

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-31-.01 PATIENT COUNSELING, AND NOTICE OF PUBLIC HEARING**

TO ALL INTERESTED PERSONS AND PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes amendments to the Georgia Board of Pharmacy Rules, Rule 480-31-.01 PATIENT COUNSELING (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m. Monday through Friday, except official State holidays, at the Department of Community Health at 2 Peachtree Street NW, Atlanta, Georgia, 30303. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at www.gbp.georgia.gov.

A public hearing is scheduled to begin at 9:00 AM on September 16, 2020 via conference call at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street NW, 6th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. Written comments are welcome. To ensure their consideration, written comments must be received prior to September 9, 2020. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, 6th Floor, Atlanta, Georgia 30303. You may email your comments to elacefield@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on 9/16/2020 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 6th Floor, Atlanta, Georgia 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. § 26-4-85.

At its meeting on January 15, 2020, the Board voted 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 O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

Also, at its meeting on January 15, 2020, the Board voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this chapter will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 4th day of August, 2020.



Eric R. Lacefield
Executive Director
Georgia Board of Pharmacy

Posted: August 4th, 2020

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-31-.01 PATIENT COUNSELING**

Purpose of Rule: The purpose of this amendment is to address concerns relating to how a "personal offer" to counsel may be made.

Main Feature: The main feature of this amendment is to clarify the counseling requirement and to ensure that the offer to counsel is clearly expressed to the patient even when the prescription is not personally handed to the patient by the pharmacist.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-31-.01 PATIENT COUNSELING**

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

480-31-.01 Patient Counseling

Purpose: The purpose of the regulations issued in this part is to comply with the requirements of the Omnibus Budget Reconciliation Act of 1990 and to enhance the public health and welfare by providing that pharmacists shall offer consultation to patients regarding their medications and various conditions which could affect or be affected by the use of those medications.

(a) Patient Records.

1. A patient record system shall be maintained by all pharmacies for patients for whom Prescription Drug Orders are dispensed. For purposes of the regulations under this part, "Prescription Drug Order" is defined to mean the lawful order of a Practitioner for a Drug or Device for a specific patient. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The Pharmacist or his designee shall make a reasonable effort to obtain, record, and maintain the following information:

- (i) full name of the patient for whom the Drug is intended.
- (ii) address and telephone number of the patient;
- (iii) date of birth; and
- (iv) patients gender.

2. The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs, or devices currently being used by the patient which may relate to Prospective Drug Review unless the patient or the patient's agent refuses such information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

- (i) A list of all Prescription Drug Orders obtained by the patient at the Pharmacy where the Prescription Drug Order is being filled within the preceding two years,

showing prescription number, name and strength of the Drug, the quantity and date dispensed, the name of the Practitioner; and

(ii) comments from the Pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or Drug.

3. A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(b) Prospective Drug Review.

1. A pharmacist shall review the patient record and each Prescription presented for Dispensing for purposes of promoting therapeutic appropriateness by identifying:

- (i) over-utilization or under-utilization;
- (ii) therapeutic duplications;
- (iii) drug-disease contraindications;
- (iv) Drug-Drug interactions;
- (v) incorrect Drug dosage or duration of Drug treatment;
- (vi) Drug-allergy interactions;
- (vii) clinical abuse/misuse.

2. Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(c) Patient Counseling.

1. Upon receipt of a Prescription Drug Order and following a review of the patient's record, the dispensing Pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. The personal offer to counsel may be made verbally or in written format; a written offer must provide a telephone number and business hours during which the dispensing pharmacist can be reached. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling, based on the professional judgment of the pharmacist. Such elements may include but are not limited to the following:

- (i) the name and description of the Drug;
- (ii) the dosage form, dose, route of Administration, and duration of drug therapy;
- (iii) intended use of the Drug and expected action;
- (iv) special directions and precautions for preparation, Administration, and use by the patient;
- (v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (vi) techniques for self-monitoring drug therapy;
- (vii) proper storage;
- (viii) prescription refill information;
- (ix) action to be taken in the event of a missed dose; and
- (x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

2. Additional forms of patient information shall be used to supplement Patient Counseling when appropriate.

3. Patient Counseling, as described above and defined in the Act, shall not be required for:

- (i) in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).
- (ii) inmates of correctional institutions where pharmacy services are provided by the Georgia Department of Corrections or by county or municipal political subdivisions either directly or by a subcontractor of the above; or
- (iii) patients receiving drugs from the Georgia Department of Human Resources Division of Public Health; provided however, that pharmacists who provide medications to patients in accordance with Section 43-34-26.1 of the Official Code of Georgia Annotated shall include in all dispensing procedures a written process whereby the patient or the caregiver of such patient is provided with the information contained in Chapter 480-31 of the Rules of the Georgia State Board of Pharmacy.
- (iv) refills of prescription drug orders for which, in the professional judgment of the Pharmacist, appropriate counseling has taken place or has been declined. The need for counseling on refills resides in the professional judgment of the dispensing Pharmacist.

4. A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

5. These rules will become effective January 1, 1993.

(d) Nothing in these rules shall be interpreted so as to prohibit the pharmacist from being remunerated for said professional services.

Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-80, and 26-4-85.