)	probation	
177	i. Failure to take a biennial	\$1000 fine	\$2,500 fine and one (1)
178	inventory		year probation
179	(893.07(1)(a), (2), (3), (4),		
180	(5), F.S.)		
181	j. Failure to maintain a	\$1,000 fine and	Revocation
182	complete and accurate	one (1) year	
183	record of controlled	probation	
184	substances		
185	(893.07(1)(b), (2), (3), (4),		
186	(5), F.S.)		
187	k. Dispensing controlled	\$2,500 fine and	Revocation
188	substances in other than	one (1) year	
189	good faith	probation	
190	(Section 893.08(3)(b), F.S.)		
191	l. Inappropriate selling of	\$1,500 fine and	One (1) year suspension
192	Schedule V controlled	one (1) year	
193	substance	probation	
194	(Section 893.08(3)(c), F.S.)		
195	m. Unlawful possession of	\$2,500 fine and	Revocation
196	controlled substance	one (1) year	
197	(Section 893.13, F.S.)	probation	
198	4. Violation of Federal Drug	\$1,000 fine and	\$5,000 fine and one (1)
199	Abuse Act 21 U. S. C. 821	one (1) year	year suspension
200	et seq.	probation	
201	(f) Criminal conviction	Misdemeanor:	\$5,000 fine, one (1)
202	related to pharmacy	\$1,000 fine	year suspension and
203	(Section 465.016(1)(f), F.S.)		two (2) years probation

204	(Section 465.023(1)(d), F.S.)		
205		Felony: One (1) year	Revocation
206		suspension, two (2) years	
207		probation & \$5,000 fine	
208	(g) Using in the	\$1,000 fine and	Revocation
209	compounding of a	one (1) year	
210	prescription, or furnishing	probation	
211	upon prescription, an		
212	ingredient or article		
213	different in any manner		
214	from the ingredient or		
215	article prescribed, except as		
216	authorized in 465.019(6),		
217	F.S., or 465.025, F.S., or		
218	compounding, dispensing or		
219	distributing legend drugs		
220	outside professional practice		
221	of pharmacy		
222	(465.016(1)(g), F.S.)		
223	(465.016(1)(i), F.S.)		
224	(h) Filing a false report or		
225	failing to file a report		
226	required by law		
227	1. Knowing violation	\$2,000 fine and	Revocation
228	one (1) year		
229	probation		
230	2. Negligent violation	Reprimand	One (1) year probation
231			and \$1,000 fine
232	(i) Failure to make	Letter of guidance	\$1,000 fine and
233	prescription price		one (1) year probation
234	information available		
235	(Section 465.016(1)(k), F.S.)		
236	(j) Improperly placing	\$1,500 fine	\$3,000 fine and one (1)
237	returned drugs into the stock		year probation

238	of a pharmacy		
239	(Section 465.016(1)(l), F.S.)		
240	(k) Violating a rule or order		
241	of the board or		
242	Department		
243	(Section 465.016(1)(n), F.S.)		
244	1. Rules of Board of		
245	Pharmacy		
246	a. 64B16-28.101 to	\$1,000 fine	One (1) year probation
247	64B16-28.104		and \$2,000 fine
248	64B16-27.100		
249	64B16-28.106		
250	64B16-28.107		
251	64B16-28.109		
252	64B16-27.103		
253	64B16-28.111		
254	64B16-27.104		
255	64B16-26.400		
256	64B16-26.401		
257	64B16-28.404		
258	64B16-26.301		
259	64B16-28.114		
260	64B16-27.105		
261	b. 64B16-28.105	Suspension until	Revocation
262	(sanitation)	compliance	
263	c. 64B16-27.101		Same as penalty for
264	(counterfeit drugs)		adulterated
265	drugs (see subparagraph		
266	64B16-30.001(2)(e)2., F.A.C.)		
267	d. 64B16-28.110 (outdated	\$500 fine	One (1) year probation
268	pharmaceuticals)		and \$2,000 fine (if drugs
269			dispensed, one (1) year
270			suspension)

271	e. 64B16-28.112		Same as underlying
272	(violations)		statutory or rule violation
273	f. 64B16-26.300 (Serving as	\$500 per month	One (1) year suspension
274	consultant pharmacist	up to a \$5,000	of pharmacist license
275	without being licensed as a	maximum	
276	consultant pharmacist)		
277	g. 64B16-28.140 and	\$1,000 fine	\$5,000 fine and two (2)
278	64B16-28.150 (Data		years probation
279	processing systems)		
280	h. 64B16-28.120 (Location	\$1,000 fine	\$5,000 fine and two (2)
281	of legend drugs)		years probation
282	i. 64B16-28.900,		
283	64B16-28.901,		
284	64B16-28.902 (Nuclear		
285	pharmacy)		
286	(i) Practicing nuclear	\$1,000 fine and	Revocation of pharmacist's
287	pharmacy without being	one (1) year	license or permit
288	licensed as a nuclear	probation	
289	pharmacy		
290	(Section 64B16-28.903, F.A.C.)		
291	(ii) Failure to follow	One (1) year	Revocation of license of
292	technical requirements	probation and	practice nuclear pharmacy
293	(64B16-28.901 and	\$1,000 fine	
294	64B16-28.902, F.A.C.)		
295	j. 64B16-28.202 and	\$1,500	Revocation of permit
296	64B16-28.203 (transfer of		
297	prescription files and drugs)		
298	2. Violation of orders of	\$2,500 fine and	Revocation
299	Board or Department	one (1) year probation	
300	(l) License disciplined by		Same penalty as imposed
301	another jurisdiction		in other jurisdiction or as
302	(Section 465.016(1)(h), F.S.)		closely as possible to
303			penalties set forth in Florida
304			Statutes

305	(m) Failure to comply with	\$750 fine	\$2,500 fine and, one (1)
306	Board's rule on patient		year probation
307	counseling		
308	(64B16-27.800,		
309	64B16-27.810,		
310	64B16-27.820, F.A.C.)		
311	(n) Violation 465.018 by	Penalty as	
312	and through 465.016 and	closely as	
313	465.023	possible to those	
314	set forth in the		
315	Disciplinary		
316	Guidelines		
317	(o) Violating 456.072, F.S.		
318	1. Making misleading,	\$2,500 fine and	\$5,000 fine and one (1)
319	deceptive, or fraudulent	one (1) year	year suspension
320	representations in or related	probation	
321	to the practice of the		
322	licensee's profession.		
323	2. Intentionally violating	\$1,500 fine	\$2,500 fine and one (1)
324	any rule adopted by the		year probation
325	Board or the Department, as		
326	appropriate.		
327	3. Being convicted or found	Misdemeanor:	\$5,000 fine and one (1)
328	guilty of, or entering a plea	\$1,000 fine	year suspension
329	of guilty or nolo contendere to,	Felony: \$3,000 fine and	Revocation
330	regardless of adjudication, a	one (1) year probation	
331	crime in any jurisdiction		
332	which relates to the practice		
333	of, or the ability to practice,		
334	a licensee's profession.		
335	4. Failing to comply with	\$500 fine	\$1,000 fine
336	the educational course		
337	requirements for human		
338	immunodeficiency virus and		

373	fraudulent		
374	misrepresentation, or		
375	through an error of the		
376	Department or the Board.		
377	8. Except as provided in	\$500 fine and	\$1,000 fine and two (2)
378	Section 465.016, F.S., failing	one (1) year	years probation
379	to report to the Department	probation	
380	any person who the licensee		
381	knows is in violation of this		
382	part, the chapter regulating		
383	the alleged violator, or the		
384	rules of the Department or		
385	the Board.		
386	9. Aiding, assisting,	\$2,000 fine	\$5,000 fine and one (1)
387	procuring, employing, or		year suspension
388	advising any unlicensed		
389	person or entity to practice a		
390	profession contrary to this		
391	part, the chapter regulating		
392	the profession, or the rules		
393	of the Department or the		
394	Board.		
395	10. Failing to perform any	\$2,000 fine	\$5,000 fine and one (1)
396	statutory or legal obligation		year probation
397	placed upon a licensee.		
398	11. Making or filing a report	\$3,000 fine and	\$5,000 fine and one (1)
399	which the licensee knows to	two (2) years	year suspension
400	be false, intentionally or	probation	
401	negligently failing to file a		
402	report or record required by		
403	state or federal law, or		
404	willfully impeding or		
405	obstructing another person		
406	to do so. Such reports or		

407 records shall include only
408 those that are signed in the
409 capacity of a licensee.

410 12. Making deceptive,	\$10,000 fine and	\$10,000 fine and one (1)
411 untrue, or fraudulent	two (2) years	year suspension
412 representations in or related	probation	
413 to the practice of a		
414 profession or employing a		
415 trick or a scheme in or		
416 related to the practice of a		
417 profession.		

418 13. Exercising influence on	\$3,000 fine and	\$5,000 fine and one (1)
419 the patient or client for the	two (2) years	year suspension
420 purpose of financial gain of	probation	
421 the licensee or a third party.		

422 14. Practicing or offering to	\$2,000 fine and	\$5,000 fine and one (1)
423 practice beyond the scope	two (2) years	year suspension
424 permitted by law or	probation	
425 accepting and performing		
426 professional responsibilities		
427 the licensee knows, or has		
428 reason to know, the licensee		
429 is not competent to perform.		

430 15. Delegating or	\$2,000 fine and	\$5,000 fine and one (1)
431 contracting for the	two (2) years	year suspension
432 performance of professional	probation	
433 responsibilities by a person		
434 when the licensee		
435 delegating or contracting for		
436 performance of such		
437 responsibilities knows, or		
438 has reason to know, such		
439 person is not qualified by		
440 training, experience, and		

441	authorization when required		
442	to perform them.		
443	16. Violating any provision	\$1,000 fine	\$5,000 fine and two (2)
444	of this part, the applicable		years probation
445	professional practice act, a		
446	rule of the Department or		
447	the Board, or a lawful order		
448	of the Department or the		
449	Board, or failing to comply		
450	with a lawfully issued		
451	subpoena of the		
452	Department.		
453	17. Improperly interfering	\$2,500 fine and	\$5,000 fine and one (1)
454	with an investigation or	two (2) years	year suspension
455	inspection authorized by	probation	
456	statute, or with any		
457	disciplinary proceeding.		
458	18. Failing to report to the	\$1,000 fine	\$2,500 fine and one (1)
459	board in writing within 30		year probation
460	days after the licensee has		
461	been convicted or found		
462	guilty or entered a plea of		
463	nolo contendere to,		
464	regardless of adjudication,		
465	a crime in any jurisdiction.		
466	19. Testing positive for any	\$2,500 fine and	\$5,000 fine and one (1)
467	drug, as defined in	two (2) years	year suspension
468	Section 112.0455, F.S., on	probation	
469	any confirmed preemployment		
470	or employer ordered drug		
471	screening when the		
472	practitioner does not have		
473	a lawful prescription and		
474	legitimate medical reason		

475 for using such drug.
476 20. Being terminated from Suspension until successful Revocation
477 or failing to successfully completion or receipt of written
478 complete an impaired confirmation of compliance with
479 practitioners treatment ongoing treatment and a fine of
480 program up to \$1,000.
481 (Section 456.072(1)(hh), F.S.)

482 (3) The board shall be entitled to deviate from the above-mentioned guidelines upon a
483 showing of aggravating or mitigating circumstances by clear and convincing evidence presented
484 to the board prior to the imposition of a final penalty. The fact that an Administrative Law Judge
485 of the Division of Administrative Hearings may or may not have been aware of the below-
486 mentioned aggravating or mitigating circumstances prior to a recommendation of penalty in a
487 Recommended Order shall not obviate the duty of the board to consider aggravating and
488 mitigating circumstances brought to its attention prior to the issuance of a Final Order.

489 (a) Aggravating circumstances; circumstances which may justify deviating from the above
490 set forth disciplinary guidelines and cause the enhancement of a penalty beyond the maximum
491 level of discipline in the guidelines shall include but not be limited to the following:

492 1. History of previous violations of the practice act and the rules promulgated thereto.

493 2. In the case of negligent acts, the magnitude and scope of the damage or potential
494 damage inflicted upon the patient or the general public by the licensee's misfeasance.

495 3. Evidence of violation of professional practice acts in other jurisdictions wherein the
496 licensee has been disciplined by the appropriate regulatory authority.

497 4. Violation of the provision of the practice act wherein a letter of guidance as provided in
498 Section 456.073(3), F.S., has previously been issued to the licensee.

499 (b) Mitigating circumstances; circumstances which may justify deviating from the above set
500 forth disciplinary guidelines and cause the lessening of a penalty beyond the minimum level of
501 discipline in the guidelines shall include but not be limited to the following:

502 1. In cases of negligent acts, the minor nature of the damage or potential damage to the
503 patient's or the public's health, safety and welfare resulting from the licensee's misfeasance.

504 2. Lack of previous disciplinary history in this or any other jurisdiction wherein the licensee
505 practices his profession.

506 3. Restitution of any monetary damage suffered by the patient.

507 4. The licensee's professional standing among his peers.

508 5. Steps taken by the licensee to insure the non-occurrence of similar violations in the future

509 including continuing education.

510 6. The degree of financial hardship incurred by a licensee as a result of the imposition of
511 fines or the suspension of his practice.

512 (4) All fines imposed by the Board shall be paid within a period of thirty (30) days from the
513 date of the final order entered by the Board. This time limitation may be modified by the
514 Board for good cause shown in order to prevent undue hardship.

515 Specific Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079 FS.

516 History—New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001,

517 Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02,

518 11-29-06.

1 **64B16-30.002 Minor Violations.**

2 (1) The Board sets forth the following guidelines for use by Department investigators when a
3 licensee is in noncompliance of an initial offense of a minor violation. The Board deems the
4 following violations, depending upon severity, to be consistent with Section 456.073(3), F.S.

5 (a) Outdated pharmaceuticals – Rule 64B16-28.110, F.A.C.

6 (b) Failure to meet regulation of daily operating hours – Rule 64B16-28.404, F.A.C.

7 (c) Generic substitution sign not displayed – Section 465.025(7), F.S.

8 (d) Information required on controlled substance prescriptions: practitioner's address,
9 practitioner's DEA registration number, patient's address – Section 893.04, F.S.

10 (e) Failure to have certified by dispensing pharmacists the daily hard-copy printout or daily log –
11 paragraph 64B16-28.140(3)(c) or (e), F.A.C.

12 (f) Failure to have pharmacy minimally equipped i.e. references, compounding equipment, and a
13 current copy of the laws and rules governing the practice of pharmacy in the State of Florida –
14 Rule 64B16-28.107, F.A.C.

15 (g) Failure to properly identify pharmacy technicians – Rule 64B16-27.410, F.A.C.

16 (h) Results of P&E quality assurance program not documented or available for inspection –
17 paragraph 64B16-28.820(3)(d), F.A.C.

18 (i) Improper storage of legend drugs – Rule 64B16-28.120, F.A.C.

19 (j) Improper documentation of destruction of controlled substances – Rules 64B16-28.301,
20 64B16-28.303, F.A.C.

21 (k) Consultant pharmacist's monthly reports not current or available for inspection – Rule
22 64B16-28.501, subsection 64B16-28.702(2), F.A.C.

23 (l) Controlled substance prescription labels lack transfer crime warning labeling – paragraph
24 64B16-28.502(2)(c), F.A.C.

25 (2) The Department's investigator may issue a Notice of Deficiencies when the above conditions
26 occur and the requirements of Section 456.073(3), F.S., are met. In such cases licensees shall
27 correct the violation and respond to the investigator on forms provided by the Department and
28 with other evidence of compliance as may be necessary, within 30 days, to certify current
29 compliance. Failure to do so shall subject the licensee to further proceedings.

30 Specific Authority 456.073(3), 465.005 FS. Law Implemented 456.073(3) FS. History–New 11-
31 12-90, Formerly 21S-17.002, 21S-30.002, 61F10-30.002, 59X-30.002, Amended 12-9-98, 8-26-
32 02.

1 **64B16-30.003 Citations.**

2 (1) Pursuant to Section 456.077, F.S., the Board sets forth in (3) of this rule those violations for which there is
3 no substantial threat to the public health, safety and welfare; or, if there is a substantial threat to the public
4 health, safety and welfare, such potential for harm has been removed prior to the issuance of the citation.
5 Next to each violation is the fine to be imposed.

6 (2) Prior to issuance of the citation, the Department must confirm that the violation has been corrected or is in
7 the process of being corrected. If the violation is a substantial threat to the public health, safety and welfare,
8 such potential for harm must be removed prior to issuance of the citation.

9 (3) The following violations with accompanying fines may be disposed of by citation:

10 (a) Practicing pharmacy as an inactive licensee (465.015(2)(b), F.S.) Fine based on length of time in practice
11 while inactive; \$200/month or \$5,000
12 maximum (penalty will require licensee to
13 renew license or cease practice).

14 (b) Operating a pharmacy with an inactive permit (465.015(1)(a), F.S.) \$500 per month to a maximum of \$5000
15 (penalty will require permittee to renew
16 permit or cease practice).

17 (c) First time failure to complete the required
18 continuing education during the biennial
19 licensure period.
20 (456.072(3), F.S.)

21 Failure to complete less than 10 hours \$500

22 Failure to complete 10 or more hours \$1000

23 In addition, licensees shall take two additional hours of continuing education for each of the continuing
24 education deficiencies. Said hours shall not count for continuing education renewal requirements for the next
25 biennium.

26 (d) Failure to timely pay a fine or costs imposed by a final order. \$500 per month late to a maximum of
27 \$5,000 (penalty will require permittee or
28 licensee to also pay the original fine
29 and/or costs).

30 (e) Failure to display any sign, license or permit
31 required by statute or rule. \$500

32 (f) Failure to have any reference material required by statute or
33 \$500
34

35 rule available.

36 (g) Failure to notify the	Fine based on the length of time
37 board of a change in	prior to notifying board.
38 a prescription department	\$200 a month to \$5,000 maximum.
39 manager or consultant	
40 pharmacist.	

41 (h) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article
42 different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6)
43 or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed,
44 provided that:

- 45 1. No allegation of harm or ill effects is present;
- 46 2. The licensee has no prior disciplinary history; and
- 47 3. The event did not result in or pose a significant threat to the health and safety of the patient or the
48 public.

49 The penalty shall be a letter of concern, payment of costs, and completion of an approved continuing
50 education course in the prevention of medication dispensing errors, of no less than eight (8) hours.

51 (4) Once the citation becomes a final order, the citation and complaint become a public record pursuant to
52 Chapter 119, F.S., unless otherwise exempt from the provisions thereof. The citation and complaint may be
53 considered as aggravating circumstances in future disciplinary actions pursuant to paragraph 64B16-
54 30.001(3)(a), F.A.C.

55 (5) The procedures described herein apply only for an initial offense of the alleged violation. Subsequent
56 violation(s) of the same rule or statute shall require the procedures of Section 456.073, F.S., to be applied. In
57 addition, should an initial offense for which a citation could be issued occur in conjunction with violations not
58 described herein, then the procedures of Section 455.225, F.S., shall apply.

59 Specific Authority 456.073, 456.077, 465.005 FS. Law Implemented 456.077 FS. History—New 12-22-91,
60 Formerly 21S-30.003, 61F10-30.003, 59X-30.003, Amended 4-3-00, 1-2-02, 8-26-02, 1-12-03.

1 **64B16-30.0035 Mediation.**

2 (1) "Mediation" means a process whereby a mediator appointed by the Department acts to encourage and
3 facilitate resolution of a legally sufficient complaint. It is an informal and nonadversarial process with the
4 objective of assisting the parties to reach a mutually acceptable agreement.

5 (2) The Board finds that mediation is an acceptable method of dispute resolution for the following violation as
6 it is economic in nature or can be remedied by the licensee: failure of the licensee to timely pay any assessed
7 administrative fines or costs.

8 (3) A "mediator" means a person who is certified in mediation by the Florida Bar, the Florida Supreme Court,
9 or the Division of Administrative Hearings.

10 Specific Authority 456.078 FS. Law Implemented 456.078 FS. History—New 11-21-94, Formerly 59X-30.0035.