GEORGIA BOARD OF PHARMACY Board Policies

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In the September 15, 1998 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy. In the May 13, 2003 Board Meeting, the Board revisited this policy and made amendments.

Guidelines for Administratively Approving Initial Applications

Applications will be approved administratively once all criteria as outlined in the law and Board rules have been met. The administrative processing of licenses means that the Board staff has reviewed the documents and approved licensure based upon the laws, rules and board policies that pertain to that specific type of licensure. License reinstatements will be administratively processed in compliance with the Board's current

Reinstatement/Reactivation Policy. The Board will review any applicant with an affirmative answer to the conviction or Board sanction questions. Administratively issued licenses are considered for a vote to ratify at the next regularly scheduled board meeting.

In the September 15, 1998 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy. In the May 13, 2003 Board Meeting, the Board revisited this policy and made amendments.

Guidelines for Summoning People to Investigative Interviews

- 1. The Board secretary is to record the vote at the Board meeting for an investigative interview.
- 2. The Board secretary is to work with the Cognizant Board Member and GDNA to establish a date and time for each investigative interview.
- 3. The Board secretary shall reserve a meeting room for the investigative interview.
- 4. The Board secretary will notify each person scheduled, of the place, date and time for their investigative interview, allowing the persons scheduled ten (10) days after receipt of the letter of notification to notify the Board of whether or not he he/she will attend the interview. This notification will be sent via certified mail along with a signed return receipt to be sent back by the persons scheduled.

One week prior to the scheduled investigative interviews, the Board secretary shall notify the Cognizant Board Member, the GDNA and the Board's attorney of those persons scheduled to attend, those who will not attend and/or those who have not responded to the Board's notification letter.

Guidelines for Reinstatement/Reactivation of Pharmacists' Licenses who have NOT been actively practicing pharmacyfor the past four (4) years or longer.

(This pertains to a pharmacist whose license is on "Inactive" status or administratively lapsed due to non-renewal, voluntarily suspended for disciplinary reasons.) The applicant <u>must</u> complete the following:

- 1. All applicants must submit the completed application to the Board's office for reinstatement/reactivation.
- 2. Re-take and achieve a passing score on the Jurisprudence Examination (MPJE).
- 3. Complete and submit proof of 30 hours of Pharmaceutical Continuing Education.
- 4. Pay all back renewal and/or penalty fees.

Once the above conditions have been met, the Board staff will forward the file to the Attorney General's office for issuance of a consent order requiring:

1. Applicants who have been out of practice between four (4) or more years will be required to work under direct supervision in an "intern-like" setting as follows:

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      4 years – 1000 hours
      10 years – 1600 hours

      5 years – 1100 hours
      11 years – 1700 hours

      6 years – 1200 hours
      12 years – 1800 hours

      7 years – 1300 hours
      13 years – 1900 hours

      8 years – 1400 hours
      14 or more years – 2000 hours

      9 years – 1500 hours
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When working in this "intern-like" setting, an applicant can work a minimum of twenty (20) hours and maximum of fifty (50) hours per week. At the completion of this practice, the supervisor must provide an affidavit attesting to the applicant's level of competency.

- 2. Once the hours are completed, all applicants must take and pass the Georgia practical examination.
- 3. Applicants may choose to complete 1000 hours in an "intern-like" setting and retake and pass the NAPLEX in lieu of working the total number of hours required above.

In its discretion, the Board may require one or all of the following: Applicants who have been out of practice for over ten (10) years may be required to re-take and achieve a passing score on the NAPLEX.

- Submit further evidence of competency or stipulations as may be determined by the Board.
- 2. Inclusion in the CE audit pool for the upcoming renewal cycle.
- 3. Board may request to meet with licensee prior to the license being reinstated.

Guidelines for Reinstatement/Reactivation of Pharmacists' Licenses who HAVE been actively practicing pharmacyduring the past four (4) years.

(This could pertain to a pharmacist whose license is on "Inactive" status, or a pharmacist whose license was administratively lapsed due to non-renewal, voluntarily surrendered or suspended for disciplinary reasons.)

- 1. All applicants must submit a written request to the Board's office for reinstatement/reactivation.
- 2. Pay all back renewal and/or penalty fees.
- 3. Complete and submit proof of 30 hours of Pharmaceutical Continuing Education obtained during the past two (2) years.
- 4. Submit a Curriculum Vitae (CV) indicating past work activities going back to date of expiration.
- 5. If licensed in another state, have verification of licensure forwarded to the Georgia Board of Pharmacy's office.

If the license was administratively lapsed due to non-renewal, the Board, in its discretion may also require one or all of the following:

- 1. Inclusion in the CE audit pool for the upcoming renewal cycle.
- 2. Board may request to meet with licensee prior to the license being reinstated.

In the November 17-18, 1998 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy. In the February 12, 2008 Board Meeting, the Board revisited this Policy and amended as needed.

Guidelines for Reinstatement of Pharmacists' Licenses that have been Administratively Lapsed for Failure to Renew.

It is the Board's Policy that licenses that have been Administratively Lapsed due to nonrenewal shall be reinstated to include the following stipulations:

- 1. Pay a reinstatement fee plus a renewal fee for each licensing renewal period that the pharmacist did not renew his/her license. Current fees may be found on the approved fee schedule.
- 2. Complete and submit proof of 30 Hours of Pharmaceutical Continuing Education.
- 3. Automatic Inclusion in the continuing education audit pool in the following biennium.
- 4. Board may request to meet with licensee prior to license being renewed.
- 5. Must also follow requirements in Policy 3(A) if applicant has not been actively practicing pharmacy for the past four (4) years or longer.

In the October 22-23, 1997 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy. In the May 13, 2003 Board Meeting, the Board revisited this Policy and made no amendments.

Guidelines to Ensure Safe Pharmacy Practice

Purpose: The Georgia State Board of Pharmacy has developed these guidelines to ensure the protection of the health, safety and welfare of Georgia's citizens as related to the scope and quality of Pharmacy Care and Services provided by the licensed Pharmacies and Pharmacists under the Board's jurisdiction.

General Guidelines: The following guidelines constitute what the Board feels is necessary to ensure Safe Pharmacy Practice:

- Each individual workplace should be designed to provide adequate space and workflow design that will accommodate the workplace in an organized fashion.
- Computers and other automated equipment should be of a design that drug interactions and contraindications MUST BE REVIEWED BY THE PHARMACIST. Further, the computer system should be of a design to support counseling, DUR documentation and other safeguards to meet legal and regulatory requirements. Adequately trained or experienced professional and supportive staff levels should be maintained to meet the demands of the practice site, workload and clientele served. It should be noted that both the number and the training or experience level of all staff are important. Other factors that could increase staffing levels include demand for OTC recommendations by customers, telephone interruptions, patient teaching and demands of managed care organizations and other third party programs.
- Staff should have the opportunity to take periodic "breaks" and/or meal periods to relieve fatigue and mental and physical stress. Staff should also have opportunities for training and education to keep them abreast of new information and changes in the field.
- Workload quotas or formulas such as strictly using the number of prescriptions or orders processed to set staffing patterns must include other considerations such as peak workload periods, workplace design, training of staff on duty, etc. to adequately meet the needs of the public.

Discussion: Ensuring that practicing pharmacists and pharmacies serving the public are providing accurately filled prescriptions, accurate and timely information for the use of the prescriptions filled and that the desired outcome of the therapy is achieved is the essence of Pharmacy Care. In today's competitive marketplace, the issues related to achieving this should provide the opportunity to succeed.

Institution of quotas and/or additional regulations would be difficult and hard to enforce but might be required. Liability, responsibility and sanctions must be shared equitably by the owner or management of the pharmacy and the individual practitioner. In addition to the

above guidelines, the Board officers below, indicators that workload is too great for the staff or the Safe Pharmacy Practice Guidelines are not being followed and disciplinary action may be in order.

Indicators:

- An inordinate number of filling errors occur
- Patients are not properly counseled
- Patient or customer complaints
- Continuing pharmacist complaints related to working conditions
- Failure to comply with patient counseling or other rules and regulations
- Inadequate supervision and training of supportive personnel

In the January 26-27, 1999 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy. In the May 13, 2003 Board Meeting, the Board revisited this policy and made an amendment.

Guideline for Mailing Renewal Forms

1. ALL license renewals will be mailed at least ninety (90) days prior to expiration. This shall apply to all pharmacy and pharmacist renewals.

In the September 27-28, 2000 Board Meeting, the Board voted to develop a policy pertaining to Electronic Drug Orders. In the May 13, 2003 Board Meeting, the Board revisited this policy and made amendments. Pursuant to O.C.G.A. §26-4-80(i), the Georgia State Board of Pharmacy (Board) makes the following policy statement:

ELECTRONIC DRUG ORDERS

Computer or electronically generated prescriptions must bear the original signature
of the issuing practitioner. It is legal for the body of the prescription drug order to be
generated electronically, however, to be considered valid and legal, the practitioner
must manually sign, in indelible ink, said drug order.

Pursuant to O.C.G.A. §26-4-80(c), the Georgia State Board of Pharmacy (Board) makes the following policy statement:

FACSIMILE PRESCRIPTION DRUG ORDERS

 It is valid and legal for a pharmacy to accept a prescription drug order, which is transmitted via facsimile, as long as the drug order has been sent by the practitioner or the practitioner's agent under the supervision of the practitioner. Prescription drug orders must be sent directly from the practitioner to the pharmacy without anyone intercepting the order as transmitted by the practitioner.

Drug orders submitted via facsimile shall include the following:

- Complete name and address of the practitioner;
- If for a controlled substance, the DEA registration number of the practitioner;
- The telephone number of the practitioner for verbal confirmation;
- Complete name and address of the patient;
- Time and date of the transmission:
- The full name of the person transmitting the order.

Nothing in the Georgia Code prohibits an electronically/computer generated drug order from being transmitted via facsimile as long as the drug order bears the original signature of the practitioner.

In the November 17-18, 1998 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy. In the May 13, 2003 Board Meeting, the Board revisited this Policy and amended as needed.

Guidelines for C.E. Audits: Non-Compliance

If a pharmacist is randomly selected for a Continuing Education Audit and does not provide proof of the required 30 hours of C.E. for the biennium, the pharmacist will need to comply with the following in order to late renew or reinstate the license:

- 1. The pharmacist must obtain two (2) C.E. credit hours for every one (1) C.E. credit hour he/she is deficient.
- 2. The pharmacist may be fined \$50.00 per deficient hour, not to exceed a maximum of \$500.00.
- 3. A public reprimand that will become a permanent document in the licensee's record may be issued to the pharmacist.

The pharmacist may not use the additional required hours in the present or next biennium. The hours are to comply with the past renewal biennium and may not be counted again.

In the July 22-23, 2002 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy. In the May 13, 2003 Board Meeting, the Board revisited this Policy and amended as needed.

No-Show Policy

Anyone who does not appear before the Board for his or her scheduled appointment without a valid reason, upon reapplying, will have a six (6) month waiting period.

In the September 17, 2003 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy.

P.B.M. Exemption Policy

Pharmacy Benefit Managers (P.B.M.'s) are exempt from questions 5-8 on the application. These questions are considered exemptions as follows:

- 5. Do you have a Class A Balance and other equipment as provided for under "Minimum Equipment for Prescription Department", Chapter 480-10-.12 of the Rules and Regulations?
- 6. Does the store keep an exempt narcotic register?
- 7. Are narcotics stored or locked in a secure place? Mixed with stock?
- 8. Does the store keep a poison register?

In the October 12, 2011 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy.

Specialty Pharmacy Accreditation Recognition

Pursuant to the authority delegated to the Board in O.C.G.A. § 26-4-28(a)(21), and acting as the sole governmental or other authority with the authority to (1) approve or recognize accreditation programs for specialty pharmacy practice, and (2) determine the acceptability of entities which may accredit pharmacies or certify pharmacists in a specialty of pharmacy practice in the State of Georgia, the Board approves and recognizes the URAC Specialty Pharmacy Accreditation Standards, Version 2.0, July 2010 ("URAC Accreditation") as an accreditation program for specialty pharmacy practice.

This policy does not require pharmacists or pharmacies to obtain URAC Accreditation as a prerequisite to specialty or advance pharmacy practice.

At its meeting on November 18, 2015, the Georgia Board of Pharmacy voted to recognize ACHC (Accreditation Commission for Healthcare) as an accreditation agency.

At its meeting October 22, 2014, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy.

LABELING OF PRESCRIPTION DRUGS

In response to numerous inquiries about the proper labeling of prescriptions drugs, the Georgia State Board of Pharmacy has examined the issue in light of state law. O.C.G.A. Section 26-4-80(k) expressly provides:

All out-patient prescription drug orders which are dispensed shall be appropriately labeled in accordance with the rules and regulations promulgated by the board as follows:

- (1) Before an out-patient prescription drug is released from the dispensing area, the prescription drug shall bear a label containing the name and address of the pharmacy, a prescription number, the name of the prescriber, the name of the patient, directions for taking the medication, the date of the filling or refilling of the prescription, the initials or identifying code of the dispensing pharmacist, and any other information which is necessary, required, or, in the pharmacist's professional judgment, appropriate; and
- (2) The pharmacist who fills an out-patient prescription drug order shall indicate the identity of the dispensing pharmacist on the label of the prescription drug. Identification may be made by placing initials on the label of the dispensed drug. The label shall be affixed to the outside of the container of the dispensed drug by means of adhesive or tape or any other means which will assure that the label remains attached to the container.

Board Rule 480-27-.05 is consistent with this rule in regards to recordkeeping.

However, it appears that O.C.G.A. Section 16-13-73 currently requires that whenever a pharmacist dispenses a dangerous drug, the pharmacist shall place a label upon each container that has the name of the "physician" prescribing the drug. Since persons other than physicians are authorized to prescribe dangerous drugs under Georgia law, see, e.g., O.C.G.A. Section 16-13-78.1 and 16-13-70.1, the Board plans to ask the General Assembly to pass legislation during the 2015 Session to make Code section 16-13-72 consistent with the other statutory provisions and to eliminate any confusion in this area.

Until such time as the law can be changed, the Board will consider compliance with O.C.G.A. Section 26-4-80(k) and its rules regarding labeling to be compliance with the laws and rules for purposes of any disciplinary action. That means that pharmacists may use the name of the prescribing or ordering practitioner on the label. A practitioner is a physician, dentist, podiatrist, physician's assistant, advanced practice registered nurse, or other person licensed, registered, or otherwise authorized under the laws of this state to prescribe or order dangerous drugs or controlled substances.

** This policy applies <u>ONLY</u> to Opioid Treatment Program ("OTP") Clinic Pharmacies. In no way should any portion of this policy be construed to apply to any other type of pharmacy permit issued by the Georgia State Board of Pharmacy ("Board"). **

The Director of Pharmacy Services of an OTP clinic pharmacy shall provide each patient with a pre-printed agent authorization form or document. By signing this document, each patient will be able to authorize one or more licensed health care professional who is/are employed by the OTP to be his or her authorized agent. A patient must sign and date a separate document naming each licensed health care profession the patient authorizes to be his or her agent. A patient can only authorize a health care professional who is authorized by state law to administer medication.

The take-home medication <u>must</u> have been previously prepared at the OTP by a pharmacist. The take-home medications for each patient must be labeled in accordance with all federal and state laws and regulations. Each patient's set of take-home medications must be maintained together in a package bearing the name of and other necessary information required to identify the patient.

The OTP Director of Pharmacy must maintain a set of Policy and Procedures describing the procedure by which patients authorize an agent to deliver their take-home medications to them, and describing how patients obtain their take-home medications from their agent. This procedure must include at a minimum, but is not limited to:

- Details on how a patient's take-home medications are transferred from the pharmacist to the patient's authorized agent,
- How a patient authorizes their agents by use of an agent designation form
- How each authorized agent receives training from the pharmacist on receiving and delivering take-home medications to patients.
- The names of all persons who are authorized to access the safe containing take-home medications.
- What action is to be taken when a change is made in patient's take-home medications,
- The record keeping involved in all phases of this procedure, and
- How the take-home medications are delivered to the patient.

Once each patient's container of take-home medications has been transferred from the pharmacist to a patient's authorized agent, the container cannot be stored in the pharmacy area safe. The patient's authorized agent must secure each patient's container of take-home medications in a safe located outside of the pharmacy area. All safes and security systems in use to store a patient's take-home medications must meet the minimum requirements set forth in U.S. Drug Enforcement Administration (DEA) and U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) rules and laws.

The OTP Director of Pharmacy shall maintain a signed log and record detailing the quantity of the take-home medication prepared and dispensed for each patient, the signature of the patient's authorized agent who received the take-home medication, and the signature of the patient when his/her medication was received from the authorized agent.

A patient's authorized agent may act as such only while on the property of the specific OTP where the patient receives his/her medication. A patient's authorized agent can only deliver take-home medications from the specific OTP where the patient receives his/her medication. The patient's authorized agent my not leave the OTP premises with any patient's take-home medication, nor shall a patient's take-home medication be delivered to the patient in any manner except that authorized by DEA and SAMHSA rules and laws.

This policy is subject to any and all federal and state laws, rules and guidelines which address the delivery of take-home medications at an OTP licensed and operated in the State of Georgia.

October 2009

Agent Designation Form for Delivery of Take Home Doses

I,	, a patient at the
Opioid Treatment Pro	gram Clinic (OTPC), do hereby designate
	, LPN/RN, GA License Number:
a nurse licensed by the	State of Georgia and employed at and by this treatment clinic as
my agent to receive fro	om the clinic pharmacist any and all of my prescribed OTPC take-
home medication dose	s and maintained at this OTPC. In turn, my agent will personally
deliver all such take-h	ome doses to me only at this OTPC clinic. It is my understanding
that before the deliver	y of such doses, each one will have been previously prepared by
the pharmacist and pl	aced in a container displaying a prescription label with my name
and all of the other red	uirements of Pharmacy Board Rule 480-1806 and the rules and
laws of SAMHSA and	he DEA. I understand that a copy of this designation will be
maintained by the OT	C pharmacy as part of my patient record, and it shall remain in
effect until such time	s I revoke it, or it is revoked by the OTPC pharmacy or the OTPC
clinic.	
Patient Signature:	Date:
(Printed Name of Pati	ent:)
Agent Signature:	Date:
(Printed Name of Age	nt:)
Signature of Pharmac	st: Date:
(Printed Name of Pha	emacist:

At its meeting May 10, 2017, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy.

Guidelines for a Change in Ownership or Change in Location

If a change of ownership or change in location is submitted during the period in which the same facilities are in renewal (push-period), the status shall go into Active-Renewal Pending status until the application is complete. In these instances, where a change of ownership or change in location application fee is submitted, it will not be necessary for the entity to pay the renewal fee.