TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control___**580**____Department or Agency__**Mental Health** ___
Rule No. ___**Chapter 580-9-46** _____
Rule Title: ___**General Medical and Pharmacy**
_____New _____Amend ____X___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? _____ NO_____

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 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 Reference Service.

Signature of certifying officer Debbie S Popwell

Date 10/14/11

RECD & FILED
OCT 14 2011
LEGISLATIVE REF SERVICE

Alabama Department of Mental Health

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Mental Health

RULE NO. & TITLE: Chapter 580-9-46 General Medical and Pharmacy "Repealed"

INTENDED ACTION: Repeal

SUBSTANCE OF PROPOSED ACTION:
Replaced by proposed new chapter 580-9-44, Program Operation

TIME, PLACE, MANNER OF PRESENTING VIEWS:
All interested persons may submit data, views, or arguments in writing to Debbie Popwell, Director, Office of Certification Administration, Alabama Department of Mental Health, 100 North Union Street, Montgomery, Alabama 36130 by mail or in person between the hours of 8:00AM and 5:00PM, Monday through Friday, or by electronic means to debbie.popwell@mh.alabama.gov until and including Dec 5, 2011. Persons wishing to submit data, views, or arguments orally should contact Ms. Popwell by telephone at (334) 353-2069 during this period to arrange for an appointment.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Dec. 5, 2011

CONTACT PERSON AT AGENCY:
Persons wishing a copy of the proposal may contact
Debbie Popwell
Department of Mental Health
100 North Union Street
Montgomery, Alabama 36130
(334) 353-2069
A copy of the proposed change is available on the department's website at http://mh.alabama.gov
Click on Commissioner's Office and then Certification Administrative to find code with changes.

Debbie Popwell

Debbie Popwell, Director
Office of Certification

ALABAMA DEPARTMENT OF MENTAL HEALTH AND MENTAL RETARDATION SUBSTANCE ABUSE SERVICES ADMINISTRATIVE CODE

CHAPTER 580-9-46
GENERAL MEDICAL AND PHARMACY (Repealed)

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580-9-46-.01 General Medical And Pharmacy.

(1) The agency must demonstrate that all medical care aspects of the program are performed or supervised by a physician licensed to practice in the State of Alabama.

(2) The agency must have written medical procedures which describe the steps for the management of medical emergencies.

(3) All residential programs must demonstrate their client's accessibility to a local licensed hospital for the purpose of providing emergency hospital care.

(4) All substance abuse treatment programs must provide for, or be able to refer, clients for physical and/or laboratory examinations when clinically appropriate in accordance with the supervising physician's written medical procedures. However, programs are not required to provide uncompensated medical care.

(5) For those situations where drug screening by urinalysis is deemed appropriate and necessary by the program director, or supervising physician, the program must:

(a) Establish procedures which protect against the falsification and/or contamination of any urine sample;

(b) Provide assurance that no client will be discharged from treatment solely on the basis of a single positive urine analysis (not applicable to substance abuse residential programs).

(6) The agency must, at all times, meet applicable federal and state requirements regarding the storing and/or dispensing of "prescription legend" and/or "controlled substance" drugs (including, but not limited to: Code of Ala. 1975, Section 34-23-94, Code of Ala. 1975, Section 20-2-1 through 20-2-93; Federal Controlled Substance Act of 1970; Indigent Drug Program Manual for Mental Health Centers, where applicable).

(7) Any agency storing bulk quantities of "controlled substance" or "prescription legend" drugs must document that one of the following Drug Enforcement Administration (DEA) registration procedures has been met:

(a) The supervising or consulting physician for the program has registered the facility as one of his offices with the DEA Registration Branch, or;

(b) The program itself has been registered with the DEA Registration Branch when there is more than one physician involved with the program.

(8) The agency must demonstrate accurate accounting/tracking procedures for all "controlled substance" and/or "prescription legend" drugs purchased/dispensed by the program. These procedures must additionally account for any client owned medication that is present in the facility. The following records must be kept on all such drugs received, and administered, or self-administered:

(a) A medication log/running inventory on which the following information is recorded:

1. Date on which drug(s) were placed in inventory;

2. Brand name/generic name;

3. Quantity/dosage of drug(s);

4. Date drug(s) were administered;

5. Initials/signature of nurse administering drug(s).

(b) A medication sheet for each individual client on which the following information is recorded each time drugs are administered:

1. Brand name/generic name;

2. Date/time drugs were administered;

3. Quantity/dosage;

4. Initials/signature of nurse administering drugs, or initial/signature of client when self medicating;

5. Client's name;

(c) Non-prescription medication allowed to be self-administered to a client in a substance abuse residential treatment program shall be recorded on the medication sheet.

(d) The agency must document that a reconciliation of the drug inventory, performed under the supervision of the program director or supervising physician, is performed according to the following:

1. At least semiannually;

2. Each time there is a change in the responsibilities among those individuals with designated access to the drug supplies.

(9) All "controlled substances" and/or "prescription legend" drugs kept in the facility must be stored in a locked cabinet or other substantially constructed storage that precludes surreptitious entry.

(10) All such storage units must be locked when not in use.

(11) Access to all "controlled substances" and/or prescription legend" drugs must be restricted to the absolute minimum number of employees needed to handle daily transactions of such drugs.

(12) A listing of those employees permitted access to the drugs will be on file at the agency. This listing should be displayed in the drug storage area.

(13) In the event of loss or the theft of controlled substances, the agency must perform the following:

(a) Notify local law enforcement personnel immediately upon the detection of the loss;

(b) Notify the supervising physician immediately upon the loss if the supervising or consulting physician has registered the program as one of his offices with the DEA Registration Branch;

(c) Notify the DEA Registration Branch directly if the program itself has been registered with the DEA Registration Branch;

(d) Notify the Director, Substance Abuse Services Division, Department of Mental Health within 24 hours of the detection of the loss;

(e) Provide a subsequent written description of the events and extent of the loss to the Director, Substance Abuse Services Division, Department of Mental Health. This written description must be mailed within 72 hours from loss detection.

(14) For residential services, there shall be a registered nurse or licensed practical nurse as a full-time or part-time employee or a consultant to the provider who is responsible for supervision of delegation of medication assistance to the unlicensed personnel. Access to an on-call nurse must be available 24 hours/day, 7 days/week. Providers will implement policies and procedures approved by their Boards of Directors requiring full compliance with the Alabama Board of Nursings regulation 610-X-6-.15 Alabama Department of Mental Health Residential Community Programs.

Author: Substance Abuse Services Division
Statutory Authority: Code of Ala. 1975, §22-50-11.
History: **New Filed:** July 22, 1992. **Extended:** September 30, 1992. **Extended:** December 31, 1992. **Certified:** March 30, 1993. **Effective:** May 5, 1993. **Amended:** Filed November 19, 2003; effective December 24, 2003. **Amended:** Filed September 5, 2007; effective October 10, 2007.

580-9-46-.02 Outpatient Detoxification.

(1) Supervised withdrawal from alcohol and drug intoxication in non-residential setting (client remains in usual living situation) using medication after medical evaluation and following physician approved guidelines.

(2) Any agency providing outpatient detoxification services must have written procedures that describe the protocols taken by the program to ensure the safe detoxification of any client assigned to this method of treatment.

(3) All outpatient detoxification programs must have 24-hour emergency services available, either on site or through an affiliated agreement.

(4) All detoxification programs must demonstrate by written agreement their client's accessibility to a local licensed hospital for the purpose of providing emergency hospital care.

(5) Detoxification programs will have psychosocial assessment and/or supportive services available and accessible to the client and family as soon as deemed clinically appropriate.
Author: Substance Abuse Services Division
Statutory Authority: Code of Ala. 1975, § 22-50-11.
History: New: Filed July 22, 1992. **Extended:** September 30, 1992. **Extended:** December 31, 1992. **Certified:** March 30, 1993. **Effective:** May 5, 1993.

580-9-46-.03 Residential Detoxification.

(1) Supervised withdrawal from alcohol and drug intoxication for an individual who can safely be treated outside an acute general hospital setting, using medication after medical evaluation and following physician approved guidelines, but who requires 24 hour a day supervision.

(2) Programs providing detoxification services must have coverage by a licensed physician trained in detoxification protocols and/or addiction medicine.

(3) Medical supervision of detoxification must be available twenty-four (24) hours a day, seven (7) days a week.

(4) Criteria for determining the need for detoxification with medication must be described in a written procedure approved by the physician. The procedures must include:

(a) Description of symptoms requiring medical detoxification.

(b) Continuous nursing assessment following admission to the program to determine if there are any changes in detoxification needs.

(5) All clients will be screened by a registered nurse upon admission and will be administered a physical examination by

a physician, physician's assistant or certified nurse practitioner within 24 hours of admission.

(6) The program must provide for physical and/or laboratory examination in accordance with the supervising physician's written medical procedures.

(7) There must be written protocols approved by the physician that describe care given during medical detoxification, including administration of medication, monitoring of vital signs, and emergency procedures.

(8) The licensed physician must be consulted prior to the initiation of medical detoxification.

(9) The program must provide and document clinical staff training in all detoxification protocols and emergency procedures.

(10) When detoxification procedures are initiated by phone order with the physician, these must be reviewed and signed by the physician within 24 hours of the initiation of detoxification.

(11) All programs providing detoxification must demonstrate by written document the client's accessibility to a local licensed hospital for the purpose of providing emergency hospital care.

(12) The program shall have transportation available on a 24 hour a day basis for emergency purposes.

(13) The program shall have a full time registered nurse on staff and on-call registered nurse accessibility at all times. Any time the registered nurse is not on site, an L.P.N. will be on site.

(14) The program shall have staff on duty and awake 24 hours a day.

(15) Detoxification programs will provide psychosocial assessment and/or support services to the client and family, when deemed clinically appropriate.

(16) All direct care staff employed in programs providing detoxification shall be provided basic education in methodology of detoxification treatment, the signs and symptoms of withdrawal, and approved intervention techniques.

Author: Substance Abuse Services Division

Statutory Authority: Code of Ala. 1975, §22-50-11.

History: New: Filed July 22, 1992. **Extended:** September 30, 1992. **Extended:** December 31, 1992. **Certified:** March 30, 1993. **Effective:** May 5, 1993.

580-9-46-.04 Reserved.

580-9-46-.05 Reserved.

580-9-46-.06 Reserved.

580-9-46-.07 Reserved.