DIVISION OF PROFESSIONAL REGULATION

2500 Board of Pharmacy
Statutory Authority: 24 Delaware Code,
Section 2509 (24 **Del.C.** §2509)
24 **DE Admin. Code** 2500

ORDER

A public hearing was held after due notice on May 11, 2005 at a meeting of the State Board of Pharmacy to receive public comments related to proposed changes in Regulations 1.0, 3.0, 5.0, 9.0, and 10.0. The notice appeared in two Delaware newspapers and in the *Register of Regulations*, 8 **DE Reg** 1372(4/1/05).

Summary of the Evidence and Information Submitted

1. The written comment is summarized as follows:

Daniese McMullin-Powell, Chairperson, State Council for Persons with Disabilities submitted a memorandum dated April 29, 2005 with three comments which was marked as Board Exhibit 1. First, Council recommended consistency in the use of the term "prescriber" and noted that in Regulation 5.7.2.4 and 5.7.4 the term "physician" was used.

Secondly, Council suggested correcting an inconsistency in Regulations 5.3.1. and 5.7.4. The former permits a prospective drug review by a student in a practical experience program.

Finally, Council seeks clarification and explanation of the deletion of the reinstatement standards.

John A. Werner, Chairperson, Governor's Advisory Council for Exceptional Citizens, submitted a letter dated May 2, 2005 which was marked as Board Exhibit 2. Mr. Werner repeated the three comments expressed in Board Exhibit 1 from the State Council for Persons with Disabilities.

James A. Krahulec, R.Ph., Esq., Vice President, Government and Trade Relations, Rite Aid Corporation, submitted a letter dated May 9, 2005 which was marked as Board Exhibit 3. Mr. Krahulec, on behalf of the twenty-four (24) Rite Aid pharmacy locations operating in Delaware, expressed support of the Board's proposed amendments to regulation 5.3.4 concerning patient counseling. He commended the Board's proposal to delete language under regulation 5.3.4 that requires the documentation of who made the offer to counsel as unnecessarily redundant in light of the requirement to document a patient's acceptance or refusal of counseling. Mr. Krahulec urged the Board to adopt the amendments under regulation 5.3.4 as proposed.

Kevin N. Nicholson, R.Ph., JD, Director, Pharmacy Regulatory Affairs, National Association of Chain Drug Stores, submitted a letter dated May 9, 2005 which was marked as Board Exhibit 4. Mr. Nicholson, on behalf of the approximately 143 chain pharmacies operating in the State of Delaware, repeated the comments expressed in Board Exhibit 3 and urged adoption of regulation 5.3.4 as proposed.

Gary Wirth, R.Ph., MBA, Director of Professional Services, Ahold USA Inc., submitted a letter dated May 11, 2005 that was marked as Board Exhibit 5. Mr. Wirth expressed support for the proposed change to paragraph 5.3.4 to delete the requirement to record the identity of the pharmacy associate who makes the offer to counsel. Mr. Wirth commented that the proposed amendment is consistent with the pharmacy regulations in surrounding states and simplifies administrative procedure at their SUPER G pharmacies.

2. The following verbal comment was offered on May 11, 2005:

Pat Carroll-Grant, Director of Pharmacy at the Delaware Hospital for the Chronically Ill and Director of the Delaware Pharmacy Society, submitted verbal comment at the hearing. Ms. Carroll-Grant stated that the comments were hers and those of the legislative and executive committees of the Delaware Pharmacy Society.

First, Ms. Carroll-Grant questioned the proposed language in Regulation 1.2.3 regarding preceptors that states "A pharmacist employed by a College of Pharmacy shall serve as the preceptor for a student participating in the coordinated practical experience program." She commented that her employer does not allow her to be employed by a College of Pharmacy. Ms. Carroll-Grant recommended that the Board remove the word "employed" and replace it with another term that would still get across the point that the college is responsible for certifying or selecting the preceptors. She stated that requiring a preceptor to be an employee of the college could be a problem and would limit the available preceptors of pharmacy corporations that do not want their employees to be employed by a college but that are very willing to take on students to avail them of multiple preceptors at multiple sites.

Ms. Carroll-Grant stressed that it is important for students to practice in Delaware and stated that expanded sites are needed. Ms. Carroll-Grant recommended that the Board remove the words "employed by" and replace them with "affiliated with."

Next, Ms. Carroll-Grant questioned the requirement in Regulation 1.5 that requires a pharmacist to retain supporting documentation of continuing education for a minimum of six years. She commented that there is no other documentation that a pharmacist needs to keep for six years including controlled substance documentation. She stated that six years places a burden on the pharmacist and requested that it be changed to three years to be consistent with the requirements that apply to retention of other types of documents.

Ms. Carroll-Grant also urged the Board to adopt written audit procedures as previously requested by the Delaware Pharmacy Society to expand on the provision that now only provides for a random selection of 10% of pharmacists to be audited during the biennial term. She stated that written procedures are needed to inform pharmacists of what is involved in the audit process, what years will be covered in the audit and what happens if they do not comply. Specifically, she questioned whether the pharmacist could be audited back for six years and, if so, what would happen if a pharmacist was found not to be in compliance. She commented that if an interpretation was made that they were practicing without a license as a result of the audit, issues would arise as to the prescriptions that they filled and their professional liability insurance.

Ms. Carroll-Grant also questioned the deletion of Regulation 1.6 relating to Re-Entry. She commented that the Delaware Pharmacy Society is on record as saying that they do not agree with the removal of grace periods. While they want pharmacists to pay their dues on time and be compliant with the regulations, they believe removal of the language altogether places a burden on the pharmacist. She requested that the Board at least consider some definition of a grace period.

Ms. Carroll-Grant had no issues with Regulation 3.0 and supported the Board's changes.

Finally, Ms. Carroll-Grant commented on changes to Regulation 5.0 dealing with supervision. Specifically, she questioned why Regulation 5.2 did not provide for the listed tasks to be under the direct supervision of a licensed pharmacist. Ms. Carroll-Grant commented that if she was reading the rule correctly, a pharmacy intern could be a third year pharmacy student who has never worked in a pharmacy and still sign up to be a pharmacy intern. She stated that that is not the equivalent to a student in the last year of a clerkship requirement. She questioned whether the intent of the regulation is to allow pharmacy interns to do the things listed in the rule. She commented that the pharmacy intern really does not know much more than a good technician at that point and that extra checks and balances are needed for technicians. Ms. Carroll-Grant stated that she would feel better if Regulation 5.2 included the "under the direct supervision of a licensed pharmacist language."

She questioned further with regard to this issue whether the intent of Regulation 5.2.3 is to not require the pharmacist supervising the intern to sign off and to instead allow the intern or student to have signing authority for what was done that day as being correct. Ms. Carroll-Grant pointed out that 5.3.1 does have the supervision language and stated that she believed 5.3.1 is more consistent with what she thought were the Board's concerns.

Findings of Fact with Respect to the Evidence and Information Submitted

1. The Board intends to use the term "prescriber" consistently in the Regulations to identify the person who writes a prescription. Changes will be made to Regulations 5.7.2.4 and 5.7.4. Similarly, Regulation 5.7.4 will be changed for consistency to include the pharmacy student as a person who, under supervision, can examine a patient's profile prior to dispensing. The revised text follows:

> "5.7.2.4 The original date the medication is dispensed pursuant to the receipt of a ~~physician's~~ prescriber's prescription;
>
> 5.7.4 Upon receipt of a new prescription, a pharmacist, ~~or~~ pharmacy intern, or student participating in a College of Pharmacy practical experience program under the direct supervision of a pharmacist must examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potential harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem with shall, if necessary, include consultation with the ~~physician~~ prescriber."

2. The Board deleted Regulation 1.6 regarding re-entry because of the lack of enabling legislation to support that provision. A person whose license expired less than 60 days prior to application must comply with the provisions in 24 **Del.C.** §2517(c). If the license is expired longer than 60 days, the applicant must reapply as provided in §§2514-2516. The Board currently has no authority to provide a grace period.

3. The Board does not believe that the term "employed by" as used in Regulation 1.2.3 would preclude a pharmacist who is not an employee of a College of Pharmacy from acting as a preceptor. The purpose of the amendment was to create a standard that is in place in other states to allow a student to be joined to a faculty member at a College of Pharmacy and who could be their preceptor. It does not say that a pharmacist in this state who is not employed by a College of Pharmacy cannot be a preceptor. However, for clarification and consistency purposes the Board will change the words "employed by" to "affiliated with" to clarify that there is no requirement of an actual employment relationship with the college or university. The revised text follows:

~~1.2.4~~ 1.2.3 Practical experience must be acquired under the supervision of a licensed pharmacist known as a Preceptor. The Preceptor must be a pharmacist licensed in this State or any other State and must have a minimum of two years of pharmacy practice. A pharmacist ~~employed by~~ affiliated with a College of Pharmacy shall serve as the preceptor for a student participating in the coordinated practical experience program. The Preceptor must certify that the intern has successfully completed all the requirements outlined in the Responsibilities of the Intern professional assessment form.

4. The Board is satisfied that the requirement to maintain continuing education records for six years as required by Regulation 1.5 is not unduly burdensome and that six years is a reasonable period for requiring pharmacists to maintain continuing education records. This order clarifies that audit relates to the biennial period subject to audit for renewal of licensure. The intent of the regulation is not to conduct a six year audit. The requirement of a six year retention period is to enable the Board to verify that the pharmacist is not submitting the same continuing education verification for multiple reporting periods.

5. The Board is persuaded by the public comment that Regulation 5.2 would be improved by clarifying that Regulation 5.2 and its subsections all require that the intern or student participating in an approved College of Pharmacy coordinated practical experience program must be acting "under the direct supervision of a pharmacist." The Board finds that this is best achieved by deleting the period at the end of Regulation 5.2 and adding "under the direct supervision of a pharmacist" to the end of the sentence. The revised text follows:

5.2 The practice of dispensing shall include, but not be limited to the following acts which shall be performed only by a pharmacist, or a pharmacy intern or student participating in an approved College of Pharmacy coordinated, practical experience program~~.~~ under the direct supervision of a pharmacist.

The Board determines that the changes are for clarification and consistency and are not substantive.

Text and Citation

The text of the revised rules remains as published in *Register of Regulations* except for the modifications noted herein.

Decision and Effective Date

The Board hereby adopts the changes to Regulation 1.0, 3.0, 5.0, 9.0, and 10.0 to be effective 10 days following publication of this order in the *Register of Regulations.*

SO ORDERED this 8th day of June, 2005.

STATE BOARD OF PHARMACY
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1.0 Pharmacist Licensure Requirements

1.1 Examination Requirements

1.1.1 In order to be eligible for examination for licensure, an applicant must provide proof of completion of all requirements for graduation from an approved school or college. An approved school or college of pharmacy is an institution which has established standards in its undergraduate degree program which are at least equivalent to the minimum standards for accreditation established by the American Council on Pharmaceutical Education. Provided, however, that graduates of schools or colleges of pharmacy located outside of the United States, which have not established standards in their respective undergraduate degree programs which are at least equivalent to the minimum standards for accreditation established by the American Council on Pharmaceutical Education, shall be deemed eligible for examination for licensure by providing evidence satisfactory to the Board of Pharmacy of graduation from such school or college and by successfully passing an equivalency examination recognized by the Board of Pharmacy. Certification by the National Association of Boards of Pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee (FPGEC) meets the equivalency examination requirement.

1.1.2 Candidates must obtain a passing grade as determined by the National Association of Boards of Pharmacy (NABP) on the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination for Delaware (MPJE) to be eligible for a license to practice. A candidate must take an examination within 365 days of the determination of eligibility by the Board. The Secretary will supply the grades obtained to the candidate upon receipt of a written request from that person.

1.1.3 The Board will re-confirm the eligibility of an applicant who fails the NAPLEX. The applicant shall be entitled to take a re-examination at least ninety-one (91) days following the date of the failure. If an applicant has failed the examination three times, he/she shall be eligible to re-take the NAPLEX, provided that he/she produces evidence of working full-time as an intern for a period of six months or has attended an accredited college of pharmacy as a registered student for a minimum of one semester consisting of 12 credits during the interim. A certification of satisfactory completion of such work shall be furnished by the Dean of the College or the preceptor as the case may be.

1.1.4 The Board will re-confirm the eligibility of an applicant who fails the MPJE. The applicant shall be entitled to re-take the MJPE at least thirty-one (31) days following the date of the failure. If an applicant has failed the examination three times, he or she shall be eligible to re-take the examination, provided that he or she produces evidence of working full-time as an intern for a period of three months or has completed a one semester college course on jurisprudence.

1.2 Practical Experience Requirements

1.2.1 An applicant for registration as an intern must submit an application for registration of Internship after entering the first professional year of college of pharmacy which includes an "Affidavit of Class Standing" and "Affidavit of Preceptor." This application must be obtained from the Board of Pharmacy. If the applicant is a graduate of a foreign pharmacy school, he/she must produce evidence that he/she has passed an equivalency examination by the Board.

1.2.2 Persons who register as interns in the State of Delaware shall, in accordance with the requirements of 24 **Del.C.** §2515, complete not less than 1500 hours of Board approved practical experience under the supervision of a licensed pharmacist. ~~The total 1500 hours of internship may be acquired in the community or hospital settings.~~ A minimum of 1000 hours shall be obtained in the community or hospital settings. The remaining 500 hours may be obtained in other recognized fields of practice, e.g.: Industrial Pharmacist, Drug Information Pharmacist, Military Pharmacist, Mail Order Pharmacist, HMO Pharmacist, Consultant Pharmacist (Nursing Home, Infusion, Medicaid DUR, Etc.), Home Health Care Pharmacist (may include Durable Medical Equipment, etc.), Nuclear Pharmacist, Compliance Pharmacist, Government Pharmacist, Clinical Pharmacist, Contracted Pharmacy Services.

~~1.2.3 The hours accrued during the College of Pharmacy Practical Experience Program may be applied to the 1500 hours total. These hours shall be recorded on the College Practical Experience Affidavit supplied by the Board. Additional practical experience acquired in the State of Delaware must be submitted to the Board on the Affidavit of intern Experience form provided by the Board of Pharmacy Office. Practical experience acquired in another State is acceptable if the State Board in which the applicant acquired the hours submits a letter of certification, or if the applicant's preceptor completes the Delaware State Board of Pharmacy's Affidavit of intern Experience form. Applicants who have not completed all the practical experience requirements, but who have graduated from an accredited college or have been certified by the NABP Foreign Pharmacy Graduate Examination~~

~~Committee are eligible to take the examination. However, applicants will not be fully licensed until all the requirements of the Statutes and Regulations are completed.~~

~~1.2.4~~ 1.2.3 Practical experience must be acquired under the supervision of a licensed pharmacist known as a Preceptor. The Preceptor must be a pharmacist licensed in this State or any other State and must have a minimum of two years of pharmacy practice. A pharmacist **[~~employed by~~ affiliated with]** a College of Pharmacy shall serve as the preceptor for a student participating in the coordinated practical experiance program. The Preceptor must certify that the intern has successfully completed all the requirements outlined in the Responsibilities of the Intern professional assessment form.

1.2.4 Practical experience acquired in another State is acceptable if the State Board in which the applicant acquired the hours submits a letter of certification, or if the applicant's preceptor completes the Delaware State Board of Pharmacy's Affidavit of Intern Experience form. Applicants who have not completed all the practical experience requirements, but who have graduated from an accredited college or have been certified by the NABP Foreign Pharmacy Graduate Examination Committee are eligible to take the examination. However, applicants will not be fully licensed until all the requirements of the Statutes and Regulations are completed.

~~1.2.5 An intern must notify the Board of Pharmacy in writing within ten (10) days of a change of preceptor. A change of preceptor affidavit must be completed and filed with the Board.~~ The hours accrued during the College of Pharmacy Practical Experience Program may be applied to the 1500 hours total. These hours shall be recorded on the College Practical Experience Affidavit supplied by the Board. Registration as an intern in this State is not required for school experience.

~~1.2.5~~ 1.2.6 An intern must notify the Board of Pharmacy in writing within ten (10) days of a change or preceptor. A change of preceptor affidavit must be completed and filed with the Board.

1.3 Continuing Education Requirements

1.3.1 A pharmacist must acquire 3.0 C.E.U.'s (30 hours) per biennial licensure period. No carry over of credit from one registration period to another period is permitted.

1.3.2 Hardship - Hardship exemptions may be granted by the Board of Pharmacy upon receipt of evidence that the individual was unable to complete the requirements due to circumstances beyond his control.

1.3.3 Criteria for Hardship Exemption as Recommended by the Board of Pharmacy:

1.3.3.1 Applicant must notify the Board in writing concerning the nature of the hardship and the time needed for an extension. In case of medical disability, a letter from the physician with supporting documentation to corroborate the condition and the length of time of extension needed.

1.3.3.2 The Board of Pharmacy will review requests.

1.3.3.3 The Board will notify the registrant of its decision.

1.3.4 Persons who are newly licensed after the registration period begins, must complete continuing education units proportional to the total number of continuing education units required for the biennial licensure renewal. (1.25 hours/per month).

1.4 Continuing Professional Educational Programs

1.4.1 Topics of Study

Topics of study shall be subject matter designed to maintain and enhance the contemporary practice of pharmacy.

1.4.2 Approved Provider

1.4.2.1 Any provider approved by ACPE.

1.4.2.2 In-state organization which meets criteria approved by the Board.

1.4.3 Application for Delaware State Provider

1.4.3.1 Any in-state organization may apply to the Board on forms provided by the Board for initial qualification as an approved provider. The Board shall accept or reject any such application by written notice to such organization within 60 days after receipt of its application. If an organization is approved, the Board will issue a certificate or other notification of qualification to it, which approval shall be effective for a period of two years and shall be renewable upon the fulfillment of all requirements for renewal as set forth by the Board.

1.4.3.2 The Board may revoke or suspend an approval of a provider or refuse to renew such approval if the provider fails to maintain the standards and specifications required. The Board shall serve written notice on the provider by mail or personal delivery at its address as shown on its most current application specifying the reason for suspension, revocation, or failure to renew. The provider so affected shall, upon written request to the Board within ten days after service of the notice, be granted a prompt hearing before the Board at which time it will be permitted to introduce matters in person, or by its counsel, to defend itself against such revocation, suspension, or failure to renew, in accordance with the provisions set forth in the State's Administrative Procedures Act.

1.4.4 Criteria for Approval of Delaware State Providers. Only applicants who are located within the State of Delaware are eligible. Such Continuing Education providers shall provide evidence of ability to meet the

following criteria or approval as a Continuing Pharmaceutical Education Provider. Other persons must apply through ACPE for approval or be acceptable to other Boards of Pharmacy that certify continuing education for relicensure.

1.4.4.1 Administration and Organization

1.4.4.1.1 The person who is in charge of making sure that the program meets the quality standards must have a background in the administration of education programs.

1.4.4.1.2 There shall be an identifiable person or persons charged with the responsibility of administering the continuing pharmaceutical education program.

1.4.4.1.3 Such personnel shall be qualified for such responsibilities by virtue of experience and background.

1.4.4.1.4 If an approved provider presents programs in co-sponsorship with other non-approved provider(s), the approved provider has the total responsibility for assurance of quality of that program. If more than one approved provider co-sponsors a program, they have the joint responsibility for assuring quality.

1.4.4.1.5 Administrative Requirements include:

1.4.4.1.5.1 The development of promotional materials which state:

1.4.4.1.5.1.1 Educational objectives.

1.4.4.1.5.1.2 The target audience.

1.4.4.1.5.1.3 The time schedule of the activities.

1.4.4.1.5.1.4 Cost to the participant/covered items.

1.4.4.1.5.1.5 Amount of C.E. credit which will be awarded.

1.4.4.1.5.1.6 Credentials of the faculty, presenters, and speakers.

1.4.4.1.5.1.7 Self-evaluation instruments.

1.4.4.1.5.2 Compliance with a quantitative measure for C.E. credit.

1.4.4.1.5.2.1 The number of C.E.U.'s to be awarded for successful completion shall be determined by the provider and reported in the promotional materials.

1.4.4.1.5.2.2 In cases where the participants' physical presence is required, C.E. credit will only be awarded for that portion of the program which concerns itself with the lecture(s), evaluation and question and answer segments.

1.4.4.1.5.2.3 The measure of credit shall be a fifty-minute contact hour. In the case of other programs such as home study courses, the amount of credit awarded shall be determined by assessing the amount of time the activity would require for completion by the participant if delivered in a more formal and structured format.

1.4.4.1.5.2.4 The provider must provide the Board upon request with appropriate records of successful participation in previous continuing education activities.

1.4.4.1.5.2.5 The provider must present to the participant a form or certificate as documentation of the completion of the program. The form must be at least 4" x 6" and no larger than 8 1/2" x 11". That certificate must show the name, address, and license number of the participant, the name of the provider, the title and date of the program, the number of credits earned, and an authorized signature from the provider.

1.4.4.2 Program Faculty. The selection of program faculty must be based upon proved competency in the subject matter and an ability to communicate in order to achieve a learning experience.

1.4.4.3 Program Content Development

1.4.4.3.1 Such programs shall involve effective advance planning. A statement of educational goals and/or behaviors must be included in promotional materials. Such objectives and goals must be measurable and accessible to evaluation. In determining program content, providers shall involve appropriate members of the intended audience in order to satisfy the educational needs of the participants. All programs of approved providers should pertain to the general areas of professional pharmacy practices which should include, but not be limited to:

1.4.4.3.1.1 The social, economic, behavioral, and legal aspects of health care,

1.4.4.3.1.2 the properties and actions of drugs and drug dosage forms,

1.4.4.3.1.3 the etiology, characteristics, therapeutics and prevention of the disease state,

1.4.4.3.1.4 pharmaceutical monitoring and management of patients.

1.4.4.3.2 All ancillary teaching tools shall be suitable and appropriate to the topic.

1.4.4.3.3 All materials shall be updated periodically to include up-to-date-practice setting.

1.4.4.3.4 It is the responsibility of the provider to be sure that the programs are continuously upgraded to meet educational objectives of the Practice of Pharmacy. The needs of the pharmacist participant must be considered in choosing the method of delivery. Innovation in presentations is encouraged within the limits of budget

resources and facilities. Whatever method of delivery is used, it must include the participation of the pharmacist as much as possible within the program, i.e. questions and answers, workshops, etc.

1.4.4.4 Facilities. The facilities shall be adequate for the size of the audience, properly equipped (all appropriate audio/-visual media materials), well lighted and ventilated to induce a proper learning experience.

1.4.4.5 Evaluation. Effective evaluation of programs is essential and is the responsibility of both the provider and participant.

1.4.4.5.1 Participant - Some evaluation mechanisms must be developed by the provider to allow the participant to assess his/her own achievement per the program.

1.4.4.5.2 Provider evaluation - a provider shall also develop an instrument for the use of the participant in evaluating the effectiveness of the program including the level of fulfillment of stated objectives.

1.4.5 Criteria for Awarding Continuing Education Credits. Individual programs must meet the criteria for provider approval in order to be considered. In those cases where the provider is not an ACPE provider, nor a Board of Pharmacy approved provider, a registrant may complete an application provided by the Board for approval of individual programs.

1.4.5.1 In order to receive full credit for non-ACPE approved programs of one-to-two hour lengths, evidence of a post test must be presented. An automatic 25% deduction if no post test presented.

1.4.5.2 In order to receive full credit for non ACPE approved programs of three or more hours in length, evidence of a pre and post test must be presented. Automatic 25% deduction if no pre and post test presented.

1.4.5.3 Credit will be assigned only for the core content of the program which explicitly relates to the contemporary practice of Pharmacy.

1.4.5.4 A maximum of 2 credit hours will be awarded for First Aid, attendance at a Board of Pharmacy meeting and CPR/BCLS courses one time only per registration period.

1.4.5.5 Credit for Instructors of Continuing Education

1.4.5.5.1 Any pharmacist whose primary responsibility is not the education of health professionals, who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy related topics in organized continuing education or inservice programs, shall be granted continuing education credit for such time expended during actual presentation, upon adequate documentation to the Delaware Board of Pharmacy.

1.4.5.5.2 Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses or others on pharmacy related topics outside his/her formal course responsibilities (that is, lectures or instructions must be prepared specifically for each program) in a learning institution.

1.4.5.5.3 Credit for presentations of in-service training programs or other lectures shall be granted only for topics meeting the criteria for continuing pharmacy education, and shall be granted only once for any given program or lecture. (Any topic completely revised would be eligible for consideration.)

1.4.5.5.4 A maximum of 6 hours (0.6 C.E.U.'s) in this category may be applied toward fulfilling the total biennial continuing education requirements.

1.4.5.6 Credit for On the Job Training:

1.4.5.6.1 The Board of Pharmacy does not as a general rule encourage the submission of "on the job training" for fulfilling the continuing education requirements. All programs meeting this definition shall be reviewed on an individual basis.

1.4.5.6.2 All programs that are submitted for credit must meet the criteria for continuing pharmacy education.

1.4.5.6.3 No credit shall be awarded for programs required by an employer for continued employment of the employee. (Examples OSHA training, Infection Control Education required by JCAHO.)

1.4.5.6.4 A maximum of 4 hours (0.4 C.E.U.'s) in this category may be applied toward fulfilling the total biennial continuing education requirements.

1.5 The Verification of Continuing Education - ~~A pharmacist shall complete the required continuing education and submit the signed renewal form with appropriate fees to the Board of Pharmacy.~~ A pharmacist shall retain the supporting documentation, such as certification of completion for a minimum of six years. The Board will randomly audit the documentation of at least 10% of licensed pharmacists every biennial term. Supporting documentation may be requested for up to six years. Pharmacists who were not selected for audit do not send supporting documentation to the Board. Submitting a false documentation may constitute grounds for discipline under 24 **Del.C.** §2518 (a)(1).

~~1.6 Re-Entry - A pharmacist may have his/her license reinstated by completing the following requirements:~~

~~1.6.1 Payment of any back fees;~~

~~1.6.2 Successfully obtaining a grade of 75 on an examination on the Practice of Pharmacy if the pharmacist has not practiced in three years;~~

~~1.6.3 Submission of evidence of completion of at least 20 hours of approved C.E. from the date of application for reinstatement if the pharmacist has practiced within the last three years.~~

1.~~7~~6 Reciprocal Requirements

1.~~7~~6.1 An applicant for licensure by reciprocity shall be of good moral character and shall:

1.~~7~~6.1.1 submit proof that he or she was qualified for licensure in Delaware at the time of initial licensure by examination;

1.~~7~~6.1.2 submit proof of licensure in good standing from each state where he or she is or has been licensed; and

1.~~7~~6.1.3 obtain a passing score on the MPJE on the laws applicable in this State as provided in Regulation 1.1.

1.~~7~~6.2 Reciprocity applicants who took examinations after June 1, 1979, must have passed the NAPLEX or an examination deemed equivalent by the Board and obtained scores required for applicants for licensure by examination.

1.~~7~~6.3 Applicants who are licensed by reciprocity must begin accruing continuing education units at a rate of 1.25 hours/per month beginning with the month of licensure.

Regulation 1.2 revised 10/11/96

Regulation 1.3.2 revised 2/6/97

Regulation 1.3.2 deleted, 1.3.3.1 amended, 1.4 amended Effective date 10/11/98

1 DE Reg. 1965 (6/1/98)
2 DE Reg. 683 (10/1/98)
4 DE Reg. 163 (7/1/00)
4 DE Reg. 1501 (3/1/01)
6 DE Reg. 488 (10/1/02)
7 DE Reg. 309 (9/1/03)

3.0 Pharmacy Requirements

3.1 Pharmacist in Charge

3.1.1 Application for permit to operate a pharmacy in the State of Delaware must be on a form approved by the Board. The form shall include the statement to be signed by the pharmacist in charge, "I understand that I am responsible for conducting and managing the prescription department in compliance with applicable State and Federal laws."

3.1.2 The Board interprets the responsibilities of the Pharmacist-in-Charge to include, but not be limited to the following:

3.1.2.1 Maintain necessary pharmaceutical equipment and reference texts in accordance with the State Board of Pharmacy requirements.

3.1.2.2 Maintain records required by the Uniform Controlled Substances Act and other relevant State and Federal regulations.

3.1.2.3 Maintain proper security of particular pharmacy operation during and after normal business hours.

3.1.2.4 Establish procedures within operation that maintain standard of practice as it relates to the dispensing of pharmaceuticals. These procedures shall include proper supervision of supportive personnel and delegation of authority to another pharmacist when not on duty.

3.1.2.5 The pharmacist on duty is directly responsible for his own actions.

3.1.2.6 Notify the Board of Pharmacy in writing within 10 days of termination as pharmacist-in-charge.

3.2 Owner's Affidavit. The owner or owners and, in the case of a corporation, an authorized official of the corporation must present an affidavit properly notarized containing the statement, "I hereby swear or affirm that the foregoing statements are correct and do hereby agree to abide by the pharmacy laws of the State of Delaware and to all rules and regulations of the Delaware State Board of Pharmacy." The Board must be notified within 10 days of change of ownership.

3.3 Equipment and Reference Materials. Each pharmacy shall have the following equipment and maintain a library of the latest edition and supplements of current reference sources (either hard copy or electronically accessible) appropriate to the individual pharmacy practice and to the care of the patients served. The reference sources must:

3.3.1 References:

3.3.1.1 Provide information on the therapeutic use, dosing, pharmacology, adverse effects, and interactions of drugs dispensed to patient.

3.3.1.2 Provide information helpful in the counseling of patients on the use of drugs dispensed.

3.3.1.3 Enable the pharmacist to properly compound medicines within accepted standards of pharmacy practice.

3.3.1.4 Include a listing of therapeutic equivalents for drugs dispensed.

3.3.1.5 Include current Delaware and federal laws and regulations governing pharmacy and controlled substances.

3.3.1.6 Provide any other information necessary to the safe and effective practice of pharmacy for the specific practice setting.

3.3.2 Equipment

3.3.2.1 Prescription Scale, Class A

Set of Metric Weights if balance is used

3.3.2.2 Graduates, (must be glass) Metric

One of Each:

30 ml

60 ml

125 ml

500 ml

(or Set with both metric and Apothecary Graduations may be used)

3.3.2.3 Mortars and Pestles

~~1~~ One 8 ounce glass

~~1~~ One 8 ounce wedgewood

3.3.2.4 Filter Paper

3.3.2.~~4~~5 Prescription/physician Order Files

3.3.2.~~5~~6 Two Spatulas

3.3.2.~~6~~7 One Glass Funnel

3.3.2.~~7~~8 One Glass Stirring Rod

3.3.2.~~8~~9 Ointment Slab or Papers

3.3.2.~~9~~10 ~~Purified~~ Distilled Water

Each Pharmacy shall have such additional equipment as is necessary to perform a specific procedure.

All equipment must be clean and must be maintained in such a manner that allows the pharmacist to accurately weigh, measure and compound ingredients.

3.4 Physical Facilities. Have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing and storage of drugs and devices. Such facilities shall include:

3.4.1 A dispensing area of adequate size and space for proper compounding, dispensing and storage of drugs and devices, to ensure the safety and well being of the public and pharmacy personnel.

3.4.2 Sufficient environmental control, i.e. lighting, ventilation, heating and cooling to maintain the integrity of drugs and devices. The area in which drugs and devices are stored shall be accurately monitored using control devices to maintain room temperature between ~~59× and 86×~~ 59 degrees and 86 degrees Fahrenheit.

3.4.3 The pharmacy department or prescription area must contain a sink with hot and cold running water. It must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized.

3.4.4 Suitable refrigeration with appropriate monitoring device. Refrigerators and freezers (where required) will be maintained ~~at~~ within the USP/NF range:

Refrigerator - ~~36× to 46×~~ 36 degrees to 46 degrees Fahrenheit

Freezer - ~~plus 4× to minus 14×~~ Minus 13 degrees to plus 14 degrees Fahrenheit.

A sign with letters not less than 3/4" in height in the vicinity of the prescription department visible to the public which shows the name of the pharmacists employed at that pharmacy or the name of the pharmacist on duty.

3.5 Building Standards. An application to operate a new pharmacy must include (3) copies of floor plans drawn to scale of the proposed prescription department. The floor plans must include the following:

3.5.1 The requirements listed in §2534(~~F~~f)(1) through (4).

3.5.2 ~~A partitioned~~ An area which assures patient privacy will be provided to facilitate counseling. This area must afford the patient privacy from auditory detection by any unauthorized person or persons. ~~The minimum requirement would be a 9 square foot partitioned area.~~ An area partitioned by a 5 foot divider on 2 sides with a minimum of 9 square feet would satisfy this requirement in most settings.

3.5.3 The floor plans shall include the location of the sink, all doors, storage room, approved Schedule II controlled substance safe or cabinet, and the method of securing the prescription department from floor to ceiling, when the prescription department is closed and the remainder of the store is open.

3.5.4 The floor plans must include the type of alarm system to be installed, and the name, address and phone number of alarm provider. The alarm system, as required by Regulation 5 of the Delaware Controlled Substance Act, must be reviewed and approved for compliance by the Office of Narcotics and Dangerous Drugs.

3.5.5 The above requirements shall also apply for any remodeling or change of location of the prescription department. The pharmacist-in-charge or applicant for permit must submit the floor plans requirements to the Delaware Board of Pharmacy and the Office of Narcotics and Dangerous Drugs prior to any construction and at least 15 days prior to the next scheduled Board of Pharmacy meeting for its review.

3.6 Security. When the pharmacist is ~~off duty~~ not physically present and the operation is open for business, the pharmacy department shall be physically or electronically secured from floor to ceiling. The partitioned off section required by 24 **Del.C.** §2534 must be five feet high measured from the floor. A conspicuous sign with letters not less than three inches in height, reading "PRESCRIPTION LABORATORY TEMPORARILY CLOSED, NO PROFESSIONAL SERVICES RENDERED," or words of similar import, must be posted in the front section of the operation or in front of the prescription area, room or partitioned off section where it can be seen by the public.

3.7 Board Interview. Applicants for permit to operate a pharmacy in the State of Delaware must appear before the Board for an interview. The owner or authorized official must be present in addition to the pharmacist-in-charge. Whenever there is a change of pharmacist-in-charge, if that person has never held that position in the State of Delaware, he/she must appear before the Board for an interview within ninety days after assuming the position.

Regulation 3.5.2 revised 6/16/97

Regulation 3.5.6 revised Effective date 10/11/98

2 DE Reg. 683 (10/1/98)
6 DE Reg. 488 (10/1/02)
7 DE Reg. 309 (9/1/03)
7 DE Reg. 1666 (6/1/04)

5.0 Dispensing

5.1 Definitions

"Agent" An employee of the pharmacy supervised by the pharmacist or a person acting on behalf of the ultimate user.

"Automated Data Processing System (ADP)" A system utilizing computer software and hardware for the purposes of recordkeeping.

"Cell" Any container which holds the medication for automatic dispensing.

"Common Data Base" A file or data base created by ADP that enables authorized users to have common access to this file regardless of physical location.

"Compounding" The art of the extemporaneous preparation and manipulation of drugs as a result of a practitioner's prescription order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, including the reconstitution of powders for administration and the preparation of drugs in anticipation of drug orders based on routine, regularly observed prescribing patterns. Pharmaceutical compounding must be in compliance with FFDCA Section 503A and any regulations promulgated by FDA concerning compounding, pertaining to this section.

"Computer" Programmable electronic device, capable of multifunctions including but not limited to storage, retrieval and processing of information.

"Controlled Substance" Those drug items regulated by Federal (CSA of 1970) and/or State Controlled (dangerous) Substances Act.

"CRT" Cathode Ray Tube used to impose visual information on a screen.

"Delivery" The transfer of a dispensed prescription to the ultimate user (patient) or his/her agent.

"Dispensing" To furnish or deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner; including the preparation, packaging, labeling or compounding necessary to prepare the drug for that delivery.

"Downtime" That period of time when a computer is not operable.

"Facsimile (FAX) Prescription" A facsimile prescription is an order which is transmitted by an electronic device over telephone lines which sends an exact copy image to the receiver (pharmacy).

"Final Container" is that which holds the article, designed to hold a quantity of drug product intended for administration as a single dose, multiple dose, or a single finished device intended for use promptly after the container is opened.

"New Medication" A medication not previously dispensed by the pharmacy for the ultimate user.

"Patient Counseling" The offer to discuss the patient's prescription made by the pharmacist or the pharmacist's designee in a face-to-face communication with the patient or his/her agent, unless in the professional judgment of the pharmacist it is deemed impracticable and in such instances, it would be permissible for the offer to counsel to be made through alternative means.

"Pertinent Patient Medication Information" Information which increases the patient's ability to minimize the risks and enhance the benefits of drug use. The type of information the pharmacist should consider is contained in the latest edition of USP DI "Advice for the Patient."

"Prescriber" A practitioner authorized to prescribe and acting within the scope of this authorization.

"Prescription" An order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user, (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.) A written order from a practitioner authorized to prescribe and acting within the scope of this authorization, (other terminology: prescription order) or a telephone order reduced to writing by the pharmacist.

"Printout" A hard copy produced by computer that is readable without the aid of any special device.

"Reduced to Writing" For new prescriptions this means the preparation of a paper document containing all the information required for a written prescription including the State requirement (Section 2553)for drug product selection;

For a refill authorization, it may be handled as a new prescription as in above, or by placing on the original prescription or the patient profile (whichever document is consistently used to document refills) the date, a statement "O.K. for 'x' number of additional refills", or words of similar import, and the pharmacist's initials. In no instance, shall the refill authorizations exceed the legal limits established by State and Federal laws.

If the prescriber authorizing additional refills differs from the Prescriber whose name appears on the signature line of the original prescription, then that authorization is considered a new prescription and must be handled as described above.

"Regulatory Agency" Any Federal or State agency charged with enforcement of pharmacy or drug laws and regulations.

"**Stop Date"** A date established by an appropriate authority which indicates when medication will no longer be administered or dispensed in the absence of a specific time period directed by the prescriber.

"Supportive personnel" A person who is not registered as an intern or pharmacist with the Board who may perform tasks as authorized by this Regulation.

5.2 The practice of dispensing shall include, but not be limited to the following acts which shall be performed only by a pharmacist, or a pharmacy intern or student participating in an approved College of Pharmacy coordinated, practical experience program **[, under the direct supervision of a pharmacist.]**

5.2.1 Receive oral prescriptions and reduce them immediately to writing~~.~~

5.2.2 Certification of the prescription order - (This involves authenticating the prescription, confirming proper dosage and instructions, and reviewing for incompatibility, etc.)

5.2.3 ~~Record refill dates and initials of the dispensing pharmacist on the prescription (or on another appropriate uniformly maintained readily retrievable record such as the medication records)~~ The pharmacist, intern or student who dispenses the original prescription shall hand-sign or initial the prescription. Initials mechanically or electronically generated are acceptable in lieu of the above provided that the individual verifies either on a daily printout or in a bound log book daily that the information on the prescription is correct. The verification must be hand-signed and dated by the individual.

5.3 Patient Counseling

5.3.1 Before dispensing or delivering a new medication to a patient or his or her agent, a pharmacist, or pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program and working under the direct supervision of the pharmacist, shall conduct a prospective drug review. ~~A pharmacist or pharmacy intern may conduct a~~ A prospective drug review may be conducted before refilling a prescription to the extent deemed appropriate. ~~by the pharmacist or pharmacy intern in his/her professional judgment. Such~~ A prospective drug review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-drug interactions, including serious interactions with over-the-counter drugs, drug-disease contraindications, if disease is known, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse based on available information received by the pharmacist.

5.3.2 ~~Except when a prescriber requests that information regarding a prescribed drug not be given to a specific patient, a~~ A pharmacist, or a pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program and working under the direct supervision of a pharmacist shall, with each new medication dispensed, provide verbal counseling to the patient or the patient's agent on pertinent medication information. The counseling may include, but not be limited to the following:

5.3.2.1 the name and description of the prescribed drug;

5.3.2.2 the dosage and the dosage form;

5.3.2.3 the method and route of administration;

5.3.2.4 the duration of the prescribed drug therapy;

5.3.2.5 any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;

5.3.2.6 common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;

5.3.2.7 patient techniques for self-monitoring of the drug therapy;

5.3.2.8 proper storage;

5.3.2.9 prescription refill information;

5.3.2.10 the action to be taken in the event of a missed dose; and

5.3.2.11 current over-the-counter medication use.

5.3.3 This section does not apply to a pharmacist dispensing drugs for inpatient use in a hospital or other institution where the drug is to be administered by a nurse or other appropriate health care provider.

5.3.4 Nothing in this section requires a pharmacist or pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program and working under the direct supervision of a pharmacist, to provide patient counseling when a patient or the patient's agent refuses the counseling. There must be a record in a uniform place that documents a patient's acceptance or refusal of counseling. ~~The record must indicate who made the offer to counsel.~~

5.3.5 If the dispensed prescription is delivered by an agent of the pharmacy when the pharmacist is not present (i.e. home delivery, pharmacist off duty and non-resident pharmacies) written or printed information shall be included with the prescription. The patient or his/her agent shall be informed that the pharmacist will be available for consultation.

~~5.3.6 The pharmacist shall in his/her professional judgment refill prescriptions in keeping with the number of doses ordered and the directions for use~~.

~~5.3.7 The pharmacist who dispenses the original prescription shall hand-sign or initial the prescription. Initials mechanically or electronically generated are acceptable in lieu of the above provided that the pharmacist verifies either on a daily printout or in a bound log book daily that the information on the prescription is correct. The verification must be hand-signed and dated by the pharmacist.~~

5.4 Supportive personnel

5.4.1 Qualifications and training

5.4.1.1 The pharmacist-in-charge is responsible for ensuring proper training of all supportive personnel. The actual training may be delegated to a pharmacist or other trained supportive personnel.

5.4.1.2 The areas of training required are to be determined by the pharmacist-in-charge and will be appropriate to the practice site and responsibilities assigned to the supportive personnel. Areas of training shall include:

5.4.1.2.1 general drug and dosage form knowledge

5.4.1.2.2 medical terminology

5.4.1.2.3 pharmaceutical calculations

5.4.1.2.4 prescription labeling requirements

5.4.1.2.5 general filling/dispensing responsibilities

5.4.1.2.6 patient profile record system requirements

5.4.1.2.7 requirements for patient counseling

5.4.1.2.8 confidentiality

5.4.1.2.9 safety practices

5.4.1.2.10 inventory functions

5.4.1.2.11 knowledge of applicable State and Federal Statutes and Regulations

5.4.1.2.12 other site-specific parameters

5.4.1.3 The general content of the training program must be maintained in the policy and procedure manual.

5.4.1.4 Documentation of successful training in specific areas by oral or written evaluation will be maintained and will be available for inspection by the Board of Pharmacy.

5.4.2 Supervision. Supportive personnel must be supervised by a registered pharmacist who will be responsible for the activities of these persons.

5.4.3 Activities allowed

5.4.3.1 Supportive personnel will be allowed to perform only those duties permitted by this regulation.

5.4.3.2 Supportive personnel may aid in the dispensing of prescriptions as authorized in Section 2513 under the supervision of a pharmacist by performing the following tasks:

5.4.3.2.1 Obtaining the medication from stock.

5.4.3.2.2 Typing the label after the pharmacist has interpreted the directions.

5.4.3.2.3 Counting, pouring and selecting prefabricated medications and selecting individual prepackaged unit dose medication provided that these are not in conflict with the state and federal law (Federal Comprehensive Controlled Substances Act) and that a final check by the pharmacist is made after the medication is placed in the final container prior to dispensing and administration to the patient. There will be a final check by a licensed pharmacist prior to dispensing and administration, except where the Board of Pharmacy grants, in writing, an exemption for good cause shown.

5.4.3.3 Compounding is the responsibility of the pharmacist or pharmacy intern under the direct supervision of the pharmacist. All compounding must be in compliance with FFDCA Section 503A and any regulations promulgated by FDA concerning compounding pertaining to this section. The pharmacist may utilize the assistance of supportive personnel if the following is performed:

5.4.3.3.1 The formulation is developed by the pharmacist before proceeding with the compounding.

5.4.3.3.2 The compounding ingredients are checked by the pharmacist before proceeding with the compounding.

5.4.3.3.3 Every weight and measurement is checked by the pharmacist before proceeding with the compounding.

5.4.3.3.4 The finished product is checked by the pharmacist before dispensing.

5.4.3.3.5 A log is maintained showing the identity of the person actually compounding the medication and the identity of the pharmacist who has performed each of the checks indicated above for each step of the procedure. If policies and procedures are in place ensuring adequate checks by the pharmacist per regulation, the requirement for a log will be waived.

5.4.3.4 Only supportive personnel or persons being trained as supportive personnel as required by this regulation, may perform the activities defined by this regulation.

5.5 Automatic Dispensing Devices. If any automatic counting device is used by a pharmacy, each cell shall have clearly displayed thereon, the date filled, the name of the drug, the batch number, the manufacturer's name, and the expiration date of the particular batch number. No drug can be added to the cell until the present supply is depleted.

5.6 Authorization for renewal of prescriptions. A prescription written for medication which, pursuant to State and Federal law, may be sold, dispensed, or furnished only upon prescription, shall not be renewed without specific authorization of the prescriber. The pharmacist shall in his/her professional judgment refill prescriptions in keeping with the number of doses ordered and the directions for use. Refills beyond one year of the date of the original prescription shall not be dispensed without further authorization of the prescriber.

5.7 Mandatory Patient Profile Record System

5.7.1 A patient profile record system must be maintained at all pharmacies for persons for whom prescriptions are dispensed. The patient profile system shall be devised so as to entitle the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing.

5.7.2 The following information shall be recorded by a pharmacist or designee:

5.7.2.1 The family name and first name of the person for whom the medication is intended (the patient);

5.7.2.2 The address of the patient and phone number;

5.7.2.3 The patient's age, or date of birth, and gender;

5.7.2.4 The original date the medication is dispensed pursuant to the receipt of a **[~~physician's~~ prescriber's]** prescription;

5.7.2.5 The number or designation identifying the prescription;

5.7.2.6 The prescriber's name;

5.7.2.7 The name, strength, quantity, directions and refill information of the drug dispensed;

5.7.2.8 The initials of the dispensing pharmacist and the date of dispensing medication as a renewal (refill) if said initials and such date are not recorded on the original prescription;

5.7.2.9 If the patient refuses to give all or part of the required information, the pharmacist shall so indicate and initial in the appropriate area.

5.7.2.10 Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

5.7.3 The pharmacist or pharmacy intern under the direct supervision of a pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any chronic disease states and frequently used over-the-counter medication as communicated to the pharmacist by the patient. If the answer is none, this must be indicated on the profile.

5.7.4 Upon receipt of a new prescription, a pharmacist **[~~or~~]** pharmacy intern **[or student participating in a College of Pharmacy practical experience program]** under the direct supervision of a pharmacist must examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potential harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem which shall, if necessary, include consultation with the **[~~physician~~ prescriber.]**

5.7.5 A patient profile record must be maintained for a period of not less than one year from the date of the last entry in the profile record unless it is also used as a dispensing record.

5.8 Exchange of Valid Non-Controlled Prescriptions Between Pharmacies

5.8.1 Verbal Exchange of Prescriptions - When a pharmacy receives a verbal request for a prescription transfer, it may be honored provided that:

5.8.1.1 The request comes from a registered pharmacist.

5.8.1.2 The copy is immediately reduced to writing and contains the information required on a written prescription as listed in Regulation 5.0, and includes the first and last name of the pharmacist transmitting the information.

5.8.1.3 The prescription used for refills must be clearly identified as a copy.

5.8.1.4 The copy shows the date and the file number of the original prescription and indicates the name and address of the pharmacy providing the copy.

5.8.1.5 The copy shows the last date of dispensing.

5.8.1.6 Only the actual number of refills remaining are indicated.

5.8.1.7 A notation indicating a copy was given and refills are no longer valid must be placed on either the original prescription or patient profile. The document used must be the same one used for the recording of refills per the pharmacy's policy.

5.8.2 A copy prepared or transmitted that does not meet the requirements of this Regulation is deemed to be an invalid prescription.

5.8.3 Written copies of prescriptions are for information only and are not valid for refilling.

5.9 Automated Data Processing Systems

5.9.1 Profiles. When ADP's are used to maintain patient profile records, all the requirements of Delaware Pharmacy Regulation 5.0 must be met.

5.9.2 Prescription (Drug Order) Information. Prescription information (drug order) shall include, but not be limited to:

5.9.2.1 Original dispensing date

5.9.2.2 Name and address of patient (patient location if in an institution)

5.9.2.3 Name of prescriber

5.9.2.4 DEA number of prescriber in the case of a controlled substance

5.9.2.5 Name, strength, dosage form and quantity, (or Stop Date), and route of administration if other than oral form of drug prescribed

5.9.2.6 Renewals authorized

5.9.2.7 Directions of use for patient

5.9.3 Records of Dispensing. Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for three years. Information must be immediately accessible for a period of not less than one year from the date of last entry. Information beyond one year but up to three years from the date of last entry may be

maintained off-line but must be produced no later than five days upon request from proper authorities. The information shall include, but not be limited to:

5.9.3.1 Quantity dispensed

5.9.3.2 Date of dispensing

5.9.3.3 Serial Number (or equivalent if an institution)

5.9.3.4 The identification of the pharmacist responsible for dispensing

5.9.3.5 Record of renewals to date

5.9.3.6 Name and strength of medicine

5.9.4 Record Retrieval (Documentation of Activity). Any such ADP system must provide via CRT display and or hard copy printout a current history of all authorized prescription activity. This information shall include, but not be limited to:

5.9.4.1 Serial number of prescription (equivalent if an institution)

5.9.4.2 Date of processing

5.9.4.3 Quantity dispensed

5.9.4.4 The identification of the pharmacist responsible for dispensing

5.9.4.5 Medication dispensed

5.9.5 Auxiliary Recordkeeping System. An auxiliary recordkeeping system shall be established for the documentation of renewals if the ADP is inoperative for any reason. The auxiliary system shall insure that all renewals are authorized by the original prescription and that the maximum number of renewals are not exceeded. When the ADP is restored to operation, the information regarding prescriptions dispensed and renewed during the inoperative period shall be entered into the automated data processing system.

5.9.6 Common Data Base. Two or more pharmacies may establish and use a common data file or base to maintain required or pertinent dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file or data base; provided however, any such common file must contain complete and adequate records of such prescription and renewals dispensed. Where common data base is used, this shall not be considered a transfer under Board Regulation 5.0 for non-controlled substances.

5.9.7 Transfer of Prescriptions via ADP. A pharmacist may transfer a prescription electronically (ADP) for Schedule III, IV, or V controlled substances to another pharmacy for renewal purposes in accordance with Title 21, Code of Federal Regulations Section ~~1306.26~~ 1306.25. A pharmacist may transfer a prescription electronically (ADP) for non-controlled drug for renewal purposes in accordance with current State Regulations.

5.9.7.1 Any pharmacy using ADP must comply with all applicable State and Federal regulations.

5.9.7.2 A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall assure continuity in maintenance of records.

5.9.7.3 The computer record shall reflect the fact that the prescription order has been transferred, the name of the pharmacy to which it was transferred, the date of transfer, the name of the pharmacist transferring information, and any remaining refill information, if applicable.

5.9.7.4 The pharmacist receiving the transferred prescription drug order shall reduce it to writing with the following information:

5.9.7.4.1 Write the word "TRANSFER" on the face of the transferred prescription.

5.9.7.4.2 Provide all information required to be on the prescription drug order pursuant to State and Federal laws and regulations.

5.9.7.5 To maintain the confidentiality of patient's prescriptions (drug orders) or other pertinent records, there must exist adequate safeguards of security. This shall also pertain to prevent non-user access.

5.10 Electronic Transmission Of Prescriptions

5.10.1 All Prescription Drug Orders communicated by way of Electronic Transmission shall:

5.10.1.1 be transmitted directly to a Pharmacist in a licensed Pharmacy of the patient’s choice with no intervening Person having access to the Prescription Drug Order;

5.10.1.2 identify the transmitter’s phone number for verbal confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by Federal or State law;

5.10.1.3 be transmitted by an authorized Practitioner or his designated agent; and

5.10.1.4 be deemed the original Prescription Drug Order provided it meets the requirements of this subsection.

5.10.2 The prescribing Practitioner may authorize his agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission to a Pharmacist in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order.

5.10.3 The Pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the Prescription Drug Order communicated by way of Electronic Transmission consistent with existing Federal or State laws and rules.

5.10.4 All electronic equipment for receipt of Prescription Drug Orders communicated by way of Electronic Transmission shall be maintained so as to ensure against unauthorized access.

5.10.5 Persons other than those bound by a confidentiality agreement pursuant to Section 2.A. (2)(k) shall not have access to Pharmacy records containing Confidential Information or personally identifiable information concerning the Pharmacy's patients.

5.10.6 Controlled substance prescriptions may only be electronically transmitted via a facsimile.

5.10.7 Facsimile prescriptions must meet the following requirements in addition to the above listed electronic Transmission requirements.

5.10.7.1 The prescription order shall include the fax number of the transmitter, the number of transmitted pages, the name, phone number, and electronic number of the pharmacy intended to receive the transmission, and a confidentiality statement in bold type stating the electronic transmission should not be seen by unauthorized persons.

5.10.7.2 Unless the prescription is written for a schedule II controlled substance, the prescriber should not issue the written prescription to the patient.

5.10.7.3 A facsimile transmitted prescription order must be reduced to writing, unless received as a non-fading document, with a notation that the order was received by facsimile.

5.10.7.4 The receiving facsimile machine must be in the prescription department to protect patient-pharmacist-authorized prescriber confidentiality and security.

5.10.7.5 Both non-controlled and controlled substance prescriptions may be transmitted via facsimile following state and federal requirements. All prescription orders for controlled substances shall be hand-signed by the practitioner.

5.11 Return of Medications and Supply

5.11.1 Prescriptions and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescription or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.

5.11.2 Products under the direct control of a health care professional which are packaged in manufacturer unit dose or tamper-proof unopened bulk containers, tamper proof seal in tact, including unused multi-dose punch cards, may be redispensed in accordance with expiration dating in customized patient medication package. Partially used products may not be redispensed. Nothing in this regulation precludes the Federal laws and regulations.

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Effective Date: April 14, 1997 Section 5.4 revised

Effective Date: June 11, 1998

Amended Effective September 11, 1999

1 DE Reg. 1965 (6/1/98)

3 DE Reg. 431 (9/1/99)

4 DE Reg. 163 (7/1/00)

4 DE Reg. 682 (10/1/00)

9.0 Hospital Pharmacy

9.1 Definition:

A hospital pharmacy is defined as a pharmacy registered with the Board located in a hospital facility. "Hospital pharmacy" shall not include a pharmacy operated by a hospital facility at a location other than the site of a permanent facility at which in-patient care and medical services are rendered.

9.2 Personnel

9.2.1 Director of Pharmacy. The storage, compounding, repackaging, dispensing and distribution of drugs by a hospital pharmacy shall be under the direction, supervision and responsibility of the pharmacist-in-charge, hereinafter referred to as the Director of Pharmacy, who shall be responsible for operating the pharmacy in compliance with appropriate State and Federal Statutes and Regulations. Written policies and procedures will be

established defining the operation and scope of services provided by the hospital pharmacy. The Manual shall include policy and procedures concerning:

9.2.1.1 Preparation and sterilization of parenteral medications if done within the hospital pharmacy.

9.2.1.2 Establishment of specifications for procurement of drugs, chemicals and biologicals. The procedures are subject to the approval of the appropriate committee of the hospital.

9.2.1.3 Maintaining readily available inventory of emergency drugs both in the pharmacy and patient care areas. Current antidote information and telephone numbers of regional poison control centers must also be available.

9.2.1.4 Participation in the development of a Formulary or drug list for the hospital.

9.2.1.5 The filling and labeling of all containers from which drugs are to be administered in compliance with applicable Statutes and Regulations.

9.2.1.6 The records of the transactions of the pharmacy that are required by applicable law and that are necessary for accurate control and accountability. This should include procedures for wastage of controlled substances in all areas of the hospital.

9.2.1.7 Polices and procedures shall specify the duties to be performed by pharmacy personnel.

9.2.1.8 Discontinued drug procedures to insure that discontinued drugs and containers with worn, illegible or missing labels are returned to the pharmacy for proper disposition or disposal. All outdated products should be removed from all areas and stored in a separate section in the pharmacy for proper disposition or disposal.

9.2.1.9 A recall procedure that can be implemented to insure proper disposition of the recalled materials.

9.2.1.10 A policy for drugs brought in by patients.

9.2.1.11 A policy for the proper handling of investigational drugs must be in compliance with FDA and State requirements.

9.2.1.12 The pharmacist shall be involved with the utilization review process as it pertains to drug therapy.

9.2.2 Registered Pharmacists. The Director of Pharmacy may be assisted by additional registered pharmacists who are also responsible for compliance with the applicable laws.

9.2.3 Supportive Personnel. Supportive personnel may be utilized in assisting the pharmacist. These persons must be supervised by a registered pharmacist who is present within the hospital and is responsible for the activities of those persons.

9.3 Absence of Pharmacist. When a pharmacist is not on duty, drugs may be provided for use by physicians and other authorized staff via night cabinets or other areas designated by the hospital, and in emergency circumstances by access to the pharmacy. A pharmacist shall be available to provide professional services.

9.4 Night Cabinets or Other Designated Areas

9.4.1 These drug storage areas must be securely locked and substantially constructed in a manner which prevents easy entry.

9.4.2 Access must be limited to authorized personnel.

9.4.3 Contents and use procedures should be determined by the pharmacy and those departments with access to the night cabinet or other designated areas in accordance with the hospital's policies and procedures.

9.4.4 Drugs must be properly labeled and prepackaged in sufficient quantities as defined by the hospital.

9.4.5 Accountability records documenting withdrawal and replacement of controlled drugs must be readily available.

9.4.6 The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.5 Access to Pharmacy. When a pharmacist is not available and medications cannot be obtained immediately from any other source, authorized persons may enter the pharmacy and obtain drugs per procedures established by the hospital. The procedures must include the following stipulations:

9.5.1 Entry shall be by two persons; registered nurse or physician with another nurse, physician, or security person present approved by the hospital.

9.5.2 Persons authorized to enter the pharmacy shall indicate the name and strength and amount of drug removed, the date, time and their signature, and the name and location of the patient. The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.6 Emergency Drugs. Emergency drugs must be available for use by authorized personnel at strategic locations throughout the hospital. The drugs must be available to authorized personnel and must be stored in a manner to preserve the integrity of the contents.

9.6.1 Emergency Drugs Defined - Emergency drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients.

9.6.2 Emergency drug supplies shall be clearly identified for emergencies. A list showing the contents and the strength and quantity of each item shall be attached to the exterior.

9.6.3 Removal of Drugs - Drugs shall be removed from an emergency drug supply only pursuant to a valid physician's order or by authorized personnel.

9.6.4 Notification - Whenever an emergency drug supply is accessed, the pharmacy or its designee shall be notified within 24 hours, and the pharmacy or its designee shall restock and reseal or replace the kit or cart within forty-eight hours.

9.7 Equipment and Texts. Each hospital pharmacy shall have the equipment and texts required by Board Regulation 3.0 and Regulation 10.0.

9.8 Drug Storage. Drugs must be stored in compliance with State and Federal Statutes and Regulations and according to USP/NF requirements.

9.9 Labeling

9.9.1 The drug dispensed for inpatient use shall contain a label, shall show the brand or established name and the strength of the medication. If the medication is prepacked, it must also show the source, lot number and expiration date, in compliance with the Board's prepacking regulation.

9.9.2 All drugs dispensed for outpatients must be labeled in compliance with the Pharmacy Statutes.

9.9.3 Admixtures in parenteral bags and bottles shall be labeled in accordance with Regulation 10.0.

9.10 Abbreviations. The hospital should establish a standard list of abbreviations to be used whenever medications are prescribed.

9.11 Outpatient Orders. Medication dispensed for outpatients via prescriptions are governed by applicable State and Federal Statutes Regulations. A patient profile must be maintained and counseling must be provided for each person according to Regulation 5.0.

9.12 Suspected Adverse Drug Reaction. When an adverse reaction is documented, the pharmacy department shall receive a copy.

9.13 Maintenance of Medication Orders. Patient Profile - A patient medication profile must be maintained for each inpatient whose medication is directly dispensed from the pharmacy. It must show the patient's name, location, age, allergies and diagnosis(es) as available. The profile must show the name, strength and quantity of the drug dispensed and appropriate directions and the initials of the dispenser. Prior to administration of the first dose, the pharmacist must examine the profile to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a significant potential for harm, the pharmacist should notify the prescriber and other appropriate persons. The profile must be retained and readily retrievable for 30 days after discharge.

9.14 Medication Error. Medication error as defined by the hospital shall be documented and reported immediately to the pharmacy. It should also be reported to the attending physician.

9.15 Monthly Inspections. A member of the pharmacy staff shall conduct monthly inspections of each nursing station and patient care areas where medications are dispensed, administered or stored. Such documented inspections shall verify that:

9.15.1 Disinfectants and drugs for external use are stored separately.

9.15.2 Drugs are stored under proper conditions.

9.15.3 No outdated drugs are present.

9.15.4 Distribution, administration, and disposition of controlled substances audits indicates proper recordkeeping and administration.

9.15.5 Emergency drug supplies and floor stock drug levels are properly maintained.

9.15.6 Drugs are properly secured.

9.16 Hospital Operating with an Off-site Pharmacy Provider.

9.16.1 Definition. A hospital operating with an off-site pharmacy is one that obtains pharmacy services from another hospital, community pharmacy, or infusion pharmacy that can provide services as necessary for operation.

9.16.2 Personnel.

9.16.2.1 There must be a Director of Pharmacy or Consultant Pharmacist available on an on-call procedure 24 hours per day. The storage, compounding, repackaging, dispensing and distribution of drugs by an off-site Provider Pharmacy shall be under the direction, supervision and responsibility of a Pharmacist-in-Charge or

Director of Pharmacy. This person shall be responsible for operating the pharmacy in compliance with appropriate State and Federal Statutes and Regulations.

9.16.2.2 The Director of Pharmacy or Pharmacist-in-Charge may be assisted by additional registered pharmacists who are also responsible for compliance with the applicable laws. Any of these registered pharmacists may act as the Consultant Pharmacist for the institution if he/she is licensed to practice pharmacy in the State of Delaware. Additional supportive personnel may be utilized as required.

9.16.2.3 The Director of Pharmacy or Pharmacist-in-Charge must provide written policies and procedures establishing the operation and scope of services provided by the off-site Pharmacy Provider. The Policy and Procedure Manual shall include all items as outlined in ~~"B."~~ 9.2 of this section. In addition, the manual shall include a written statement of pharmaceutical services provided and the responsibilities of the off-site Provider Pharmacy.

9.16.3 Monthly Inspections. The Director of Pharmacy or Consultant Pharmacist must perform monthly medication area inspections as outlined in ~~"O"~~ 9.15 of this section.

9.16.4 Storage

9.16.4.1 Drugs must be stored at the off-site Pharmacy Provider in compliance with State and Federal Statutes and Regulations and according to USP/NF requirements.

9.16.4.2 The Pharmacy Provider must also provide any special handling and/or packaging and/or storage conditions for compounded sterile preparations when delivering from the pharmacy to the institution as necessary to maintain the sterility and stability of the preparation. This includes any product that is frozen or that requires refrigeration.

9.16.5 Patient Profiles. The off-site Pharmacy Provider must maintain complete patient profiles as outlined in Regulation 5.0.

9.16.6 Medication Errors or Adverse Reactions

9.16.6.1 Any medication errors or adverse drug reactions, as defined by the hospital, shall be documented and reported to the off-site Pharmacy Provider.

9.16.6.2 This information shall also be reported to the Director of Pharmacy, Pharmacist-in-Charge, or Consultant Pharmacist for their review and documentation for the patient profile.

~~9.16.7 Emergency Medications~~

~~9.16.7.1 All legend drugs not dispensed in patient name shall be approved by the Board of Pharmacy in order for those emergency medications to be kept as "stock" at the institution.~~

~~9.16.7.2 The procedure for approval of emergency medications must be followed as outlined in Regulation 11.3.~~

9.16.7 Emergency Use Medications

9.16.7.1 Emergency use medications are those which may be required to meet the immediate therapeutic needs of patients, as determined by the prescriber, and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients by delay resulting from obtaining such drugs from other sources.

9.16.7.2 It is the responsibility of the facility and provider pharmacy to determine the supply of emergency use medication that are to be stocked as well as documenting their locations within the facility. A list of current contents must be attached to the medication supply.

9.16.7.3 Accountability for emergency use medications.

9.16.7.3.1 The pharmacy provider must be contacted within 24 hours after medication is used from the supply and the pharmacy must restock the supply within a reasonable time to prevent harm to patients.

9.16.7.3.2 The provider pharmacy is responsible for the accuracy of all emergency use medications at the time of the filling of the medication. This check must also include any medication that became available when the medication is accessed. Records documenting use of an emergency medication must be kept for a minimum of 2 years at the provider pharmacy and must be readily available for inspection by the Board.

9.16.7.3.3 Failure to comply with these procedures can result in the suspension or denial of the use of emergency use medications.

9.16.7.3.4 Violations of accountability procedures for emergency use medications may result in review proceedings before the Board.

10.0 Sterile Pharmaceuticals and Antineoplastic Agents

This regulation contains minimum pharmacy practices for the preparation, compounding and dispensing of sterile preparations and antineoplastic agents by licensed pharmacies.

10.1 Definitions. As used in this part, the following terms shall have the meanings specified:

“Admixture” A solution for parenteral administration to which one or more additional drugs have been added.

“Antineoplastic Agent” A drug used to treat various forms of cancer.

“Aseptic Technique” A procedure for compounding sterile preparations designed to minimize/prevent contamination during the compounding procedure.

“Class 100" A classification of an airflow unit capable of producing an environment containing no more than 100 airborne particles of a size 0.5 micron and larger per cubic foot (3.5 particles/liter) of air.

“Enteral Nutrition” The administration into the gastro-intestinal tract of calories, nitrogen, and/or other nutrients to achieve tissue synthesis and anabolism for patients requiring medically prescribed, defined formula, liquid diets.

“HEPA” (High-efficiency particulate air) Filter - A filter that provides a minimum-efficiency of 99.97% in removal of particles 0.3 micron or larger from the effluent air.

“Laminar Airflow” An entire body of air moving with uniform velocity along parallel flow lines.

“Parenteral” A sterile preparation intended for injection and used in the diagnosis, cure, mitigation, or treatment of disease or modification of physiological functions in human beings, but not including blood or blood products or as otherwise defined in the current United States Pharmacopeia.

“Sterile Pharmaceutical” A dosage form free from living microorganisms.

“Total Parenteral Nutrition” The intravenous administration of calories, nitrogen, and other to achieve tissue synthesis and anabolism.

10.2 General Requirements. A licensed pharmacy in the State of Delaware desiring to compound and dispense prescriptions or physician's orders for sterile pharmaceuticals and antineoplastic agents shall meet the following requirements:

10.2.1 Facilities and Equipment

10.2.1.1 The environment for the preparation of such prescriptions shall be set in a low traffic area, clean and free of contaminants and dust, and equipped to permit controlled aseptic/antineoplastic compounding.

10.2.1.2 The area for preparing sterile/antineoplastic prescriptions shall be segregated from general non-aseptic work and storage areas and shall be used solely for sterile pharmaceutical/anti-neoplastic compounding. The area shall be maintained at controlled room temperatures as defined by the United States Pharmacopeia.

10.2.1.3 The area(s) shall provide space for a minimum of one class 100 environment. Additionally, the space shall be of a size to accommodate equipment as required herein and sufficient space to allow personnel working therein to safely and accurately fulfill their duties.

10.2.1.4 Minimum requirements for equipment, supplies and publications are as follows:

10.2.1.4.1 Minimally, a class 100 air flow unit

10.2.1.4.1.1 The air flow unit must be in compliance with recommendations from OSHA guidelines.

10.2.1.4.2 Refrigerator

10.2.1.4.3 Sink and wash area easily accessible to the sterile preparation/antineoplastic compounding area(s)

10.2.1.4.4 Appropriate waste containers for:

10.2.1.4.4.1 Used needles and syringes

10.2.1.4.4.2 All antineoplastic wastes including apparel used in their preparation

10.2.1.4.5 Supplies:

10.2.1.4.5.1 Disposable needles and syringes and other supplies needed for sterile pharmaceutical/antineoplastic compounding

10.2.1.4.5.2 Disinfectant cleaning agents

10.2.1.4.5.3 Single-use lint free towels or air-driers

10.2.1.4.5.4 Handwashing materials with bactericidal action

10.2.1.4.5.5 Equipment and materials for cleaning antineoplastic agent spills

10.2.1.4.6 References: In addition to compliance with the reference requirements as set forth in Delaware Board Regulation 3.0, the pharmacy must have the following texts ~~(items b and c required~~ if chemotherapy agents are prepared~~)~~:

~~10.2.1.4.6.1Handbook of Injectable Drugs by the American Society of Hospital Pharmacists.~~

10.2.1.4.6.~~2~~1Procedures for handling Antineoplastic Drugs Technical Bulletin - most current edition published by the American Society of ~~Hospital~~ Health Systems Pharmacists.

10.2.1.4.6.~~3~~2Most current edition of OSHA Guidelines for the handling of antineoplastic agents.

~~10.2.1.4.6.4The Policy and Procedures Manual prepared under Section F of this Regulation.~~

10.2.1.4.7 Drug Components: All drug components that are received, stored, or used in compounding prescriptions shall meet official compendial requirements. If this cannot be met, pharmacists shall use their professional judgment to procure alternatives.

10.3 Personnel

10.3.1 The compounding of sterile pharmaceuticals/anti-neoplastic agents shall be under the control and supervision of a licensed pharmacist. The licensed pharmacist-in-charge or licensed pharmacist designee shall be on duty and on premises during all hours of operation of said pharmacy.

10.3.2 A pharmacist shall be accessible by telephone 24 hours a day to answer questions and to provide consultation regarding the dispensed preparation.

10.3.3 Supportive Personnel: The pharmacist managing the section of the pharmacy providing sterile/ anti-neoplastic product pharmacy services may be assisted by supportive personnel. These personnel must have specialized training in this field, and shall work under the supervision of a licensed pharmacist. The training provided to these personnel must be described in writing in a training manual. The duties and responsibilities of these personnel must be consistent with their training and experience.

10.4 Storage, Preparation, Dispensing, and Handling

10.4.1 A pharmacy shall provide any special handling and/or packaging and/or storage conditions for compounded sterile/antineoplastic preparations when delivering from the pharmacy to the patient or institution as necessary to maintain sterility and stability of the preparation.

10.4.2 Each pharmacy shall develop product sampling plans and shall have the ability to determine or know where to readily procure services to assure the quality of the products compounded or prepared.

10.4.3 Delivery service. The pharmacist managing the section of the pharmacy providing sterile/ antineoplastic product pharmacy services is responsible for the environmental control of all products shipped. Therefore, any compounded, sterile parenteral product or antineoplastic agent that is frozen, or that requires refrigeration, must be shipped or delivered to a patient in appropriate coolers and stored appropriately in the patient's home.

10.5 Labeling

10.5.1 Each compounded preparation shall bear a label indicating the date beyond which it should no longer be administered and the temperature or conditions under which it should be stored.

10.5.2 If the preparation is an antineoplastic product, it must be labeled with a warning label clearly identifying the product as such.

10.5.3 The following "beyond use" dates shall be used: Admixtures in parenteral bags and bottles shall be labeled with a distinctive supplementary label, indicating the name and amount of the drug added, date, expiration date of the container and name or initials of the person preparing the solution.

10.5.3.1 Admixtures: Maximum of seventy-two hours when stored under refrigerated conditions from the time of compounding unless the manufacturer's recommendation is to store at room temperature and/or longer storage times can be substantiated with documentation.

10.5.3.2 If medications with expiration periods of less than forty-eight hours are added to a parenteral solution, or if the manufacturer indicates an expiration period of less than forty-eight hours, the "beyond use" date of the solution shall be the shorter expiration period and shall appear on the label.

10.6 Policy and Procedures Manual

10.6.1 A Policy and Procedures Manual shall be prepared and be available at each pharmacy site where sterile pharmaceuticals/antineoplastic agents are prepared for inspection by authorized agents of the Board of Pharmacy. The Policy and Procedures Manual shall contain the objectives, operational guidelines and standard operating procedures of the pharmacy pertaining to sterile products/antineoplastic agents. A procedure shall be included that addresses how a contaminated product is detected, recall measures and follow up.

10.6.2 The manual shall include procedures to be used by the pharmacy to prevent contamination of the products during preparation, storage, and dispensing.

10.6.3 The manual shall include written policies and procedures for cleaning and maintenance of the sterile pharmaceutical compounding/antineoplastic agent area(s) with records kept in the pharmacy department for one year.

10.6.4 Documentation of the following shall be included:

10.6.4.1 Replacement of filters and prefilters.

10.6.4.2 Certification of clean air source by an outside agency at least once a year.

10.6.4.3 Cleaning and maintenance of the equipment.

10.6.5 If antineoplastic agents are compounded in the pharmacy, protection shall be provided for its personnel by utilizing the proper equipment and protective garb and having a Policy and Procedures Manual for said antineoplastic agents. The Manual shall include, among the other requirements, the following special requirements outlined in sections 10.2 - 10.5 the following special requirements:

10.6.5.1 Procedures for disposal of all unused drugs and materials used in the preparation of antineoplastic agents in accordance with accepted professional standards, such as the most current OSHA Guidelines, regarding the handling of antineoplastic agents.

10.6.5.2 Safety standards which stress proper technique in handling antineoplastic agents and which include:

10.6.5.2.1 A certified vertical laminar air flow hood.

10.6.5.2.2 Protective garb, i.e., gloves, face and eye protection, and gowns.

10.6.5.3 In the event that antineoplastic agents and other parenterals are prepared within the same air flow unit, procedures shall be provided for a thorough scrub down and air purge of at least twenty minutes after compounding of the antineoplastic agent(s).

10.6.6 The Policy and Procedures Manual shall be maintained on a current basis. It shall be reviewed at least annually and changes shall show the effective date.

Revised Effective Date: April 14, 1997 (10.2 General Requirements revised)

9 DE Reg. 85 (07/1/05)(Final)