

APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-4-.07
Rule Title: Emergency Prescription Refill

 New X Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? NO

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer *William J. ...*

Date: August 21, 2023

REC'D & FILED
AUG 22 2023
LEGISLATIVE SVC AGENCY

APA-2

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-4-.07, Emergency Prescription Refill


INTENDED ACTION: Amend the rule

SUBSTANCE OF PROPOSED ACTION: Amend the rule to: authorize emergency dispensing of the smallest package size if a 72-hour supply is not readily available; clarify that Schedule I or II substances are not authorized for emergency dispensing; allow emergency dispensing of Schedule III substances; remove the list of categories of allowable drugs; require that the pharmacist has a record of a prescription at the pharmacy within the last 90 days; disallow emergency dispensing of the same drug to the same patient more than one time in a 12-month period; provide that the pharmacist inform the patient that practitioner authorization is required for any future refill; require the statement "Emergency Fill" on the written prescription order; decrease the time to notify the prescriber from 72 to 24 hours.

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to: Carla Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or email (bme@albme.gov), until and including October 5, 2023. Persons wishing to submit data, views, or comments in person should contact Carla Kruger by telephone (334-242-4116) during the comment period. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: October 5, 2023

CONTACT PERSON AT AGENCY: Carla Kruger


(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

540-X-4-.07 Emergency Prescription Refill

(1) If a pharmacist receives a request for a prescription refill, ~~the original of which is maintained in the pharmacy files,~~ and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72 hour supply of the prescribed medication or the smallest dispensable package size if a 72 hour supply is not readily available, provided that under the following conditions:

(a) The prescription is not a medicinal agent listed in Schedule I or II appearing in pursuant to Title 20, Chapter 2, or the controlled substance list for Schedule I or II maintained by the State Board of Health.

~~(b) The prescription is not a medicinal agent listed in Schedule III appearing in Title 20 Chapter 2.~~

~~(c) The medication is essential to the maintenance of life or the continuation of therapy in a chronic condition including but not limited to drugs listed in the following categories, according to the latest edition of Facts and Comparisons, U.S.P./N.F.,~~

~~P.D.R. or A.M.A. Drug evaluation:~~

~~1. Blood Modifiers~~

~~(i) Iron Products~~

~~(I) Oral Iron~~

~~(II) Parenteral Iron~~

~~(III) Iron Combinations (with Vitamins, with Liver, with B12 and Intrinsic Factor)~~

~~(ii) Folic Acid~~

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- ~~(i) Leucovorin-Calcium~~
 - ~~(iii) Vitamin-B12~~
 - ~~(i) Cyanocobalamin~~
 - ~~(ii) Hydroxocobalamin~~
 - ~~(iii) Liver Preparations~~
 - ~~(iii) Vitamin-K~~
 - ~~(iv) Recombinant Human Erythropoietin~~
 - ~~(v) Colony Stimulating Factors~~
 - ~~(i) Filgrastim~~
 - ~~(ii) Sargramostim~~
 - ~~(vi) Antiplatelet Agents~~
 - ~~(i) Dipyridamole~~
 - ~~(ii) Ticlopidine~~
 - ~~(vii) Anticoagulants~~
 - ~~(i) Heparin~~
 - ~~(ii) Coumarin and Indandione Derivatives~~
 - ~~(viii) Heparin Antagonist~~
 - ~~(i) Protamine-Sulfate~~
 - ~~(ix) Tissue-Plasminogen Activator~~
 - ~~(x) Thrombolytic Enzymes~~
 - ~~(xi) Hemorrhologic Agent~~
 - ~~(xii) Antithrombin~~
 - ~~(xiii) Antithrombotic Products~~

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- ~~(i) Antihemophilic factor~~
 - ~~(ii) Anti-inhibitor coagulant complex~~
 - ~~(iii) Factor IX complex (Human)~~
 - ~~(xiv) Hemostatics~~
 - ~~(i) Systemic~~
 - ~~(ii) Topical~~
 - ~~(xv) Plasma Protein Fractions~~
 - ~~(xvi) Dextran Adjuvant~~
 - ~~(xvii) Plasma Expanders~~
 - ~~(xviii) Perfluorochemical Emulsion~~
 - ~~(xix) Hemin~~

~~2. Hormones~~

- ~~(i) Sex Hormones~~
- ~~(i) Estrogens~~
- ~~(ii) Progestins~~
- ~~(iii) Estrogens and Progestins, Combines~~
- ~~(iv) Oral Contraceptives~~
- ~~(v) Levonorgestrel Implant~~
- ~~(vi) Intrauterine Progesterone~~
- ~~(vii) Androgens~~
- ~~(viii) Anabolic Steroids~~
- ~~(ix) Estrogen and Androgen Combinations~~

- ~~_____ (X) Ovulation Stimulants~~
- ~~_____ (XI) Gonadotropins~~
- ~~_____ (XII) Chorionic Gonadotropin~~
- ~~_____ (XIII) Gonadotropin-Releasing Hormones~~
- ~~_____ (XIX) Danazol~~
- ~~_____ (ii) Growth Hormone~~
- ~~_____ (iii) Pituitary (Growth Hormone) Test~~
- ~~_____ (iv) Octreotide Acetate~~
- ~~_____ (v) Posterior Pituitary Hormones~~
- ~~_____ (I) Vasopressin Derivatives~~
- ~~_____ (II) Oxytocics~~
- ~~_____ (vi) Uterine Relaxant~~
- ~~_____ (vii) Abortifacients~~
- ~~_____ (I) Prostaglandins~~
- ~~_____ (II) Sodium Chloride~~
- ~~_____ (viii) Adrenal Cortical Steroids~~
- ~~_____ (I) Corticotropin (ACTH)~~
- ~~_____ (II) Mineralocorticoids~~
- ~~_____ (III) Glucocorticoids~~
- ~~_____ (ix) Adrenal Steroid Inhibitors~~
- ~~_____ (x) Pituitary Function Test~~
- ~~_____ (xi) Antidiabetic Agents~~
- ~~_____ (I) Insulin~~

- ~~———— (II) ———— Sulfonylureas~~
- ~~———— (xi) ———— Glucose Elevating Agents~~
- ~~———— (I) ———— Glucagon~~
- ~~———— (II) ———— Diazoxide~~
- ~~———— (III) ———— Glucose~~
- ~~———— (xii) ———— Alglucerase~~
- ~~———— (xiii) ———— Thyroid Drugs~~
- ~~———— (I) ———— Thyroid Hormones~~
- ~~———— (II) ———— Iodine Products~~
- ~~———— (III) ———— Antithyroid Agents~~
- ~~———— (xix) ———— Calcitonin~~
- ~~———— (xv) ———— Etidronate Disodium~~
- ~~———— (xvi) ———— Gallium Nitrate~~

~~3. ———— Diuretics and Cardiovasculars~~

- ~~———— (i) ———— Diuretics~~
- ~~———— (I) ———— Carbonic Anhydrase Inhibitors~~
- ~~———— (II) ———— Thiazides and Related Diuretics~~
- ~~———— (III) ———— Loop Diuretics~~
- ~~———— (IV) ———— Potassium Sparing Diuretics~~
- ~~———— (V) ———— Diuretic Combinations~~
- ~~———— (VI) ———— Osmotic Diuretics~~
- ~~———— (VII) ———— Nonprescription Diuretics~~

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- _____ (ii) _____ **Cardiac Glycosides**
 - _____ (iii) _____ **Amrinone**
 - _____ (iv) _____ **Antianginal Agents**
 - _____ (I) _____ **Combinations**
 - _____ (v) _____ **Antiarrhythmic Agents**
 - _____ (vi) _____ **Calcium Channel Blocking Agents**
 - _____ (vii) _____ **Peripheral Vasodilators**
 - _____ (I) _____ **Combinations**
 - _____ (viii) _____ **Drugs used in Shock**
 - _____ (ix) _____ **Beta-Adrenergic-Blocking Agents**
 - _____ (x) _____ **Alpha-Beta-Adrenergic-Blocking Agents**
 - _____ (xi) _____ **Antihypertensives**
 - _____ (I) _____ **Antiadrenergic Agents**
 - _____ I. _____ **Centrally-Acting**
 - _____ II. _____ **Peripherally-Acting**
 - _____ (II) _____ **Vasodilators**
 - _____ (III) _____ **Angiotensin-Converting-Enzyme-Inhibitors**
 - _____ (IV) _____ **Agents for Pheochromocytoma**
 - _____ (V) _____ **Agents for Hypertensive Emergencies**
 - _____ (VI) _____ **Miscellaneous Agents**
 - _____ (VII) _____ **Combinations**
 - _____ (xii) _____ **Potassium Removing Agents**
 - _____ (xiii) _____ **Cardioplegia Solution**

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- ~~_____ (xix) Salt Substitutes~~
 - ~~_____ (xv) Edentate Disodium~~
 - ~~_____ (xvi) Antihyperlipidemic Agents~~

 - ~~4. _____ Respiratory Drugs~~
 - ~~_____ (i) Bronchodilators~~
 - ~~_____ (i) Sympathomimetics~~
 - ~~_____ (ii) Xanthine Derivatives~~
 - ~~_____ (ii) Respiratory Inhalant Products~~
 - ~~_____ (i) Corticosteroids~~
 - ~~_____ (ii) Acetylcysteine~~
 - ~~_____ (iii) Atropine Sulfate~~
 - ~~_____ (iv) Ipratropium Bromide~~
 - ~~_____ (v) Cromolyn Sodium~~
 - ~~_____ (iii) Nasal Decongestants~~
 - ~~_____ (i) Combinations~~
 - ~~_____ (iv) Intranasal Steroids~~
 - ~~_____ (v) Alpha-Proteinase Inhibitor~~
 - ~~_____ (vi) Antihistamines~~
 - ~~_____ (i) Miscellaneous Preparations~~
 - ~~_____ (ii) Combined Preparations~~
 - ~~_____ (vii) Antitussives~~
 - ~~_____ (i) Narcotic~~

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- _____ (ii) ~~Non-narcotic~~
 - _____ (viii) ~~Expectorants~~
 - _____ (i) ~~Miscellaneous Preparations~~
 - _____ (ix) ~~Respiratory Combination Products~~
 - _____ (i) ~~Anti-asthmatic Combinations~~
 - _____ I. ~~Xanthine Combinations~~
 - _____ A. ~~Capsules and Tablets~~
 - _____ B. ~~Liquids~~
 - _____ II. ~~Xanthine Sympathomimetic Combinations~~
 - _____ A. ~~Capsules and Tablets~~
 - _____ B. ~~Liquids~~
 - _____ (x) ~~Upper Respiratory Combinations~~
 - _____ (i) ~~Decongestant Combinations~~
 - _____ (ii) ~~Antihistamine and Analgesic Combinations~~
 - _____ (iii) ~~Decongestants and Antihistamines~~
 - _____ I. ~~Sustained Release~~
 - _____ II. ~~Capsules and Tablets~~
 - _____ III. ~~Liquids~~
 - _____ IV. ~~Miscellaneous~~
 - _____ (iv) ~~Decongestant, Antihistamine and Analgesic Combinations~~
 - _____ (v) ~~Decongestant, Antihistamine and Anticholinergic Combinations~~
 - _____ (vi) ~~Cough Preparations~~
 - _____ I. ~~Antitussive Combinations~~

- ~~_____ A. Capsules and Tablets~~
- ~~_____ B. Liquids~~
- ~~_____ II. Expectorant Combinations~~
 - ~~_____ A. Capsules and Tablets~~
 - ~~_____ B. Liquids~~
- ~~_____ III. Antitussives and Expectorants~~
 - ~~_____ A. Narcotic~~
 - ~~_____ B. Non-narcotic~~
- ~~_____ IV. Antitussive and Expectorant Combinations~~
 - ~~_____ A. With Decongestants~~
 - ~~_____ B. With Antihistamines~~
 - ~~_____ C. With Decongestants and Antihistamines~~
- ~~_____ V. Pediatric Cough Preparations~~

- ~~_____ 5. Central Nervous System Drugs~~
 - ~~_____ (i) CNS Stimulants~~
 - ~~_____ (I) Analeptics~~
 - ~~_____ (II) Amphetamines~~
 - ~~_____ (III) Anorexiant~~
 - ~~_____ (IV) Non-prescription Diet Aids~~
 - ~~_____ (ii) Analgesics~~
 - ~~_____ (I) Narcotic Agonist Analgesics~~
 - ~~_____ (II) Narcotic Analgesic Combinations~~

- ~~_____ (III) Narcotic Agonist-Antagonist Analgesics~~
- ~~_____ (IV) Other Central Analgesics~~
- ~~_____ (V) Acetaminophen~~
- ~~_____ (VI) Salicylates~~
- ~~_____ (VII) Non-narcotic Analgesic Combinations~~
- ~~_____ (VIII) Nonsteroidal Anti-Inflammatory Agents~~
- ~~_____ (IX) Antirheumatic Agents~~
- ~~_____ (X) Agents for Gout~~
- ~~_____ (XI) Agents for Migraine~~
- ~~_____ I. Combinations~~
 - ~~_____ (iii) Antiemetic/Antivertigo Agents~~
 - ~~_____ (iv) Psychotherapeutic Drugs~~
 - ~~_____ (I) Antianxiety Agents~~
 - ~~_____ (II) Antidepressants~~
 - ~~_____ (III) Antipsychotic Agents~~
 - ~~_____ (IV) Miscellaneous Psychotherapeutic Agents~~
 - ~~_____ (V) Sedative and Hypnotic~~
 - ~~_____ (VI) Non-barbiturates~~
 - ~~_____ (VII) Nonprescription Sleep Aids~~
 - ~~_____ (VIII) Barbiturates~~
 - ~~_____ (vi) General Anesthetics~~
 - ~~_____ (I) Barbiturates~~
 - ~~_____ (II) Non-barbiturates~~

- ~~_____ (III) Gases~~
- ~~_____ (IV) Volatile Liquids~~
- ~~_____ (vii) Anticonvulsant~~
- ~~_____ (viii) Muscle Relaxants~~
- ~~_____ (I) Adjuncts to Anesthesia~~
- ~~_____ (II) Skeletal~~
- ~~_____ (III) Combinations~~
- ~~_____ (ix) Anti-parkinson Agents~~

~~6. Gastrointestinal Drugs~~

- ~~_____ (i) Antacids~~
- ~~_____ (I) Combinations~~
- ~~_____ (ii) Sucralfate~~
- ~~_____ (iii) Gastrointestinal Anticholinergic/ Antispasmodics~~
- ~~_____ (I) Combinations~~
- ~~_____ (iv) Histamine H2 Antagonists~~
- ~~_____ (v) Prostaglandins~~
- ~~_____ (vi) Antiflatulents~~
- ~~_____ (vii) GI Stimulants~~
- ~~_____ (I) Metoclopramide~~
- ~~_____ (II) Dexpanthenol~~
- ~~_____ (viii) Digestive Enzymes~~
- ~~_____ (ix) Gastric Acidifiers~~

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- ~~(ix) Choleresics~~
 - ~~(xi) Hydrocholeresics~~
 - ~~(i) Combinations~~
 - ~~(xii) Miscellaneous Digestive Products~~
 - ~~(xiii) Gallstone Solubilizing Agents~~
 - ~~(i) Chenodiol~~
 - ~~(ii) Ursodiol~~
 - ~~(iii) Monocetanein~~
 - ~~(xiv) Laxatives~~
 - ~~(i) Saline~~
 - ~~(ii) Stimulant~~
 - ~~(iii) Bulk~~
 - ~~(iv) Emollient~~
 - ~~(v) Fecal Softeners~~
 - ~~(vi) Hyperosmolar Agents~~
 - ~~(vii) Enemas~~
 - ~~(viii) CO₂ Releasing Suppositories~~
 - ~~(ix) Bowel Evacuants~~
 - ~~(x) Lactulose~~
 - ~~(xi) Combinations~~
 - ~~(xv) Antidiarrheal~~
 - ~~(i) Diphenoxylate/Atropine~~
 - ~~(ii) Loperamide~~

~~_____ (III) Bismuth Subsalicylate~~

~~_____ (IV) Combinations~~

~~_____ (xvi) Mesalamine~~

~~_____ 7. Antineoplastic Agents~~

~~_____ (i) Chemotherapeutic Regimens~~

~~_____ (ii) Alkylating Agents~~

~~_____ (I) Nitrogen Mustards~~

~~_____ I. Mechlorethamine HCl~~

~~_____ II. Chlorambucil~~

~~_____ III. Cyclophosphamide~~

~~_____ IV. Uracil Mustard~~

~~_____ (II) Nitrosoureas~~

~~_____ I. Lomustine~~

~~_____ II. Carmustine~~

~~_____ III. Streptozocin~~

~~_____ (III) Thiotepa~~

~~_____ (IV) Busulfan~~

~~_____ (V) Pipobroman~~

~~_____ (VI) Cisplatin~~

~~_____ (iii) Antimetabolite~~

~~_____ (I) Methotrexate~~

~~_____ (II) Fluorouracil and Floxuridine~~

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- ~~_____ (III) Cytarabine~~
 - ~~_____ (IV) Mercaptopurine~~
 - ~~_____ (V) Thioguanine~~
 - ~~_____ (iv) Hormones~~
 - ~~_____ (i) Androgens~~
 - ~~_____ I. Testosterone~~
 - ~~_____ (ii) Progestins~~
 - ~~_____ I. Megestrol Acetate~~
 - ~~_____ II. Medroxyprogesterone Acetate~~
 - ~~_____ (iii) Estrogens~~
 - ~~_____ I. Diethylstilbestrol Diphosphate~~
 - ~~_____ II. Polyestradiol Phosphate~~
 - ~~_____ (iv) Estrogen/Nitrogen Mustard~~
 - ~~_____ I. Estramustine Phosphate~~
 - ~~_____ (V) Anti-estrogen~~
 - ~~_____ I. Tamoxifen~~
 - ~~_____ (VI) Gonadotropin Hormone-Releasing Antigen~~
 - ~~_____ I. Leuprolide Acetate~~
 - ~~_____ (v) Antibiotics~~
 - ~~_____ (i) Bleomycin Sulfate~~
 - ~~_____ (ii) Doxorubicin HCl~~
 - ~~_____ (iii) Daunorubicin HCl~~
 - ~~_____ (iv) Mitoxantrone HCl~~

- ~~_____ (V) Mitomycin~~
- ~~_____ (VI) Dactinomycin~~
- ~~_____ (VII) Picamycin~~
- ~~_____ (vi) Mitotic Inhibitors~~
- ~~_____ (I) Etoposide~~
- ~~_____ (II) Vincristine Sulfate~~
- ~~_____ (III) Vinblastine Sulfate~~
- ~~_____ (vi) Radiopharmaceutical~~
- ~~_____ (I) Sodium Iodide I~~
- ~~_____ (II) Sodium Phosphate P~~
- ~~_____ (III) Chromic Phosphate P~~
- ~~_____ (vii) Miscellaneous~~
- ~~_____ (I) Interferon Alfa-2a~~
- ~~_____ (II) Interferon Alfa-2b~~
- ~~_____ (III) Hydroxyurea~~
- ~~_____ (IV) Procarbazine HCl~~
- ~~_____ (V) Dacarbazine~~
- ~~_____ (VI) Mitotane~~
- ~~_____ (VII) Asparaginase~~
- ~~_____ (viii) NCI Investigational Agents~~

(b) The medication is essential to the maintenance of life or the continuation of therapy and in the pharmacist's professional judgement, the interruption of therapy

might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(c) The pharmacist has a record of a prescription at the pharmacy or has been presented proof of a prescription filled within the last 90 days in the name of the patient for whom the request of the emergency supply is being made.

(d) A pharmacist or pharmacy shall not dispense or sell the same drug to the same patient, as provided in this section, more than one time in any 12-month period.

(e) The pharmacist must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill.

(ef) The dispensing pharmacist shall creates a written prescription order containing all of the prescription information required by federal and state statutes, rules and regulations and shall also include the statement "Emergency Fill".

(eg) The dispensing pharmacist shall ~~notifiesy~~ the prescriber, orally or in writing, of the emergency dispensing within ~~seventy-two~~ twenty-four (24) hours after such dispensing.

(2) This rule is adopted jointly by the Board of Pharmacy and the Board of Medical Examiners.

Author: Alabama Board of Medical Examiners.

Statutory Authority: § 34-23-75 and §34-24-53, Code of Alabama 1975.

History: Filed: December 17, 1992 (for publication). Refiled for Publication: August 11, 1993. Approved/Adopted: October 20, 1993. Effective Date: November 25, 1993. (This rule has been jointly adopted by the BME and the Pharmacy Board.)