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GUAM BOARD OF EXAMINERS FOR PHARMACY
RULES AND REGULATIONS

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1 **GUAM BOARD OF EXAMINERS FOR PHARMACY**

2 **Chapter Phar 1**

3 **AUTHORITY AND DEFINITIONS**

4
5 **Phar 1.01 Authority**

6 **Phar 1.02 Definitions**

7
8 **Phar 1.01 Authority**

9 Rules in Chap. Phar 1 to 14 are adopted under authority of P. L. 24-207, Repealed
10 and Reenacted May 13, 1998, Article 6 Chapter 12 of Title 10 of Guam Code
11 Annotated.

12
13 **Phar 1.02 Definitions. As used in Chapters. Phar 1 to 14:**

14 (1) **“Board”** means the *Guam Board of Examiners for Pharmacy*.

15
16 (2) **“Controlled Substance”** means those drugs and drug products that come
17 under the jurisdiction of the current Federal Controlled Substance Act of
18 1970 or Guam Controlled Substance Act (P.L. 24-149).

19
20 (3) **“Cosmetics”** including soap, dentifrice and toilet articles, means (1) an
21 article intended to be rubbed, poured or sprinkled on, introduced into or
22 otherwise applied to the human body, or any part thereof for cleansing,
23 beautifying, or promoting attractiveness; and (2) articles intended for use
24 as a component of any such articles.

25
26 (4) **“Dangerous Drug” or “Dangerous Device”** means any drug or device
27 unsafe for self-medication and includes any drug or device which bears
28 the legend: ‘Caution: Federal law prohibits dispensing without a
29 prescription’ or “Rx Only”.

30 If the Board finds after open hearing following due notice to persons who
31 have filed written request to the Board for such notice, that any drug or

1 device is dangerous to the public health or safety, the Board may make
2 other rules, not inconsistent with this sub-chapter, limiting or restricting
3 the furnishing of such drug.
4

5 (5) **“Dispense or Dispensing”** means the interpretation, evaluation, and
6 implementation of a prescription drug order, including the preparation
7 delivery of a drug or device to a patient or patient’s agent in a suitable
8 container appropriately labeled for subsequent administration to or use
9 by the patient.
10

11 (6) **“Drug”** means:

- 12 (a) articles recognized as drugs in any official compendium, or
13 supplement thereto, designated from time to time by the Board for
14 use in the diagnosis, cure, mitigation, treatment or prevention of
15 disease in human or other animals;
16 (b) articles intended for use in the diagnosis, cure, mitigation,
17 treatment or prevention of disease in human or other animals;
18 (c) articles, other than food, intended to affect the structure of any
19 function of the body of human or other animals; and
20 (d) articles intended for use as a component of any articles specified
21 in clauses (a), (b) or (c) of this subsection.
22

23 (7) **“Examinations”** means the NAPLEX, FPGEE , Jurisprudence
24 examinations, or any other examinations as required by the Board.
25

26 (8) **“FPGEE”** means Foreign Pharmacy Graduate Equivalency Examination
27 which establishes educational equivalency of a foreign graduate.
28

29 (9) **“Guam Controlled Substance Program”** is a division of Department of
30 Environmental Health that regulates P.L. 24-149, Title 9, Chapter 67,
31 Article 3 known as the Guam Controlled Substance Act.

- 1 (10) ***“Licensed Practitioner”*** – means a physician, dentist, podiatrist,
2 osteopathic physician, veterinarian, or optometrist or other health
3 professionals licensed by law to prescribe and administer within the
4 scope of their practice.
5
- 6 (11) ***“NAPLEX”*** means the North American Pharmacist Licensing
7 Examination.
8
- 9 (12) ***“Patent Medicine” or “Proprietary Preparation”*** means a drug in its
10 unbroken original package, which is sold to the public by or under the
11 authority of the manufacturer or primary distributor thereof under a
12 trademark, trade name, or other trade symbol privately owned, whether or
13 not registered in the United States Patent Office, and labeling of which
14 conforms to the provisions of Guam and Federal Government laws.
15
- 16 (13) ***“Patient”*** means the individual for whom drugs are prescribed or to
17 whom prescription drugs are administered.
18
- 19 (14) ***“Pharmaceutical Care”*** means the provision of drug therapy and other
20 patient care services intended to achieve outcomes related to the cure or
21 prevention of a disease, elimination or reduction of a patient’s symptoms,
22 or arresting or slowing of a disease process as defined in the rules of the
23 Board.
24
- 25 (15) ***“Pharmacist”*** means an individual currently licensed by the Board to
26 engage in the practice of pharmacy.
27
- 28 (16) ***“Pharmacist-in-charge”*** means a pharmacist currently licensed in Guam
29 who accepts responsibility for the operation of a pharmacy in conformance
30 with all the laws and rules pertinent to the practice of pharmacy and the

1 distribution of drugs, and who is personally in full and actual charge of
2 such pharmacy and personnel.

3
4 (17) **“Pharmacy”** means every store, shop or place where (1) drugs are
5 dispensed, sold or displayed for a sale at retail; (2) where prescriptions or
6 drug preparations are compounded; (3) which has upon it, displayed
7 within it, affixed to or used in conjunction ‘drug store’, ‘druggist’,
8 ‘drugs’, ‘medicines’, ‘amot’, ‘Medicine Store’, ‘drug sundries’,
9 ‘remedies’, or any word or words of similar or like import; or (4) any store
10 or other place with respect to which any of the above words or
11 combination of words are used in any advertisement but does not include
12 the place used by a drug manufacturer or drug wholesaler or the place of
13 business of a non-registered person selling non-narcotic proprietary
14 preparations;

15 (18) **“Pharmacy Intern”** means and individual who is:

- 16 (a) currently licensed by the Board to engage in the practice of
17 pharmacy while under the personal supervision of a pharmacist
18 and is satisfactorily progressing toward meeting the requirements
19 for licensure as a pharmacist, or;
20 (b) a graduate of an approved college of pharmacy or a graduate who
21 has established educational equivalency by obtaining a Foreign
22 Pharmacy Graduate Examination Committee (FPGEC) Certificate,
23 who is currently registered by the Board of Pharmacy for the
24 purpose of obtaining practical experience as a requirement for
25 licensure as a pharmacist, or;
26 (c) a qualified applicant awaiting examination for licensure, or;
27 (d) an individual participating in a residency or fellowship program.

28
29 (19) **“Pharmacy Manager”** means a person, pharmacist or non-pharmacist
30 who has over-all responsibility of pharmacy operations and duties not
31 requiring pharmacist license.

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(20) **“Pharmacy owner”** means a person or entity to whom a Pharmacy permit is issued whether the owner is a sole proprietorship, partnership, association, corporation or otherwise.

(21) **“Practice of pharmacy”** means the interpretation, evaluation and implementation of medical orders; the dispensing of prescription drug orders; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care, including primary care; and the responsibility for compounding and labeling of drugs and devices, except labeling by a manufacturer, repackaged, or distributor of non-prescription drugs and commercially packaged legend drugs and devices, proper and safe storage of drugs and devices, and maintenance of proper records for them.

(22) **“Prescription”** means an order given individually for the person for whom prescribed, either directly from a licensed practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine, and any other person licensed by their health boards to the pharmacist or indirectly by means of written order for the compounding or dispensing of drugs bearing the name and address of the prescriber, his license classification, the name and address of the patient, the name and quantity of the drug prescribed, directions for use and the date of issue.

(23) **“Professional service area”** means the area of a pharmacy in which prescriptions are compounded or dispensed, hypodermic needles, syringes, poisons and all controlled substances as listed in the Federal Control Substances Act, and Guam Controlled Substance Act , are available.

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(24) **“Registered Pharmacist/Licensed Pharmacist/Doctor of Pharmacy”**
means an individual currently licensed by the Board to engage in the
practice of Pharmacy.

(25) **“Supportive Personnel”** means all persons other than the pharmacist,
intern, or technician paid regularly and performs tasks that does not
require license, certificate, or permit.

(26) **“Telepharmacy”** means the provision of pharmaceutical care
through the use of telecommunications and information technologies to
patients at a distance.

1 **Chapter Phar 2**
2 **QUALIFICATION AND APPLICATION PROCEDURE**
3 **FOR PHARMACIST LICENSURE AND INTERNSHIP REGULATIONS**
4

5 **Phar 2.01 Qualifications**

6 **Phar 2.02 Application Procedure**

7 **Phar 2.03 Internship Regulations**
8

9 **Phar 2.01 Qualifications.** An applicant for licensure as a pharmacist may be admitted to
10 NAPLEX under P.L. 24-207, if the applicant:

- 11 (1) is at least eighteen (18) years of age,
- 12 (2) is of good moral character and temperate habits, and
- 13 (3) is a graduate of a school or college of pharmacy or department of a
14 university which school or college or department is recognized and
15 approved by the Board.
- 16 (4) files proof satisfactory to the Board of a minimum of 1500 hours of
17 internship experience in any state or territory of the United States
18 in a pharmacy under the supervision of registered pharmacist. Service and
19 experience in a pharmacy under the supervision of a registered pharmacist
20 as required in this Section shall be predominantly related to the selling of
21 drugs, compounding prescriptions, preparing pharmaceutical preparations,
22 and keeping records and making reports required under territorial and
23 federal statutes.
- 24 (5) is a foreign graduate who has established educational equivalency by
25 obtaining a Foreign Pharmacy Graduate Examination Committee
26 (FPGEC) Certificate.

27
28
29 **Phar 2.02 Application Procedure.**

- 30 (1) Each applicant shall submit a completed notarized
31 application no later than 30 days prior to the examination date on forms

1 provided by the Board. The application shall include:

- 2 (a) The signature of the applicant.
- 3 (b) A statement from the Dean of the School of Pharmacy or the
4 Academic Records Office of the respective educational institution
5 that the applicant has graduated from the pharmacy school.
- 6 (c) Two recent ~~notarized~~ passport size photographs.
- 7 (d) The fees as specified by the Board.
- 8 (e) Any change of name made prior to admission to examination shall
9 be supported by a notarized affidavit of the applicant.

10
11 **Phar 2.03 Internship Regulations.**

12 1. Definitions

13 **“Pharmacy intern”** means an individual who is:

- 14 (a) currently licensed by the board to engage in the practice of
15 pharmacy while under the personal supervision of a pharmacist
16 and is satisfactorily progressing toward meeting the requirements
17 for licensure as a pharmacist; or,
- 18 (b) a graduate of an approved college of pharmacy or a graduate who
19 has established educational equivalency by obtaining a Foreign
20 Pharmacy Graduate Examination Committee (FPGEC) Certificate,
21 who is currently licensed by the Board of Pharmacy for the
22 purpose of obtaining internship experience as a
23 requirement for licensure as a pharmacist; or,
- 24 (c) a qualified applicant awaiting examination for licensure; or,
- 25 (d) an individual participating in a residency or fellowship program.

26
27 **“Preceptor”** means an individual who is currently licensed as a
28 pharmacist by the Board of Pharmacy meets the qualifications as a
29 preceptor under the rules of the Board and participates in the instructional
30 training of pharmacy interns.

31

1 2. Initial Application – Forms – Fees – Annual License.

2 (a) Forms for the initial application for licensure as a pharmacy intern,
3 for the internship experience reports and for the renewal of the
4 intern license may be obtained from the Board office.

5 (b) The initial license for a qualified pharmacy intern shall be issued
6 by the Board after the receipt of the completed application and
7 payment of the fee prescribed by the Board and approval of the
8 Board.

9 (c) A pharmacy intern license shall be renewed by
10 September 30 biannually of each odd-numbered year

11 (d) The pharmacy intern license must be conspicuously displayed in
12 the internship experience area at all times.

13
14 3. Internship Requirements:

15 (a) Internship shall consist of not less than 1500 hours of practical
16 experience in a pharmacy setting.

17 (b) In the second year of college of pharmacy education

18 (c) Credit may be given for internship experience gained during
19 vacation periods between the terms or semesters of enrollment in a
20 school or college of pharmacy, in addition to the summer vacation
21 periods.

22 (d) No more than 40 hours per week may be credited toward the
23 internship requirement.

24
25 4. Change of Internship Experience Area.

26 When a pharmacy intern changes experience areas before completing the
27 1500 hours time requirement, he/she shall submit written notification to
28 the Board within fifteen (15) days and provide the name of his new
29 preceptor, and the name and address of the new experience area. Failure
30 to do so may result in denial of internship credit for experience
31 obtained in the new area prior to notification of the Board.

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5. Eligibility for Internship Experience

A pharmacy intern shall not be eligible for internship experience unless he/she is pursuing a degree in good faith, or such a degree is conferred, by the school or college or enrollment, that qualified him/her for licensure as a pharmacist.

6. Internship Reports.

- (a) Internship experience reports, on forms provided by the Board, shall be submitted to the Board for approval for each place of internship when a pharmacy intern changes preceptors in an internship experience area.
- (b) Approval of internship experience reports shall be given by the Board when the reports are completed and indicated that significant progress in internship experience toward achieving competency in the practice of pharmacy has been made.
- (c) The internship experience reports shall be signed by the pharmacy intern and the preceptor(s) on forms provided by the Board.
- (d) The internship experience report shall list the actual number of hours worked per week under the supervision of his/her preceptor and the dates covered by those hours.

7. Preceptor Responsibilities.

- (a) A registered preceptor shall be actively engaged in the practice of pharmacy during two years prior to supervising a pharmacy intern.
- (b) The preceptor shall actively supervise the pharmacy intern during the internship experience time requirement, and should registered preceptor be absent, no credit will be given to intern for hours obtained during the preceptor's absence.
- (c) The preceptor shall certify the internship experience report when the intern leaves his supervision permanently, or upon graduation.
- (d) The preceptor shall assure that the intern is currently licensed.

1 **Chapter Phar 3**
2 **EXAMINATION**

3
4 **Phar 3.01 Administration**

5 **Phar 3.02 Passing Scores**

6 **Phar 3.03 Results**

7 **Phar 3.04 Failures and Re-Examination**
8

9 **Phar 3.01 Administration.**

- 10 (a) An applicant found by the Board to have violated rules of any
11 examination required for licensure may be denied licensure by the Board.
12 (b) An applicant for licensure as a pharmacist is required to take the
13 NAPLEX, and may be required to take a jurisprudence examination.
14 (c) The jurisprudence examination shall determine an applicant's familiarity
15 with Guam laws and rules and federal laws and regulations governing the
16 practice of pharmacy.
17 (d) An applicant must sign an acknowledgement to attest to having read the
18 Uniform Guam Controlled Substance Act.
19

20 **Phar 3.02 Passing Scores**

- 21
22 (a) The passing scores set by the Board represent the minimum competency
23 required to protect the public health and safety.
24 (b) Each exam is scored separately and an applicant shall earn passing scores
25 on each required examination to qualify for licensure.
26 (c) The Board requires a minimum average score of 75.0 in the chemistry,
27 mathematics, pharmacology, and pharmacy sections of the NAPLEX, with
28 no score less than 60.0 on any of the four sections. A minimum score of
29 75.0 on the practice of the pharmacy section of NAPLEX is required.
30 (d) A minimum score of 75.0 is required in jurisprudence.
31

1 **Phar 3.03 Results**

- 2
- 3 (a) The Board shall send written notification of results to applicants by
- 4 registered or certified mail.
- 5 (b) An applicant shall be offered the opportunity to make written comments
- 6 and objections within 30 days after notification of the examination results.
- 7 (c) Any unsuccessful applicant may request in writing that his or her answer
- 8 sheet be rescored by hand to verify the accuracy of scoring. Within 30
- 9 days after notification of the examination results.
- 10 (d) The cost of rescoring shall be paid by the applicant.
- 11

12 **Phar 3.04 Failures and Re-Examination**

- 13
- 14 (a) All applicants have the option for re-examination of the NAPLEX in
- 15 accordance with NAPLEX guidelines.
- 16 (b) An applicant who fails to earn a passing score in the jurisprudence, may
- 17 repeat the failed examination subject to Phar 3.01 (c) and/or NAPLEX
- 18 guidelines. The Board may limit the number of re-examinations taken by
- 19 an applicant at the Board's discretion.
- 20 (c) An applicant who fails to earn a passing score in any examination for
- 21 licensure may be re-examined, but not earlier than the next scheduled test
- 22 date.
- 23 (d) Application for re-examination shall be made on forms provided for that
- 24 purpose by the Board. For each re-examination, the applicant shall file the
- 25 re-examination fee specified by the Board.
- 26 (e) Any unsuccessful applicant may request in writing to meet with the Board
- 27 to discuss any grievance concerning the examination.
- 28 (f) The Board may recommend a refresher course or any competency
- 29 examination.
- 30
- 31

1 **Chapter Phar 4**

2 **PHARMACISTS LICENSURE RENEWAL**

3
4 **Phar 4.01 Requirements**

5 **Phar 4.02 Change of Name or Address**

6 **Phar 4.03 Display of Licenses**

7 **Phar 4.04 Renewal Prohibited; Re-Licensure**

8 **Phar 4.05 Renewal After Lapse**

9
10 **Phar 4.01 Requirements.**

- 11
- 12 (a) Pharmacists licensed under P.L.24-207 may be licensed
- 13 biannually by applying for renewal between September 1st through
- 14 September 30th of each odd-numbered year and paying the fee specified
- 15 by the Board. No pharmacist license renewal will be issued by the Board
- 16 of Pharmacy unless the applicant, preceding the renewal application, has
- 17 satisfactorily completed 3.0 units (30 hours) of continuing pharmacy
- 18 education program or programs approved by the Board within the
- 19 preceding two-year period.
- 20 (b) No one without a current renewal card may engage in the practice of
- 21 pharmacy, nor hold him or herself out to be a pharmacist nor use the title
- 22 or letter “Pharmacist”, “Registered Pharmacist”, “R. Ph.”, “Pharm. D.”, or
- 23 “Doctor of Pharmacy”.
- 24

25 **Phar 4.02 Change of Name or Address.**

- 26
- 27 (a) A pharmacist shall notify the Board in writing when his or her name has
- 28 been legally changed.
- 29 (b) A pharmacist shall notify the Board in writing of his or her new address
- 30 within “fifteen” (15) days after the change.

1 **Phar 4.03 Display of Licenses**

2

3 A pharmacist who engages in the practice of pharmacy shall display his or her
4 license in a manner conspicuous to the public view. Biennial renewal cards shall
5 be placed in the lower right hand corner of the license and shall be posted when
6 received in the pharmacy where he or she engages in the practice of pharmacy.

7

8 **Phar 4.04 Renewal Prohibited; Re-Licensure.**

9

10 Any person whose license is currently suspended or revoked may not renew his
11 or her license. A person whose license has been suspended or revoked and
12 subsequently reinstated by the Board may renew his or her license upon
13 completion of a renewal form and filing of the required renewal fee.

14

15 **Phar 4.05 Renewal After Lapse.**

16

17 (a) Any holder of an expired license may be reinstated as a registered pharmacist
18 upon satisfactory completion of continuing education requirements and upon
19 payment of a penalty established by the Board and all fees which he/she would
20 have paid if he/she had continuously renewed his/her license. Re-examination
21 shall be determined by the Board for renewal of license after lapse.

22

23 (b) Any pharmacist whose licensed under Guam laws has expired after three years
24 must pass an examination for license renewal except that a person who
25 has continually practiced pharmacy in another State or US Territory under a
26 license by authority of such State may renew his license upon payment of
27 designated fee.

28

29

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1 **Chapter Phar 5**

2 **CONTINUING PHARMACY EDUCATION**

3
4 **Phar 5.01 Continuing Pharmacy Education Required for Pharmacist License Renewal**

5 **Phar 5.02 Continuing Pharmacy Education Programs**

6 **Phar 5.03 Continuing Pharmacy Education – Non-Resident – Dual Licenses**

7 **Phar 5.04 Notification of Biennial License Renewal**

8 **Phar 5.05 Renewal of Application**

9 **Phar 5.06 Reinstatement.**

10
11 **Phar 5.01 Continuing Pharmacy Education Required for Pharmacist License Renewal.**

12 (a) No pharmacist license renewal will be issued by the Board of Pharmacy
13 unless the applicant has satisfactorily completed three (3.0) continuing
14 pharmacy education units (30) hours in an approved continuing pharmacy
15 education program. (ACPE Program) or programs approved by the Board.

16
17 (b) Additional of 1.5 continuing pharmacy education units (15 hours)
18 requirement for those who fail to renew on time. Plus payment of twice
19 the amount of the renewal fee required.

20
21 (c) Suspension – Any pharmacist who repeatedly does not fulfill continuing
22 education requirements upon renewal may have their license suspended at
23 the Board’s discretion.

24
25 **Phar 5.02 Continuing Pharmacy Education Programs.**

26 (a) A continuing pharmacy education program means classes of post graduate
27 studies, informal study group participation, institutes, seminars, lectures,
28 conferences, workshops, extension study, correspondence courses,
29 teaching, planned and professional meetings, self-study courses, cassette
30 or audio-visual tape(s), slides or materials, and other self-instruction units
31 and such other methods approved by the Board.

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1. A program shall consist of pharmaceutical post-graduate education in the general areas of: therapeutics; the properties and actions of drugs and dosage forms and the etiology, characteristics and treatment of the disease state, administrative, socio-economic and legal aspects of health care. A least fifteen (15) of the required thirty (30) hours of continuing education credits must be earned in the areas of therapeutics.
 2. Programs shall provide for examination or other evaluation methods to assure satisfactory completion by participants.
 3. The person or persons who are to instruct or who are responsible for the delivery or content of the program shall be qualified in the subject matter by education, experience, or preparation, to the tasks and method of delivery.
- (b) The continuing pharmacy education programs requiring approval by the Board of Pharmacy shall meet the following requirements. Application for approval shall be made on hand in accordance with forms established by the Board. The Board shall require information relating to:
1. Name of provider or sponsor;
 2. Type of program offered;
 3. Description of subject matter;
 4. Number of clock hours offered;
 5. Method of evaluation satisfactory completion of program;
 6. Dates and location of program;
 7. Name and qualification of instructors or other persons responsible for the delivery or content of the program;
- (c) Ten clock hours of education or preparation and presentation in an

1 approved continuing pharmacy education program or programs constitutes
2 one continuing pharmacy education unit. One clock hour shall consist of
3 at least 50 minutes of education.
4

- 5 (d) Continuing pharmacy education credit accumulated in excess of the
6 required three (3.0) continuing pharmacy education units (30 hours) for
7 biennial license renewal cannot be carried forward and applied to
8 succeeding license renewal period.
9

10 **Phar 5.03 Continuing Pharmacy Education – Non-Resident – Dual Licenses.**
11

- 12 a. Any Guam licensed pharmacist residing and/or practicing in another state shall, in order
13 to receive Guam license renewal, meet Guam requirements for continuing pharmacy
14 education.
15
- 16 b. Continuing pharmacy education programs attended by Guam licensed pharmacists for
17 purposes of satisfying licensing requirements of another state, must be either ACPE or
18 approved by the Guam Board of Examiners for Pharmacy in order to be recognized for
19 purposes of renewal of Guam license.
20
- 21 c. Upon request, the Board may certify to another state’s licensing authority the status of a
22 licensee’s continuing pharmacy education participation.
23
- 24 d. The Board may request certification from another state’s licensing authority regarding the
25 status of an applicant’s continuing education.
26

27 **Phar 5.04 Notification of Biennial License Renewal.**
28

- 29 a. The Board shall mail a biennial renewal notice to all licensed pharmacists prior to
30 August 1st of each renewal year. Failure to receive renewal notice does not relieve
31 applicant from renewing.

- 1 b. The notice will state the biennial pharmacist license fee due for license renewal.
- 2 c. The notice will include the continuing pharmacy education time requirement and any
- 3 other information considered pertinent for the renewal requirements.

4

5 **Phar 5.05 Renewal of Application.**

6

- 7 a. The biennial renewal application shall be returned to the Board with the
 - 8 appropriate fee and continuing education report signed by the licensee. The
 - 9 completed form shall identify the approved continuing education program or programs
 - 10 completed, date completed, and location. The form will be filed in the licensee's
 - 11 continuing pharmacy education file. Incomplete renewal applications will not be
 - 12 processed and will be returned to the applicant with an explanatory note.
- 13
 - 14 b. The Board may randomly select submitted renewal notice forms for audit and verification
 - 15 of contents.

16

17 **Phar 5.06 Reinstatement.**

18

- 19 a. Any petitioner for a reinstatement of a license after suspension, revocation, or refusal to
 - 20 renew as provided within P. L. 24-207 and Chapter 5 of the rules and regulations of the
 - 21 Guam Board of Examiners for Pharmacy, shall produce certification of the continuing
 - 22 education requirements for all years in which the license has been suspended, revoked or
 - 23 not renewed prior to restoration of license.
- 24
 - 25 b. Retired or any pharmacist whose license has lapsed who wish reinstate their license
 - 26 shall refer to Chapter Phar 4.05 of the rules and regulations of the Guam Board of
 - 27 Examiners for Pharmacy.

1 **Chapter Phar 6**

2 **PHARMACY PERMITS AND EQUIPMENT**

3
4 **Phar 6.01 Permits; Application**

5 **Phar 6.02 Permits; Change of Location or Ownership**

6 **Phar 6.03 Changes in Pharmacist-in-Charge**

7 **Phar 6.04 Floor Design**

8 **Phar 6.05 Sanitation**

9 **Phar 6.06 Equipment**

10 **Phar 6.07 Storage**

11 **Phar 6.08 Compliance to Rules and Regulations**

12
13 **Phar 6.01 Permits; Application.**

14
15 Requirements and procedures for applying for a pharmacy permit are specified in P. L. 24-207,
16 Section 12628. Application forms are available from the Guam Board of Examiners for
17 Pharmacy. Appointments for the required pharmacy inspection may be made by calling the
18 Board office. A permit application and fee shall be on file with the Board at least 30 days prior
19 to the granting of the pharmacy permit. A pharmacy may not operate unless a pharmacy permit
20 has been granted.

21
22 **Phar 6.02 Permits; Change of Location of Ownership.**

23
24 a. A pharmacy permit authorizes a pharmacy to operate only at the location designated on
25 the permit. Permits may not be transferred to another location.

26
27 b. Any change in pharmacy ownership shall be reported to the Board office and the
28 pharmacy permit of the former owner returned. A pharmacy permit must be granted to
29 the new pharmacy owner before the pharmacy may operate.

1 **Phar 6.03 Changes in the Pharmacist-in-Charge**

2

3 The pharmacy owner shall report to the Board any change of Pharmacist-in-Charge within five
4 days following the change.

5

6 **Phar 6.04 Floor Design.**

7

8 a. Professional Service Area. The professional service area of a pharmacy shall not be less
9 than 150 sq. ft. *No more than 20% of the space may be used for storage of bulk*
10 *pharmaceuticals.* If the pharmacy is open at any time solely as a
11 nonprescription or sundry outlet, without a pharmacist present, the professional service
12 area shall be secured. A variance to the 150 sq. ft. professional service area requirement
13 may be authorized by the Board upon submission of a specific plan describing the
14 manner in which the proposed professional service area
15 plan varies from the requirement.

16

17 b. Prescription Counter Space. A pharmacy shall have a prescription counter with a free
18 working surface of 18 or more inches in depth and at least 12 square feet in area. This
19 free-working surface must be used only for the compounding and dispensing of
20 prescriptions.

21

22 c. Submit a copy of floor plan of professional service area and a copy of a security alarm
23 system contract.

24

25 d. Professional Service Area Requirements Where Pharmacist is Absent.

26

27 1. A pharmacy may convert to a non-prescription or sundry outlet without a
28 pharmacist present if the following requirements of the professional services area
29 are met:

30

31 a) A secured, physical barrier surrounds the professional service area of the

1 pharmacy and precludes access to the area by unlicensed personnel. A
2 secured barrier may be constructed of other than a solid material with a
3 continuous surface. If constructed of other than a solid material, the
4 openings or interstices in the material shall not be large enough to permit
5 removal of items from the professional service area by any means. Any
6 material used in the construction of the barrier shall be of sufficient
7 strength and thickness that it cannot be readily or easily removed,
8 penetrated or bent. The plans and specifications of the barrier shall be
9 submitted to the Board for approval.

- 10
- 11 b) The barrier is locked in the absence of the pharmacist.
- 12
- 13 c) The business hours of the prescription service area shall be plainly posted.
- 14

- 15 2. The Pharmacist-in Charge is responsible for compliance with all professional
16 service area security requirements.
- 17

18 **Phar 6.05 Sanitation.**

19

20 The professional service area of a pharmacy shall have a sink convenient and suitable for
21 cleaning pharmaceutical equipment and supplied with hot and cold running water. Detergent
22 and waste disposal and container also shall be provided in the professional service area.

23

24 **Phar 6.06 Equipment**

25 The professional service area of a pharmacy shall have the following equipment:

- 26 a. A prescription balance capable of weighing substances 5mg to 50gm to a
27 degree of accuracy within 95% - 105%.
- 28 b. One set of accurate weights capable of weighing substances of 50mg to
29 50gm.
- 30 c. A supply of transparent cylindrical graduates in metric scale capable of
31 measuring one ml to 100 ml.

- 1 d. A supply of wedge wood and glass mortars and pestles.
- 2 e. Stainless steel spatulas in assorted sizes and at least one non-metallic spatula.
- 3 f. An assortment of acid/base and solvent-resistant funnels.
- 4 g. A heating device.
- 5 h. A marble or glass ointment slab or parchment paper to prepare ointments.

6

7 **Phar 6.07 Storage**

- 8 a. The professional service area shall have a refrigerator adequate for the storage of
9 biological and other drugs requiring refrigeration. All refrigerators must be
10 equipped with thermometers in the freezer and lower compartment.
- 11 b. All storage of pharmaceuticals in professional service area must be in
12 compliance with federal and local laws and regulations.
- 13 c. The professional service area shall have sufficient shelf, drawer or cabinet space
14 for the proper storage of a representative stock of prescription labels, an assorted
15 stock of prescription containers, and an adequate stock of prescription drugs,
16 chemicals and required pharmacy equipment.
- 17 d. Controlled substances shall be stored in a securely locked, substantially-
18 constructed cabinet or dispersed throughout the inventory of non-controlled
19 substances in a manner that obstructs theft.
- 20 e. Working security alarm should be installed within the professional service area.

21

22 **Phar 6.08 Compliance to Rules & Regulations:**

23

24 All existing and new pharmacies must conform to the above rules and regulations.

25

26

27

28

29

30

31

1 **Chapter Phar 7**

2 **MANUFACTURER’S AND OTHER DRUG DISTRIBUTION PERMITS**

3
4 Licensure of pharmaceutical manufacturer who intend to manufacture in Guam shall be
5 licensed by the Guam Board of Pharmacy and shall annually renew the license with the
6 Board.

7
8 Guam Board of Pharmacy shall license any FDA-approved manufacturer, including its
9 affiliates, subsidiaries, agents and other entities under common ownership and control of
10 the manufacturer, that exclusively distributes its own FDA-approved prescription drug
11 and/or biologic product, and that has not left the manufacturer’s chain of custody, and
12 shall comply with all Federal and local laws and regulations prior to issuance of license
13 to manufacture.

14
15 For further information and regulations, refer to the following website:

16 <http://www.fda.gov/cder/dmpq/cgmpregs.htm>

1 **Chapter Phar 8**
2 **PHARMACY PRACTICE**
3

- 4 **Phar 8.01 Minimum Procedures for Compounding and Dispensing**
5 **Phar 8.02 Prescription Label; Name of Drug or Drug Product Dispensed**
6 **Phar 8.03 Prescription Renewal Limitations**
7 **Phar 8.04 Return or Exchange of Drugs Prohibited**
8 **Phar 8.05 Prescription Records**
9 **Phar 8.06 Complete Pharmaceutical Service**
10 **Phar 8.07 Public Health Emergencies**

11
12 **Phar 8.01 Minimum Procedures for Compounding and Dispensing**
13

- 14 1. Except as provided in sub.(4), a pharmacist who compounds or dispenses according to a
15 prescription order shall follow the procedures described in this rule and other applicable
16 procedures.
17

18 The pharmacist or intern shall:

- 19 a. Receive oral or written prescription orders of a prescriber, review all original and
20 renewal prescription orders, written or oral, and determine therapeutic
21 compatibility and legality of the prescription order. The review shall include,
22 when indicated or appropriate, consultation with the prescriber.
23
- 24 b. Read and interpret a prescriber's directions for use for the purpose of accurately
25 transferring the instructions to the prescription label.
26
- 27 c. Select, compound, mix, combine, measure, count and otherwise prepare drugs
28 needed to dispense a prescription except that an agent of the pharmacist may
29 procure, measure or count prefabricated dosage forms if a pharmacist verifies
30 accuracy of the agent's action.
31

- 1 d. Make a final check on the accuracy and correctness of the prescription. For
2 all original and renewed prescriptions, the prescription order shall identify the
3 pharmacist responsible for the prescription.
4
- 5 e. Transfer the prescription to the patient or agent of the patient and give the patient
6 or agent appropriate consultation relative to the prescription except that
7 prescriptions may be delivered by an authorized agent of the pharmacist to a
8 patient's residence if the delivery is accompanied by appropriate directions and
9 an indication that consultation is available by contacting the pharmacist.
10
- 11 f. Obtain, when required by law and standard professional practice, permission to
12 renew from authorized prescriber, and note on the reverse side of the prescription
13 order or a medication profile or a readily retrievable log book the following data:
14 1) Date renewed.
15 2) Name of practitioner authorizing renewal, if different from the original
16 prescriber.
17 3) Quantity of drug dispensed.
18 4) Identification of the pharmacist renewing the prescription.
19
- 20 2. Sub. (1)(d) and (e) does not prohibit institutional pharmacists or community pharmacists
21 serving institutions from receiving prescription orders, dispensing and returning
22 prescription medications consistent with accepted inpatient institutional drug distributions
23 systems. Sub (1) applies to any institutional pharmacy dispensing to outpatients,
24 including prescriptions for discharged patients.
25
- 26 3. A pharmacist may supervise no more than one pharmacy intern and (3) non-
27 pharmacists engaged in compounding and dispensing activities as described in sub (1),
28 except a higher ratio may be authorized by the Board upon request to and approval by the
29 Board of a specific plan describing the manner in which additional interns or non-
30 pharmacists shall be supervised.
31

1 4. A system for compounding and dispensing not in conformance with subs. (1) to (3) may
2 be used if reviewing and approved by the Board.

3

4 **Phar 8.02 Prescription label; Name of Drug or Drug Product Dispensed**

5

6 All prescriptions drugs dispensed by a pharmacy pursuant to a prescription shall be properly
7 labeled and contain the following information.

8 1) The name, address and phone number of the dispensing pharmacy.

9 2) The number under which the prescription is filed in the pharmacy.

10 3) The prescribing physician's name.

11 4) The name of the person for whom the drug was prescribed.

12 5) The date filled

13 6) The name (generic or proprietary) of the medication.

14 7) The directions for use.

15 8) The date of expiration of the effectiveness of the drug if this information is
16 required on the original label of the manufacturer.

17

18 **Phar 8.03 Prescription Renewal Limitations**

19

20 A prescription order for any drug other than controlled substances, which bears renewal
21 authorization permitting the pharmacist to renew the prescription as needed by the
22 patient, may not be renewed beyond one year from the date originally prescribed. If
23 additional medication is needed, the original order shall be voided and a new one
24 obtained after the one year period.

25

26 **Phar 8.04 Return or Exchange of Drugs Prohibited**

27 1) No drugs, medicines or items of personal hygiene, after taken from a pharmacy where
28 sold, distributed or dispensed, may be returned to that pharmacy. Except, a healthcare
29 facility may return them to the pharmacy provided they are in their original containers
30 and the pharmacist determines the contents are unadulterated and uncontaminated.

31

- 1 2) Each pharmacy shall post a sign that states “ No Drugs, Medicines or items of
2 personal hygiene, after taken from a pharmacy may be returned.”
3

4 **Phar 8.05 Prescription Records**

- 5 1) A record of prescription dispensed shall be maintained for a period of five years
6 after the date of the last renewal.
- 7 2) A record of all prescriptions renewed shall be maintained by indicating on the
8 original prescription order or on a readily retrievable medication profile record or
9 log book the date and amount of the renewal.
- 10 3) The transfer of original prescription information for the purpose of refill
11 dispensing is permissible between two pharmacies pursuant to the following
12 requirements:
- 13 a) The transfer is communicated directly between two pharmacists and the
14 pharmacist making the transfer records the following information.
- 15 1) The name and address of the pharmacy to which it is transferred,
16 the name of the pharmacist receiving the prescription, the date and
17 the name of the pharmacist transferring the information.
- 18 2) The pharmacist receiving the transferred information shall record
19 in writing the following:
- 20 a) The date of issuance of the original prescription order.
21 b) The date the prescription was dispensed originally.
22 c) The number of valid refills remaining.
23 d) The date of the last refill.
24 e) The pharmacy name, address, the original prescription
25 number from which the prescription was transferred.
26 f) The name of the pharmacist making the transfer.
- 27 b) The original and transferred prescription order shall be maintained for a
28 period of five years from the date of the last refill.
29
30

31 **Phar 8.06 Complete Pharmaceutical Service**

1 Complete pharmaceutical service including compounded prescriptions, shall be available
2 to the public normally served by the pharmacy.

3

4 **Phar 8.07 Public Health Emergencies**

5 **1. Purpose and Scope**

6 By the provision of these rules by the Board, the primary purpose of the section is to
7 enable Pharmacists and Pharmacies to assist in the management and containment of a
8 Public Health Emergency or similar crisis within the confines of a regulatory framework
9 that serves to protect the welfare and health of the public

10

11 **2. Definitions.**

12

13 ***“Declared Disaster Areas”*** are areas designated by state or federal authorities as those
14 that have been adversely affected by a natural or man-made disaster and require extraordinary
15 measures to provide adequate, safe, and effective health care for the affected population.

16

17 ***“Emergency Prescription Drug Order”*** means a standing Prescription Drug Order issued
18 by the State Health Officer for Pharmacists to Dispense designated Prescription Drugs during a
19 Public Health Emergency requiring mass Dispensing to expeditiously treat or provide
20 prophylaxis to large numbers of Patients.

21

22 ***“Mobile Pharmacy”*** means a Pharmacy that is self propelled or movable by another
23 vehicle that is self propelled.

24

25 ***“Public Health Emergency”*** means an imminent threat or occurrence of an illness or
26 health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and
27 highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a
28 substantial risk of a significant number of human fatalities or incidents of permanent or long-
29 term disability that is beyond the capacity of local government or nongovernmental
30 organizations to resolve.

1 **“State of Emergency”** means a governmental declaration, usually issued as a result of a
2 Public Health Emergency, that may suspend certain normal functions of government, alert
3 citizens to alter their normal behaviors, and/or direct government agencies to implement
4 emergency preparedness plans.

5
6 **“Temporary Pharmacy Facility”** means a facility established as a result of a Public Health
7 Emergency or State of Emergency to temporarily provide Pharmacy services within or adjacent
8 to Declared Disaster Areas.

9
10 **3. Emergency Prescription Drug Order**

11 (A) For the duration of a State of Emergency issued due to a Public Health Emergency, a
12 Pharmacist may Dispense a Prescription Drug pursuant to an Emergency Prescription Drug
13 Order if the Pharmacist:

- 14 (1) performs, to the extent possible, a Prospective Drug Regimen Review and Patient
15 Counseling in accordance with these rules;
16 (2) reduces the information to a form that may be maintained for the time required by
17 law or rule, indicates it is an “Emergency Prescription Drug Order,” and files and
18 maintains the record as required by state and federal law.

19
20 **4. Public Health Emergency Refill Dispensing**

21 (A) For the duration of the State of Emergency issued due to a Public Health Emergency in
22 the affected state and in other states engaged in disaster assistance pursuant to a governmental
23 declaration or rule of the Board, a Pharmacist may Dispense a refill of a Prescription Drug, not
24 to exceed a thirty (30) day supply, without Practitioner authorization if:

- 25 (1) in the Pharmacist’s professional judgment, the Prescription Drug is essential to
26 the maintenance of the Patient’s life or to the continuation of therapy;
27 (2) the Pharmacist makes a good faith effort to reduce the information to a form that
28 may be maintained for the time required by law or rule, indicates it is an
29 “Emergency Refill Prescription,” and maintains the record as required by state
30 and federal law, as well as state and federal disaster agencies for consideration for

1 possible reimbursement programs implemented to ensure continued provision of
2 care during a disaster or emergency; and

- 3 (3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing
4 that the Prescription Drug is being provided without the Practitioner's
5 authorization and that authorization of the Practitioner is required for future
6 refills.

7
8 (B) For the duration of the State of Emergency, in an effort to provide patients with the best
9 possible care in light of limited Drug availability and/or limited information on patients' current
10 Drug therapy, a Pharmacist may initiate or modify Drug therapy and Dispense an amount of such
11 Drug to accommodate a patient's health care needs until that patient may be seen by a
12 Practitioner. Pharmacists performing such activities must utilize currently accepted standards of
13 care when initiating or modifying Drug therapy. These activities may be undertaken if:

- 14 (1) in the Pharmacist's professional judgment, the Prescription Drug is essential to
15 the maintenance of the Patient's life or to the continuation of therapy;
16 (2) the Pharmacist makes a good faith effort to reduce the information to a form that
17 may be maintained for the time required by law or rule, indicates that drug therapy has
18 been initiated or modified due to a disaster or emergency, and maintains the record as
19 required by state and federal law; and

- 20 (3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing
21 that the Prescription Drug is being provided without the Practitioner's
22 authorization and that authorization of the Practitioner is required for future
23 refills.

24 (C) The Practitioner and Pharmacist shall not incur any liability as a result of the performance
25 of these activities in good faith pursuant to this section.

26
27 **5. Temporary Recognition of Non-Resident Licensure**

28 (A) When a State of Emergency is declared due to a Public Health Emergency:

- 29 (1) a Pharmacist not licensed in this State, but currently licensed in another

1 state, may Dispense Prescription Drugs in areas affected by the Declared
2 Disaster during the time that the State of Emergency exists if:

3 (a) the Board can verify current licensure in good standing of
4 the Pharmacist directly with the state or indirectly via a third-party
5 verification system; and

6 (b) the Pharmacist is engaged in a legitimate relief effort.

7 (2) a Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy
8 Intern not registered or licensed in this State, but currently registered or
9 licensed in another state, may assist the Pharmacist in Dispensing
10 Prescription Drugs in affected Disaster Areas during the time that the State
11 of Emergency exists if:

12 (a) the Board can verify current registration or licensure in good
13 standing of the Certified Pharmacy Technician, Pharmacy
14 Technician, or Pharmacy Intern directly with the state or indirectly
15 via a third-party verification system; and

16 (b) the Certified Pharmacy Technician, Pharmacy Technician, or
17 Pharmacy Intern is engaged in a legitimate relief effort.

18
19 (3) a Wholesale Drug Distributor not licensed in this State, but currently
20 licensed in another state, may Distribute Prescription Drugs in affected
21 Disaster Areas during the time that the State of Emergency exists if:

22 (a) the Board can verify current licensure in good standing of the
23 Wholesale Drug Distributor directly with the state or indirectly via a third-
24 party verification system; and

25 (b) the Wholesale Drug Distributor is engaged in a legitimate relief
26 effort.

27
28 (4) the temporary recognition of non-resident licensure or registration shall
29 cease with the termination of the State of Emergency.

30
31

1 **6. Temporary Pharmacy Facilities or Mobile Pharmacies**

2 (A) Pharmacies located in Declared Disaster Areas, non-resident Pharmacies, and Pharmacies
3 licensed in another state but not licensed in this State, if necessary to provide Pharmacy services
4 during a State of Emergency, may arrange to temporarily locate or relocate to a Temporary
5 Pharmacy Facility or Mobile Pharmacy if the Temporary Pharmacy Facility or Mobile
6 Pharmacy:

7 (1) is under the control and management of the Pharmacist-in Charge or designated
8 supervising Pharmacist;

9 (2) is located within the Declared Disaster Area or affected areas;

10 (3) notifies the Board of its location;

11 (4) is properly secured to prevent theft and diversion of Drugs;

12 (3) maintains records in accordance with laws and regulations of the state in which
13 the disaster occurred; and

14 (6) ceases the provision of services with the termination of the State of Emergency,
15 unless it is successfully licensed by the Board of Pharmacy in accordance to the
16 Board rules.

17 (B) The Board, in accordance with Board rules, shall have the authority to approve or
18 disapprove Temporary Pharmacy Facilities and Mobile Pharmacies and shall make arrangements
19 for appropriate monitoring and inspection of the Temporary Pharmacy Facilities and Mobile
20 Pharmacies on a case-by-case basis. Approval of Temporary Pharmacy Facilities and Mobile
21 Pharmacies will be based on the need, type, and scope of Public Health Emergency, as well as
22 the ability of the Temporary Pharmacy Facilities or Mobile Pharmacies to comply with state and
23 federal drug law.

24 (C) A Temporary Pharmacy Facility wishing to permanently operate at its temporary site
25 must be licensed by the Board of Pharmacy in accordance with the Board rule .

26 (D) Mobile Pharmacies, placed in operation during a State of Emergency, may not operate
27 permanently, unless approved by the Board.

28
29
30
31

1 **Chapter Phar 9**
2 **CONTROLLED SUBSTANCES**

3
4 **REQUIREMENTS FOR CONTROLLED SUBSTANCES**

- 5
- 6 1. The Board from time to time may monitor a pharmacy for violations of federal
7 and government laws and make referrals of such violations as necessary to the
8 food and Drug Administration or the Department of Public Health and Social
9 Services. All controlled substances will require a Prescription Drug Order.
- 10
- 11 2. All individual or entities licensed by the Board shall comply with Guam
12 Controlled Substances Act P.L. 24-149, Title 9, Chapter 67, Article 3 and the
13 Federal Controlled Substance Act.
- 14
- 15 3. Prescription of controlled substances should be written by a practitioner who is
16 registered by the Federal Drug Enforcement Administration and Guam Controlled
17 Substance Division. Guam Memorial Hospital emergency room physicians'
18 prescription for a controlled substance may use the hospital's DEA number but
19 must have a hospital ER number.
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1 **Chapter Phar 10**

2 **PHARMACY TECHNICIANS AND SUPPORTIVE PERSONNEL**

3
4 **Phar 10.01 Definitions**

5 **Phar 10.02 Requirements**

6 **Phar 10.03 Supportive Personnel**

7 **Phar 10.04 Registration of Pharmacy Technician**

8 **Phar 10.05 Ratios**

9 **Phar 10.06 Sterile Pharmaceuticals**

10
11 **Phar 10.01 Definitions**

12
13 *Pharmacy Technician “Tech”, “Rx Tech”* means those individuals who have been issued a
14 permit by the Board, utilized in pharmacies whose responsibility it shall be to provide technical
15 services that do not require professional judgement and distribution of drugs under the direct
16 supervision of and responsible to a pharmacist.

17
18 *Supportive Personnel* means all persons other than Pharmacist/Intern/ Technicians paid
19 regularly, who performs tasks that does not require license, certificate or permits.

20
21 *Certified Pharmacy Technician* means a person who has been certified by a nationally-
22 recognized Technician certification organization approved by the Board.

23
24 **Phar 10.02 Requirements**

25 All pharmacy technicians and supportive personnel shall have a high school or equivalent
26 degree, e.g. GED or be currently enrolled in a program which awards such a degree.

27
28 **Phar 10.03 Supportive Personnel**

29 A. Training

30 Supportive personnel training shall be outlined in a training manual. Such training manual
31 shall, at a minimum, contain the following:

- 1 a. written procedures and guidelines for the use and supervision of supportive
2 personnel . Such procedures and guidelines shall:
3
- 4 i. specify the manner in which the pharmacist responsible for the supervision
5 of personnel will supervise such personnel and verify the accuracy and
6 completeness of all acts, tasks and functions performed by such personnel;
7 and,
 - 8 ii. specify duties which may and may not be performed by supportive
9 personnel;
- 10 b. instruction in the following areas and any additional areas appropriate to the
11 duties of supportive personnel in the pharmacy;
- 12 i. Orientation
 - 13 ii. Job descriptions
 - 14 iii. Communication techniques
 - 15 iv. Laws and rules
 - 16 v. Security and safety
 - 17
 - 18 vi. Prescription drugs:
 - 19 a) Basic pharmaceutical nomenclature
 - 20 b) Dosage forms
 - 21 vii. Prescription drug orders:
 - 22 a) Prescribers
 - 23 b) Directions for use
 - 24 c) Commonly-used abbreviations and symbols
 - 25 d) Number of dosage units
 - 26 e) Strengths and systems of measurement
 - 27 f) Routes of administration
 - 28 g) Frequency of administration
 - 29 h) Interpreting directions for use
 - 30 viii. Prescription drug order preparation:
 - 31 a) Creating or updating patient medication records

1 v. entering medication order and drug distribution information into a data processing
2 system, provided judgmental decisions are not required and a pharmacist checks
3 the accuracy of the information into the system prior to releasing the order.
4

5 vi. loading bulk unlabeled drugs into an automated compounding or drug dispensing
6 system provided a pharmacist supervises, verifies that the system was properly
7 loaded prior to use, and affixes his or her signature (first initial and last name or
8

9 C. Limitations

10 Supportive personnel shall not:

- 11 (1) receive new prescription orders verbally from a licensed practitioner or the
12 practitioner's agent
13
- 14 (2) consult with a patient or the patient's agent regarding medication, either
15 before or after it has been dispensed, or regarding any medical information
16 contained in a patient medication record system
17
- 18 (3) perform any identification, evaluation, interpretation or needed
19 clarification of a prescription
20
- 21 (4) consult with the licensed practitioner or the practitioner's agent regarding
22 a patient or any medication information pertaining to the patient's prescription
23 prescription
24
- 25 (5) interpret the clinical data in a patient medication record system
26
- 27 (6) perform professional consultation with licensed practitioners, nurses or other
28 health care professionals or their authorized agent
29
- 30 (7) verify a prescription prior to its release for patient use
31

- 1 (8) determine generically and therapeutically equivalent drug products to be
- 2 substituted for brand name products
- 3
- 4 (9) may not call physician for refill authorization if there are any changes to the
- 5 prescription and/ or if the professional consultation is involved, the pharmacist
- 6 must handle the call
- 7
- 8 (10) transfer prescription from one pharmacy to another
- 9

10 **Phar 10.04 Registration of Pharmacy Technician**

11 No person may perform the duties of a pharmacy technician until he has been

12 issued a certificate of registration signed by the Chairman of the Guam Board of

13 Examiners for Pharmacy. Upon receipt of an application and the required fee, the Board,

14 unless they had good cause to deny the registration , shall issue a registration certificate

15 to the pharmacy technician.

16

17 (A) Requirement

18 An applicant for registration as a pharmacy technician must:

- 19 (a) Be 18 years of age or older
- 20 (b) Be a high school graduate or equivalent degree, ex. GED or be currently
- 21 enrolled in a program which awards such a degree
- 22 (c) Not have been convicted of any felony or a misdemeanor involving moral
- 23 turpitude, dishonesty or the unlawful possession, sale or use of drugs.
- 24 (d) Have no history of drug abuse
- 25 (e) Be certified pharmacy technician by a national organization approved by
- 26 the Board or have undergone a training program approved by the Board
- 27 (f) Complete Board requirement of practical experience

28

29 (B) Duties of Pharmacy Technician

30 A pharmacy technician under the direct supervision of a pharmacist may:

- 1 a) prepackage and label unit dose and unit of use and repackage drugs if a pharmacist
2 inspects the final product and affixes his initials to the appropriate records for
3 controlling quality
- 4 b) prepare, package, compound and label prescription drugs pursuant to prescriptions or
5 order of medications, if a pharmacist inspect the preparation.
- 6 c) Mix drugs with parenteral fluids, if pharmacist inspects the final product and affixes
7 his initials to the appropriate records controlling for quality.
- 8 d) Prepare bulk compounds if a pharmacist inspects the final product and affixes his
9 initials to the appropriate records for controlling quality.
- 10 e) Distribute routine orders and stock medications and supplies in the pharmacy or areas
11 where care is provided to patients.
- 12 f) Maintain inventories of supplies of drugs.
- 13 g) Maintain pharmaceutical records.
- 14 h) Request authorization to refill a prescription from the prescribing practitioner.
- 15 i) To ensure the continuing competency of a technician, a proof of 2.0 units (20 hours)
16 of continuing education from a nationally-accredited program approved by the Board
17 must be submitted upon renewal of registration every two (2) years.

18

19 C) Limitations

20 A pharmacy technician may not:

- 21 1) Perform any action requiring a judgmental decision regarding a drug, the
22 interpretation of a prescription or the instructions for the preparation of a
23 prescription.
- 24 2) Take new prescription or chart order by telephone.
- 25 3) Distribute medications pursuant to a chart order or dispense a prescription
26 unless the order or prescription has been verified by a pharmacist
- 27 4) Transfer prescriptions from one pharmacy to another

28

29 D) Training of Candidates for Registration

- 30 1) A person may perform the duties of a pharmacy technician while he is receiving the
31 training and experience

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- 2) The pharmacist-in-charge of the pharmacy where a candidate in training is employed to receive the training and experience, shall file with Board a signed affidavit certifying:
 - a) the number of hours of training and experience the trainee has successfully completed (minimum of 1500 hours).
 - b) the specific training and experience the trainee has completed.
 - c) that the trainee is competent to perform the duties of a pharmacy technician

Phar 10.05 Ratios

- a. The ratio of pharmacists to pharmacy technicians may not exceed 1:2
- b. The ratio of pharmacists to pharmacy technicians may be 1:3 provided that at least one of the three technicians is certified. Section 21a-308-8. The ratio of supportive personnel to licensed pharmacists shall not exceed two supportive personnel to one supervising licensed pharmacist, except that for intravenous admixtures and other sterile products preparation, unit dose and unit of use dispensing and bulk compounding, the ratio shall not exceed three supportive personnel to one supervising licensed pharmacist.

Phar 10.06 Sterile pharmaceuticals

- a. Only pharmacy technicians who have completed the training may compound sterile pharmaceuticals pursuant to medication orders providing a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (the initials are not required on the label if it is maintained in a permanent record of the pharmacy).
- b.. Only pharmacy technicians who are certified and who have completed the training may compound sterile pharmaceuticals pursuant to medication orders providing a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not

1 required on the label if it is maintained in a permanent record of the pharmacy). May
2 compound only if pharmacist verifies the final product for accuracy, efficacy, patient
3 utilization and has a mechanism to verify the measuring of active ingredients. In addition,
4 a pharmacy technician may type a prescription label, enter data into a computer record
5 system and obtain a prescription refill authorization.

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1 **Chapter Phar 11**
2 **DRUG SUPPLIER PERMITS**
3

4 **Phar 11.01 Definitions**

5 **Phar 11.02 Drug Supplier Requirements**

6 **Phar 11.03 Registration**

7 **Phar 11.04 Fees**

8 **Phar 11.05 Expiration Date**

9 **Phar 11.06 Change of Location of Place of Business**

10
11 **Phar 11.01 Definitions**
12

13 The following words or terms, when used in this Subchapter, shall have the following meaning,
14 unless the context clearly indicates otherwise:
15

16 ***“Drug supplier”*** means a licensed retail pharmacy or wholesaler or distributor which supplies
17 legend drugs to licensed practitioners for their office administration and/or which supplies legend
18 drugs to hospitals and other licensed pharmacies for their dispensing.
19

20 ***“Legend drugs”*** means including, but not limited to, drugs, medicines, poison, and/or chemicals
21 which bear the legend “Caution: Federal Law Prohibits Dispensing Without Prescription” or
22 “RX only”, or any other label FDA may require which restricts drugs to dispensing with a
23 practitioner’s prescription.
24

25 ***“Licensed practitioner”*** means a physician, dentist, podiatrist, osteopathic physician,
26 veterinarian, or optometrist , or licensed health practitioner licensed by law to prescribe and
27 administer within the scope of their practice.
28

29 ***“Wholesale distribution”*** means distribution to a person other than a consumer or patient, and
30 includes distribution by a manufacturer, repacker, own label distributor, jobber, or wholesaler or
31 as indicated in the Guam Pharmacy Act.

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“*Place of business*” means each location at which a drug for wholesale distribution is located.

Phar 11.02 Drug Supplier Requirements.

- (a) **Permit eligibility.** In order to obtain and maintain a drug supplier permit in Guam, the applicant must have a valid business license and Guam Board of Pharmacy license.
- (b) **Total annual sales.** The total annual sales of the drug supplier shall not exceed five percent (5%) of the total annual sales of the pharmacy.
- (c) **Records.** Separate records of sales will be kept on file by the permitted establishment for period of minimum of 5 years. The files will include, but not be limited to, invoices of sales with name and address of purchaser, quantity sold, drug description, price, and date of transaction, These files must be readily available for inspection.
- (d) **Controlled Dangerous Substances.** Sales of controlled dangerous substances must conform with statutes and regulations of the Guam Controlled Substances Division, Department of Environmental Health , the Federal Drug Enforcement Administration and/or any other federal, state of municipal laws, ordinances or regulations.

Phar 11.03 Registration

The registration statement must contain :

- (1) the name under which the business is conducted;
- (2) the address of each place of business in this state that is registered;
- (3) the name and residence address of:
 - (A) the proprietor, if the business is a proprietorship;
 - (B) all partners, if the business is a partnership; or

- 1 (C) all principals, if the business is an association;
2 (4) the date and place of incorporation, if the business is a corporation;
3 (5) the names and residence addresses of the individuals in an administrative capacity
4 showing:
5 (A) the managing proprietor, if the business is a proprietorship;
6 (B) the managing partner, if the business is a partnership;
7 (C) the officers and directors, if the business is a corporation; or
8 (D) the persons in a managerial capacity, if the business is an association; and
9 (6) the residence address of an individual in charge of each place of business in this
10 state.

11
12 **Phar 11.04 Fees**

- 13 (a) The Board shall collect fees for:
14 (1) a registration that is filed or renewed
15 (2) a registration that is amended, including a notification of a change in the location
16 of a registered place of business
17 (3) an inspection performed in enforcing this subchapter and rules adopted under this
18 subchapter.
19 (b) The Board may charge annual fees
20 (c) The Board by rule shall set the fees as prescribed by law.
21 (1) reviewing and acting on a registration;
22 (2) amending and renewing registration;
23 (3) inspecting a registered facility; and
24 (4) implementing and enforcing this subchapter, including a rule or order adopted or
25 a registration issued under this subchapter.

26
27 **Phar 11.05 Expiration Date**

- 28 (a) The Board by rule may provide that registrations expire on September 30 of every year.
29 (b) If the Board changes a registration expiration, the board shall prorate the registration fee
30 payable to on or before September 1 so that the registration is required to pay only that
31 portion of the fee that is allocable to the number of months during which the registration

1 is valid.

2 (c) The total renewal registration fee is payable when the registration is renewed on the new
3 expiration date.

4

5 **Phar 11.06 Change of Location of Place of Business**

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7 The registrant shall notify the Board in writing of a change in the location of a registered
8 place of business, including the address of the new location, and the name and residence address
9 of the individual in charge of the business at the new location. Permits are non-transferable from
10 one location to another.

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1 **Chapter Phar 12**

2 **PARENTERAL PHARMACY PERMITS**

- 3
- 4 **Phar 12.01 Scope and Purpose**
- 5 **Phar 12.02 Definitions**
- 6 **Phar 12.03 Parenteral Permit Requirements**
- 7 **Phar 12.04 Permit Issuance**
- 8 **Phar 12.05 Policy and Procedure Manual**
- 9 **Phar 12.06 Parenteral Pharmacy Physical Requirements**
- 10 **Phar 12.07 Manager**
- 11 **Phar 12.08 Pharmacist Accessibility**
- 12 **Phar 12.09 Drug Distribution and Control**
- 13 **Phar 12.10 Cytotoxic Drugs**
- 14 **Phar 12.11 Quality Assurance**
- 15 **Phar 12.12 Pharmacist Manager Responsibility**

16

17 **Phar 12.01 Scope and Purpose.**

18 The rules of this Subchapter provide standards for the preparation, labeling, and
19 distribution of sterile therapeutic preparations by licensed retail pharmacies, pursuant to an order
20 or prescription. These standards are intended to apply to all compounded sterile therapeutic
21 preparations, notwithstanding the location of the patient.

22

23 **Phar 12.02 Definitions.**

24 The following words or terms, when used in this Subchapter, shall have the following
25 meaning, unless the context clearly indicates otherwise:

26 **“Biological safety cabinet” or “Class II safety cabinet”** means a containment unit
27 suitable for the preparation of low to moderate risk agents where there is a need for protection of
28 the product, personnel, and environment, according to NSF Standard 49.

29 **“Class 100 environment”** means an atmospheric environment which contains less than
30 100 particles 0.5 micrometers and larger in diameter per cubic foot of air, according to Federal
31 Standard 209E et seq.

1 “*Cytotoxic Agent*” means a pharmaceutical that has the capability of killing living cells.

2 “*Federal Standard 209E et seq*” means the U.S. Supply Service, General Services
3 Administration (GSA) federal standard for “Airborne Particulate Classes in Clean Rooms and
4 Clean Zones”.

5 “*National Safety Foundation*” or “*NSF*” means the foundation that certifies that
6 Biological or Class II safety cabinets meet NSF Standard 49.

7 “*Parenteral*” means a sterile preparation for injection through one or more layers of the
8 skin.

9 “*Parenteral pharmacy*” means a licensed retail pharmacy with an additional specialized
10 board-approved parenteral permit to allow the compounding and dispensing of sterile therapeutic
11 preparations by a Guam licensed registered pharmacist pursuant to a prescription order.

12 “*Sterile therapeutic preparations*” means preparations for parenteral therapy, parental
13 nutrition and/or sterile preparations of cytotoxic or antineoplastic nutrition and/or sterile
14 preparations of and/or sterile solutions for nebulization, which are free from living micro-
15 organisms (aseptic).

16
17 **Phar 12.03 Parenteral Permit Requirements.**

18 The following are required to obtain and maintain a parenteral pharmacy permit:

- 19 (1) **Valid retail license.** The applicant must have a valid retail pharmacy license.
20 (2) **Equipment and supplies.** The pharmacy must have the required equipment and
21 supplies pursuant to the rules and regulations of the Guam Board of Examiners for
22 Pharmacy regarding parenteral pharmacy permits.
23 (3) **Manager.** The pharmacy manager of a parenteral pharmacy will have sufficient
24 knowledge, education and /or experience in the practice of parenteral pharmacy.

25
26 **Phar 12.04 Permit Issuance.**

- 27 (a) **Required permit.** A parenteral pharmacy permit will be required of all pharmacies
28 practicing parenteral pharmacy beginning July 1, 200_.
29 (b) **Fee.** The parenteral permit fee will be set by the Board.
30 (c) **Renewal.** The parenteral pharmacy permit will be renewed annually with the retail
31 pharmacy license.

1 **Phar 12.05 Policy and Procedure Manual.**

2 (a) **Availability.** To obtain a parenteral pharmacy permit, a policy and procedure manual as
3 it relates to sterile therapeutic preparations and services that are provided shall be available for
4 inspection at the pharmacy location.

5 (b) **Review.** The policy and procedure manual shall be reviewed and/or revised on an annual
6 basis. A copy of the policy and procedure manual shall be available for inspection and submitted
7 to the Board upon request by the Board.

8 (c) **Pre-approved by the Board of Examiners for Pharmacy.** The Guam Board of
9 Examiners
10 for Pharmacy may choose to pre-approve all policy and procedure manuals prior to inspection of
11 the parenteral pharmacy area.

12
13 **Phar 12.06 Parenteral Pharmacy Physical Requirements.**

14 (a) **Area.** The parenteral pharmacy shall have an area designated for the preparation of
15 sterile therapeutic preparations. This area must be designated to avoid unnecessary traffic and
16 airflow disturbances from activities within the controlled facility. It shall be used only for the
17 preparation of sterile therapeutic preparations. It shall be of sufficient size to accommodate a
18 laminar airflow hood and to provide for the proper access of drugs and supplies under
19 appropriate conditions of temperature, light, moisture, sanitation, ventilation and security.

20 (b) **Equipment and Supplies.** The parenteral pharmacy shall contain the following
21 equipment and supplies:

22 (1) Appropriate environmental control devices capable of maintaining at least Class
23 100 environmental conditions in the work space where critical objects are exposed and
24 critical activities are performed during normal activity. Examples of appropriate devices
25 include laminar airflow hoods and zonal flow of HEPA-filtered air. These products
26 should indicate that they meet Federal Standard 209E et seq.;

27 (2) Sink with hot and cold running water which is convenient to the compounding
28 area for the purposes of hand scrubs prior to compounding;

29 (3) Appropriate disposal container for used needles, syringes, etc., and if applicable,
30 appropriate disposal containers for cytotoxic waste from the preparation for
31 chemotherapy agents, and infectious wastes from the patients' homes;

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(c) **Access.** For security purposes, no one may have access to the parenteral pharmacy in the absence of a Guam registered pharmacist.

(d) **Reference Materials.**

(1) The parenteral pharmacy shall have , in addition to the library reference material required for retail licensure, one or more reference materials from the following list;

(A) Handbook of Injectable Drugs (ASHP reports)

(B) King’s Guide to Parenteral Admixtures

(C) Procedures for Handling Cytotoxic Drugs (ASHP)

(2) The following information is for reference purposes only, these standards are not required to be maintained by or in the pharmacy,

(A) The NSF Standard 49 may be obtained from the National Safety Foundation in Ann Arbor, MI, (734) 769-8010.

(B) The Federal Standard 209E et seq. may be obtained from General Services Administration of the Institute of Environmental Sciences, Mount Prospect, IL, (708) 255-1561.

Phar 12.07 Manager

Each parenteral pharmacy shall be managed by a pharmacist who is licensed to practice pharmacy in Guam, and who is knowledgeable in the specialized functions of compounding, preparing and dispensing sterile therapeutic preparations, including the principles of aseptic technique and quality assurance. This knowledge may be obtained through residence training programs, continuing education programs and /or experience in an infusion admixture facility.

Phar 12.08 Pharmacist Accessibility.

A qualified pharmacist shall be accessible at all times at each parenteral pharmacy to respond to patients and other health professionals relative to questions and needs. A 24-hour telephone will be provided.

Phar 12.09 Drug Distribution and Control.

(a) **Labeling.** Each therapeutic preparation dispensed to patients by a parenteral pharmacy

1 shall be labeled with the following information with a permanent label;

2 (1) Name, Address, and telephone number of the pharmacy;

3 (2) Date and prescription number;

4 (3) Patient's name;

5 (4) Name, strength, and amount of each drug;

6 (5) Directions for use, including infusion rate where applicable;

7 (6) Prescriber's name;

8 (7) Required controlled substances transfer warnings, where applicable;

9 (8) Date of compounding;

10 (9) Expiration date and time;

11 (10) Identity of pharmacist compounding and dispensing;

12 (11) Storage requirements;

13 (12) Auxiliary labels, where applicable;

14 (13) Cytotoxic drug auxiliary labels, where applicable.

15 (b) **Records and Reports.** The pharmacy shall maintain access to and submit, as
16 appropriate, such records and reports as are required to patient health, safety and welfare.
17 Such records shall be readily available, maintained in accordance with federal, state and
18 municipal law and regulation, and subject to inspection by the Board of Pharmacy or its agents.
19 Information regarding individual patients shall be maintained in a manner to assure
20 confidentiality of the patient's record. Release of this information shall be in accordance with
21 federal, state, or municipal laws and/ or regulations.

22 (c) **Delivery Service.** The pharmacy manager shall assure the environmental control of all
23 products shipped. Therefore, any compounded, sterile pharmaceutical must be shipped in
24 appropriate containers to insure minimal temperature fluctuation (as defined by USP standards),
25 and stored appropriately in the patient's home. Chain of possession for the delivery of Schedule
26 II
27 controlled substances via courier must be documented.

28 (d) **Disposal of Infectious Waste.** The pharmacy manager is responsible for assuring that
29 there is a system for the disposal of infectious waste in a manner so as not to endanger the public
30 health.

31 **Phar 12.10 Cytotoxic Drugs.**

1 The following additional requirements are necessary for those parenteral pharmacies that
2 prepare cytotoxic drugs to insure the protection of the personnel involved and the public health:

- 3 (1) All cytotoxic drugs shall be compounded in a vertical flow, Class II biological
4 safety cabinet. Other products shall not be compounded in this cabinet unless proper
5 cleaning procedures have been followed prior to each occurrence.
- 6 (2) Protective apparel shall be worn by personnel compounding cytotoxic agents.
- 7 (3) Appropriate safety and containment techniques for compounding cytotoxic drugs
8 shall be used in conjunction with the aseptic techniques required for preparing
9 sterile products.
- 10 (4) Disposal of cytotoxic waste shall comply with all applicable local, state and
11 federal requirements.
- 12 (5) Written procedures for handling both major and minor spills of cytotoxic agents
13 must be developed and must be included in the policy and procedure manual.
- 14 (6) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper
15 precautions inside and outside, and shipped in a manner to minimize the risk of
16 accidental rupture of the primary container.

17
18 **Phar 12.11 Quality Assurance.**

19 There shall be a documented, ongoing quality assurance control program that monitors personnel
20 performance, component verification and usage, Disinfection, sterilization, equipment, and
21 facilities that are appropriate to the Risk Level of the Sterile Pharmaceutical(s) being prepared.
22 Appropriate samples of finished products shall be examined to ensure that the Pharmacy is
23 capable of consistently preparing Sterile Pharmaceuticals meeting specifications.

- 24 (a) All clean rooms and laminar flow hoods shall be certified by an independent contractor
25 according to the International Organization of Standardization Classification of
26 Particulate Matter in Room Air (ISO14644-1) for operational efficiency at least every six
27 months. Appropriate records shall be maintained.
- 28 (b) There shall be written procedures requiring sampling on a frequent basis and special
29 measures taken when microbial contamination is suspected.
- 30 (c) If bulk Compounding of sterile solutions is performed using chemicals that initially are
31 non-sterile, extensive end-product microbial testing must be documented prior to the

1 release of the product from quarantine. This process must include appropriate tests for
2 particulate matter, pyrogens, and microbes.

3 (d) There shall be written justification of the chosen Beyond-Use Dates for Compounded products.

4 (e) There shall be documentation of quality assurance audits at regular, planned intervals,
5 including infection control and sterile technique audits. Intervals shall be based on the
6 type of operations performed and shall increase as the Risk Level increases

7 (g) There shall be policies and procedures on the retraining or recertification of trained
8 Pharmacy Compounding personnel in various aspects of aseptic behavior. The training
9 program shall include a demonstration of ongoing competency. Training to ensure skills
10 such as aseptic technique, clean room behavior, and knowledge of the hazards posed by
11 contaminated drugs shall be conducted

12 (h) Pharmacy Compounding Personnel shall wear sterile garb if conducting one or more
13 aseptic manipulation of sterilized equipment or product.

14
15 (i) An effective Disinfection program shall be implemented, including adequate provisions
16 for preventing emergence of unsafe levels of spore forming organisms.

17 (j) A system shall be in place for monitoring Pharmacy Compounding personnel and
18 environmental conditions.

19
20 **Phar 12.12 Pharmacist Manager Responsibility**

21 Pharmacist Manager must assure that all written policies and guidelines in the preparations for
22 mixing I.V. are being followed.

1 **Chapter Phar 13**

2 **GROUND FORS SUSPENSION OR REVOCATION OF CERTIFICATE, LICENSE,**
3 **REGISTRATION OR PERMIT OR DENIAL OF APPLICATION**

4
5 The Board of Pharmacy may suspend or revoke any certificate, license registration or permit
6 issued and deny the application of any person for a certificate or permit, if the holder or
7 applicant:

- 8
- 9 1) Is not of good moral character.
 - 10 2) Is guilty of habitual intemperance.
 - 11 3) Becomes or is intoxicated or under the influence of liquor, any depressant drug or a
12 controlled substance, unless taken pursuant to a physician’s prescription, while on duty in
13 any establishment licensed by the Board.
 - 14 4) Is guilty of unprofessional conduct or conduct contrary to the public interest.
 - 15 5) Is addicted to the use of any controlled substance.
 - 16 6) Has been convicted of a violation of any law or regulation of the Federal Government or
17 of this or any other state related to controlled substances, dangerous drugs, drug samples,
18 or the wholesale or retail distribution of drugs.
 - 19 (7) Has been convicted of a felony or other crime involving moral turpitude, dishonesty or
20 corruption.
 - 21 (8) Has willfully made to the Board or its authorized representative any false statement.
 - 22 (9) Has obtained any certificate, certification, license or permit by the filing of an
23 application, or any record, affidavit or other information in support thereof, which is false
24 fraudulent.
 - 25 (10) Has violated any provision of the Federal Food, Drug and Cosmetic Act or any other
26 federal law or regulation relating to prescription drugs.
 - 27 (11) Has violated, attempted to violate, assisted or abetted in the violation of or conspired to
28 violate any law or regulation relating to drugs, the manufacture or distribution of drugs or
29 the practice of pharmacy, or has permitted, allowed, condoned or failed to report a
30 violation of any law or regulations relating to drugs, the manufacture or distribution of
31 drugs or the practice of pharmacy committed by the holder of a certificate, license,

- 1 registration or permit.
- 2 (12) Has failed to renew his certificate, license or permit by failing to submit the application
3 for renewal or pay the renewal fee therefore.
- 4 (13) Has had his certificate, license, or permit suspended or revoked in another state on
5 grounds which could cause suspension or revocation of certificate, license or permit.
- 6 (14) Has, as a managing pharmacist, violated any provision of law or regulation concerning
7 recordkeeping or inventory in a store over which he presides, or has knowingly allowed a
8 violation of any local, state or federal laws or regulations relating to the practice of
9 pharmacy by personnel of the pharmacy under his supervision.
- 10 (15) Has repeatedly been negligent, which may be evidenced by claims of malpractice settled
11 against him.
- 12 (16) Has failed to maintain and make available to a local, state or federal officer and to
13 member of the Board of Pharmacy any records relating to sale, wholesale distribution of
14 drugs and devices.

15

16 **MENTAL ILLNESS: Immediate Suspension of Right to Practice**

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18 The adjudication of insanity or mental illness, or the voluntary commitment or admission to any
19 hospital for mental illness of any certificate holder, shall operate as an immediate suspension of
20 the right of the certificate holder to practice pharmacy in this territory and such suspension shall
21 continue until restoration to or declaration of sanity or mental competence.

22

23 **MENTAL ILLNESS: Reinstatement of Suspended Certificate, License, Registration or**
24 **Permit; Procedure for Reinstatement.**

25

- 26 1) A person whose certificate, license, registration or permit has been suspended by the
27 Board, may petition the Board for reinstatement of the certificate, license, registration or
28 permit after restoration or declaration of sanity or mental competence.
- 29
- 30 2) The Board shall not restore any suspended certificate, license, registration or permit until
31 it has found, in a hearing held for that purpose, that with due regard for the public interest

1 the petitioner's right to practice, or to perform the duties and conduct the business
2 covered by the certificate, license, registration or permit, may be safely reinstated.

3
4 3) In any such hearing, the Board may consider the results of its own investigation as well
5 as evidence pertaining to the petitioner's restoration to sanity or mental competence. The
6 affirmative vote of a majority of Board members is necessary to restore the certificate,
7 license, registration or permit. The Board may require before reinstatement, the
8 petitioner to pass an examination, either oral or written, to determine his present fitness to
9 resume his practice or conduct his business in the public interest.

10
11 4) In any hearing, conducted for the purpose of reinstating any certificate, license,
12 registration or permit, the Board may employ expert witnesses considered necessary in
13 order to determine the competency and ability of the practitioner.

14
15 **RECORDS: Consent to Inspection; Copies; Penalty for Refusal to Permit Inspection.**

16
17 1) The acceptance of a license issued by the Board constitutes a consent by the licensee to
18 the inspection of his records maintained inside and outside this territory by any
19 authorized representative of the Board.

20
21 2) Is such a licensee does not maintain a records within this territory of his shipments of
22 controlled substances, poisons or drugs or devices or appliances that are restricted by
23 federal law to sale by or on the order of a physician to persons in this territory, he shall,
24 on receipt of a written demand from the chairman of the Board, furnish a true copy of the
25 records to the Boards.

26
27 3) The Board may authorize as its representative any member or representative of the Board
28 of Pharmacy or similar agency of the territory in which the records are located.

29
30 4) Failure to furnish a true copy of the required records or refusal to permit their inspection
31 is a ground for the revocation or suspension of any license issued.

1 **METHODS OF DISCIPLINE**

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3 1) The holder of any certificate, license, or permit issued by the Board, whose default has
4 been entered or who has been heard by the Board and found guilty of the violations
5 alleged in the accusation, may be disciplined by the Board by one or more of the
6 following methods:

7

8 a) Suspending judgment

9 b) Placing the certificate, license or permit holder on probation

10 c) Suspending the right of the certificate holder to practice or the right to use any
11 license or permit.

12 d) Revoking the certificate, license or permit.

13 e) Public or private reprimand.

14 f) Imposition of a fine not to exceed \$1,000 for each count of the accusation

15 g) Requiring the certificate, license or permit holder to pay all costs incurred by the
16 Board relating to the discipline of the person.

17

18 2) Such action by the Board is final, except that the propriety of such action is subject to
19 review upon questions of law by a court of competent jurisdiction.

20

21 **FALSE OR MISLEADING ADVERTISING**

22

23 No registered pharmacist or owner of any pharmacy may make, disseminate or cause to be made
24 or disseminated before the public in this territory in any newspaper or other publication, or any
25 advertising device or in any manner or means whatever, any statement concerning prices or
26 services, professional or otherwise, which is untrue or misleading, and which is known, or which
27 by the exercise of reasonable care should be known, to be false or misleading.

28

29 **REBATES, REFUNDS AND COMMISSIONS:**

30

31 1) No registered pharmacist, or owner of any pharmacy may offer, deliver or pay any

1 unearned rebate, refund, commission, preference, patronage dividend, discount or other
2 unearned consideration to any persons, whether in the form of money or otherwise, as
3 compensation or inducement to such person for referring prescriptions, patients, clients or
4 customers to such pharmacist or pharmacy, irrespective of any membership, proprietary
5 interest or co-ownership in or with any person by whom such prescriptions, patients,
6 clients or customers are referred.

- 7
- 8 2) The furnishing to a practitioner by a pharmacist or a pharmacy of a prescription blanks
9 bearing the name or name and address of any pharmacy is an unearned rebate and an
10 inducement to refer patients to such pharmacist or pharmacy.

11

12 **UNLAWFUL ACTS AND PENALTIES:**

- 13 1) False representation as practitioner or agent, unauthorized transmission or order for
14 prescription by agent.

15

16 a) It is unlawful for any person falsely to represent himself as a practitioner entitled
17 to write prescriptions in this territory or the agent of such a person, for the
18 purpose of transmitting to a pharmacist an order for a prescription.

19

20 b) It is unlawful for the agent of a practitioner entitled to write prescriptions in this
21 territory willfully to transmit to a pharmacist an order for a prescription if the
22 agent is not authorized by the practitioner to transmit such order.

- 23
- 24 2) Unlawful dispensing and sales.

25

26 a) Being the licensed proprietor of a pharmacy, fails to place a registered pharmacist
27 in charge of such pharmacy, or permits the compounding or dispensing of drugs
28 or prescriptions, or the selling of drugs, poisons or devices, the sale of which is
29 restricted, by any person other than a registered pharmacist or an intern
30 pharmacist, is guilty of a misdemeanor.

31

1 b) Is not a registered pharmacist and who takes charge of or acts as manager of any
2 pharmacy, compounds or dispenses any prescription, or sells any drug, poison or
3 device, the sale of which is restricted, is guilty of a misdemeanor.
4

5 3) Unlawful sales by wholesalers and manufacturers.
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7 It is unlawful for any wholesaler or manufacturer to furnish, sell, offer for sale, or deliver any
8 drugs, poisons, chemicals or devices, to any person not authorized by the laws of this territory to
9 handle, sell, possess or deal in such drugs, poisons, chemicals or devices.
10

11 **IMMUNITY FROM CIVIL ACTION FOR ASSISTING ADMINISTRATIVE**
12 **PROCEEDING:**
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14 The Board of Pharmacy or any person who initiates or assists in any lawful investigation or
15 administrative proceeding concerning the discipline of a pharmacist or any holder of license,
16 certificate or permit is immune from any civil action for that initiation or assistance or any
17 consequential damages, if the person acted without malicious intent.
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1 **Chapter Phar 14**

2 **Rules of Confidentiality of Patient Health Information**

3
4 A. Uses and Disclosures of Protected Health Information. A Pharmacy, Pharmacist, Pharmacy
5 Benefits Manager, or Person licensed or registered by the Board may not use or disclose
6 Protected Health Information, except as permitted or required by this Section.

7 (1) Permitted Uses and Disclosures. A Pharmacy, Pharmacist, Pharmacy Benefits
8 Manager, or Person licensed or registered by the Board is permitted to use or disclose
9 Protected Health Information as follows:

- 10 (a) To the patient;
- 11 (b) For the treatment, payment, or health care operations as permitted or required
12 by Paragraph B of this Section;
- 13 (c) Incident to a use or disclosure otherwise permitted or required by this
14 Paragraph;
- 15 (d) Pursuant to and in compliance with a valid authorization under Paragraph C
16 of this Section;
- 17 (e) Pursuant to an agreement under, or as otherwise permitted by, Paragraph D
18 of this Section;
- 19 (f) As permitted by and in compliance with this Paragraph, Paragraph E, or
20 Paragraph G.

21 (2) Required disclosures. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or
22 Person licensed or registered by the Board is required to disclose Protected Health
23 Information:

- 24 (a) To a patient, when requested under, and required by 45 CFR §164.524 or
25 §164.528; and
- 26 (b) When required to investigate or determine the Pharmacy, Pharmacist,
27 Pharmacy Benefits Manager, or Person licensed or registered by the Board's
28 compliance with this Section and Federal privacy regulations.

29 B. Uses and Disclosures of Protected Health Information.

30 (1) Permitted Uses and Disclosures

- 31 (a) Except with respect to uses or disclosures that require an authorization under
32 Paragraph C, a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or
33 Person licensed or registered by the Board may use or disclose Protected
34 Health Information for treatment, payment, or health care operations.

- 1 (2) Treatment, Payment, or Health Care Operations
- 2 (a) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or
- 3 registered by the Board may use or disclose Protected Health Information for
- 4 their treatment, payment, or health care operations.
- 5 (b) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or
- 6 registered by the Board may disclose Protected Health Information for
- 7 treatment activities of a health care provider.
- 8 (c) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or
- 9 registered by the Board may disclose Protected Health Information to a
- 10 covered entity defined by 45 CFR §160.103 for the payment activities of the
- 11 entity that receives the information.
- 12 (d) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or
- 13 registered by the Board may disclose Protected Health Information to a
- 14 covered entity defined by 45 CFR §160.103 for health care operations
- 15 activities of the entity that receives the information if each Pharmacy,
- 16 Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by
- 17 the Board has had a relationship with an individual who is the subject of the
- 18 Protected Health Information being requested, the Protected Health
- 19 Information pertains to such relationship, and the disclosure is:
- 20 (i) For a purpose listed in Paragraph (1) or (2) of the definition of “Health
- 21 Care Operations”; or
- 22 (ii) For the purpose of health care fraud and abuse detection or
- 23 compliance.
- 24 (e) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or
- 25 registered by the Board that participates in an organized health care
- 26 arrangement may disclose Protected Health Information about a patient to a
- 27 covered entity defined by 45 CFR §160.103 that participates in the organized
- 28 health care arrangement for any health care operations activities of the
- 29 organized health care arrangement.

30 C. Uses and Disclosures for which an Authorization is Required.

- 31 (1) Authorization for Uses and Disclosures.
- 32 (a) Authorization required. General rule. Except as otherwise permitted or
- 33 required by this section, a Pharmacy, Pharmacist, Pharmacy Benefits

1 Manager, or Person licensed or registered by the Board may not use or
2 disclose Protected Health Information without an authorization that is valid
3 under this section. When a Pharmacy, Pharmacist, Pharmacy Benefits
4 Manager, or Person licensed or registered by the Board obtains a valid
5 authorization for its use and disclosure of Protected Health Information, such
6 use or disclosure must be consistent with such authorization.

7 (b) Authorization required. Marketing.

8 (i) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person
9 licensed or registered by the Board must obtain authorization for any
10 use or disclosure of Protected Health Information for marketing, except
11 if the communication is in the form of:

12 (-a-) A face-to-face communication made by a Pharmacy,
13 Pharmacist, Pharmacy Benefits Manager, or Person licensed or
14 registered by the Board;

15 (-b-) A promotional gift of nominal value provided by the
16 Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person
17 licensed or registered by the Board.

18 (ii) If the marketing involves direct or indirect remuneration to the
19 Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person
20 licensed or registered by the Board from a third party, the authorization
21 must state that such remuneration is involved.

22 (c) Valid authorizations. A valid authorization is a document that contains the
23 elements listed in Paragraph (2) of this subsection.

24 (d) Prohibition on conditioning of authorizations. A Pharmacy, Pharmacist,
25 Pharmacy Benefits Manager, or Person licensed or registered by the Board
26 may not condition the provision to a patient of treatment on the provision by
27 a patient of an authorization, except:

28 (i) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person
29 licensed or registered by the Board may condition the provision of
30 research-related treatment on the provision of an authorization for the
31 use or disclosure of Protected Health Information for such research; or

32 (ii) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person
33 licensed or registered by the Board may condition the provision of

1 health care that is solely for the purpose of creating Protected Health
2 Information for disclosure to a third party on provision of an
3 authorization for the disclosure of the Protected Health Information to
4 such third party.

5 (e) Revocation of authorizations. A patient may revoke an authorization at any
6 time, provided that the revocation is in writing, except to the extent that the
7 Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or
8 registered by the Board has taken action in reliance thereon.

9 (f) An authorization obtained by a Pharmacy, Pharmacist, Pharmacy Benefits
10 Manager, or Person licensed or registered by the Board must be retained for a
11 minimum of six years from the date of its creation or the date when it was
12 last in effect, whichever is later.

13 (2) Authorization: Content Requirements.

14 (a) Core elements. A valid authorization must contain at least the following
15 elements:

16 (i) A specific description of the information to be used or disclosed;

17 (ii) The name or other specific identification of the person(s), or class of
18 persons, authorized to make the requested use or disclosure;

19 (iii) The name or other specific identification of the person(s), or class of
20 persons, to whom the Pharmacy, Pharmacist, Pharmacy Benefits
21 Manager, or Person licensed or registered by the Board may make the
22 requested use or disclosure;

23 (iv) The purpose for the requested use or disclosure. The statement “at the
24 request of the individual” is sufficient when a patient initiates the
25 authorization and does not, or elects not to, provide a statement of the
26 purpose;

27 (v) An expiration date or an expiration event that relates to the patient or
28 the purpose for the use or disclosure;

29 (vi) Signature of the patient and date. If the authorization is signed by a
30 patient’s agent, a description of such agent’s authority to act for the
31 patient must also be provided.

1 (b) Required statements. In addition to the core elements, the authorization must
2 contain statements adequate to place the patient on notice of all of the
3 following:

4 (i) The patient's right to revoke the authorization in writing, and either:

5 (-a-) the exceptions to the right to revoke and a description of how the
6 patient may revoke the authorization; or

7 (-b-) a reference to the notice of privacy practices of the Pharmacy,
8 Pharmacist, Pharmacy Benefits Manager, or Person licensed or
9 registered by the Board, that addresses the exceptions to the right
10 to revoke and a description of how to revoke the authorization.

11 (ii) The conditions under which the Pharmacy, Pharmacist, Pharmacy
12 Benefits Manager, or Person licensed or registered by the Board may
13 condition treatment or payment on the provision of an authorization or
14 those conditions under which the Pharmacy, Pharmacist, Pharmacy
15 Benefits Manager, or Person licensed or registered by the Board cannot
16 condition treatment or payment on the provision of an authorization,
17 and the consequences of a refusal to provide authorization.

18 (iii) The potential for information disclosed pursuant to the authorization to
19 be subject to redisclosure by the recipient and no longer be protected
20 by these regulations.

21 (c) Plain language requirement. The authorization must be written in plain
22 language.

23 (d) Copy to the patient. If a Pharmacy, Pharmacist, Pharmacy Benefits Manager,
24 or Person licensed or registered by the Board seeks an authorization from a
25 patient for a use or disclosure of Protected Health Information, the Pharmacy,
26 Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by
27 the Board must provide the patient with a copy of the signed authorization.

28 D. Uses And Disclosures Requiring An Opportunity For The Patient To Agree Or To Object.
29 A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by
30 the Board may use or disclose Protected Health Information provided that the patient is
31 informed in advance of the use or disclosure and has the opportunity to agree to or prohibit
32 or restrict the use or disclosure, in accordance with the applicable requirements of this

1 subsection. The Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or
2 registered by the Board may orally inform the patient of and obtain the patient's oral
3 agreement or objection to a use or disclosure permitted by this subsection. Uses and
4 disclosures permitted under this subsection are set out in 45 CFR §164.510 (a) and (b).

5 E. Uses And Disclosures For Which An Authorization Or Opportunity To Object Is Not
6 Required.

7 A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by
8 the Board may use or disclose Protected Health Information without the written
9 authorization of the patient or the opportunity for the patient to agree or object according to
10 the standards set out in 45 CFR §164.512 (a) – (l). When the Pharmacy, Pharmacist,
11 Pharmacy Benefits Manager, or Person licensed or registered by the Board is required by
12 this subsection to inform the patient of, or when the patient may agree to, a use or
13 disclosure permitted by this subsection, the Pharmacy, Pharmacist, Pharmacy Benefits
14 Manager, or Person licensed or registered by the Board's information and the Pharmacy,
15 Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board's
16 agreement may be given orally.

17 F. Other Requirements Relating To Uses And Disclosures Of Protected Health Information.

18 (1) De-identification and Re-identification of Protected Health Information. The de-
19 identification and re-identification of Protected Health Information must conform
20 with the standards and specifications set out in 45 CFR §164.514 (a) – (c).

21 (2) Minimum Necessary. Uses and disclosures of Protected Health Information must
22 meet the minimum necessary standards and specifications set out in 45 CFR
23 §164.514 (d).

24 (3) Limited Data Set. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person
25 licensed or registered by the Board may use or disclose a limited data set as indicated
26 in 45 CFR §164.514(e).

27 (4) Verification. Uses and disclosures of Protected Health Information must meet the
28 verification standards and specifications set out in 45 CFR §164.514 (h).

29 G. Notice of Privacy Practices for Protected Health Information.

30 A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by
31 the Board must provide each patient with a notice of privacy practices as indicated in 45
32 CFR §164.520.

33 H. Right to Request Privacy Protection for Protected Health Information.

1 A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by
2 the Board must permit a patient to request that the Pharmacy, Pharmacist, Pharmacy
3 Benefits Manager, or Person licensed or registered by the Board restrict the use or
4 disclosure of Protected Health Information as indicated in
5 45 CFR §164.522.

6 I. Access of Patients to Protected Health Information.

7 A patient has a right of access to inspect and obtain a copy of Protected Health Information
8 about the patient in a Designated Record Set, for as long as the Protected Health
9 Information is maintained in the Designated Record Set, as indicated in
10 45 CFR §164.524.

11 J. Amendment of Protected Health Information.

12 A patient has a right to have a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or
13 Person licensed or registered by the Board to amend Protected Health Information about the
14 patient in a Designated Record Set, for as long as the Protected Health Information is
15 maintained in the Designated Record Set, as indicated in 45 CFR §164.526.

16 K. Accounting of Disclosures of Protected Health Information.

17 (1) A patient has a right to receive an accounting of disclosures of Protected Health
18 Information made by a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or
19 Person licensed or registered by the Board in the six years prior to the date on which
20 the accounting is requested, except for the following disclosures:

- 21 (a) To carry out treatment, payment, and health care operations, as provided in
22 Paragraph B of this section;
- 23 (b) To patients, of Protected Health Information about them;
- 24 (c) Incident to a use or disclosure otherwise permitted or required by this
25 Paragraph, as provided in Paragraph A;
- 26 (d) Pursuant to an authorization, as provided in Paragraph C;
- 27 (e) For the facility's directory or to persons involved in the patient's care or
28 other notification purposes as provided in Paragraph D;
- 29 (f) For national security or intelligence purposes as provided in 45 CFR
30 §164.512(k)(2);
- 31 (g) To correctional institutions or law enforcement officials as provided in
32 45 CFR §164.512(k)(5);
- 33 (h) As part of a limited data set in accordance with 45 CFR §164.514(e); or

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(i) That occurred prior to the compliance date of April 14, 2003, for the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board.

(2) (a) The Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must temporarily suspend a patient’s right to receive an accounting of disclosures to a health oversight agency or law enforcement official for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the patient would be reasonably likely to impede the agency’s activities and specifying the time for which the suspension is required.

(b) If the agency or official statement in Paragraph K(2)(a) is made orally, the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must:

- (i) Document the statement, including the identity of the agency or official making the statement;
- (ii) Temporarily suspend the patient’s right to an accounting of disclosures subject to the statement; and
- (iii) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to Paragraph K(2)(a) is submitted during that time.

(3) A patient may request an accounting of disclosures for a period of time less than six years from the date of the request.

(4) The accounting of disclosures of Protected Health Information must conform to the requirements set out in 45 CFR §164.528 (b), (c), and (d).

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