GEORGIA BOARD OF PHARMACY
South University School of Pharmacy
709 Mall Blvd, Savannah, GA 31406
Minutes for April 9, 2025 Board Meeting

Board Members present:
Cecil Cordle, PharmD, President
Young Chang, Vice-President
Michael Azzolin, PharmD
Michael Brinson
Jim Bracewell
Young Chang
Michael Farmer
Chuck Page
Dean Stone

Board Staff present:
Clint Joiner, Executive Director
Michael Karnbach, Director, GDNA,
Alec Mathis, Deputy Director, GDNA
Tommy Roe, Special Agent
Itovia Evans, Deputy Director of Licensing
Dowlin Ryals, Assistant Attorney General
Angela Johnson, Board Administrative Secretary

Visitors:
Brad Bolton, Cardinal Health NPHS
Stephanie Kirkland, Elder Care Pharmacy
Heather Hughes, Publix
Kranti Patel, eClinical Works
Michael Laycob, eClinical Works
Justin Stein, eClinical Works
Rich Palombo, Cigna/ Express Scripts
Ron Hartman, Tanner Health/ GSHP
Jeenu Philip, Walgreens
Cameron Boyd, Walmart
John Mark Carter, South University
Zach Holmes, South University
Eric Holgate, Custom Pharmacy
Emily Doppel, McKesson
Jonathan Marquess, GPhA/ AIP
Susan DelMonico, Genoa
Evan Lane
Dustin Orvin
Ross Shephard, Nelson Mullins
Steven Slack, South University
Julie Mendoza, Walgreens
Michael Melroy, St. Joseph's Hospital
Rondell Jaggers, St. Joseph's Hospital
Adegoke Adeniji, South University
David Ombengi, South University

Public Hearing

President Cordle welcomed the guests to the meeting and called the public hearing to order at 9:05 a.m.

President Cordle advised that there are two changes to the language of the proposed rules, but that the Board will move forward on adopting the proposed rules as presented today and follow up with an amendment to make any changes rather than tabling the rule and starting the process over again. The changes will not disturb the content of language in the rules as presented today for consideration.

Written responses were received from Lauren Paul with CVS Health, Richard Marasco with SeniorPharm.com and Stephanie Kirkland with ElderCare Pharmacy & Magnolia Manor Pharmacy.

Proposed Rules:

Rule 480-11-.10. Exceptions

(1) The requirements of this chapter do not apply to the compounding or mixing of FDA-approved drug preparations pursuant to the manufacturer's directions for dispensing including but not limited to the reconstitution of oral suspensions, combination of the components of topical preparations, etc.
(2) The act of adding flavoring agents to conventionally manufactured drug products, on its own, shall not be considered an act of pharmaceutical compounding.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-86.

A written response was received from Lauren Paul with CVS Health requesting that the Board clarify that flavoring of medications is not an act of pharmaceutical compounding and therefore is not subjected to USP 795 standards. No further comments were received.

Mr. Stone made a motion to adopt Rule 480-11.10 Exceptions. Mr. Farmer seconded, and the Board voted unanimously in favor of the motion.

Rule 480-15-.02. Registration of Pharmacy Technicians and Continuing Education Requirements

(1) Effective August 1, 2011, a pharmacy may only employ registered pharmacy technicians to perform pharmacy technician duties.
(2) In order to be registered as a Pharmacy Technician in this State, an applicant shall:
    (a) Submit an application to the Board on the form prescribed by the Board;
        1. Mere submission of an application to the Board is not registration pursuant to this Rule.
        2. No applicant shall be deemed registered until such time as his/her application has been completely processed by the Board's administrative office, to include receipt and processing of any applicable fees, and a registration number has issued to the applicant;
    (b) Attest that applicant is at least 17 years old;
    (c) Attest that applicant is currently enrolled in high school, or has a high school diploma, or has a GED, or has a postsecondary education or college degree;
    (d) Consent to, provide the necessary information to conduct, and pay for a background check to be conducted by the Board, its agent or a firm or firms approved by the Board, which background check will include a criminal history, driver license history and other information as the Board deems necessary, and will authorize the Board and the Georgia Drugs and Narcotics Agency to receive the results;
    (e) Submit the name and address of employer and place of employment;
    (f) Pay application fees; and
    (g) If certified, submit evidence of training supporting designation as certified.
(3) The Board may deny registration or conditionally grant registration for any of the reasons set forth in Code sections 26-4-60 or 43-1-19. This includes convictions, pleas of nolo contendere and guilty pleas related to misdemeanor crimes of moral turpitude or marijuana and to felonies. In addition, no pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.
(4) The denial of an application for registration as a pharmacy technician shall not be a contested case and the applicant shall not be entitled to a hearing under the Georgia Administrative Procedures Action, O.C.G.A. T. 50, Ch. 13, but such applicant may be entitled to an appearance before the Board.
(5) A registration, once issued, is renewable biennially, upon payment of a fee. Registrations shall expire on June 30th of each odd-numbered year. If the application for renewal is not made and the fee paid before September 1st of the odd-numbered year, the registration shall lapse and shall not be renewed. An application for a new registration shall be required.
(6) On and after July 1, 2023, as a requirement for the biennial renewal of his/her registration, a pharmacy technician must complete not less than twenty (20) hours of approved continuing education.
    (a) "Approved continuing education" means courses approved by the Board as described in Rule 480-3-.03.

(b) One hour of C.E. is defined as 0.1 C.E.U. Each pharmacy technician in the State of Georgia must obtain 20 hours of continuing education or 2.0 C.E.U.'s per biennium for registration renewal.
    1. Certificates documenting 20 hours of approved continuing education or 2.0 C.E.U.'s must be completed and date within the biennium.
(c) C.E. requirements during the technician's first biennial registration cycle:
    1. A pharmacy technician registered during the first six (6) months of the biennium (July 1, Year-One to December 31, Year-One), shall be required to obtain 20 hours of C.E.
    2. A pharmacy technician registered during the following twelve (12) months (January 1, Year-Two to December 31, Year-Two), shall be required to obtain 10 hours of C.E.
    3. A pharmacy technician registered during the last six (6) months (January 1, Year-Three to June 30, Year-Three) of the biennium, shall be exempt from continuing education for that biennium only.
    4. A pharmacy technician qualified to administer vaccines pursuant to O.C.G.A. 26-4-52 and Ga. Comp. R. & Regs. R. 480-15-.04(i) shall complete two hours, or 0.2 C.E.U.'s, of immunization related continuing pharmacy education from an approved continuing education course per biennium for registration renewal.
(d) In the event of an audit and a pharmacy technician fails to submit certificates, which document his/her required continuing education credits, the Board will not process his/her request to renew the registration until the continuing education requirements are provided to the Board.
    1. The pharmacy technician may not carry over continuing education credits from one registration period to the next.
    2. Nothing is meant to prohibit representatives from the Georgia Drugs and Narcotics Agency (GDNA) from checking, auditing, or verifying a pharmacy technician's continuing education certificates as needed.
    3. Each registered pharmacy technician shall maintain these certificates of attendance at continuing education meetings for a period of two (2) years from the date of the preceding renewal period.
(e) The staff of the Georgia Board of Pharmacy may audit, or otherwise select randomly, the continuing education of a percentage of registrants as determined by the Board.

(7) A registrant has a responsibility to update the Board with a change of home address and employment address within ten (10) days of such change.

Authority: O.C.G.A. §§ 16-13-111, 26-4-5, 26-4-20, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-84, 26-4-85, 26-4-88, 26-4-110, 43-1-19.

No public comments were made.

Mr. Stone made a motion to adopt Rule 480-15-.02 Registration of Pharmacy Technicians and Continuing Education Requirements. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Rule 480-15-.04. Duties of the Pharmacist in Charge Related to Registered Pharmacy Technicians

(1) The Pharmacist in Charge shall be responsible for:
(a) Providing updated information to the Board in accordance with rules and regulations regarding the registered pharmacy technicians employed in the pharmacy for purposes maintaining the registry of registered pharmacy technicians established by the Board pursuant to paragraph (7) of subsection (a) of Code Section 26-4-28.

(b) Ensuring the reporting the separation of employment or termination of any Registered pharmacy technician for any suspected or confirmed criminal occupational-related activities committed or any drug-related reason, including but not limited to Adulteration, abuse, theft or diversion and shall include in the notice the reason for the termination.
(c) Assuring that all pharmacists and pharmacy interns and externs employed at the pharmacy are currently licensed and that registered pharmacy technicians employed at the pharmacy are currently registered with the Board of Pharmacy.
(d) Notifying the Board of any change in the employment status of all registered technicians in the pharmacy within 10 days of the technician's separation date from employment,
(e) Ensuring that registered pharmacy technicians 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 title. The Pharmacist-in-Charge is responsible for ensuring that such persons wear or display such identification at all times when they are working in the prescription department.
(f) Shall ensure that the current registration for each registered pharmacy technician is readily accessible for inspection by the Board or Drugs and Narcotics Agents.
(g) Ensuring that a pharmacist is responsible for the dispensing of all prescription drug orders and for all activities of any pharmacy technician in the preparation of the drug for delivery to the patient, and that a pharmacist shall be present and personally supervising the activities of any pharmacy technician at all times.
(h) At the discretion of the supervising pharmacist, a qualified pharmacy technician may be authorized to administer vaccines pursuant to this Rule, under the following conditions:
    1. Vaccine administration has been delegated by the supervising pharmacist to the qualified pharmacy technician;
    2. The supervising pharmacist is and remains readily and immediately available to the qualified pharmacy technician administering the vaccine;
    3. The patient receiving such vaccine is not less than 18 years of age;
    4. The vaccine being administered is authorized or licensed for use by the United States Food and Drug Administration; and
    5. In the case of a COVID-19 vaccine, the vaccine shall be dispensed and administered according to the Advisory Committee on Immunization Practices of the United States Centers for Disease Control and Prevention COVID-19 vaccine recommendations.
(i) To be qualified to administer vaccinations pursuant to this Rule, a pharmacy technician shall:
    1. Have completed a course of training accredited by the Accreditation Counsel for Pharmacy Education or similar health authority or professional body approved by the Board, which course shall include hands-on training in injection techniques, and recognition and treatment of emergency adverse reactions to vaccines; and
    2. Maintain current certification in Basic Cardiac Life Support.
(j) The supervising pharmacist shall:
    1. Comply with all record-keeping and reporting requirements established by the Board;
    2. Make and document reasonable efforts to obtain the name of the patient’s primary care provider and to notify such provider of the administration of the vaccine within 72 hours of such administration;
    3. Be responsible for compliance with reporting requirements relative to adverse events;
    4. Check the Georgia Registry of Immunization Transactions and Services prior to dispensing the vaccine or authorizing a qualified pharmacy technician to administer a vaccine;

5. Be responsible for entering the patient's vaccine information into the Georgia Registry of Immunization Transactions and Services in accordance with said registry's requirements; and
6. Comply with any applicable requirements or conditions of use set forth in the United States Centers for Disease Control and Prevention's COVID-19 vaccine provider agreement, and any other federal requirements that apply to the administration of COVID-19 vaccines

(k) Nothing in this rule shall be construed to require any pharmacist to authorize a pharmacy technician to administer vaccines or to require any pharmacy technician to administer vaccines.

(l) Nothing in this rule shall be construed to authorize a qualified pharmacy technician to order vaccines.

(2) The Board of Pharmacy can take disciplinary action against the license of a pharmacist in charge who violates the provisions of this rule as authorized by O.C.G.A. §§ 43-1-19 and 26-4-60.

Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-110, 43-1-19.

No public comments were made.

Mr. Stone made a motion to adopt Rule 480-15-.04 Duties of the Pharmacist in Charge Related to Registered Pharmacy Technicians. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule 480-24-.02 Personnel

(1) The responsibilities of the Consulting Pharmacist shall include, at a minimum, review of each patient's drug regimen monthly and report of any irregularities to the Medical Director and Administrator of the nursing facility, written reports of pharmaceutical services, and monitoring of established policies and procedures for medication handling and storage.

(2) The responsibilities of the Vendor Pharmacist shall include, at a minimum, proper drug labeling, storage, transport, and record keeping in compliance with all federal, state and local laws and regulations.

Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, and 26-4-110

No public comments were made.

Mr. Stone made a motion to adopt Rule 480-24-.02 Personnel. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Rule 480-24-.03. Physical Requirements

The Vendor Pharmacist shall establish standards to ensure that all drugs are stored in a manner sufficient to insure the proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110.

A written response was received from Stephanie Kirkland with ElderCare Pharmacy & Magnolia Manor Pharmacy suggesting that there could be multiple vendor pharmacies involved in servicing a nursing center and that the language should read "Primary Vendor Pharmacy." No further comments were received.

Mr. Chang made a motion to adopt Rule 480-24-.03 Physical Requirements. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule 480-24-.04. Drug Distribution

(1) Dispensing of drugs to the facility shall be pursuant to lawful prescription drug orders for individual patients: standing medication orders shall not be allowed.
   (a) Chart Orders shall be considered lawful prescription drug orders, provided such Order includes the following:
      1. Date of issue;
      2. Name of the patient;
      3. Address of the patient, or the location of the patient in an institutional facility;
      4. Patient's date of birth or medical record number;
      5. Name of the ordering practitioner;
      6. Name, strength and dosage form of the drug ordered;
      7. Directions for use by the facility; and
      8. Any cautionary statements as may be required or necessary.

(2) All drugs supplied to the facility must be obtained from a pharmacy having a retail pharmacy permit.

(3) For use inside the facility, all drugs dispensed shall be dispensed in appropriate containers, as defined by the Food and Drug Administration and the Consumer Protection Agency, and adequately labeled with the following information:
   (a) Name, address, and telephone number of the pharmacy;
   (b) Date of issuance and identifying serial number;
   (c) Full name of patient;
   (d) Brand and/or generic name of drug, strength, and quantity dispensed;
   (e) Directions for use, which may be placed on the container label or on a Medication Administration Record available and consulted at the time of the administration of each dose, provided, however, that both methods may be utilized inside a single facility;
   (f) Name of ordering practitioner;
   (g) Required precautionary information regarding controlled substances;
   (h) Such other and further accessory cautionary information as may be required or desirable for proper use and absolute safety to the patient; and
   (i) Expiration date.

(4) Prescription drug orders and Chart Orders
   (a) Drugs may be dispensed or administered only upon orders of an authorized prescriber. For schedule II drugs refer to the Georgia Controlled Substances Act, Code Section 16-13-41, and Chapter 480-22 of the Board rules and regulations. For other drugs orders may be received by the pharmacy by fax or delivery of:
      1. A direct copy of a prescription drug order;
      2. A direct copy of a chart order;
      3. Obtaining a signed prescription drug order from the ordering practitioner; or
      4. A verbal or telephone order from the authorized practitioner or duly authorized agent.
      5. An electronically prescribed chart order from an institutional patient's chart.
   (b) For purposes of recordkeeping under this chapter, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the retail pharmacy and must be filed by the usually consecutively serial numbered prescription file or by patient name or by any other means that assures a complete, retrievable and accurate record. Any refill information subsequently

authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(3).

(5) Emergency kits. Emergency kits may be placed in licensed nursing homes by the pharmacy of the consultant or vendor pharmacist provided the following guidelines are met:

(a) A record of the drugs to be kept in an emergency drug kit be kept in the nursing home and the Vendor Pharmacy;

(b) Drugs shall not be accessed for use from the emergency drug kit in an emergency situation without a new prescription drug order from a licensed practitioner. A valid, signed prescription drug order or chart order for any such drug must be issued to the vendor pharmacy, supplying the emergency drug kit, within 72 hours of the drug being taken from the kit.

(c) Emergency drug kits shall be stored in limited access areas and sealed to prevent unauthorized access and to insure a proper environment for preservation of the drugs therein. The provider pharmacy shall develop a method to readily determine if an emergency drug kit has been accessed without authorization;

(d) An emergency drug kit must be inventoried at least once a month by a pharmacist from the Vendor Pharmacy, and a record of the dates of each such inventory shall be kept with the kit. Nothing herein, shall prohibit the inventory record from being maintained electronically, provided the electronic record is immediately retrievable for inspection by GDNA. The Vendor Pharmacy must maintain an adequate record of such inspections.

(e) Special Agents of the GDNA shall have the authority to check emergency drug kits as well as the records in the provider pharmacy to determine that drugs and records are accurate, and the emergency drug kit is being properly used;

(f) The Vendor Pharmacy must apply on an individual basis to the Board, in care of the GDNA Director, for approval to place an emergency drug kit in each individual nursing home and a copy of this approval will be kept on file in both the nursing home and the provider pharmacy. Upon recommendation by the GDNA Director, the Board may revoke the approval for an emergency drug kit in any nursing home where abuse or misuse of drugs from the emergency drug kit is used for any purpose other than emergency purposes;

(g) The Board shall have the authority to approve on an individual basis the drugs and the amounts of each individual drug allowed to be kept in an emergency drug kit. Any change in the drugs and amounts kept in a kit must be submitted in writing to the GDNA Director who shall make recommendations to the Board. After Board approval, a copy of this approval will be maintained in the GDNA provider pharmacy file and by the nursing home. Any emergency drug kit approval becomes null and void once the approved pharmacy ceases to provide that kit.

(h) Each solid oral dosage form placed in an emergency drug kit must be individually labeled with the name and strength of the drug, lot number, expiration date, and other appropriate cautionary information; and

(i) The exterior of an emergency drug kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for "EMERGENCY USE ONLY.” The name of the pharmacist and the dates of inventory should be readily available on or within the kit. This information may be provided electronically. In addition, a listing of the drugs contained therein, including the name, address, and telephone number(s) of the provider pharmacy shall be attached to both the exterior and the interior of an emergency drug kit.

(6) Accountability of scheduled drugs and other specified drugs.

(a) Proof of use. Proof of use of Schedule II, III, IV and V controlled substances and such other drugs as may be specified by the appropriate committee of the facility shall be provided to

the Vendor Pharmacy. Proof of use may be provided by written or electronic means and shall specify at a minimum:

1. Name and strength of the drug;
2. Dose and route of administration for the drug;
3. Name of ordering prescriber;
4. Name of patient;
5. Date and time of administration to patient;
6. Signature and title of individual administering, the medication; and
7. 7. Documentation of destruction of all unused portions of single doses shall include signature verifications of two licensed authorized personnel.

(b) Container requirement. Any medication that has to be counted and accounted for by proof of use must be dispensed in a container that allows verification of individual doses. Containers for solid oral doses must allow identification of individual doses and individual accountability.

(7) Medications brought by patients. When patients bring drugs into the facility, such drugs shall be sent to the vendor pharmacist who shall handle these drugs in accordance with guidelines established by the appropriate committee within the facility.

(8) The vendor pharmacy shall establish policies and procedures for safe and effective drug therapy, distribution, use, and control. At a minimum, the pharmacist shall:

(a) Make periodic inspections, which shall occur at least every 30 days of drugs and medication records kept within the facility. A written report of inspection shall be maintained at the facility; and,

(b) Remove for proper disposal any drugs or narcotics which are in a deteriorated condition, expired, discontinued for use, or the patient for whom they are ordered is no longer a patient These drugs shall be the responsibility of the vendor pharmacy.

Authority: O.C.G.A. §§ 16-13-21(23), 16-13-34, 16-13-35, 16-13-39, 16-13-41, 16-13-45, 16-13-72, 16-13-77, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-80, and 26-4-110.

A written response from Stephanie Kirkland with ElderCare and Magnolia Pharmacy expressed concern there may be no relationship identified between the vendor pharmacy/pharmacist and the consultant pharmacist. She suggested that this may be needed to complete the checks and balances of the responsibility of the medication management of the facility. A written response from Richard Marasco suggested some language changes to sections (3)(e) and (4)(a).

A written response from Lauren Paul with CVS suggested that the Board consider striking “the location of the patient in an institutional facility” and replace with “name of the institutional facility” in (1)(a)(3) as the location of the patient, such as room number, is not always provided. She suggested that the Board consider striking “dosage form” in (1)(a)(6) due to this element is not commonly included when ordering non-controlled substances. She added that CVS is concerned that this would lead to either a delay in therapy as orders are clarified or an enforcement/audit risk if not included. No further comments were made.

Mr. Stone made a motion to adopt Rule 480-24-.04 Drug Distribution. Mr. Farmer seconded, and the Board voted unanimously in favor of the motion.

Rule 480-24-.05. Duties of Consultant Pharmacist

(1) A pharmacist serving as a consultant to a facility must contract with the facility in writing for those services.

(2) When providing contracted services, the consultant pharmacist is held to the same professional standards for a licensed pharmacist as set forth in state law and by the rules and regulations of the Board.
(3) If a Consultant Pharmacist is required, they shall be responsible to review orders as required by federal and state law and by the rules and regulations of the Board.

Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, and 26-4-110.

A written response from Richard Marasco suggested that section (4) If a Consultant Pharmacist is required...." is redundant since the entire section is about Nursing Homes where a monthly drug regimen review is required. He also suggested that this rule be changed to include Assisted Living Communities and Personal Care Homes or that the Board create a new section for these facilities since they might not have chart orders. No further comments were made.

Mr. Stone made a motion to adopt Rule 480-24-.05 Duties of Consultant Pharmacist. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule 480-24-.06. Destruction of Drugs

(1) The following methods of destruction of non-controlled substances are approved by the Board for medications dispensed to patients residing in long term care facilities (nursing home or skilled nursing facility) or other facility where a consultant pharmacist's services are required under state or federal regulations:
    (a) When non-controlled drugs are expired, discontinued from use or the patient for whom they were ordered is no longer a patient, the drugs shall be immediately removed from the active stock and inventoried by two people who shall both be licensed as a pharmacist, a nurse, or a licensed practical nurse. The completed inventory record shall be signed and dated by these two individuals. The original inventory record shall be maintained by the facility for two years, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs can either be:
        1. Placed in a secure storage area at the facility separated from medications with active orders. The drugs can be destroyed at the facility by the consultant pharmacist and another pharmacist, nurse, or licensed practical nurse 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 along with the inventory record for two years. This record shall include at a minimum the date, time, personnel involved with the destruction and the method of destruction; or
        2. Removed from the facility and kept by the pharmacist until they are returned to the vendor pharmacy for destruction. The pharmacist shall make a receipt for the drugs removed, and the original receipt shall be kept by the facility and a copy of the receipt shall be kept by the pharmacist. The receipt shall reflect: the date the drugs were removed from the facility, the name of the person removing the drugs, the name and address of the pharmacy to which the drugs have been removed. Both the receipt and its copy must be maintained for two years. Before any drugs can be removed for destruction, their inventory must be verified by at least one pharmacist and one other licensed health care practitioner. Once taken to the vendor pharmacy, the drugs must be stored in a secure, location, separate from active inventory, within the pharmacy. When the drugs are disposed of, a record of such disposal of the drugs shall be maintained by the vendor pharmacy for two years. The disposal record shall include at a minimum:
            (i) If the drugs are destroyed at the pharmacy:
                (I) Manner of destruction;

(II) Date and time of destruction;

(III) Names of at least one pharmacist and one other licensed health care practitioner witnessing the destruction.

(ii) If the drugs for destruction are removed from the pharmacy by transfer to a reverse distributor with a current permit issued by the Board:

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

(II) The name, Board permit number, address, and telephone number of the reverse distributor removing the drugs;

(III) The name and signature of the responsible person representing the reverse distributor physically removing the drugs;

(IV) The name and signature of the pharmacist transferring the drugs to the reverse distributor.

(2) The following methods of on-site destruction of controlled substances are approved by the Board:

(a) When controlled drugs are expired, discontinued from use or the patient for whom they are ordered is no longer a patient, the medication shall be removed from the active stock of the facility immediately and inventoried and verified by two people who shall both be licensed as a pharmacist, a nurse, or a licensed practical nurse. The completed inventory record shall be signed and dated by those two individuals. An inventory form will be established by the pharmacist, which must include the following data:

1. Date of discontinuance or inventory date;
2. Name of patient;
3. Name of issuing pharmacy;
4. Identifying serial numbers of the prescriptions;
5. Name and strength of drug; and
6. Quantities of drugs in containers when inventoried.

(b) After being removed from active stock, controlled substances to be destroyed must be placed in a secure cabinet or area as identified by the consultant or vendor pharmacist.

(c) On-site destruction can be as follows:

1. The consultant or vendor pharmacist will notify the GDNA as to the date and time the destruction will take place at least two weeks prior to destruction at the facility. (Please note that the consultant may set up a specific schedule of destruction - an example would be the first Tuesday in each month at 10:00 a.m.)
2. Three licensed professionals or law enforcement officers, one of whom must be a pharmacist, must witness the destruction of these drugs.
3. Destruction must take place within the facility.
4. Inventory of final destruction must be taken in duplicate, one copy shall be retained by the facility, and one copy shall be retained by the consultant pharmacist. The inventory shall be certified by all three 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."

_____(Signature)

_____(Signature)

_____(Signature)

5. The Board and/or the GDNA, or the DEA, may prohibit any consultant pharmacist or facility from utilizing this method.

(3) Methods of off-site destruction as follows:

(a) When controlled substances are expired, discontinued from use or the patient for whom they are ordered is no longer a patient, the medication shall be removed from the active stock immediately and inventoried and verified by two people who shall be licensed either as a pharmacist, a nurse, or a licensed practical nurse. The completed inventory record shall be signed and dated by those two individuals. An inventory form will be established by the pharmacist, which must include the following data:

1. Date of discontinuance or inventory date;
2. Full name of patient;
3. Name of issuing pharmacy;
4. Identifying serial numbers of the prescriptions;
5. Name and strength of drug; and
6. Quantities of drugs in containers when inventoried.

(b) After being removed from active stock, controlled substances to be destroyed must be placed in a secure cabinet or area as identified by the consultant or vendor pharmacist.

(c) The drugs, along with a copy of the permanent record, can then be transferred to the vendor pharmacy by the consultant pharmacist to hold for disposal by a Board licensed reverse drug distributor or by a GDNA Agent. The consultant pharmacist shall make a receipt for the drugs removed, and the original receipt is to be kept by the facility and a copy of the receipt kept by the consultant pharmacist, both for two years. The receipt shall reflect at a minimum:

1. The date the drugs were removed from the facility;
2. The name and signature of the consultant pharmacist removing the drugs;
3. The name and signature of the Director of Nursing witnessing the drug removal;
4. The name and address of the pharmacy to which the drugs are being removed.

(d) Once received by the pharmacy, the drugs for disposal must be stored in a secure location within the pharmacy. When disposal of the drugs takes place, a record of the disposal will be maintained by the pharmacy for two years. The type of disposal record shall be, either:

1. On a separate receipt showing the drugs for destruction were removed from the pharmacy by transfer to a Board licensed reverse distributor, showing:
   (i) The date and time the drugs were taken from the pharmacy;
   (ii) The name, address, telephone number and Board permit number of the reverse distribution firm taking possession of the drug;
   (iii) The name and signature of the responsible person representing the reverse distributor firm and physically removing the drugs;
   (iv) The name and signature of the pharmacy representative transferring possession of the drugs; and
   (v) A copy of the permanent drug inventory destruction record from the facility; or
2. On the permanent record showing the drugs were destroyed by a GDNA Agent with:
   (i) The signature of the GDNA Agent;
   (ii) The signature of the pharmacy manager as listed on the pharmacy license; and
   (iii) The date and time of the drug destruction.

Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110, 26-4-113, 26-4-115.

A written response from Richard Marasco suggested the Board should consider preparing separate and distinct regulations and rules that appropriately address the requirements and limitations of Assisted Living Communities and Personal Care Homes. A written comment from Stephanie Kirkland suggested language changes that would match DEA's Federal Rule of Disposal of Controlled Substances. No further comments were made.

Mr. Stone made a motion to adopt Rule 480-24-.06 Destruction of Drugs. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule 480-5-.03. Code of Professional Conduct

The Board is authorized to take disciplinary action for unprofessional conduct. Consistent with the authority to assure that licensees operate in a professional manner and the Board's responsibility to protect the public health with a safe, dependable and sufficient supply of medication, the Board establishes a Code of Professional Conduct which shall apply to and be observed by all persons engaged in the practice of pharmacy in the State of Georgia.

(1) Ethics. No pharmacist, intern, extern, technician, or pharmacy owner shall engage in conduct in the practice of pharmacy or in the operation of a pharmacy which endangers the public health, safety and welfare, or have been guilty of any fraud, misrepresentation, culpable negligence, concealment, dishonest dealings, fix, scheme or device, or breach of trust in the practice of pharmacy or in the conduction of business related to prescriptions, drugs or devices.

(2) Patient Self-Referral. No pharmacist, employee or agent thereof acting on his/her behalf, shall offer, agree to accept, or receive compensation in any form for the referral of professional services to or from another health care provider or entity. This prohibition includes any form of fee division or charging of fees for the referral of patients.

(3) Error or Uncertain Prescriptions. No pharmacist or pharmacy intern/extern shall compound or dispense any prescription, which, in his/her professional opinion, contains any error omission, irregularity or ambiguity. Upon receipt of such prescription, the pharmacist, pharmacy intern/extern shall contact the prescriber and confer with him/her before dispensing the prescription. No pharmacist or intern/extern shall dispense any medication by virtue of a prescription if said pharmacist or intern has any doubt existing in his mind that such prescription is not legitimate.

(4) Diagnosis or Treatment. No pharmacist or employee of a pharmacy shall diagnose, treat, prescribe for, or attempt to do so, any disease, illness, or organic disorder. This limitation shall not be construed to prevent a licensed pharmacist from advising individuals on matters concerning simple ailments, first aid measures, sanitary matters, or the merits and qualities of medicines, nor shall it prevent the full practice of pharmacy as provided in O.C.G.A. Section 26-4-4.

(5) Coded Prescriptions. No pharmacist, pharmacy intern, or extern shall compound or dispense any prescription that is coded. A "coded" prescription is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directors for its use, other than normal letters, numbers, words, symbols or other media recognized by the profession of pharmacy as a means for conveying information by prescription. No symbol, word or any other device shall be used in lieu of the name of said preparation.

(6) False or Misleading Advertising. No pharmacist or licensed pharmacy shall intentionally disseminate through any communication media any false, misleading or fraudulent advertising.

(7) Changes in Prescriptions. No pharmacist, pharmacy intern or extern shall supply medications or devices which contain an ingredient or article different in any manner from the medication or device that is prescribed upon a prescription unless prior approval has been obtained from the prescriber thereof. Such difference shall immediately be recorded upon said prescription after

being approved by said prescriber, showing the date, time and method of ascertaining the said approval.

(8) Prescription Sub-Stations. No pharmacist, employer or employee of a licensed pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Board, from which to solicit, accept or dispense prescriptions.

(9) Physician Agreements. No pharmacist or licensed pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with an physician or other practitioner for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement if any kind, whereby in any way a patient's free choice of a pharmacist or licensed pharmacy is or may be limited.

(10) Independent Judgment and Practices. No pharmacist shall offer or engage in professional pharmaceutical services under any terms and conditions that shall tend to interfere with or impair the free and complete exercise of professional judgment and skill of a pharmacist or enter into any agreement that denies the public the right of free choice of pharmacists or pharmacies.

(11) Return of Prescriptions. Except as authorized by Rule 480-10-.17, no pharmacist or employer or employee of a pharmacy may knowingly place in the stock of any pharmacy any part of any prescription dispensed to, or compounded for, any patient of any pharmacy and returned by said patient.

(12) Evasion of Code of Professional Conduct. No pharmacist, licensed pharmacy or employee or agent thereof, shall act in any way to evade the rules and regulations of the Board and the laws applying to licensed pharmacies and pharmacists, interns, externs and technicians, but may apply methods of their own to enhance compliance with said laws, rules and regulations. Said persons shall be responsible for being acquainted with said laws, rules and regulations.

(13) Refusal to Fill Prescription. It shall not be considered unprofessional conduct for any pharmacist to refuse to fill any prescription based on his/her professional judgment or ethical or moral beliefs.

(14) Valid Prescription Drug Orders. Prescription drugs shall be dispensed only pursuant to a valid prescription drug order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription. A pharmacist shall have the same corresponding liability for prescriptions as an issuing practitioner as set forth in 21 C.F.R. as such regulation exists on January 1, 2013. Valid prescription drug orders shall include those issued by a physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state, or of any state or territory of the United States, to prescribe dangerous drugs or controlled substances or both.

(15) Violations of the Code of Professional Conduct. The above set out Code of Professional Conduct is expressly adopted by the Board and shall govern the conduct of all those admitted to practice pharmacy in their capacities as pharmacists, all those issued licenses as a pharmacy in their capacities as licensees and all pharmacy interns/externs in their capacities as pharmacy interns/externs. A license to practice pharmacy or a permit to operate a licensed pharmacy confers to vested right to the holder thereof, but is a conditional privilege revocable for cause. The primary purpose of this Code of Professional Conduct is the protection of the profession of pharmacy and the public health, safety and welfare. It is the responsibility of the Board to maintain quality, accountability, and integrity within the profession, and to remove those unworthy to practice pharmacy or operate pharmacies in this state. It is the obligation of every licensed pharmacy holder and every licensed pharmacist to give unlimited cooperation and assistance to the Board in the discharge of this responsibility. Violation of this code may subject the violator to suspension or revocation of any license issued to him/her by the Board and/or

public reprimand, fines, probation, letters of concern or other disciplinary actions deemed appropriate by the Board.

Authority: O.C.G.A. §§ 43-1-19, 26-4-4, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-110, 26-4-113, and 26-4-115.

No public comments were made.

Mr. Brinson made a motion to adopt Rule 480-5-.03 Code of Professional Conduct. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Rule 480-7C-.01 Definitions

(1) "Controlled substance" means a controlled substance defined in the Georgia Controlled Substance Act.

(2) "Dangerous drugs" means a drug defined in the Georgia Dangerous Drug Act.

(3) "Third-party logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, wholesale distributor, or chain pharmacy but does not take title to a drug or have general responsibility to direct the sale or other disposition of the drug.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, and 26-4-28.

No public comments were made.

Mr. Brinson made a motion to adopt Rule 480-7C-.01 Definitions. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

Rule 480-7C-.02 Third-Party Logistics Provider Licensing Requirements

(1) Every third-party logistics provider located in the State of Georgia, and every out-of-state third party logistics provider which is not licensed by its resident state or by the United States Food and Drug Administration, must be licensed by the Georgia State Board of Pharmacy (Board) in accordance with the laws and regulations of this state before providing third-party logistics services involving dangerous drugs and controlled substances.

(2) Minimum required information for licensure: An applicant for initial licensure or renewal of a Third-Party Logistics Provider License shall provide the following:

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business names used by the licensee:

(c) Address, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of dangerous drugs and controlled substances;

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

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

1. If a person, the name of the person;

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

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

4. If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

(f) Where operations are conducted at more than one location by a single third-party logistics provider, each such location shall be licensed by the Board.

(g) Every third-party logistics provider located in this state is required to be located in a commercially zoned business district and possess the appropriate local business license. No third-party logistics provider may be located in or operate out of a residential dwelling, building, or location, or a building, dwelling or location attached to a residential location.

(3) Applications for Licensure.

(a) Registration of a third-party logistics provider will be considered based on the application filed with the Board, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications of a license.

(b) Application fees shall not be refundable.

(c) No license issued under this Rule shall be transferred or assigned by a licensee. However, the Board may reassign a license to a licensee or successor entity by request upon application to the Board.

(d) Prior to any change in name, ownership, mode of operation or location of a third-party logistics provider, licensees shall apply for approval of such change by submitting a Board-approved application to the Board and paying a fee. To comply with the requirements of this Rule, applications must be made and approved prior to the change.

1. A change of ownership is deemed to have occurred upon the closure of any transaction which results in a change to any of the ownership information submitted to the Board as part of the licensee's initial application for licensure or renewal of licensure.

(e) Licensees shall notify the Board in writing of the occurrence of any change to any of the information submitted to the Board as part of the licensee's initial application for licensure or application for renewal of licensure. This shall not apply to any event the occurrence of which these rules require immediate notification to the Board, in which event such immediate notification shall be made.

(f) Licenses are renewed for two years and 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. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

(4) Minimum Qualifications.

(a) The Board will consider the following factors in determining eligibility for licensure for persons who engage in third-party logistics services involving prescription drugs:

1. Any convictions of the applicant under any Federal, State, or local laws relating to dangerous drugs and controlled substances.

2. Any felony convictions of the applicant under Federal, State, or local laws;

3. The applicant's past experience in the manufacture or distribution of dangerous drugs and controlled substances;

4. The furnishing by the applicant of false or fraudulent material in any application to the Board;

5. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant related to third-party logistics services involving dangerous drugs and controlled substances;

6. Compliance with licensing requirements under previously granted licenses, if any;

7. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by third-party logistics providers; and

8. Any other factors or qualifications the Board considers relevant to and consistent with public health and safety.

(b) The Board reserves the right to deny a license to any applicant if it determines that the granting of such a license would not be in the public's interest.

(5) Violations:

(a) A license issued to a third-party logistics provider pursuant to this rule shall be subject to revocation or suspension upon conviction of the license holder of violations of Federal, State, or local drug laws and/or regulations.

(b) Violation of any of the provisions of any applicable Board laws or rules shall be grounds for the suspension or revocation of the license issued hereunder.

(c) Any revocation or suspension of a license pursuant to this part shall be carried out pursuant to the Georgia Administrative Procedure Act, O.C.G.A. Title 50 Chapter 13.

(6) The following are required for the storage and handling of dangerous drugs and controlled substances, and for the establishment and maintenance of distribution records by a third-party logistics provider.

(a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

3. Have a quarantine area for storage of dangerous drugs and controlled substances that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

4. Be maintained in a clean and orderly condition; and

5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. All facilities used for third-party logistics services shall be secure from unauthorized entry.

1. Access from outside the premises shall be kept to a minimum and be well controlled.

2. The outside perimeter of the premises shall be well lighted.

3. Entry into areas where dangerous drugs and controlled substances are held shall be limited to authorized personnel.

4. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion.

(c) Storage. All dangerous drugs and controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with United States Pharmacopeia (USP) standards or manufacturer's recommendations.

1. If no storage requirements are established for a dangerous drug and controlled substance, the drug may be held at controlled room temperature, as defined in USP, to help ensure that its identity, strength, quality, and purity are not adversely affected.

2. Appropriate manual or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of prescription drugs. If ~~electronic~~ temperature alarms/alerts for excursions are not in place, the temperature recordings shall be reviewed at least once daily during operations.

3. Prescription drugs exposed to temperature and humidity excursions shall be evaluated and quarantined (if applicable) according to the manufacturer's recommendations.

(d) Examination of materials.

1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs and controlled substances that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

2. Each outgoing shipment shall be carefully inspected for identity of the dangerous drugs and controlled substances products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

3. The record keeping requirements in subparagraph (f) of this section shall be followed for all incoming and outgoing dangerous drugs and controlled substances.

(e) Returned, damaged, and outdated dangerous drugs and controlled substances.

1. Dangerous drugs and controlled substances that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

2. If the conditions under which a dangerous drug or controlled substance has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which the drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the third-party logistics provider shall consider, among other things, the conditions under which the drugs has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(f) Record keeping:

1. Third-party logistics providers shall maintain a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility.

2. Third-party logistics providers shall maintain (or have immediate access to) inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs and controlled substances. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The date of receipt and distribution or other disposition of the drugs.

(iv) Any transaction data required to be kept in compliance with the Federal Drug Supply Chain Security Act.

(g) When a third-party logistics provider ships/receives dangerous drugs or controlled substances, it shall be the responsibility of the third-party logistics provider or the owner of the drugs to ensure the person or firm shipping/receiving the drugs is properly licensed, permitted, or otherwise authorized to purchase or receive such drugs.

(h) Inventories and all records required under this rule shall be made immediately available for inspection and photocopying by the Board or GDNA for a period of two (2) years following deposition of the drugs.

(7) Written Policies and Procedures. Third-party logistics providers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs and controlled substances, including policies and procedures for identifying recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Third-party logistics providers shall have written policies and procedures to:

(a) address receipt, security, storage, inventory, shipment, and distribution of a dangerous drugs and controlled substances;

(b) identify, record, and report confirmed losses or thefts in the United States;

(c) correct errors and inaccuracies in inventories;

(d) provide support for manufacturer recalls;

(e) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(f) ensure that any expired dangerous drug or controlled substance is segregated from other products and returned to the manufacturer or repackager or destroyed;

(g) maintain the capability to trace the receipt and outbound distribution of a product (as defined in the DSCSA), and supplies and records of inventory; and

(h) quarantine or destroy a suspect dangerous drug and controlled substance if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

(8) Responsible persons. Third-party logistics providers shall establish and maintain lists of officers, directors, managers, and other persons with access to dangerous drugs and controlled substances including a description of their duties and a summary of their qualifications. Such information shall be readily available during inspections by the Board or GDNA.

(9) Events requiring immediate notification to the Board. The following occurrences require written notification to the Board at its address of record, within 24 hours of the occurrence.

(a) Permanent closing of a licensed third-party logistics provider's facility. Notification shall include the name and contact information for the person responsible for maintaining the facility's records after the facility has closed and the location of such records.

(b) Change of ownership or location of a licensed third-party logistics provider's facility.

(c) Any theft or loss of drugs or devices in the custody and control of a licensed third-party logistics provider. This notification must also be made to the Georgia Drugs and Narcotics Agency, and if involving controlled substances, the third-party logistics provider must comply with Rule 480-16-.06.

(d) Any known conviction of any employee of a licensed third-party logistics provider of any violation of state or federal drug laws, not previously reported.

(e) Theft, destruction, or loss of dangerous drug or controlled substance records of a licensed third-party logistics provider.

(10) Compliance with Federal, State, and local laws. Third-party logistics providers shall operate in compliance with applicable Federal, State, and local laws and regulations.

(a) Third-party logistics providers shall permit the Board and GDNA to enter and conduct unannounced inspections of their premises and delivery vehicles, and to audit their records and written operation procedures. In the event the records, or any other information, required by this rule are maintained by the owner of the dangerous drug or controlled

substance, it shall be the responsibility of the third-party logistics provider to have immediate access to such records during inspections by the Board or GDNA.

(b) Third-party logistics providers that deal in controlled substances shall register with the appropriate controlled substance authority, and shall comply with all applicable State, Local, and DEA regulations.

(c) Third-party logistics providers shall report to and/or be licensed by the Food and Drug Administration (FDA) and shall comply with all applicable State, Local, and FDA regulations.

Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, 43-1-19, 50-36-1, and 50-36-2.

No public comments were made.

Mr. Stone made a motion to adopt Rule 480-7C-.02 Third-Party Logistics Provider Licensing Requirements. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of Georgia law. Also, that the formulation and adoption of the rules will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

The public hearing concluded at 9:15 a.m.

Open Session

President Cordle established that a quorum was present and called the meeting to order at 9:15 a.m.

President Cordle greeted the members of the public who were present.

Adegoke Adeniji, the Interim Dean for South University School of Pharmacy welcomed the Board and guests to South University.

Approval of Minutes

President Cordle advised that due to the substantial volume of content that the minutes from the March 19, 2025, meeting have been postponed until the May meeting.

Report of Licenses Issued

Director Joiner reported that the Board has issued 359 licenses since the last meeting. Mr. Farmer made a motion to ratify the list of licenses issued. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion

Petitions for Rule Waiver or Variance

Northeast Georgia Rehabilitation Hospital LLC – Rule 480-13-.05(2)(b) Request for waiver of rule regarding Laminar airflow hood.

Mr. Stone advised that this facility is requesting a waiver of Rule 480-13-.05(2)(b) and is requesting to go to an immediate use model for compounding and waive the laminar flow hood.

Dr. Azzolin advised that this request is incomplete. The request should be for Rule(s) 480-13-.05(2)(b)1 and 480-11-.04(3)(b)1. The Board determined that Northeast Georgia Rehabilitation Hospital will need to submit a new waiver request with the correct rules.

Director Karnbach asked if the Board would allow GDNA to move forward with the application process and allow the facility to open and get the license without the flow hood. The Board agreed to allow the application to go forward but advised that the faculty will need to resubmit the waiver request with the correct rules for the Board to consider within three (3) months. After the three (3) months grace period the rule will be enforced.

Dr. Azzolin made a motion to deny the request for waiver of Rules 480-13-.05(2)(b). Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Mr. Stone directed the Board Staff to respond to the correspondence as discussed.

The Board discussed changing the proposed language of this rule to be similar to the language in the retail pharmacy rule. The Board opted to table this conversation to next month's work session.

First Choice Primary Care – Rule 480-10-.12(1)(e)1 Request for waiver of rule regarding Class A Balance or Electronic Balance.

Mr. Stone asked if anyone was present from First Choice Primary Care. It was established that a representative was not present. This facility is requesting a waiver of the rule regarding Class A Balance or Electronic Balance. Mr. Brinson commented that the waiver of this rule is not necessary if the pharmacy is not compounding and that the pharmacy should not be held accountable for having a Class A Balance or Electronic Balance as long as the pharmacy is not compounding.

Dr. Azzolin commented that to save time, effort, and energy the Board needs to review the wording of this rule. The Board agreed to add this conversation to next month's work session.

Mr. Stone made a motion to deny the request for waiver of Rule 480-10-.12(1)(e)(1) and Mr. Brinson seconded, and the Board voted unanimously in favor of the motion

Appling Healthcare System – Rule(s) 480-10-.12(1)(f)(2), 480-10-.12(1)(f)(5) and 480-10-.12(1)(f)(6) Request to waive specified equipment under the minimum equipment for prescription departments rule.

Mr. Stone asked if anyone was present from Appling Healthcare System. It was established that a representative was not present. This facility is requesting a waiver of the rule regarding the requirement for facilities to possess mortars, pestles, ointment slab, tile or ointment paper pad and stirring rods since this facility will not be compounding.

The Board discussed the need to approve this request due to the Board having intentions of modifying this rule for facilities that will not be compounding.

Mr. Stone made a motion to approve the request for waiver of Rule(s) 480-10.12(1)(f)2, 480-10-.12(1)(f)5 and 480-10.12(1)(f)6. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion

<u>Correspondences</u>

Correspondence from Melinda Fowler

Mr. Page asked if Ms. Fowler was present. It was established that she was not present. Ms. Fowler is

requesting clarification if her virtual pharmacy needs to be registered as an additional location. The Board discussed Ms. Fowler's correspondence and determined that it is not required.

Mr. Stone directed the Board Staff to respond to the correspondence as discussed.

Correspondence from Jenkins County Medical Center– Request for Key Lock Box
Mr. Page asked if anyone was present on behalf of Jenkins County Medical Center. It was established that a representative was not present.

Jenkins County Medical Center requested permission to use a lock box to store the entry key for the pharmacy located at 931 E. Winthrope Avenue, Millen, GA 30442 and provided documentation for the request. The Board denied the facility's previous request due to the location of the key lock box. The Board reviewed the documentation provided and discussed this correspondence. Director Karnbach advised that the new proposed location for the Key Lock Box is in a more secure location than previously requested and that GDNA did not see any problems approving this request. The Board approved the request at the new location.

Mr. Page directed the Board Staff to respond to the correspondence as discussed.

Correspondence from Piedmont Healthcare Encompass Health Rehabilitation Hospital of Athens – Request for Remote Order Entry

This facility submitted their policy and procedures for remote pharmacy services along with their remote order entry manual, requesting approval of the implementation of remote pharmacy services. The Board reviewed the documentation provided and discussed this correspondence. It was determined that the Board did not see any problems with the request.

Mr. Page commented that he didn't see any issues with the proposed submission and that he was not sure why it is necessary for the Board to have to approve these types of requests. Dr. Azzolin responded that it was required by law that the Board review these requests.

Dr. Azzolin asked if these types of requests are required by law to be submitted by a pharmacist. Director Joiner responded that there is nothing in the law that specifies that it must be submitted by a pharmacist so long as the Board is willing to accept them from a non-pharmacist and provided that the policy is sufficient for the purpose.

Correspondence from Wellstar Cobb (PHH003534) and Wellstar Roosevelt (PHH007944) - Remote Order Entry Request

This facility submitted its remote pharmacy information along with policy and procedures for remote pharmacy services requesting approval for the implementation of remote pharmacy services for the Wellstar Cobb Hospital Pharmacy to provide services to Wellstar Roosevelt Pharmacy during the pharmacy's closed hours. The Board reviewed the documentation provided and discussed this correspondence. It was determined that the Board did not see any problems with the request.

Correspondence from eClinical Works (eClinical) – Response to Board's Request for Appearance
Mr. Page briefly summarized the history of this matter which was discussed at the Board's meetings in February and March. In February, the Board requested additional information about prescriptions transmitted by eClinical. The Board was concerned that these transmissions do not meet the requirements of prescription drug orders when they are transmitted by eClinical. At the March Board Meeting, the Board discussed correspondence from eClinical proposing to add language to their

transmission that the transmission is not a prescription. The Board was concerned that the proposed solution—adding explanatory language to faxed prescriptions indicating they are not valid prescriptions—does not resolve the core issue of compliance with Georgia law. As outlined in O.C.G.A. § 26-4-80(c)(2)(G) and Board Rule 480-27-.02(2)(a), a prescription transmitted via fax must contain an electronically reproduced visual image or original signature of the prescriber to be considered valid. The Board determined that further discussion on potential solutions with eClinical is necessary and requested that they appear at the April Board Meeting.

Mr. Page explained that in response to the Board's concerns eClinical has agreed to add an electronically reproduced visual image of the prescriber's signature to the transmitted faxes so that they constitute valid prescriptions. eClinical provided an example of what a pharmacy located within the state of Georgia can expect to receive once the enhancement has been made available and the customer has accepted the change. Mr. Page asked if GDNA had any issues with the proposed solution. Director Karnbach advised that GDNA did not see any issues with the changes.

Mr. Farmer stated that as of Monday this change has not been implemented in the faxes. Dr. Azzolin mentioned that the letter indicated that the change would take 90 days to implement. President Cordle expressed concern about the delay and stated that the timeline needs to be shortened.

President Cordle asked if anyone was present on behalf of eClinical. It was established that representatives were present. President Cordle asked the representatives to introduce themselves and to provide comments.

Mr. Michael Laycob, chief compliance officer for eClinical, introduced himself along with lead pharmacist Dr. Justin Stein, and Ms. Kranti Patel who is a senior member of their product management.

Mr. Laycob thanked the Board for the invitation to join the meeting and for allowing them to engage in discussion. He explained that the first letter from the Board was unclear on the Board's preference for a possible solution, which is why they proposed adding the language to the faxes making it clear that it was not a prescription. He advised that the follow-up letter from the Board gave a clearer indication of the Board's view.

Mr. Laycob explained that their engineering and quality assurance teams have been working towards adding the electronic signature to the fax transmission to comply with Georgia law and regulatory requirements. He explained that a software development "life cycle" is required to complete the enhancement and that they anticipate implementing and releasing the update to their customers within 90 days from the date that they receive confirmation from the Board that the proposed solution is acceptable. They are hoping that the process will take less than 90 days. He added that with the Board's approval that will start the process right away. He also mentioned that the upgrade will need to be accepted by the customers to take effect and that they will be tracking the acceptance internally.

Dr. Azzolin thanked the representatives for appearing and considering the Board's requests by applying the changes to the software. He stated that most software companies would not necessarily make the change and that the Board appreciates the initiative to resolve this problem. He added that the previous versions created workflow issues for both providers and pharmacies and increased the amount of time to fill prescriptions.

Mr. Laycob commented that they appreciated the engagement and were happy to come join the meeting. He added that they send out approximately twenty-five million prescriptions every month around the country and that they want to make sure that what they are doing comports with the Board's views and wishes.

Mr. Stone commented that he wanted to echo Dr. Azzolin's comments. He asked to clarify the timeline for implementation so that the Board could properly advise pharmacies if they are having software issues to accept the updates. Dr. Azzolin asked if eClinical could inform the Board once the testing has been completed and the upgrade has been deployed to the users.

Mr. Laycob advised that they will continue corresponding with the Board and advise when the resolution is deployed. He commented that they have processes in place to notify the users that changes are coming and that they will be notified when the patch is available. She advised that they expect that like any patch that goes to the customers, most customers will adopt the patch without delay and there will be some subset of customers that have their processes and who might wait to accept this update.

Mr. Page asked in the interim will there still be a note on transmissions that states that it is not a valid prescription. Mr. Laycob responded that to avoid confusion that the fax transmission will go back to the way they were before the "not a valid prescription" wording was added. President Cordle asked if the transmission will go back to the way they were in December 2024. Mr. Laycob confirmed they would go back to the previous version that was used in December.

Mr. Farmer thanked eClinical for their engagement and commented that he agreed with Dr. Azzolin that a lot of software companies would not have made the change. He asked if when the fax is generated when an inappropriate discontinued inactive NDC number is chosen, could it be communicated back to the prescriber before it goes to the pharmacy, that an error is occurring and that they will need to resubmit the order with the appropriate NDC.

Dr. Stein advised that in a way the process being used today provides warning signs or notifications to the prescriber. He added that they have matching algorithms to try to remedy the issues but that they will still pass on the transmission and that they are not rejecting the errors at that stage. Mr. Farmer asked if at some point they would consider this issue.

Dr. Stein responded that 98% of electronic prescriptions are going out without an issue and that the percentage keeps getting higher. He advised that they would continue working on reducing the errors but at the same time want to avoid patient care delays by continuing to transmit to meet the prescriber's intent and keep the process moving.

President Cordle asked if the problem was a database issue with the drugs or if it is a situation where the physician chose the inappropriate discontinued NDC. He added that it is common for a pharmacy to see a lot of rejections with simple prescriptions.

Dr. Stein replied that what often happens when medication is ordered to a patient's record that overtime the medication description changes. When the new description passes through the hub it funnels through all of the traffic to be able to provide validation, which is operating with the latest data. This is where most of the mismatches happen. At this point the validation could be considered a false positive because the system can't prove 100% that the information is accurate. The hub will try to reconcile the discrepancy and builds a knowledge database of synonyms to facilitate the transfer to the appropriate NDC.

President Cordle commented that the system works very well and that it is very helpful to pharmacies. He added that the change that is being implemented will make a significant impact on pharmacists by making it easier to get medications to the patients. He asked what the percentage of electronic versus paper prescriptions they see. Ms. Patel stated that they did not have that information available.

Director Karnbach reminded everyone that state law requires pharmacies to understand that they must ensure that these prescriptions are compliant with Federal regulation and State regulations. He advised that the language of the CFR states that electronically signed prescription that are faxed, must have a manual signature for controlled substances.

Georgia Drugs and Narcotics Agency – Mr. Michael Karnbach

Director Karnbach introduced Special Agent Tommy Roe. Special Agent Roe covers the Southeastern part of the state and serves as supervisor for the Southern region.

Director Karnbach reported that GDNA has conducted 2,732 inspections FTD and the total number of complaints received FTD is 360. He noted that at this time last year the agency completed 2,142 inspections, which is a significant increase.

President Cordle asked the Board if they had any comments on how GDNA should proceed with the changes to the flavoring part of the rule that is being adopted given previous discussion on possible amendments. The Board discussed pausing the rule. The Board determined that GDNA will go forward with enforcement of the proposed rule.

President Cordle thanked GDNA for their hard work.

Attorney General's Report – Mr. Dowlin Ryals

No Report.

Executive Director's Report – Mr. Clint Joiner

Director Joiner reported that the legislative session is over, and that the Board received all of the budget items it asked for except one position. Funding was secured for new licensing software and two positions which will allow for the Board to complete its ongoing reorganization.

Director Joiner thanked the Board for their help in advocating for the Pharmacy industry and profession along with the patients in Georgia. Director Joiner also thank Mr. Brinson for working with him to advocate for both the Board of Pharmacy and the Board of Dentistry.

Mr. Brinson congratulated Director Joiner for surviving his first year as executive director. He thanked Director Joiner for his hard work and dedication to serving the Board.

Legal Services – Mr. Clint Joiner

No Report.

Miscellaneous

Path for reinstatement for Pharmacy Technicians

Director Joiner announced that the Board has decided to start allowing reinstatements for pharmacy technicians. The process is being developed. He advised that he should have a proposal for the Board to review at the May work session.

Rule 480-10A-.08 Remote order entry process

Mr. Page commented that when the Board reviewed the remote order entry process and rules the Board agreed to remove the obligation for a sign to notify patients. He added that under the central fill rules, there is still a requirement to notify patients via a sign. He recommends eliminating this obligation. Mr. Brinson agreed with Mr. Page.

Rule 480-10A-.08. Notification to Patients

(1) An originating pharmacy that utilizes central filling services must, prior to outsourcing the prescription, notify patients that prescription filing may be outsourced to another pharmacy.

(a) The patient shall have the choice to not have the prescription outsourced.

(b) Notification may be provided through the use of a sign located in the originating pharmacy which is clearly visible to and readable by the public.

The Board agreed that this topic needs further scrutiny and will bring it back for discussion at the May work session. Director Joiner advised that he would prepare a draft for the Board to review.

President Cordle asked if anyone had any questions or comments. President Cordle reminded everyone that the next scheduled meeting of the Georgia State Board of Pharmacy will be a work session and an agency review which will be held on Wednesday, May 21 through Thursday, May 22, 2025, at 9:00 a.m. at the Board's office located at 2 Martin Luther King Jr Drive SE, East Tower, 11th floor, Atlanta, GA 30334.

He requested that any department or member of the public that wishes to be added to an upcoming meeting must submit the information prior to the Wednesday before the scheduled meeting to be considered for the agenda. He thanked the public for their attendance and participation.

Mr. Bracewell made a motion and Mr. Brinson seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h) and § 43-1-2(h) to deliberate and to receive information on applications, investigative reports, and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Michael Azzolin, Jim Bracewell, Michael Brinson, Young Chang, Cecil Cordle, Michael Farmer, Chuck Page, and Dean Stone.

Executive Session

Appearances:

M.D.	E.L.

Georgia Drugs and Narcotics Agency - Mr. Michael Karnbach

Cognizant's Report – Mr. Young Chang

T35641	T35632	T35714	B35680	B35681
A35330	A35366	A35435	A35481	A35586
A35630	A35640	A35651	A35678	A35692
A35702	A35703	A35706	A35734	A354651
A35559	A35618	A35634	A35655	

Anti -Steering Cases

SB34488	SB34505	SB34690	SB33684	SB34328	SB34333
SB35292	SB33332	SB33326	SB33327	SB33329	SB33333
SB33339	SB33352	SB33355	SB33440	SB33445	SB33452
SB33479	SB33328	SB33330	SB33331	SB33335	SB33342
SB33393	SB33461				

Attorney General's Report – Mr. Dowlin Ryals, Assistant Attorney General

Mr. Ryals presented the following consent orders for acceptance:

D.S.I.	N.S.	E.F.P.	R.C.	R.M.

M.M.	S.C.	Q.T.	J.M.	

Status Open Cases

C.P.S./ E.H.	J.K.C.	E.S.P.	A.H.	P.A.J.	V.P.L.
R.G.H.E.	M.L.D.	P.S.I.	C.I.	B.H.P.	B.T.Y

Executive Director's Report – Mr. Clint Joiner
No Report.

Legal Services – Mr. Clint Joiner

Applications

D.W.	T.B.	P.B.	J.M.	C.T.	L.S.
N.F.	J.W.	J.C.	K.J.	M.K	N.G.
B.G.	R.L.	E.P.	N.R.	D.L.	M.M
R.S.	C.N.	T.J.			

Correspondences/Requests

E.P.	I.P.	I.C.	A.P.	C.P.	B.D.C.
H.O.	W.P.	O.A.	A.P.	J.P.	P.M.
G.Q.	J.P.	Z.S.	C.P.		

Open Session

Mr. Stone made a motion for the Board to take the following action:

Cognizant's Report

GDNA Case #	Licensee	Recommendation
T35641	C.H.B.	Accept the signed voluntary surrender
T35632	S.D.S.	Revoke technician registration
T35714	T.L.D.	Revoke technician registration
B35680	L.F.H./ G.S.O.	Case Closed. GDNA referred to outside agency.
B35681	B.P.	Letter of Concern
A35330	W.P.	Referred to AG's Office
A35330	C.H.E.D.L.	Cease and Desist Order
A35366	R.C.P. / A.G.Y. / H.W.	Referred to AG's Office
A35435	J.H.L. / W.P.	Letter of Concern
A35481	M.C.P.E.L. / D.R.H.	Referred to AG's Office
A35586	C.C.P. / J.D.E.	Referred to AG's Office
A35630	C.D.I. / S.N.R. / W.D.	Referred to AG's Office
A35640	W.P. / K.M.M.	Referred to AG's Office
A35651	A.S.I.	Null and Void the license
A35678	A.H.D.L. / A.A.W.	Referred to AG's Office
A35692	P.P.P.I.	Null and Void the license
A35702	W.G./ L.B.H.	Referred to AG's Office
A35703	S.J.S.	Letter of Concern
A35706	B.L.M.S.	Null and Void the license
A35734	A.R.L. A.P. / A.G.P.	Referred to AG's Office
A35461	S.S.A.	Close
A35559	J.D.S.F./ J.D.S.C.	Close
A35618	C.P./ M.S.L.	Close
A35634	W.P. / X.T.H.N.	Close

A35655	L.M.B. M.B.P. / J.A.P.	Close

Steering Committee

GDNA Case #	Licensee	Recommendation
SB34488	E.S.	Close
SB34505	C.C. / C.P.	Referred to AG's Office
SB34690	E.S. / G.	Close
SB33684	AL.I.C. / CVS P.	Referred to AG's Office
SB34328	A.B. / E.S./ C.P.	Close
SB34333	A.L.I.C.	Close
SB35292	C.C.	Close
SB33332	E.D.S. / C.P. / P.B.M.-C.	Close
SB33326	A. / C.C. / C.P.	Letter of Concern
SB33327	A.B. / E.S.	Close
SB33329	C.P./ A.B. / C.C.	Letter of Concern
SB33333	BI. / C.C. / C.P.	Letter of Concern
SB33339	C.C. / C.P.	Letter of Concern
SB33352	C.H.L.I. / C.P.	Close
SB33355	C.C. / C.C.G.L.I. / C.P.	Letter of Concern
SB33440	A.L.I.C. / C.C.	Letter of Concern
SB33445	C.C./ A.L.I.C. / C.C.	Letter of Concern
SB33452	C.C. / A.L. / C.P.	Letter of Concern
SB33479	O / C / W.G.	Close
SB33328	A.	Close
SB33330	E.S.	Close
SB33331	B.C.	Close
SB33334	A.	Close
SB33335	B.I. / E.S./M.P. / C.P.	Close
SB33342	A.L.I.C. / C.C.	Close
SB33393	B.I. / A.R.S.P.	Close
SB33461	C.C. / C.P.	Close

Orders: All proposed orders were approved for docketing.
Counterproposals: N/A.

Applications

Applicant	Type of License	Status
D.W.	Pharmacy Technician	Approved
T.B.	Pharmacy Technician	Approved
P.B.	Pharmacy Technician	Denied
J.M.	Pharmacy Technician	Approved
C.T.	Pharmacy Technician	Approved
L.S.	Pharmacy Technician	Approved
N.F.	Pharmacy Technician	Approved
J.W.	Pharmacist Intern	Approved
J.C.	Pharmacist Intern	Approved
K.J.	Pharmacist Intern	Approved
M.K.	Pharmacist	Approved
N.G.	Pharmacist	Approved
B.G.	Pharmacist	Denied
R.L.	Pharmacist (Reciprocity)	Approved
E.S.P.	Pharmacist	Denied & Referred to AG's Office
N.R.	Pharmacist (Reciprocity)	Approved
D.L.	Pharmacist Certification of DTM	Approved

M.M.	Pharmacist Certification of DTM	Approved
R.S.	Pharmacist Certification of DTM	Approved (New Protocol)
C.N.	Nuclear Pharmacist	Approved
T.J.	Nuclear Pharmacist	Tabled. Need proof of completion of 500 hours of clinical nuclear training.

Notices of Discipline: The Board reviewed the notices and agreed that these notices are for information only and that no further action is necessary at this time

E.P.	I.P.	I.C.	A.P.	C.P.
B.D.C.	H.O.	W.P.		

Correspondences/Requests

Licensee	Request	Decision
O.A.	Anonymous complaint	GDNA to take as a complaint to investigate
A.P.	Request to take NAPLEX for 5th attempt	Approved
J.P.	Request to take MPJE for the 4th attempt	Approved
P.M.	Self-Report Arrest	Take as information
G.Q.	Request to take MPJE for 4th attempt	Approved
J.P.	Request to take MPJE for 5th attempt	Approved
Z.S.	Request to take NAPLEX for 4th Attempt	Approved
C.P.	Requesting Appearance for Reinstatement	Denied

Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 3:34 p.m. The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, May 21 through Thursday, May 22, 2025, at 9:00 a.m. at the Board's office located at 2 Martin Luther King Jr Drive SE, East Tower, 11th floor, Atlanta, GA 30334

Minutes recorded by Angela Johnson, Board Administrative Secretary
Edited by J. Clinton Joiner, II, Executive Director