

The Georgia State Board of Pharmacy met on May 9, 2007, at the Office of the Professional Licensing Boards Division, 237 Coliseum Drive, Macon, GA 31217.

Members Present:

- Judy Gardner, President
- Pat McPherson, Vice President
- William "Bill" Prather
- Charles W. Palmer
- Mickey Tatum
- Fred Barber
- Robbie Dial
- Steve Wilson

Absent:

Bill Atkins, Director, Georgia Drugs and Narcotics Agency

Visitors:

Scott Biddulph, Target
Mary D. Peters, Corky Peters
Cindy Hill, Hospice of Central Georgia
Charlene Bunts, WellStar Hospice

Staff Present:

- Janet Wray, Attorney General's Office
- Rick Allen, Deputy Director, Georgia Drugs and Narcotics Agency
- Lisa Durden, Executive Director
- Dianne W. Patterson, Administrative Assistant
- Wanda Jackson, Testing and Examination Unit

Ms. Gardner established that a quorum was present, and called the meeting to order at 9:45 a.m.

Mr. Tatum moved, Mr. Prather seconded, and the Board voted to enter into **EXECUTIVE SESSION** in accordance with O.C.G.A §§43-1-19(h) (2) and 43-1-2(k) to review applications, deliberate on disciplinary matters, and to receive information on investigative reports. Voting in favor of the motion were those present who included Board Members Mr. Barber, Mr. McPherson, Mr. Palmer, Mr. Dial and Mr. Wilson.

At the conclusion of the EXECUTIVE SESSION, the Board declared an **Open Session** to vote on the matters discussed in Executive Session and to conduct other Board business.

APPOINTMENT (S)

- The Board met with Katie Steward, Esq., Associate Counsel Sr. Director, Regulatory Affairs to discuss ExcelleRx for authorization to provide remote pharmacy services utilizing automated dispensing systems to hospice inpatient units.
- The Board met with J.R. and Advocate to discuss possible reinstatement of a Georgia Pharmacist license.

Katie Steward, Esq. Associate Counsel Sr. Director, Regulatory Affairs: Additional review by the Board.

J.R.: Mr. Tatum made a motion to **approve** J.R.'s request for reinstatement of her Georgia Pharmacist license. The case will be forwarded to the Attorney General's Office for a Private Consent Order. Mr. Prather seconded the motion and it carried unanimously.

Janet Wray, Board Attorney General's Office:

Mrs. Wray updated the Board on all open cases in the Attorney General's Office and presented one Public Consent Order, three Private Consent Orders and information on seven additional cases.

- **Stephanie Boyd, RPH019531:** Mr. Palmer made a motion to **accept** the signed Public Consent Order. Mr. Prather seconded the motion and it carried unanimously.
- **J.C.:** Mr. Palmer made a motion to **accept** the signed Private Consent Order. Mr. Prather seconded the motion and it carried unanimously.
- **J.F.R.:** Mr. Palmer made a motion to **accept** the signed Private Consent Order. Mr. Prather seconded the motion and it carried unanimously.
- **J.R.:** Mr. Palmer made a motion to **accept** the signed Private Consent Order. Mr. Prather seconded the motion and it carried unanimously.
- **J.A.P.:** Consent Order mailed.
- **G.J.:** Consent Order mailed; Board voted to **accept** upon receipt of signed consent order.
- **R. O.:** Waiting on Initial Decision.
- **D.I.:** Waiting on Initial Decision.
- **C.P.:** Investigative Interview.
- **C.V.S.:** Meeting with Attorney General Office.
- **G.G.S.:** Has not responded to Voluntary Surrender; schedule hearing.

Rick Allen, Deputy Director, Georgia Drugs and Narcotics Agency Report:

- Vehicles re: Stolen vehicle from Agent's home.
- Legislation provided increase in salary to Public Safety employees except the Georgia Drugs and Narcotics Officers.
- Certification re: Certified addiction counselors. Discussion about what credential to be accepted and approved treatment providers.
- Questions from GPHA concerning the APRN Law. GPHA must follow the Law.

Pat McPherson, Cognizant Board Member reported on the following cases:

GDNA Case #A06-44: The Cognizant member recommended sending an agent to investigate the facility. Mr. Prather made a motion to accept the cognizant's recommendation. Mr. Tatum seconded the motion and it carried unanimously.

GDNA Case A28-070: The Cognizant member recommended the candidate to take the Georgia Board of Pharmacy Examination. Mr. Prather made a motion to accept the cognizant's recommendation. Mr. Tatum seconded the motion and it carried unanimously.

GDNA Case #A06-45/Kenneth Lee Arthur, RPH013139: The Cognizant member recommended **accepting** the signed Voluntary Surrendered Order. Mr. Tatum made a motion to accept the cognizant's recommendation. Mr. Palmer seconded the motion and it carried unanimously.

GDNA Case #A07-20/William C. Sammons, RPH011863: The Cognizant member recommended **sending** a Public Interim Consent Order. Mr. Prather made a motion to accept the cognizant's recommendation. Mr. Barber seconded the motion and it carried unanimously.

GDNA Case #A07-21/ Kathy Frye Dangar, RPH011458: The Cognizant member recommended **referring** the case to the Attorney General's Office for a Consent Order to include a \$500.00 fine, attend the Law Review Course, 5-Years Probation and a Public Reprimand. Mr. Prather made a motion to accept the cognizant's recommendation. Mr. Tatum seconded the motion and it carried unanimously.

GDNA Case #A07-23: The Cognizant member recommended **referring** the case to the Drugs and Narcotics Agency for an Investigative Interview. Mr. Prather made a motion to accept the cognizant's recommendation. Mr. Dial seconded the motion and it carried unanimously.

Board Complaint #B28065: The Cognizant member recommended **referring** the case to the Drugs and Narcotics Agency for an Investigative Interview. Mr. Prather made a motion to accept the cognizant's recommendation. Mr. Tatum seconded the motion and it carried unanimously.

GDNA Complaint #A28067: The Cognizant member recommended **sending** a letter of concern to include a recommendation that the pharmacist attend the Law Review Course and submit proof of completion of course. Mr. Prather made a motion to accept the cognizant's recommendation. Mr. Tatum seconded the motion and it carried unanimously.

Lisa Durden Executive Director's Report:

- Intern re: Matt Kloiber from Georgia College State and University creating system for Compliance and Program Providers.
- Staff position re: Request a position for a compliance person.

Wanda Jackson, Exam Analyst, Report:

- Examination re: 127 Candidates scheduled for the June 14, 2007 Examination
- Profiling re: Samples prescription questions for examination.

Judy Gardner, Board President Report:

- HB 330: Staff was instructed to invite GPHA, GHSP and Steve Jordanson to the next meeting for discussion of counseling rule on refills.

Executive Session Items:

Application submitted by R.W.D.: Mr. Prather made a motion to **approve** the applicant's application for reciprocity. Mr. Tatum seconded the motion and it carried unanimously.

Application submitted by S.H.: Mr. Tatum made a motion to **deny** the applicant's application for reciprocity. Mr. Prather seconded the motion and it carried unanimously.

Application submitted by C.A.E.: Mr. Prather made a motion to **deny** the applicant's application for reinstatement. Mr. Tatum seconded the motion and it carried unanimously.

Application submitted by D.P.D.: Mr. Prather made a motion to **approve** the applicant's application for reciprocity. Mr. Tatum seconded the motion and it carried unanimously.

Application submitted by L.A.G.: Mr. Tatum made a motion to **approve** the applicant's application for intern license. Mr. Prather seconded the motion and it carried unanimously.

Application submitted by D.M.B.: Mr. Prather made a motion to **approve** the application for Nuclear Pharmacist licensure. Mr. Tatum seconded the motion and it carried unanimously.

Application submitted by D.M.D.: Mr. Prather made a motion to **approve** the application for Nuclear Pharmacist licensure. Mr. Tatum seconded the motion and it carried unanimously.

AGENDA ITEMS:

Information regarding Impaired Pharmacist/Pharmacy Intern Treatment Facility submitted by Joel L. Morgan,M.D.: The Board will table until the June 2007 meeting.

Information submitted by Eric Funderburg,RPH017229: Mr. Prather made a motion to **approve** Mr. Funderburg's request to meet with the Board to discuss possible reinstatement of his Pharmacist license. Mr. Tatum seconded the motion and it carried unanimously.

Information regarding Drug Usage submitted by Greg M. Powell,RPH019641: The Board directed the staff to send a letter referring him to the Federal Drug Administration and the Manufacturer.

Information regarding Usage equipment for the Talyst Unit Dose Barcode submitted by Robertiena Fletcher, RPH: The Board directed the staff to send a letter stating that a manufacture's license is required.

Newly Licensed Pharmacists dated 4/7/07-4/30/07: Mr. Barber made a motion to **approve** the newly licensed Pharmacists. Mr. Tatum seconded the motion and it carried unanimously.

LICENSE NUMBER	NAME	PROFESSION	ISSUE DATE
RPH023530	Bell, Niesha Nicole	Pharmacist	4/13/2007
RPH023531	Addo, Anselm Kwaku	Pharmacist	4/13/2007
RPH023532	Ho, Matthew Kawika	Pharmacist	4/13/2007
RPH023533	Wray, Christopher Campbell	Pharmacist	4/13/2007
RPH023534	Hsieh, Angela Anchieh	Pharmacist	4/18/2007
RPH023535	Frye, Karen Hanley	Pharmacist	4/18/2007
RPH023536	Okadigwe, Cyril J	Pharmacist	4/18/2007
RPH023537	Carver, Kelly Lynn	Pharmacist	4/18/2007
RPH023538	Trobaugh, Craig W	Pharmacist	4/18/2007
RPH023539	Cibulas, Matthew S.	Pharmacist	4/24/2007
RPH023540	Daaboul, Mohamed K	Pharmacist	4/24/2007
RPH023541	Ibrahim, Semira M	Pharmacist	4/24/2007
RPH023542	Lewis, Dwight A	Pharmacist	4/24/2007
RPH023543	Obi, Fredrick O	Pharmacist	4/24/2007
RPH023544	Walker, Philpatrick Demon	Pharmacist	4/25/2007
RPH023545	Heenan, Patricia Ann	Pharmacist	4/25/2007
RPH023546	Jiwa, Salimah S.	Pharmacist	4/25/2007
RPH023547	Kriengkauykiat, Jane	Pharmacist	4/25/2007
RPH023548	Veres, Shawn Raie	Pharmacist	4/26/2007

Newly Licensed Pharmacist Interns dated 4/7/07-4/30/07: Mr. Barber made a motion to **approve** the newly licensed Pharmacist Interns. Mr. Tatum seconded the motion and it carried unanimously.

LICENSE #	NAME	PROFESSION	ISSUE DATE
PHI-013122	Brown, Cornelius Edward	Pharmacist Intern	4/12/2007
PHI-013123	Cofield, Allison Leigh	Pharmacist Intern	4/12/2007
PHI-013124	Crews, Rylen O'Neal	Pharmacist Intern	4/12/2007
PHI-013125	Foma, Cletus Ahidjo	Pharmacist Intern	4/12/2007
PHI-013126	Moore, Logan Elizabeth	Pharmacist Intern	4/12/2007
PHI-013127	Pauley, Deana Elizabeth	Pharmacist Intern	4/12/2007
PHI-013128	Nguyen, Lylian H	Pharmacist Intern	4/17/2007
PHI-013129	Rolle, Annalea Inez	Pharmacist Intern	4/17/2007
PHI-013130	Tucker, Brian Jeffery	Pharmacist Intern	4/18/2007
PHI-013131	Tyson, Brittney NaTaria	Pharmacist Intern	4/18/2007
PHI-013132	Elgebaly, Mostafa M	Pharmacist Intern	4/20/2007
PHI-013133	Beall, Jennifer Lynn	Pharmacist Intern	4/20/2007
PHI-013134	Patel, Mansi V	Pharmacist Intern	4/20/2007
PHI-013135	Patel, Mitesh Madhusudan	Pharmacist Intern	4/25/2007
PHI-013136	Agbali, Raphael Ayegba	Pharmacist Intern	4/27/2007
PHI-013137	Bell, Randy B	Pharmacist Intern	4/27/2007
PHI-013138	Ssenkoloto, Rita Nangendo	Pharmacist Intern	4/27/2007
PHI-013139	DeVance, Delveatra Rena	Pharmacist Intern	4/27/2007
PHI-013140	Scott, Brandy Marie	Pharmacist Intern	4/30/2007

Draft of April 18, 2007 Meeting Minutes: Mr. Prather made a motion to **approve** the Board Minutes. Mr. Tatum seconded the motion and it carried unanimously.

OTHER AGENDA ITEMS:

Executive Items:

Information submitted by A.L.J.: The Board directed the staff to contact the school to verify enrollment date and attendance.

Information submitted by R.B.C.: Mr. Prather made a motion to **deny** the applicant's application for waiver of penalty fee. Mr. Tatum seconded the motion and it carried unanimously.

Rule 480-22 Requirements Of A Prescription Under Georgia Controlled Substances Act:
Mr. Prather made a motion to “Vote to Post”, Rule 480-22. Mr. Tatum seconded the motion and it carried unanimously.

**REQUIREMENTS OF A PRESCRIPTION UNDER GEORGIA
CONTROLLED SUBSTANCES ACT
PRESCRIPTION DRUG ORDER RECORD KEEPING**

Rule 480-22-.01: Definitions.

Rule 480-22-.12: Requirements of ~~Controlled Substance and Dangerous Drug~~ Prescription Drug Orders as ~~carried out~~ issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) licensed to practice in the State of Georgia.

Rule 480-22-.14: Ordering and Receipt of Samples.

480-22-.01 Definitions.

Except as noted herein, any Any term contained in this chapter shall have the same meaning as set forth in O.C.G.A. §§ 16-13-21, 26-3-2, 26-4-5, and Title 43, Chapter 34.

Authority O.C.G.A. Secs. 16-13-34, 16-13-74, 26-3-16, 26-4-27, 26-4-37, 26-4-53, 26-4-78, 43-34. History. Original Rule entitled "Requirements of a Prescription" adopted. F. Mar. 20, 1975; eff. Apr. 9, 1975. **Amended:** F. April 8, 1988; eff. Apr. 28, 1988.

Repealed: New Rule entitled "Definitions" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-22-.12 Requirements of ~~Controlled Substance and Dangerous Drug~~ Prescription Drug Orders as ~~carried out~~ issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) licensed to practice in the State of Georgia.

(5) Under O.C.G.A. § ~~43-34-26.3~~(e.1), an advanced practice registered nurse (APRN)

who is recognized by the Georgia Board of Nursing as having met the requirements

established by the Georgia Board of Nursing to engage in advanced nursing practice, and

who has entered into a nurse protocol agreement, approved by the Composite Board of

State Medical Examiners, with a delegating physician is permitted to issue a prescription

drug order or orders for any dangerous drug, as defined in O.C.G.A. § 16-13-71 without

the co-signature of a delegating physician pursuant to the authority delegated by the

APRN's delegating physician and contained in the APRN's nurse protocol.

(a) An APRN can issue a prescription drug order for any Schedule III, IV, or V

controlled substance without having such prescription co-signed by his or her delegating

physician, if such APRN has his or her own federal DEA number; An APRN has no

authority to issue a Schedule I or II controlled substance prescription. If an APRN does

not have their own federal DEA number, the prescription must be signed by the physician.

(b) An APRN is not authorized to issue refills of any dangerous drug for more than 12

months from the date of the original order, except in the case of oral contraceptives,

hormone replacement therapy, or prenatal vitamins which may be refilled for a period of

24 months: An APRN is not authorized to issue more than five (5) refills of any Schedule

III, IV, or V controlled substance for more than six (6) months from the date of the original

order.

(c) Delegation of such authority shall be contained in the nurse protocol required by

O.C.G.A. § [43-34-26.3](#). The delegating physician shall remain responsible for the

medical acts of the APRN.

(6) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to

create a presumption of liability, either civil or criminal, on the part of a pharmacist duly

licensed under Chapter 4 of Title 26, who in good faith fills a prescription drug order

presented by a patient pursuant to this Rule which was issued by an
APRN pursuant to an
approved nurse protocol agreement.

(a) A pharmacist shall presume that the prescription drug order was
issued by an APRN
duly licensed and qualified under Title 43, Chapter 34 to prescribe
pharmaceutical agents.

(b) A pharmacist shall presume that the drug prescribed by the APRN is
a drug approved
by the supervising physician in the APRN's nurse protocol, unless the
pharmacist has
actual or constructive knowledge to the contrary.

(7) The APRN shall only be authorized to exercise the rights granted by
O.C.G.A.
[§43-34-26.3](#) using a prescription drug order which includes the following:

(a) The name, address, and telephone number of the delegating
physician, and the DEA
number of the delegating physician if applicable;

(b) The name, address, and telephone number of the APRN, and the
APRN's DEA
number if applicable;

(c) The name and address of the patient;

(d) The drug name, strength and quantity prescribed;

(e) The directions to the patient with regard to taking the drug;

(f) The number of authorized refills, if any;

(g) Such prescription drug order form shall be valid only if signed by the APRN;

(h) A prescription drug order which is transmitted either electronically or via

facsimile shall conform to the requirements set out in paragraphs (1) and (2) of

subsection (c) of Code Section 26-4-80, respectively.

(4) Any prescription drug order containing less information than that described in this

subsection shall not be considered a legal prescription.

Authority O.C.G.A. Secs. [16-13-34](#), 16-13-72, 26-4-27, 43-34-103, [43-24-26.3](#), **History.** Original Rule entitled " Requirements of Controlled Substance and Dangerous Drug Prescription Drug Orders as carried out by a Physician's Assistant (PA) Licensed to practice in the State of Georgia" adopted. F. July 24, 2002; eff. Aug. 2002.

480-22-.14 Ordering and Receipt of Samples.

~~Only a practitioner which has been issued an individual permit number by the DEA is authorized to order and receive any controlled substance in a sample package, a starter package, or any other type of container. Only a practitioner that meets the requirements of O.C.G.A. §§ 16-13-72(4) and 16-13-74, and has independent prescribing authority is authorized to order and receive any dangerous drug in a sample package, a starter package, or any other type of container.~~

(1) For purposes of this rule, a practitioner means:

(a) A physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, with respect to, or to administer a controlled substance or dangerous drug in the course of professional practice in this state;

(b) An advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-26.3. For purposes of this chapter and Code Section 43-34-26.3, an advanced practice registered

nurse (APRN) who is registered with the federal Drug Enforcement Administration (DEA) and appropriate state authorities; or

(c) A physician's assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section 43-34-103, a physician's assistant (PA) who is registered with the federal Drug Enforcement Administration (DEA) and appropriate state authorities.

(2) Only a practitioner which has been issued an individual permit number by the DEA and is licensed by its respective state licensing board is authorized to order and receive a controlled substance in a sample package, a starter package, or any other type of container.

(3) Any practitioner receiving, maintaining, and dispensing professional drug

samples shall maintain records of all drug sample requested and received, along

with a complete list of the specific number and dosage of each professional drug

sample and medication dispensed by the practitioner and the person to whom the

drug samples were dispensed; Such records must be maintained for a minimum of

two years by the practitioner at each facility or office location where professional

drug samples are received, maintained, and dispensed

(4) In addition to the requirements of this rule, practitioners shall maintain all

professional drug samples as required by all applicable state and federal laws and

regulations.

Authority O.C.G.A. Secs. [16-13-21](#), [16-13-34](#), 16-13-72, 26-4-27, and [43-34-26.3](#).
History. Original Rule entitled " Ordering and Receipt of Samples" adopted. F. July 24, 2002; eff. Aug. 2002.

Rule 480-15, Pharmacy Technicians and Other Pharmacy Personnel: Mr. Tatum made a motion to "**Vote to Post**", Rule 480-15. Mr. McPherson seconded the motion and it carried unanimously.

480-15-.01 Pharmacy Technicians and Other Pharmacy Personnel

Nothing in these Rules or in O.C.G.A. 26-4 shall prohibit any person from assisting any duly licensed pharmacist in the measuring of quantities of medication and the typing of labels thereof, but excluding the dispensing, compounding, or mixing of drugs except as provided for in this chapter.

480-15-.01 Pharmacy Technicians and Other Pharmacy Personnel. Duties requiring professional judgment, and the responsibilities of a Licensed Pharmacist in regards to Pharmacy Technicians and other pharmacy personnel.

(a) In dispensing drugs, no individual other than a licensed pharmacist shall perform or conduct those duties or functions which require professional judgement. It shall be the responsibility of the supervising pharmacist to ensure to that no other employee of the pharmacy, excluding pharmacy interns or externs but including pharmacy technicians, performs, or conducts those duties or functions which require professional judgment.

(b) For all prescription drug orders, it shall be the responsibility of the pharmacist on duty at a facility to ensure that only a pharmacist, or a pharmacy intern and/or an extern under the direct supervision of a registered pharmacist provides professional consultation and counseling with patients or other licensed health care professionals, and that only a pharmacist, or a pharmacy intern or an extern under the direct supervision of a registered pharmacist, accepts telephoned oral prescription drug orders or provides or receives information in any manner relative to prescriptions or prescription drugs.

(c) The following functions require the professional judgement of a pharmacist,

or a pharmacy intern or extern, under the direct supervision of a pharmacist, and may not be performed by a pharmacy technician:

(1) Acceptance of oral prescriptions;

(2) Certification of a filled and finished prescription drug order;

(3) Weighing or measuring active ingredients without a mechanism of verification;

(4) Reconstitution of prefabricated medication without a mechanism of verification;

(5) Verification of the constituents of final IV admixtures for accuracy, efficacy, and patient utilization;

(6) Enter of order on patient medication profiles without verification by a pharmacist;

(7) Provision of drug information that has not been prepared or approved by the pharmacist.

(d) In the dispensing of all prescription drug orders:

(i) The pharmacist shall be responsible for all activities of any pharmacy technician in the preparation of the drug for delivery to the patient;

(ii) The pharmacist shall be present and personally supervising the activities of any pharmacy technician at all times;

(3) When electronic systems are employed within the pharmacy, pharmacy technicians may enter information into the system and prepare labels; provided, however, that it shall be the responsibility of the pharmacist to verify the accuracy of the information entered and the label produced in conjunction with the prescription drug order;

(4) When a prescription drug order is presented for refilling, it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether to refill the prescription drug order; and

(5) Pharmacy technicians and other pharmacy personnel, ie clerks, cashiers, etc., in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and job function; The pharmacist-in-charge is responsible for ensuring that such persons wear or display such identification at all times when they are in the prescription department. If more pharmacy technicians identified by name badge are in the prescription department than is allowed by the 3:1 technician:pharmacist ratio the pharmacy is deemed to be in violation of the technician-pharmacist ratio, and any pharmacist on duty may also be subject to disciplinary action.

(e) the pharmacist to pharmacy technician ratio shall not exceed one pharmacist providing direct supervision of three pharmacy technicians. One of the three technicians must have been certified by the Pharmacy Technician Certification Board.

(f) The board may consider and approve an application to increase the ratio in a pharmacy located in a licensed hospital. Such application must be made in writing and must be submitted to the board by the pharmacist in charge of a specific hospital pharmacy in this state.

(g) In addition to the utilization of three (3) pharmacy technicians, a pharmacist may be assisted by and directly supervise at the same time one (1) pharmacy intern, as well as one (1) pharmacy extern;

(h) No completed prescription drug order shall be given to the patient requesting same unless the contents and the label thereof shall have been verified by a registered pharmacist.

(i) Only employees or other personnel authorized either by the pharmacist-in-charge or by law are allowed in the prescription department.

Authority O.C.G.A. Sections 26-4-27, 26-4-60, 26-4-82, and 26-4-88.

Rule 480-10-18, Utilization of Previously Dispensed Prescription Drugs: Mr. Prather made a motion to “Vote to Post”, Rule 480-10-18 as amended. Mr. Palmer seconded the motion and it carried unanimously.

480-10-.18 Utilization of Unused Prescription Drugs (Mickey’s Rule).

(1) Definitions:

(a) ‘Drug formulary’ means any dangerous drug approved by the U.S. Food and Drug

Administration, excluding schedule one through five controlled substances and drugs requiring

special storage including but not limited to refrigeration, which drugs must be in the

original unit of use container and must have an expiration date of six months or more from the

date of transfer to the pharmacy.

(b) ‘Health care facility’ means an institution which is licensed as a nursing home,

intermediate care home, personal care home, home health agency, or hospice pursuant

to Chapter 7 of Title 31.

(c) ‘Medically indigent person’ means:

(i) A person who is Medicaid eligible under the laws of this state; or

(ii) A person:

(A) Who is without health insurance; or

(B) Who has health insurance that does not cover the injury, illness, or condition for which

treatment is sought; and whose family income does not exceed 200 percent of the federal

poverty level as defined annually by the federal Office of Management and Budget.

(2) Unused prescription drugs falling within the drug formulary from a health care facility

that are donated by a patient, patient's representative, or guardian pursuant to the Utilization of

Unused Prescription Drugs Act may be returned only to a licensed pharmacy approved by the

Department of Human Resources. The health care facility must obscure the patient's name,

doctor's name, and prescription number from the label on the donated drug container prior to

transferring to the pharmacy. The health care facility must package the donated drugs in a

sealed container properly addressed and labeled and arrange for a common carrier to pick up

and deliver the drugs to the pharmacy, and such common carrier must maintain the drugs in a

secure and temperature controlled environment that meets the drug manufacturers

recommendations and USP standards.

(3) A licensed pharmacist from the health care facility donating drugs must sign a document

verifying that the drugs have been maintained in a secure and temperature controlled

environment that meets the drug manufacturers' recommendations and USP standards. Such

documents must accompany the drugs to the receiving pharmacy.

(4) The receiving pharmacy must document the receipt of such donated drugs on a readily

retrievable log, and comply with all record keeping requirements of the Board of Pharmacy. All

such donated drugs shall be maintained in a separately designated area from the pharmacy's

regular stock of drugs, and such storage shall be in an area to ensure drug integrity.

(5) Donated drugs can only be dispensed to medically indigent persons pursuant to a valid

prescription drug order. The receiving pharmacy must dispense the donated drugs in the

original packaging as received from the donating health care facility, and the receiving pharmacy

must place a label on the donated drug container in conformance with Board of Pharmacy rules

and any other applicable state or federal law. The dispensing records for donated drugs must

be maintained in the same manner as all other dispensed drugs and according to Georgia law

and Board of Pharmacy Rules.

(6) Dispensing pharmacies of donated drugs may only charge a restocking fee pursuant to

Code section 49-4-152.5. Pharmacies and pharmacist shall not be subject to liability for

dispensing unused donated drug pursuant to this rule when such services are provided without

reimbursement (except the restocking fee), and in good faith and compliance with these rules and law.

Rule 480-13, Hospital Pharmacy Regulations: Mr. Prather made a motion to “Vote to Post”, Rule 480-13 with changes. Mr. Tatum seconded the motion and it carried unanimously.

CHAPTER 480-13

HOSPITAL PHARMACY

REGULATIONS

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480-13-.01 Definitions. Amended.

For purposes of these Rules and Regulations, the following definitions apply:

(a) Hospital. As defined by the Department of Human Resources;

(b) Hospital pharmacy. Hospital pharmacy is defined as that portion of a hospital facility which is engaged in the manufacture, production, sale and distribution of drugs, medications, devices, and other materials used in the prevention, diagnosis and treatment of injury, illness and disease (hereinafter referred to as "drugs"); and which is registered with the State Board of Pharmacy pursuant to O.C.G.A. § 26-4-110;

(c) Hospital pharmacy license. Hospital pharmacy license shall mean a pharmacy license issued by the Georgia State Board of Pharmacy to said hospital pharmacies, pursuant to the provisions of O.C.G.A. Sections 26-4-27, 26-4-28 and 26-4-110 whereas the licensee shall be subject to special hospital pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements. To obtain the hospital pharmacy license, there must be employed a Director of Pharmacy.

1. The Board authorizes the holder of a hospital pharmacy license to service patients of Nursing Homes, Long Term Care Facilities or Hospices as long as these entities are under the same ownership as the hospital pharmacy; however, such entities can only be serviced by the hospital pharmacy subject to the requirements as set forth by Georgia State Board of Pharmacy Rules 480-24, the rule for providing services to nursing homes, long term care facilities, and hospices. The hospital pharmacy is prohibited from maintaining standard ward (Floor Stock) inventories in such entities, but, it would allow the hospital pharmacy to supply emergency kits.

(d) In-patient. In-patient shall mean a patient who is confined to the hospital;

(e) Out-patient. Out-patient shall mean a patient who is not an in-patient, including patients on leave of absence;

(f) Remote Location. Remote location shall mean a location away from the hospital or hospital pharmacy where a pharmacist reviews and enters patient specific prescription drug orders for a hospital's in-patient.

(g) Remote Order Entry. Remote order entry shall mean the entry a pharmacist makes from a remote location indicating that the pharmacist has reviewed the patient specific drug order for a hospital in-patient, has approved or disapproved the administration of the drug for said patient, and has entered the information on the hospital's patient record system.

(h) Remote Order Entry Pharmacist. A remote order entry pharmacist shall mean a pharmacist who is licensed to practice pharmacy in the State of Georgia, who is at a remote location, and who is under contract with or employed by the hospital to review and enter patient specific prescription drug orders for hospital in-patients when the hospital pharmacy is closed.

(i) Standard ward inventory. The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be kept at one or more locations at all times within said hospital and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or his/her pharmacist designee. A standard ward inventory may be placed on an emergency vehicle licensed with the State Department of Human Resources. A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Human Resources Licensure Division and the Georgia Drugs and Narcotics Agency (GDNA) before any legend drugs may be placed on said licensed vehicle. An agreement can be made with only one hospital.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Hospitals, Nursing Homes, Extended Care Facilities, Pharmaceutical Services" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.

Repealed: New Rule entitled "Definitions" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.02 Licensure and Registration. Amended.

All hospital pharmacies shall renew biennially by June 30th of each odd-numbered year with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those hospital pharmacies which comply with the provisions of O.C.G.A. § 26-4-110, and with these Rules and Regulations.

(a) Minimum Required Information for Licensure. The Board requires the following information from each hospital pharmacy as part of the initial licensing procedure and as

part of any renewal of such license:

(b) The name, complete street address for the business, and telephone number of the applicant/licensee;

(c) All trade or business names used by the applicant/licensee;

(d) Address, telephone numbers, and the name(s) of the Hospital Administrator;

(e) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(f) The name(s) of the owner and/or operator of the applicant/licensee, including:

1. If a partnership, the name of each partner, and the name of the partnership;

2. If a sole proprietorship, the complete name of the proprietor;

3. If a corporation, the name and title of each corporate officer and director, the corporate name and the state of incorporation; and the name of the parent company, if any.

(g) Where operations are conducted at more than one location by a single hospital pharmacy, each such location shall be licensed by the Board.

1. Applications for Licensure.

(i) Registration of a hospital pharmacy shall be considered filed with the Board when an application is received by the Board, and the fee is paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license is received by the Board.

(h) Application fees shall not be refundable.

(i) A license shall be null and void upon the sale, transfer or change of mode of operation or location of the business.

(j) Licenses may be renewed for two year periods and shall expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal for each place of business. If the application for renewal is not filed with the Board, and the fee paid before September 1st of each odd numbered year, the license shall lapse and may not be renewed except by application for a new license.

(k) A licensee must submit any change of name, mode of operation or address to the Board prior to such change.

1. Minimum Qualifications.

(i) The Board shall consider the following factors when determining eligibility for licensure for each person in charge of the facility and when considering an application for a hospital pharmacy license:

(I) Any convictions of the applicant under any Federal, State, or local laws relating to drugs, wholesale or retail drug distribution, or distribution of controlled substances;

(II) Any felony convictions of the applicant under any Federal, State, or local laws;

(III) The furnishing by the applicant of false or fraudulent material or information in any application;

(IV) Suspension or revocation by any Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;

2. Failure to comply with any licensing requirements under a previously held license, if any;

3. Failure to comply with any requirements to maintain records and/or make available, said records to any State Licensing Authority or to any Federal, State, or local law enforcement officials;

4. Other factors or qualifications the Board considers relevant to and consistent with the public's health and safety;

5. The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Hospital Pharmacy License" adopted. F. Feb. 4, 1972; eff. Feb. 24, 1972. **Repealed:** New Rule entitled "Registration" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule entitled "Licensure and Registration" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.03 Personnel. Amended.

(1) Director of Pharmacy. Each hospital pharmacy shall be directed by a pharmacist, hereinafter referred to as the Director of Pharmacy, who is licensed to engage in the practice of pharmacy in this State, and who is knowledgeable in and thoroughly familiar

with the specialized functions of hospital pharmacies. The Director of Pharmacy shall be responsible for all activities of the hospital pharmacy, and for meeting the requirements of the Georgia Pharmacy Laws and Rules and Regulations of the Board of Pharmacy. The Director of Pharmacy or his/her pharmacist designee should be employed on a fulltime basis consistent with need.

(2) Supportive personnel. The Director of Pharmacy shall be assisted by a sufficient number of additional pharmacists, including remote order entry pharmacists, and ancillary personnel as may be required to operate such pharmacy competently, safely, and to meet the needs of the patients of the hospital facility.

(a) The Director of Pharmacy shall insure that trained personnel shall be employed in the pharmacy. The Director of Pharmacy shall develop and implement written policies and procedures to specify the duties to be performed by such personnel. These policies and procedures shall, at a minimum, specify that such personnel are personally and directly supervised by a licensed pharmacist and that such personnel are not assigned duties which may be performed only by licensed pharmacists. The Director of Pharmacy shall be responsible for the implementation of the written policies and responsible to the Georgia State Board of Pharmacy for the actions of the pharmacy.

(b) Secretarial and clerical assistance and support shall be provided as required to assist with record keeping, report submission, and other administrative duties, provided such personnel do not perform any dispensing duties.

(3) Supervision. All of the activities and operations of each hospital pharmacy shall be personally and directly supervised by its Director of Pharmacy. All functions and activities of non-licensed pharmacy personnel shall be personally and directly supervised by an adequate number of licensed pharmacists to insure that all such functions and activities are performed competently, safely, and without risk of harm to patients. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the hospital.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Personnel" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.04 Absence of Pharmacist. Amended.

(1) General. When a licensed pharmacist is not physically present in the hospital and the pharmacy is closed, written policies and procedures shall be prepared in advance by the Director of Pharmacy for the provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and/or by access to the pharmacy. The policies and procedures may include the use of remote order entry pharmacist to ensure that in-patient needs are met at the hospital when a licensed pharmacist is not physically present. All policies and procedures providing for the use of night cabinets and/or access to the pharmacy when a licensed pharmacist is not physically present shall be filed with the Georgia State Board of Pharmacy.

(2) A hospital utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in the State of Georgia, and the address of each location where the pharmacist will maintain records of remote order entries.

(3) The Director of Pharmacy shall insure that any remote order entry pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open. The remote order entry pharmacist must be able to contact the prescribing practitioner to discuss any concerns identified during the pharmacist's review of the patient information. Each remote entry record must comply with all recordkeeping requirements and shall identify, by name or other unique identifier, the pharmacist involved in the preview and verification of the order. The remote entry pharmacist shall maintain records of any and all records entered for the hospital for a minimum of three (3) years, and such records shall be readily available for inspection and copying by the Board or GDNA, upon request. All orders entered by a remote order entry pharmacist must be reviewed and signed by the next pharmacist physically coming into the pharmacy and such review must maintained like all other pharmacy records.

~~(2)~~ (4) Night cabinets. Access to drugs, in the absence of a licensed pharmacist, shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area to which only specifically authorized personnel as indicated by written policies and procedures may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Director of Pharmacy shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(a) Such drugs are available therein, properly labeled, with drug name, strength, lot number and expiration date;

- (b) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;
- (c) Whenever access to such cabinet(s) has been gained, written practitioner's orders and proofs of use for controlled substances must be provided;
- (d) All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and
- (e) Written policies and procedures are established to implement the requirements of this subsection.

~~(3)~~ (5) Access to pharmacy. Whenever a drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy pursuant to the physician's order and the requirements of this subsection. One nursing supervisor (registered professional nurse or licensed practical nurse) in any given eight-hour shift may have access to the pharmacy and may remove drugs therefrom. Such licensed nurse shall be designated in writing by the Director of Pharmacy of the hospital and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training given by the Director of Pharmacy in the proper methods of access, removal of drugs, and records and procedures required. The Director of Pharmacy shall document the nurse's competence following the education and training. In addition, such licensed nurse accessing a closed pharmacy must receive specific step-by-step instructions from a remote order entry pharmacist or have similar step-by-step instructions in a policy manual before accessing the pharmacy. At any time that a nurse is accessing a closed pharmacy, the Director of Pharmacy must designate a licensed pharmacist who is available to the nurse by telephone, and who, in the event of an emergency, is available to come to the hospital. Such education and training shall be given by the Director of Pharmacy, who shall require, at a minimum, the following records and procedures:—When a nurse accesses drugs directly from the closed pharmacy, the nurse must document the following the (a) R-removal of any drug from the pharmacy by an authorized nurse must be recorded—recording on a suitable form showing the name of the drug, the strength and amount of the drug removed, the date and time it was removed, and signing the form. the signature of the nurse;(b) The container from which the drug is removed shall then be placed conspicuously to be promptly reviewed and inspected by the next pharmacist coming on duty. The Director of Pharmacy's policies and procedures must provide that the next pharmacist physically coming into the pharmacy must document that they have reviewed the drugs removed and the orders filled.

~~(4)~~ (6)Emergency kits/crash carts. Drugs may also be provided for use by authorized personnel by emergency kits/crash carts, provided such kits/carts meet the following requirements:

- (a) Emergency kit/crash cart drugs defined. Emergency kit/crash cart 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 of harm to patients;
- (b) Drugs included. The Director of Pharmacy and the medical staff of the hospital shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits/crash carts;
- (c) Storage. Emergency kits/crash carts shall be sealed and stored in limited access areas to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;
- (d) Labeling — exterior. The exterior of emergency kits/crash carts shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit/crash cart and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by an agent of the Board;
- (e) Labeling — interior. All drugs contained in emergency kits/ crash carts shall be labeled in accordance with such State and Federal Laws and Regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the hospital to prevent misunderstanding or risk of harm to the patients;
- (f) Removal of drugs. Drugs shall be removed from emergency kits/crash carts only pursuant to a valid practitioner's order, by authorized personnel, or by a pharmacist of the institutional facility;
- (g) Notification. Whenever an emergency kit/crash cart is opened, the pharmacy shall be notified; and pharmacy personnel shall restock and re-seal the kit/cart within a reasonable time so as to prevent risk of harm to patients. In the event the kit/cart is opened in an

unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

(h) Inspections. Each emergency kit/crash cart shall be opened and its contents inspected by a pharmacist at least once every ninety (90) days. Upon completion of inspection, the emergency kit/ crash cart shall be re-sealed;

(i) Procedures. The Director of Pharmacy shall, in conjunction with the medical staff of the hospital, develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

~~(5) (7)~~ Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be readily available in areas outside the pharmacy where these drugs are stored.

(8) Nothing in this rule shall be construed to relieve the hospital pharmacy of the requirement of having a full-time, on-site pharmacist to provide routine pharmacy services within the hospital in order to qualify as a licensed pharmacy.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Absence of Pharmacist" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.05 Physical Requirements. Amended.

(1) Area. A hospital pharmacy shall have within the hospital which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The hospital pharmacy space requirements should be a minimum of 10 square feet per hospital bed, which includes all areas assigned and under the direct control of the Director of Pharmacy.

(2) Equipment and supplies. Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. The equipment and physical facilities shall include the following:

(a) Compounding and dispensing area:

1. A refrigerator in operating condition with a thermometer, preferably a biological refrigerator;
2. A sink in operating condition with hot and cold running water;
3. A Class A Balance and an assortment of metric weights if utilizing a Class A Balance or a Class I or II Electronic Balance as approved in writing by the Board;
4. Graduates of assorted sizes;
5. Mortar and pestle;
6. Two (2) spatulas and a counting tray;
7. Typewriter, word processor, or computer with a label printer;
8. Pill tile; and
9. Other equipment as deemed necessary by the Director of Pharmacy.

(b) Parenteral solution additives area as required in 480-13-.06(2)(a); 1. Laminar flow hood; and

2. Facility for light-dark field examination.

(c) Storage and receiving area;

(d) Manufacturing and packaging area; and

(e) Office space area.

(3) Each hospital pharmacy shall maintain a reference library which includes, at a minimum, the following:

(a) Copy of and/or electronic or computer access to the latest edition of the Georgia Pharmacy Practice Act, the Georgia Controlled Substances Act and the Rules and Regulations of the Georgia State Board of Pharmacy;

(b) Copies of and/or electronic or computer access to current reference materials appropriate to the practice of the hospital pharmacy;

(c) Copy of and/or electronic or computer access to the latest edition of the American Society of Health-system Pharmacists Formulary Service;

(d) Compatibility charts;

(e) Current drug interaction references;

(f) Current antidote information;

(g) Copy of and/or electronic access or computer access to the latest edition of text and reference works covering theoretical and practical pharmacy, reference materials on

general, organic, pharmaceutical and biological chemistry, toxicology, pharmacology, sterilization and disinfection.

(4) Storage. All drugs shall be stored in the hospital pharmacy within designated areas which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage cabinets and unit dose carts at the nursing station shall be locked when the station is not in attendance by nursing personnel.

(5) Controlled drug storage for Schedule II drugs. An enclosed controlled room with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet adequately locked that is permanently affixed to the structure is acceptable.

(6) Unattended areas. Whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.

(7) Security. All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel by force. The Director of Pharmacy shall designate in writing, by name and specific area, those persons who shall have access to particular areas within the pharmacy. These areas shall meet the security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.

(8) Variances.

(a) The Director of Pharmacy may submit to the Board a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for granting the variance which relate to the necessary or efficient delivery of health care. After consideration by the Board, the Director of Pharmacy will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as proof of the Board's approval for each variance(s) indicated in the letter, and shall be posted next to the Georgia Drugs and Narcotics Agency inspection report.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Physical Requirements" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.06 Drug Distribution and Control. Amended.

(1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally or in writing to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.

(2) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the hospital shall cooperate with the Director of Pharmacy in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials to achieve this purpose. The Director of Pharmacy shall establish written procedures for the distribution of parenteral medications to achieve this goal. Accordingly, the Director of Pharmacy shall be responsible for, at a minimum, the following:

(a) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a Laminar Flow Hood or utilizing such other equipment to protect the integrity of the product, within the pharmacy department. Individuals who prepare or administer large volume parenterals must have special training to do so. These functions of IV admixture compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas such as Intensive Care Units, Cardiac Catheterization Laboratories Intensive Care Units, etc., during emergency situations, or during unattended hours of the pharmacy department. When any part of the above functions (preparing, sterilizing, and labeling parenteral medications and solutions) is performed within the hospital but not under direct pharmacist supervision, the Director of Pharmacy shall be responsible for providing written guidelines and for approving the procedures to assure that all pharmaceutical requirements are met;

(b) All drugs must be identified up to the point of administration;

(c) The pharmacy must receive a direct copy or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by hospital stat order

policy;

(d) Utilization of a pharmacy-generated patient profile. The patient profile shall be the official record of medications dispensed to the patient. The patient profile or the ability to generate such profile electronically shall be under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:

1. Given and last name of the patient;
2. Age;
3. Sex;
4. Provisional diagnosis;
5. Room number;
6. Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
7. Identification or differentiation of controlled substances;
8. Intravenous therapy;
9. Selected medical data;
10. Drug history interview (when possible); and
11. Sensitivities and allergies to drugs and foods;

(e) No more than a 72-hour supply of a patient's medication shall be available at the patient-care area at any time except for those drugs in bulk packages which cannot be repackaged in unit-dose containers;

(f) Manufacture of drugs, if applicable;

(g) Establishment of specifications or use of compendia specifications for procurement of drugs, chemicals, devices and biologicals, subject to approval of the appropriate committee of the hospital;

(h) Participation in the development of a drug formulary for the hospital;

(i) filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;

(j) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and other material and information as may be deemed necessary shall be maintained;

(k) Records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over the accountability for all pharmaceutical drugs, devices and materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;

(l) Participation in those aspects of the hospital patient care evaluation program which relate to pharmaceutical drug, device and material utilization and effectiveness; and

(m) Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.

(3) Labeling.

(a) For use inside the hospital, all drugs dispensed by a hospital pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.

(b) For use outside the hospital, all drugs dispensed by a hospital pharmacy to patients about to be discharged or on leave of absence shall be labeled with the following information:

1. Name, address, and telephone number of the hospital pharmacy;
2. Date and identifying serial number;
3. Patient's given and last name;
4. Name of drug, (brand or generic) and strength;
5. Directions for use by patient;
6. Name of prescribing practitioner;
7. Required precautionary information regarding controlled substances; and
8. Such other and further accessory cautionary information as may be required or desirable for proper use by and safety of the patient.

(c) Drugs added to parenteral solutions. Wherever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a licensed pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and the identity of the person so adding.

(4) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(a) Full doses of controlled substances prepared for administration and not given must be destroyed by a licensed pharmacist or a licensed nurse and one witness. Any portions of controlled substances discontinued and taken from a medication delivery device shall be destroyed by a licensed pharmacist or a licensed nurse and one witness. The two persons witnessing the destruction must sign the destruction record at the time of destruction. The destruction record shall be returned to the pharmacy and must be signed by the pharmacist who is ultimately responsible for the accuracy of the information contained therein.

(b) In accordance with the policies and procedures developed by the Director of Pharmacy, discontinued non-controlled substances dispensed to hospital patients shall be returned to the pharmacy and evaluated by the licensed pharmacist to assure the integrity of the medication. If the integrity can be assured, the medication may be returned to the hospital's drug distribution system for re-issue. When the integrity cannot be assured, the medication must be separated immediately from the regular drug inventory and destroyed or transferred to a reverse distributor with a current license issued by the Board. The following method of destruction of non-controlled substances is approved by the Board for medications dispensed to hospital patients or patients residing in nursing homes or long term care units which are part of a hospital facility;

1. Placed in a secure storage area at the facility separated from other medications. The drugs may be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction and the inventory for a two year period. This record shall include at a minimum the date, time, and personnel involved with the destruction and the method of destruction; or

2. If the drugs are to be transferred to a reverse distributor with a current license issued by the Board, a record of the following must be maintained by the hospital pharmacy for a minimum of two years:

(i) An inventory of the drugs to be transferred including the names of the drugs; the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be verified by a pharmacy representative and a representative of the reverse distributor;

(ii) The date and time the drugs were taken from the pharmacy;

(iii) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;

(iv) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);

(v) The name and signature of the pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.

(c) The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

1. A securely attached wooden or metal cabinet within a locked limited-access area shall be used to store the drugs until the drugs are destroyed. When controlled drugs are discontinued or the patient expires, the medication shall be pulled from the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication shall remain within the locked cabinet until such time as it is removed for destruction.

2. The pharmacist shall establish a form, which shall include the following data:

(i) Date of discontinuance or inventory date;

(ii) Name of patient;

(iii) Name of pharmacy;

(iv) Identifying serial numbers;

(v) Name and strength of the drug; and

(vi) Quantity of the drugs in container(s) at the time of inventory.

3. A licensed pharmacist or licensed nurse and one witness must destroy the drugs.

4. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by the two witnesses present at the destruction in the following format:

"We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____ (location) on _____ (date) at _____ o'clock."

Name of drug
Strength of drug
Dosage form
Quantity of drug

(Signature and Title)

(Signature and Title)

(Signature and Title)

5. The Board and/or the GDNA may prohibit any pharmacist or hospital pharmacy from utilizing this method.

(d) A method of off-site destruction allowable by the Board is as follows:

1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until the drugs are transferred. When the drugs are transferred to a reverse distributor licensed by the Board, an inventory must be recorded and include the following information: the names of the drugs, the dosage forms of the drugs and the quantities of the drugs taken and witnessed by an authorized representative of the hospital pharmacy and the responsible person representing the reverse distributor.

2. A receipt including the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of the pharmacy representative transferring the drugs. This receipt/record must be maintained by the hospital pharmacy for a minimum of two years.

(5) Prescription drug orders. Drugs may be dispensed from the hospital pharmacy only upon written orders, direct or mechanical copies thereof, of authorized practitioners.

(a) Authorization. The appropriate committee of the hospital shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

(b) Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.

(c) Requirements — Prescription drug orders for drugs, devices or materials for use by in-patients. Prescription drugs orders for use by in-patients shall, at a minimum, contain:

1. Patient name and room number;
2. Drug name, strength, directions for use; and
3. Date and practitioner's signature.

(d) Requirements — Prescription drug orders for drugs, devices or materials for use by out-patients. Prescription drug orders for drugs, devices or materials for use by outpatients shall, at a minimum, contain all of the information required by Rule 480-13-.06(5)(c), and in addition include:

1. Quantity to be dispensed;
2. Practitioner's address and Drug Enforcement Administration identification code, if applicable, and
3. Patient's address, if applicable.

(6) Accountability of controlled drugs.

(a) Proof of use of controlled drugs on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the hospital, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Name of drug, strength, and dosage form;
2. Dose administered;
3. Name of authorized practitioner. This shall include, at a minimum, the initial and last name;
4. Given and last name of the patient;
5. Date and time of administration to the patient;

6. Signature of the individual administering, which shall include at a minimum, the initial, last name, and title;
 7. Documentation of the destruction of any and all unused portions by two signature verifications;
 8. Proof of receipt of the medications that bears identifying serial numbers; and
 9. Date the medication was issued and the date that the proof of use form was returned to the pharmacy.
- (b) Anesthesia departments that obtain controlled drugs from the hospital pharmacy must show accountability of the controlled drugs by proof of use as defined above.
- (c) Use of computer generated hard copy is permitted where such copy meets all other requirements of the law.
- (d) Any hospital pharmacy licensed by the Georgia State Board of Pharmacy and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:
1. The controlled substance is either a whole dose or a partial dose of a single-dosage unit; and
 2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
- (e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.
- (7) Recall. The Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper disposition.
- (8) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering authorized practitioner, the pharmacy, and to the appropriate committee of the hospital. An appropriate entry on the patient's medical record shall also be made.
- (9) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety and welfare. Such records shall be readily available and subject to inspections by the Board of Pharmacy, the GDNA or its employees. These shall include, at a minimum, the following:
- (a) Patient profile;
 - (b) Proof of use;
 - (c) Reports of suspected adverse drug reactions;
 - (d) Inventories of night cabinets and emergency kits/crash carts;
 - (e) Inventories of the pharmacy;
 - (f) Biennial controlled substances inventories;
 - (g) Alcohol and flammables reports; and
 - (h) Such other records and reports as may be required by state Law and the Rules and Regulations of the Board of Pharmacy.
- (10) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a hospital for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said hospital or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order. This practitioner's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A record of administration of drugs administered to patients in ancillary areas such as but not limited to the operating room, emergency room, anesthesiology, and x-ray shall be forwarded to the pharmacy and these medications shall be recorded on the patient profile. A survey of usage trends of each standard ward inventory shall be prepared monthly. Such records shall be retained for a period of two years.
- (11) Emergency room dispensing. An authorized practitioner may, when drugs or controlled substances are not otherwise available from a licensed pharmacy, dispense an emergency amount of medication, but only sufficient quantities until such time as medication can be obtained from a pharmacy licensed as a retail pharmacy. Nurses or other unauthorized personnel may not dispense medication from the emergency room. The total act of dispensing shall be performed by an authorized practitioner in accordance with Pharmacy Laws, Rules and Regulations. Such medications shall be labeled as

required in Section 480-13-.06(3)(b).

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-110. **History.** Original Rule entitled "Drug Distribution and Control" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Amended:** F. Feb. 4, 1987; eff. Feb. 24, 1987. **Amended:** F. Nov. 7, 1994; eff. Nov. 27, 1994. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.07 Administration of Drugs. Amended.

(1) General. Drugs shall be administered only upon the orders of those members of the medical staff who have been granted staff privileges. Drugs shall be administered by authorized licensed personnel in accordance with policies and procedures specified by the appropriate committee of the facility, under applicable Law and Rules and Regulations, and by usual and customary standards of good medical practice. The Director of Pharmacy shall develop and implement policies and procedures concerning selfadministration of medication.

(2) Self-administration. Self-administration of drugs by patients shall be permitted only when specifically authorized by the patient's authorized practitioner, provided, however, the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient. The Director of Pharmacy shall develop policies and procedures relating to the self-administration of drugs.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Administration of Drugs" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.08 Drugs from Outside Sources. Amended.

The Director of Pharmacy shall establish policies and procedures relating to drugs brought into the hospital by patients or patients' family members. Such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant only to an authorized practitioner's prescription drug order. If such drugs are not to be administered, the medication shall be returned to an adult member of the patient's family or stored by the pharmacy and re- turned to the patient upon discharge. Medications received from an outside source, but not to be administered, may not be stored on the patient care unit. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by an agent of the Board of Pharmacy.

Authority O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-110, 26-4-115. **History.** Original Rule entitled "Drugs from Outside Sources" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.09 Investigational Drugs. Amended.

Investigational drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal practitioner- investigator or his/her authorized clinician(s) with prior approval of the appropriate committee(s) of the hospital. Investigational drugs shall be administered in accordance with an approved protocol that includes any requirements for a patient's appropriate informed consent. Nurses may administer such drugs only after they have been educated regarding such drugs by the clinician or the pharmacist. A central unit shall be maintained wherein essential information regarding such drugs may be obtained. Investigational drugs in use shall be properly stored, distributed, and controlled maintaining the confidentiality of patient-medical staff information. The Director of Pharmacy shall be responsible for policies and procedures concerning use of investigational drugs.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Investigational Drugs" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.10 Inspections. Amended.

(1) Monthly. The Director of Pharmacy shall no less than once per month, personally or by qualified designee, inspect all matters within his/her jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections shall, at a

minimum, verify that:

- (a) Drugs are dispensed only by licensed pharmacists or licensed pharmacy interns acting under the direct supervision of a licensed pharmacist;
- (b) Non-licensed pharmacy personnel are properly directed and supervised;
- (c) Drugs for external use are stored separately, and apart from drugs for internal use or injection;
- (d) Drugs requiring special storage conditions to insure their stability are properly stored;
- (e) No outdated drugs are stocked in the hospital pharmacy or the facility it serves;
- (f) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;
- (g) Standard ward inventory (floor stock). Verification of standard ward inventory lists and accountability, including such updating, if applicable, are maintained;
- (h) All necessary and required security and storage standards are met;
- (i) Metric-apothecaries' weight and measure conversion tables and charts are available;
- (j) All policies and procedures of the Director of Pharmacy and of appropriate committees of the hospital relevant to the pharmacy are followed;
- (k) All discounted and out-dated medications are returned to the pharmacy for proper disposition; and
- (l) Disinfectants and other similar supplies intended for external use are stored separately and apart from drugs intended for internal (oral) or parenteral use.

(2) Board Inspection. The Board of Pharmacy inspections shall be conducted by representatives of the Georgia Drugs and Narcotics Agency (GDNA) no less than once every two (2) years. Such inspections shall include all aspects of the management and operation of all hospital pharmacies in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the hospital serviced by the pharmacy are protected. A written report shall be filed with the GDNA, the Director of Pharmacy, and the hospital administrator. Any discrepancies or deficiencies noted shall be corrected within a reasonable time. Written notice of such corrections shall be filed with the GDNA within thirty (30) days after receipt of the inspection notice.

(a) The Director of Pharmacy of each hospital pharmacy shall obtain a copy of the current Board permit of every drug wholesaler and/or reverse distributor from which controlled substances and/or dangerous drugs are purchased and/or returned. Such copies shall be made available during the GDNA's inspection.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Inspection" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule entitled "Inspections" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Draft of May 2, 2007 Meeting Minutes: Mr. Tatum made a motion to **approve** the meeting minutes. Mr. Barber seconded the motion and it carried unanimously.

Information submitted by A. Leroy Toliver for Charles Moyer, RPH012199: Mr. Wilson made a motion to **approve** Mr. Moyer's request to lift the restriction regarding "Supervised Practice" as noted in Part 1(b) of the Public Consent Order. Mr. Prather seconded the motion and it carried unanimously.

Information submitted by A. Leroy Toliver for Tommy C. Harrison, RPH009880: Mr. Palmer made a motion to **approve** Mr. Harrison's request to meet with the Board for possible reinstatement of his license. Mr. Prather seconded the motion and it carried unanimously.

There being no further business, the meeting adjourned at 2:52 p.m.

Judy Gardner, President

**Lisa Durden, Executive Director
Professional Licensing Boards Division**

**Minutes Prepared By: Dianne W. Patterson, Administrative Assistant
Reviewed/Edited By: Lisa Durden, Executive Director**

Minutes approved by the Board at its June 13, 2007 Board meeting.

