CHAPTER 13
GUAM BOARD OF EXAMINERS FOR PHARMACY

2017 NOTE: Sections 13101-13111 were amended and new §§ 13112-23120 were adopted by the Guam Board of Examiners for Pharmacy pursuant to the Administrative Adjudication Law, Chapter 9, Article 3 of Title 5 GCA. These rules were filed with the Legislative Secretary on Feb. 20, 2017 and became effective 90 days thereafter (May 22, 2017) pursuant to 5 GCA § 9303(c).

§ 13101. Authority and Definitions.

(a) Authority. These rules are adopted pursuant to the Board's authority under the Guam Pharmacy Practice Act.

(b) Definitions. As used in Sections 13101 to 13120:

(1) *Board* means the Pharmacy Examining Board.

NOTE: The Board address is P.O. Box 2816, Hagåtña, Guam 96910.

(2) *Managing pharmacist* means a pharmacist designate by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(3) *Pharmacist* means a person licensed by the Board under P.L. 16-123.

(4) *Pharmacist-in-charge* means a pharmacist who is physically present in the licensed facility and responsible for the routine operation of a pharmacy for the period of time specified by the managing specialist.

(5) *Pharmacy* means every store, shop or place where

(A) drugs are dispensed, sold or displayed for sale at retail;

(B) where prescriptions or drug preparations are compounded;

(C) which has upon it, displayed within it, affixed to or used in conjunction 'drug store', 'druggist', 'drugs', 'medicines', 'medicine store', 'drug sundries', 'remedies', or any word or words of similar or like import; or

(D) any store or other place with respect to which any of the above words or combination of words are used in any advertisement but does not include the place used by a drug manufacturer or wholesale drug dealer or the place of business of a non-registered person selling non-narcotic proprietary preparations;

(6) *Pharmacy owner* means a person or entity to whom a pharmacy permit is issued;

(7) *Practice of pharmacy* means any of the following:

(A) interpreting prescription orders;

(B) compounding, packaging, labeling, dispensing, and distributing drugs and devices;

(C) monitoring drug therapy and use;

(D) initiating, modifying or administering drug therapy in accordance with written guidelines or procedures previously established and approved for his or her practice by a practitioner authorized to prescribe drugs;

(E) participation in drug utilization reviews;

(F) proper and safe storage and distribution of drugs and devices and maintenance of proper records of drugs and devices;

(G) providing information on prescription and non-prescription drugs and devices which may include, but is not limited to, advice on therapeutic values, hazards and the uses of drugs and devices, and performing those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy;

(8) *Professional service area* means the area of a pharmacy in which prescriptions are compounded or dispensed, hypodermic needles, syringes, poisons and schedule V controlled substances as listed the Federal Control Substances Act, are available, or where patients are consulted;

(9) *Cosmetics* including soap, dentrifice and toilet article, means

(A) an article intended to be rubbed, poured or sprinkled on, introduced into or otherwise applied to the human body, or any part thereof for cleansing, beautifying, or promoting attractiveness; and

(B) articles intended for use as a component of any such articles;

(10) *Drug* means

(A) articles recognized in the official United States pharmacopeoia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

(B) articles intended for use in the diagnosis cure, mitigation, treatment, or prevention of disease in human beings or animals;

(C) articles (other than food or clothing) intended to affect the structure or any function of the body of human beings or animals; and

(D) articles intended for use as a component of any articles specified in clauses (A), (B), or (C) of this subsection; provided, that the term 'drug' shall not include patent medicines, electrical or mechanical devices, cosmetics and liquor;

(11) *Patent Medicine* or *proprietory preparation* means a drug in its unbroken original package, which is sold to the public by or under the authority of the manufacturer or primary distributor thereof under a trademark, trade name, or other trade symbol privately owned, whether or not registered in the United States patent office, and labelling of which conforms to the provisions of applicable United States Laws;

(12) *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, 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 patient, the name and quantity of the drug prescribed, directions for use and the date of issue; and

(13) *Registered Pharmacist* means a person licensed under this Article to practice pharmacy except where another meaning is clearly manifested by the context.

(14) (A) *Dangerous Drug* or *Dangerous Device* means any drug or device unsafe for self medication and includes any drug or device which bears the legend: 'Caution: Federal law prohibits dispensing without a prescription'.

(B) If the Board finds after open hearing following due notice to persons who have filed written request to the Board for such notice, that any drug or device is dangerous to the public health or safety, the Board may make other rules, not inconsistent with this sub-chapter, limiting or restricting the furnishing of such drug.

(15) *Controlled Substance* means those drugs and drug products that come under the jurisdiction of the Federal Controlled Substances Act of 1970 (P.L. 91-513).

(16) *Narcotic* means and includes any and all drugs or substances classified as such under the Federal Narcotic Act of 1914 and any and all amendments to the Act.

(17) *Intern Pharmacist* means a person registered with the Board who shall meet the requirements established by the Board, for the purpose of obtaining practical experience necessary for licensure pursuant to Section 27507.

(18) *NABPLEX* means the National Association of Boards of Pharmacy Licensing Examination.

(19) *Telepharmacy* means the provision of pharmacist care, by a pharmacist located within the United States, its territories, and the District of Columbia using telecommunications, *remote medication order processing*, or other automations and technologies to deliver care to patients or their agents who are located at sites other than where the pharmacist is located.

(20) *Drug regimen review* means an evaluation of prescription drug orders and patient profile records for:

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug interactions;

(G) drug-food interactions;

(H) adverse drug reactions; and

(I) proper utilization, including over-utilization or under-utilization.

(21) *Receiving Pharmacy* means an institutional pharmacy on Guam that has contracted with a remote site to provide pharmacist services after its normal business hours.

(22) *Remote Medication Order Processing* or "*RMOP***"** means the processing of a medication order for an institutional facility by a

pharmacist located at a remote site. Remote medication order processing *does not include the dispensing of a drug*, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

(23) *Remote Medication Order Processing Site* or *Facility* means a site or facility which does not stock, own, or dispense any prescription medications, and whose sole business consists of entry and/or review and/or verification of a prescriber's orders and consulting services under contract for institutional facilities licensed in Guam or any other United States jurisdiction, and which provide services under the direction of a pharmacist in charge ("PIC"), licensed by the Board.

(24) *Remote pharmacist* means any person licensed to practice pharmacy by the Board, either employed or a contract employee of an institutional facility, hospital pharmacy, or remote medication order processing site or facility, processing the medication order from a remote site.

(25) *Remote site* means a site located within the United States, a territory thereof, or District of Columbia that is electronically linked to an institutional facility via a computer and/or other electronic communications system as defined in the operations, policies and procedures manual of an institutional pharmacy or remote medication order processing site or facility for the purposes of remote medication order processing.

(26) *After-hours Service* means pharmacy coverage by the remote site for all hours not covered by the receiving institutional pharmacy/facility located on Guam.

(27) *Institutional facilities* are limited to hospitals, penal institutions, or long term care facilities as defined in Chap. 12 Article 6, Title 10 Guam Code Annotated.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

2017 NOTE: Subsection/subitem designations added/altered pursuant to the authority granted by 1 GCA § 1606.

§ 13102. Qualification and Application Procedure for Pharmacists Licensure and Internship Regulations.

(a) Qualifications. An applicant for licensure as a pharmacist may be admitted to examination under P.L. 16-80, as amended by 17-80, if the applicant:

(1) is at least eighteen (18) years of age,

(2) is of good moral character and temperate habits, and

(3) graduate of a school or college of pharmacy or department of a university which school or college or department is recognized and approved by the Board.

(4) file proof satisfactory to the Board of a minimum of 1500 hours of practical experience in any state or territory of the United States in a pharmacy under the supervision of registered pharmacist as required in this Section shall be predominantly related to the selling of drugs, compounding prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under territorial and federal statutes.

(b) Application Procedure. Each applicant shall submit a completed notarized application no later than 30 days prior to the examination date on forms provided by the Board. The application shall include:

(1) The signature of the applicant.

(2) A statement from the Dean of the school of pharmacy or the academic records office of the respective educational institution that the applicant has graduated from the pharmacy school.

(3) Three recent notarized photographs.

(4) The fees as specified by the Board.

(5) Any change of name made prior to admission to examination shall be supported by a notarized affidavit of the applicant.

(6) Notarized proof of practical experience is not required for written portion of examination but is required prior to the practical or laboratory portion of examination.

(7) Graduate of Foreign Pharmacy Schools. The following are required for graduates of foreign pharmacy schools in addition to the above qualification and requirements:

(A) Shall be graduates of a school or college of pharmacy or department of a university which school or college or department is recognized by that country's accreditation body and approved by the Board.

(B) Shall first write and successfully pass the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), an examination administered by the Foreign Pharmacy Graduate Examination Commission (FPGEC). Before applying for a Guam Pharmacy License, applicant shall directly communicate with the Commission.

(C) Shall request FPGEC to certify to the Board successful writing of FPGEC on the form provided by the Board.

(c) Internship Regulations. Definitions.

(1) A *pharmacy intern* means any person who has completed the junior or their academic year of a course of study at an approved college of pharmacy and is licensed and registered with the Board as an intern.

(2) A *preceptor* means a pharmacist licensed and in good standing, registered by the Board to supervise the internship training of a registered and licensed intern. *Internship* means a professional and practical experience program approved by the Board under the supervision of a licensed pharmacist registered with the Board as a preceptor.

(3) Initial Application - Forms - Fees - Annual License.

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

(B) The initial license for a qualified pharmacy intern shall be issued by the Board after the receipt of the completed application and payment of the fee prescribed by the Board. Licensure shall be deemed registration under P.L. 16-123.

(C) Filing of the initial application for a license as a pharmacy intern authorizes the applicant to act as a pharmacy intern for a period of not to exceed 30 days from the date of acknowledgment of the filing by the Board. This authorization includes the 30-day period preceding commencement of a new licensing period.

(4) A pharmacy intern license is renewable annually prior to July 1.

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

(d) Internship Requirements.

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

(2) At least 400 hours of the total internship experience time requirement shall be acquired after graduation from an accredited school or college of pharmacy. A certification by the school or college that the intern has completed all requirements for an earned degree in pharmacy and will be conferred such degree will authorize the acquisition of the hours referred to in this section.

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

(4) Not more than 48 hours per week may be credited toward the internship requirement.

(e) Change of Internship Experience Area. When a pharmacy intern changes experience areas before completing the 1500 hours time requirement, he/she shall notify the Board within fifteen (15) days and provide the name of his new preceptor; the name and address of the new experience area. Failure to do so shall result in denial of internship credit for experience obtained in the new area prior to notification of the Board.

(f) Out-of-State Internship Experience. In order to obtain credit for internship experience outside Guam, a pharmacy intern must be licensed in the state in which he/she practiced and meet or exceed the minimum intern requirements of the Guam Pharmacy Board. The location and type of

experience and the preceptor shall be certified by the Guam Board of Examiners for Pharmacy or by the Board of Pharmacy, or other authorized certifying representative of that state.

(g) 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.

(h) Internship Reports.

(1) Internship experience reports, on forms provided by the Board, shall be submitted to the Board for approval in each of the following instances:

(A When a pharmacy intern changes preceptors in a internship experience area or upon graduation from a school or college of pharmacy, whichever occurs first.

(B) When a pharmacy intern completes the required 400 hours after graduation of the time necessary to complete the internship experience requirement.

(2) 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.

(3) The internship experience reports shall be signed by the pharmacy intern and the preceptor(s).

(4) The internship experience report shall list the actual number of hours and the dates covered by those hours. Affidavits shall be notarized.

(i) Preceptor-Responsibilities.

(1) A registered preceptor shall be actively engaged in the practice of pharmacy during the year prior to supervising a pharmacy intern.

(2) The preceptor shall provide the pharmacy intern with internship experience which in his judgment will increase his competency in the practice of pharmacy.

(3) The preceptor shall actively supervise the pharmacy intern for the majority of the internship experience time requirement and shall

designate on the internship experience report the preceptor who acts as the supervisor during his/her absence.

(4) The preceptor shall certify the internship experience report when the intern leaves his supervision permanently, or upon graduation.

(5) A preceptor may not supervise more than one intern in a given shift/day.

(6) The preceptor shall assure that the intern is currently licensed.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

2017 NOTE: Subitem designations altered pursuant to the authority granted by 1 GCA § 1606.

References to "Territory" removed and/or altered to "Guam" pursuant to 1 GCA § 420.

§ 13103. Examinations.

(a) Administration.

(1) Examinations may be written, oral, or practical.

(2) Examinations are conducted in the English language only.

(3) At least 10 days prior to the examination, the applicant shall be mailed an admission card and that card shall be presented at the door of the examination room, with a photograph which is a duplicate of that filed with the application for licensure.

(4) A number shall be assigned to each applicant. Rules of conduct shall be provided at the beginning of the examination.

(5) An applicant found by the Board to have violated rules of the examination may be denied licensure by the Board.

(6) An applicant for licensure as a pharmacist is required to take the NABPLEX, a jurisprudence examination and a laboratory practice examination.

(7) An applicant may request to take the NABPLEX examination in another licensing jurisdiction at the time the applicant is eligible to take the NABPLEX in Guam if the Board is notified in writing not less

than 30 days in advance of the exam and authorized the transfer of those graded to the Board.

(b) Competencies Tested.

(1) NABPLEX tests in five (5) areas covering basic principles of the practice of pharmacy which includes chemistry, mathematics, pharmacology, pharmacy and practice of pharmacy.

(2) The jurisprudence examination shall determine an applicant's familiarity with Guam laws and rules and federal laws and regulations governing the practice of pharmacy.

(3) The laboratory practical examination shall determine an applicant's proficiency in compounding and dispensing medications.

(c) Passing Scores.

(1) The passing scores set by the Board represent the minimum competency required to protect the public health and safety.

(2) Each exam is scored separately and an applicant shall earn passing scores on each required examination to qualify for licensure.

(3) The Board requires a minimum average score of 75.0 in the chemistry, mathematics, pharmacology, and pharmacy sections of NABPLEX, with no score less than 60.0 on any of the four sections. A minimum score of 75.0 on the practice of pharmacy section of NABPLEX is required.

(4) A minimum score of 75.0 is required in jurisprudence.

(5) A minimum score of 75.0 is required in the laboratory practical examination.

(d) Scoring.

(1) The Board shall send written notifications of results to applicants by registered mail.

(2) An applicant shall be offered the opportunity to make written comments and objections within 30 days after notification of the examination results.

(3) Any unsuccessful applicant may request in writing that his or her answer sheet be rescored by hand to verify the accuracy of scoring.

(4) The cost of rescoring shall be paid by the applicant.

(e) Failure and Re-Examination.

(1) An applicant who has not obtained a 75.0 average, subject to § 13103 with no grade less than 60.0 of NABPLEX sections on chemistry, mathematics, pharmacology and pharmacy shall repeat the section or sections with a grade less than 75.0 subject to § 13103. Any applicant earning a 75.0 average on these four sections of NABPLEX with one or more sections less than 60.0 shall repeat only those sections less than 60.0, subject to § 13103. All applicants have the option to retake all sections of NABPLEX in lieu of only those sections with grades below 75.0 or 60.0.

(2) An applicant who fails to earn a passing score in jurisprudence, laboratory practice or practice of pharmacy may repeat the failed examination subject to § 13103.

(3) An applicant who fails to earn a passing score in any examination for licensure may be re-examined, but not earlier than the next scheduled test date.

(4) Application for re-examination shall be made on forms provided for that purpose by the Board. For each re-examination, the applicant shall file the re-examination fee specified by the Board.

(5) Any unsuccessful applicant may request in writing to meet with the Board to discuss any grievance concerning the examination.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13104. Pharmacists Licensure Renewal.

(a) Requirements.

(1) Pharmacists licensed under P.L. 16-123 may be licensed biennially by applying for renewal between September 1st thru September 30th of each odd-numbered year and paying the fee specified by the Board. No pharmacist license renewal will be issued by the Board of Pharmacy unless the applicant, preceding the renewal application, has satisfactorily completed one and one-half (1.5) continuing pharmacy education program or programs approved by the Board within the preceding two-year period.

(2) No one without a current renewal card may engage in the practice of pharmacy, nor hold him or herself out to be a pharmacist nor use the title or letters "Pharmacist" or "Registered Pharmacist" or "R.PH."

(b) Change of Name or Address.

(1) A pharmacist shall notify the Board in writing when his or her name has been legally changed.

(2) A pharmacist shall notify the Board in writing of his or her new address within fifteen (15) days after the change.

(c) Display of Licenses. A pharmacist who engages in the practice of pharmacy shall display his or her license in a manner conspicuous to the public view. Biennial renewal cards shall be placed in the lower right hand corner of the license and shall be posted when received. Only current renewal cards may be posted. A pharmacist shall display his or her license in the pharmacy where he or she engages in the practice of pharmacy.

(d) Renewal Prohibited; Re-Licensure. Any person whose license is currently suspended or revoked may not renew his or her license. A person whose license has been suspended or revoked and subsequently reinstated by the Board may renew his or her license upon completion of a renewal form and filing of the required renewal fee.

(e) Renewal After Lapse. Any holder of an expired license may be reinstated as a registered pharmacist upon satisfactory completion of continuing education requirements and upon payment of a penalty established by the Board and all fees which he/she would have paid if he/she had continuously renewed his/her license.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13105. Continuing Pharmacy Education.

(a) Continuing Pharmacy Education Required for Pharmacist License Renewal**.**

(1) Commencing with the licensing period beginning September 30, 1985, and for licensing periods thereafter, no pharmacist license renewal will be issued by the Board of Pharmacy unless the applicant, in the twelve months preceding the renewal application has

satisfactorily completed one and one-half (1.5) continuing pharmacy education units (15 hours) in an approved continuing pharmacy education program or programs approved by the Board or unless he has passed an examination given by the Board as provided for in these rules.

(2) Section (1) does not apply to pharmacists applying for the first biennial renewal of their license if they have not been licensed by the Board for at least one year prior to September 30, 1985 of the renewal period.

SOURCE: Stat. Auth.: P.L. 16-123, Section 12610.

(b) Continuing Pharmacy Education Programs.

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

(A) A program shall consist of pharmaceutical post-graduate education in the general areas of:

(i) Therapeutics; the properties and actions of drugs and dosage forms and the etiology, characteristics and treatment of the disease state. At least ten of the required fifteen hours of continuing education credits must be earned in the areas of therapeutics.

(ii) Administrative; socio-economic and legal aspects of health care. Five of the required fifteen hours of continuing education credits may be earned in this area.

(B) Programs shall provide for examination or other evaluation methods to assure satisfactory completion by participants.

(C) 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.

(2) Continuing pharmacy education programs shall be approved by the Board of Pharmacy. Application for approval shall be made on hand and in accordance with forms established by the Board. The Board shall require information relating to:

(A) Name of provider or sponsor;

(B) Type of program offered;

(C) Description of subject matter;

(D) Number of clock hours offered;

(E) Method of evaluating satisfactory completion of program;

(F) Dates and location of program;

(G) Name and qualification of instructors or other persons responsible for the delivery or content of the program.

(3) Ten clock hours of education or preparation and presentation in an approved continuing pharmacy education program or programs constitutes one continuing pharmacy education unit. One clock hours shall consist of at least 50 minutes.

(4) Continuing pharmacy education credit accumulated in excess of the required one and one-half (1.5) continuing pharmacy education units (15 hours) for biennial license renewal cannot be carried forward and applied to succeeding license renewal period.

(c) Continuing Pharmacy Education Program Lists**.**

(1) The Board will maintain a list of current Board-approved continuing pharmacy education programs and will distribute the list to licensed pharmacists upon individual request. The list will include the subject matter, type of program, the provider or sponsor, the date and location, if known, and the number of continuing pharmacy education units approved for credit.

(2) Pharmacists participating in programs that are not within the list of approved programs may submit to the Board the synopsis of that program for approval.

(d) Continuing Pharmacy Education - Non-Resident - Dual Licensees.

(1) Any Guam licensed pharmacist residing in another state shall, in order to receive Guam license renewal, meet Guam requirements for continuing pharmacy education.

(2) Continuing pharmacy education programs attended by Guam licensed pharmacists for purposes of satisfying licensing requirements of another state, must be approved by the Guam Board of Pharmacy in order to be recognized for purposes of renewal of Guam license.

(3) Upon request, the Board may certify to another state's licensing authority the status of a licensee's continuing pharmacy education participation.

(4) The Board may request certification from another state's licensing authority regarding the status of an applicant's continuing education.

(e) Notification of Biennial License Renewal.

(1) The Board will develop an appropriate biennial renewal notice to be mailed to all licensed pharmacists prior to August 1 of each renewal year.

(2) The notice will state the biennial pharmacist license fee due to license renewal.

(3) The notice will include the continuing pharmacy education time requirement and any other information considered pertinent for the licensee's understanding of the renewal requirements.

(f) Renewal of Application.

(1) The biennial renewal notice shall be returned to the Board with the appropriate fee and with certification of satisfactory completion of continuing pharmacy education requirements signed by the licensee. The completed form shall identify the approved continuing education program or programs completed, date completed, and location. The form will be filed in the licensee's continuing pharmacy education file. Incomplete renewal applications will not be processed and will be returned to the applicant with an explanatory note.

(2) The Board may randomly select submitted renewal notice forms for audit and verification of contents.

(g) Reinstatement.

(1) Any petitioner for a reinstatement of a license after suspension, revocation, or refusal to renew as provided within P.L. 16-123 and § 13105 of the rules and regulations of the Board of Pharmacy, shall produce certification of the continuing education requirements for all years in which the license has been suspended, revoked or not renewed prior to restoration of license.

(2) Retired or any pharmacist whose license have lapsed who wish to reinstate their license shall refer to § 13104 of the rules and regulations of the Guam Board of Examiners for Pharmacy.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

2017 NOTE: Subsection/subitem designations altered pursuant to the authority granted by 1 GCA § 1606.

§ 13106. Pharmacy Permits and Equipment.

(a) Permits; Application. Requirements and procedures for applying for a pharmacy permit are specified in P.L. 16-123, Section 12612.

(1) Approved application forms are available from the Board.

(2) Appointments for the required pharmacy inspection may be made by telephoning the Board office.

(3) A permit application and fee shall be on file with the Board at least 30 days prior to the granting of the pharmacy permit.

(4) A pharmacy may not operate unless a pharmacy permit has been granted.

(b) Permits; Changes of Location or Ownership.

(1) A pharmacy permit authorizes a pharmacy to operate only at the location designated on the permit. Permits may not be transferred to another location.

(2) Any change in pharmacy ownership shall be reported to the Board office and the pharmacy permit of the former owner returned.

(3) A pharmacy permit shall be granted to the new pharmacy owner before the pharmacy may operate.

(c) Changes in Managing Pharmacist. The pharmacy owner shall report to the Board any change of managing pharmacist within five days following the change.

(d) Floor Design.

(1) Professional Service Area. The professional service area of a pharmacy shall not be less than 150 sq. ft.. No more than 20% of the space may be used for storage of bulk pharmaceuticals. If the pharmacy is open at any time solely as a nonprescription or sundry outlet, without a pharmacist present, the professional service area shall be secured as specified in sub.(1). A variance to the 150 sq. ft. professional service area requirement may be authorized by the Board upon submission of a specific plan describing the manner in which the proposed professional service area plan varies from the requirement.

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

(3) Professional Service Area Requirements Where Pharmacist is Absent.

(A) A pharmacy may convert to a non-prescription or sundry outlet without a pharmacist present if the following requirements of the professional service area are met:

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

(ii) The barrier is locked in the absence of the pharmacist.

(B) The managing pharmacist is responsible for compliance with all professional service area security requirements.

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

(f) Equipment. The professional service area of a pharmacy shall have the following equipment:

(1) A prescription balance capable of weighing substances to a degree of accuracy within 95% - 105%.

(2) One set of accurate metric weights capable of weighing substances of 50 mg. to 50 gm.

(3) A supply of transparent graduates in metric scale capable of measuring one ml. to 100 ml.

(4) A supply of wedgewood and glass mortars and pestles.

(5) Stainless steel spatulas in assorted sizes and at least one non-metallic spatula.

(6) An assortment of acid/base and solvent-resistant funnels.

(7) A heating device.

(g) Storage.

(1) The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

(2) The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

(3) Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

(h) Compliance to Rules and Regulations. All existing and new pharmacies must conform to the above rules and regulations by June 30, 1987.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

2017 NOTE: Subsection/subitem designations added/altered pursuant to the authority granted by 1 GCA § 1606.

§ 13107. Manufacturer's and Other Drug Distribution Permits.

The Board from time to time will monitor pharmacy for violations of federal and government laws and make referrals of such violations as necessary to the Food and Drug Administration or the Department of Public Health and Social Services.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13108. Pharmacy Practice.

(a) Minimum Procedures for Compounding and Dispensing.

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

(A) Receive oral or written prescription orders of a prescriber, review all original and renewal prescription orders, written or oral, and determine therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber.

(B) Read and interpret a prescriber's directions for use for the purpose of accurately transferring the instructions to the prescription label.

(C) Select, compound, mix, combine, measure, count, and otherwise prepare drugs needed to dispense a prescription except that an agent of the pharmacist may procure, measure or count prefabricated dosage forms if a pharmacist verifies accuracy of the agent's action.

(D) Make a final check on the accuracy and correctness of the prescription. For all original and renewed prescriptions, the prescription order shall identify the pharmacist responsible for the prescription.

(E) Transfer the prescription to the patient or agent of the patient and give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist.

(F) Obtain, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on the reverse side of the prescription order or a medication profile or a readily retrievable log book the following data:

(i) Date renewed.

(ii) Name of practitioner authorizing renewal, if different from the original prescriber.

(iii Quantity of drug dispensed.

(iv) Identification of the pharmacist renewing the prescription.

(2) Sub. (1) (D) and (E) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. Sub. (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharged patients.

(3) A pharmacist may supervise no more than one pharmacy intern and one non-pharmacist engaged in compounding and dispensing activities as described in sub. (1), except a higher ratio may be authorized by the Board upon request to and approval by the Board of a specific plan describing the manner in which additional interns or non-pharmacists shall be supervised.

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

(b) Prescription Label; Name of Drug or Drug Product Dispensed. No prescription drug may be dispensed unless the prescription label discloses the generic or brand name of the drug or drug product dispensed. If the product dispensed is not the brand prescribed, the label must include a statement, "to the effect that the product dispensed is a generic of the prescribed brand."

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

(d) Return or Exchange of Drugs Prohibited. No drugs, medicines or items of personal hygiene, after taken from a pharmacy where sold, distributed or dispensed, may be returned except a health care facility may return them to the pharmacy provided they are in their original containers and the pharmacist determines the contents are unadulterated and uncontaminated.

(e) Prescription Records.

(1) A record of prescriptions dispensed shall be maintained for a period of five years after the date of the last renewal.

(2) A record of all prescriptions renewed shall be maintained by indicating on the original prescription order or on a readily retrievable medication profile record or log book the date and amount of the renewal.

(3) The transfer of original prescription information for the purpose of refill dispensing is permissible between two pharmacies pursuant to the following requirements:

(A) The transfer is communicated directly between two pharmacists and the pharmacist making the transfer records the following information:

(i) The name and address of the pharmacy to which it is transferred, the name of the pharmacist receiving the prescription, the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription.

(ii) The pharmacist receiving the transferred prescription information shall record in writing the following:

(aa) The word "TRANSFER" on the face of the transferred prescription.

(bb) The date of issuance of the original prescription order.

(cc) The original number of refills authorized on the original prescription.

(dd) The date the prescription was dispensed originally.

(ee) The number of valid refills remaining and the date of the last refill.

(ff) The pharmacy's name, address, the original prescription number from which the prescription information was transferred.

(gg) The name of the pharmacist making the transfer.

(iii) The original and transferred prescription order shall be maintained for a period of five years from the date of the last refill.

(4) A written copy of any prescription order for a prescription drug provided by a pharmacist shall be identified in writing as "COPY-FOR-INFORMATION". No prescription drug may be dispensed based on an information copy.

(f) Complete Pharmaceutical Service. Complete pharmaceutical service including compounded prescriptions, shall be available to the public normally served by the pharmacy.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

2017 NOTE: Subitem designations altered pursuant to the authority granted by 1 GCA § 1606. Internal references altered to reflect the change.

§ 13109. Requirements for Controlled Substances.

The Board from time to time will monitor pharmacy for violations of federal and government laws and make referrals of such violations as necessary to the Food and Drug Administration or the Department of Public Health and Social Services.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13110. Standards of Professional Conduct.

(a) Authority. The rules in this chapter are adopted pursuant to the authority in P.L. 16-123.

(b) Definitions**.** In this Chapter,

(1) *Dispense* means to select, compound, mix, combine, measure, count, or otherwise prepare a drug or drugs for delivery to the patient, or to deliver a drug or drugs to the patient.

(2) *Drug* has the meaning defined in P.L. 16-123.

(3) *Patient* means the individual for whom drugs are prescribed or to whom prescription drugs are administered.

(c) Unprofessional Conduct. Violations of standards of professional conduct and offenses concerning unprofessional conduct under P.L. 16-123, Section 12605, include but not limited to:

(1) Violating, or aiding or abetting the violation of, any law substantially related to the practice of pharmacy;

(2) Being convicted of any crime the circumstances of which substantially relate to the practice of pharmacy;

(3) Administering, dispensing, supplying or obtaining a drug other than in legitimate practice, or as prohibited by law;

(4) Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public, including but not

limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist which harmed or could have harmed a patient;

(5) Dispensing a drug which the pharmacist should have known would harm the patient for whom the medication was prescribed;

(6) Dispensing or causing to be dispensed a drug which is outdated or contaminated or known by the pharmacist to be unsafe for consumption;

(7) Practicing while the ability of the pharmacist to competently perform duties is impaired by mental or emotional disorder or drug, alcohol abuse;

(8) Falsifying patient records;

(9) Disclosing to the public information concerning a patient without the consent of the patient unless the information is requested by the Pharmacy Examining Board or any Federal or Government of Guam agency having regulatory and licensing authority on Guam;

(10) Failing to report to the Pharmacy Examining Board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public;

(11) Providing false information to the Pharmacy Examining Board or its agent;

(12) Refusing to render professional services to a person because of race, color, sex, religion, or age;

(13) Obtaining or attempting to obtain any compensation by fraud or deceit;

(14) Aiding or abetting the unlicensed practice of pharmacy;

(15) Advertising in a manner which is false, deceptive or misleading;

(16) Dispensing sample drug products for any financial consideration;

(17) Exercising undue influence on or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacist or a third party;

(18) Participating in rebate or fee-splitting arrangements with health practitioners or with health care facilities;

(19) Furnishing a prescriber with any prescription order blanks imprinted with the name of a specific pharmacist or pharmacy;

(20) Using secret formula or code in connection with prescription orders;

(21) Having a pharmacist license revoked or suspended in another state or United States jurisdiction; or

(22) Violating or attempting to violate any formal disciplinary order of the Board.

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13111. Fees.

[Repealed.]

SOURCE: Amended rules filed with the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Ch. 9, Art. 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c). Repealed and superseded by P.L. 24-207 (May 13, 1998).

§ 13112. Institutional Facility as defined in §13101(b)(27); Use of Automated Pharmacy System; Policies and Procedures Required.

Any institutional facility that uses an automated pharmacy system shall develop, maintain, and comply with policies and procedures developed in consultation with the pharmacist responsible for pharmacist care for that institutional facility. At a minimum, the policies and procedures shall address the following:

(a) The description and location within the institutional facility of the automated pharmacy system or equipment being used;

(b) The name of the individual or individuals responsible for implementation of and compliance with the policies and procedures;

(c) Medication access and information access procedures;

(d) Security of inventory and confidentiality of records in compliance with state and federal laws, rules, and regulations;

(e) A description of how and by whom the automated pharmacy system is being utilized, including processes for filling, verifying, dispensing, and distributing medications;

(f) Staff education and training;

(g) Quality assurance and quality improvement programs and processes;

(h) Inoperability or emergency downtime procedures;

(i) Periodic system maintenance; and

(j) Medication security and controls.

SOURCE: Adopted Feb. 2, 2017 along with amendments to this chapter and submitted to the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Chapter 9, Article 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

2017 NOTE: In the title of this section it referenced § 13101(27). The correct reference is §13101(b)(27).

§ 13113. Automated Pharmacy System; Requirements; Location.

Automated Pharmacy Systems are subject to the requirements of § 13112.

SOURCE: Adopted Feb. 2, 2017 along with amendments to this chapter and submitted to the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Chapter 9, Article 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13114. Automated Pharmacy System; Requirements; Drugs; Limitations; Inventory; How Treated.

(a) An automated pharmacy system:

(1) is subject to the requirements of § 13112; and

(2) may be operated in an institutional facility as defined in §13101 for medication administration pursuant to a chart or medication order by a licensed health care professional.

(b) Drugs placed in an automated pharmacy system shall be in the manufacturer's original packaging or in containers repackaged in compliance with Guam and federal laws, rules, and regulations relating to repackaging, labeling, and record keeping.

SOURCE: Adopted Feb. 2, 2017 along with amendments to this chapter and submitted to the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Chapter 9, Article 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13115. Remote Medication Order Processing By a Remote Site; General Requirements.

(a) A Guam institutional facility may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(b) The pharmacist may be employed or contracted by the entity.

(1) The pharmacist must be a Guam licensed pharmacist.

(2) The entity must have a written agreement or contract with the pharmacist.

(c) The written agreement or contract shall:

(1) Outline the services to be provided.

(2) Delineate the responsibilities of each party (entity) including compliance with federal and Guam laws and regulations governing the practice of pharmacy as well as Guam and federal medical privacy requirements.

(3) Require that the parties (entities) adopt a policies and procedures manual.

(4) Provide that the parties (entities) have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

§ 13116. Pharmacist Providing Remote Medication Order Processing; Requirements.

A pharmacist providing pharmacist remote medication order processing shall:

(a) be located in a site or facility licensed by the Board;

(b) be located within the United States, a territory thereof, or the District of Columbia;

(c) maintain adequate security and privacy in accordance with state and federal laws, rules, and regulations;

(d) be linked to an institutional facility for which services are provided via computer link, video link, audio link, or facsimile transmission or other electronic devices;

(e) have access to each patient's medical information necessary to perform via computer link, video link, or facsimile transmission or other electronic devices, a prospective drug utilization review as defined in § 13101(b)(20), Drug Regimen Review; and

(f) be employed by or have a contractual agreement to provide such services with the institutional facility where the patient is located.

SOURCE: Adopted Feb. 2, 2017 along with amendments to this chapter and submitted to the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Chapter 9, Article 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

2017 NOTE: Subsection (e) contains an erroneous reference to § 13101(20); the correct reference is §13101(b)(27) and this manifest error was corrected pursuant to the authority granted by 1 GCA § 1606.

§ 13117. Notifications to patients.

An institutional facility that outsources remote medication order processing shall prior to outsourcing their order:

(a) notify patients that remote medication order processing may be outsourced to another site or facility; and

(b) provide the name of that site or facility to the patient. Such notification may be provided through a one-time written notice to the patient.

SOURCE: Adopted Feb. 2, 2017 along with amendments to this chapter and submitted to the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Chapter 9, Article 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13118. Records.

All pharmacies shall maintain appropriate records which identify, by medication order, the name(s), initials, or identification code(s) of each pharmacist and pharmacy technician who performs a processing function for medication order. Any record generated in this process whether in a hard copy or electronic format shall be maintained for a period required by local and federal law. Such records may be maintained:

(a) separately by each facility/site; or

(b) in a common electronic file as 1ong as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

(c) and have the ability to audit the activities of the individuals remotely processing medication orders.

§ 13119. Patient Privacy.

In the operation of the remote medication order processing site, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times.

SOURCE: Adopted Feb. 2, 2017 along with amendments to this chapter and submitted to the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Chapter 9, Article 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).

§ 13120. Submission to the Jurisdiction of the Board.

The filing of an application for licensure to practice telepharmacy by any applicant shall constitute the applicant's agreement to submit to the jurisdiction of the Guam Board of Examiners for Pharmacy and to abide by the laws and rules and regulations governing the practice of pharmacy in Guam.

SOURCE: Adopted Feb. 2, 2017 along with amendments to this chapter and submitted to the Legislative Secretary on Feb. 20, 2017 pursuant to 5 GCA, Chapter 9, Article 3. Effective May 22, 2017 pursuant to 5 GCA § 9303(c).
