

APA-1
6/93

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-15
Rule Title: Telehealth
 New Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? YES

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

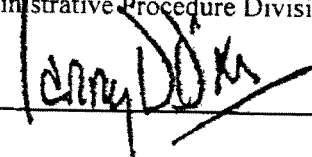
Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed 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  **REC'D & FILED**
Date: April 17, 2013 APR 17 2013

APA-2
6/93

**ALABAMA STATE BOARD
OF MEDICAL EXAMINERS**

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X-15, Telehealth

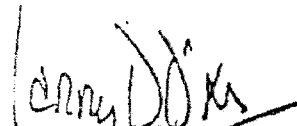
INTENDED ACTION: To add a new Chapter

SUBSTANCE OF PROPOSED ACTION: To add a new Chapter of Rules providing guidelines and standards for the provision of telehealth medical services

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: Patricia E. Shaner, General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including June 4, 2013. Persons wishing to obtain copies of the text of this rule and submit data, views, or comments or arguments orally should contact Patricia E. Shaner, by telephone (334-242-4116) during said period in order to set up an appointment for a hearing respecting such oral data, views, or arguments. Copies of the proposed rules may also be downloaded from the Board's web site, www.albme.org (see "What's New").

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: June 4, 2013

CONTACT PERSON AT AGENCY: Patricia E. Shaner, Office of General Counsel, 334-242-4116; PO Box 946, Montgomery, AL 36101-0946; 848 Washington Avenue, Montgomery, AL 36104



Larry D. Dixon, Executive Director

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

CHAPTER 540-X-15
TELEHEALTH

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540-X-15-.01 Purpose.

(1) This Chapter is promulgated to establish standards for the provision of telehealth medical services for medical practices regulated by the Alabama Board of Medical Examiners.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11,

2013.

540-X-15-.02 Telehealth Medical Services by Physicians According to Licensure Status.

(1) For the provision of telehealth medical services by an MD or DO, the following applies:

(a) Physicians who are issued certificates of qualification by the Alabama Board of Medical Examiners and who are licensed to practice medicine by the Medical Licensure Commission of Alabama pursuant to Ala. Code §§ 34-24-70 and 34-24-311 (full certificates of qualification and licenses), Rules 540-X-15-.05 through .14 apply;

(b) Physicians who are issued certificates of qualification by the Alabama Board of Medical Examiners and who are issued special purpose licenses to practice medicine or osteopathy across state lines by the Medical Licensure Commission of Alabama pursuant to Ala. Code §34-24-502 (special purpose licenses), Rule 540-X-15-.15 applies;

(c) Physicians who are issued certificates of qualification without examination by the Alabama Board of Medical Examiners and who are licensed to practice medicine without examination by the Medical Licensure Commission of Alabama pursuant to Ala. Code § 24-24-75(a) ("limited" license, Teaching Physicians), Rules 540-X-15-.16(1), (2) and (3) apply;

(d) Physicians who are issued certificates of qualification without examination by the Alabama Board of Medical Examiners and who are licensed to practice medicine without examination by the Medical Licensure Commission of Alabama pursuant to Ala. Code § 34-24-75(c) ("limited" license, Residents), Rules 540-X-15-.16(1), (2) and(4)

apply; and

(e) Physicians who are issued certificates of qualification without examination by the Alabama Board of Medical Examiners and who are licensed to practice medicine without examination by the Medical Licensure Commission of Alabama pursuant to Ala. Code § 34-24-75(b) ("limited" license, physicians at state penal and mental institutions), Rules 540-X-15-.16(1), (2) and (5) apply.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/approved: April 11, 2013.

540-X-15-.03 Scope of Practice of Non-Physician Healthcare Practitioners.

(1) The scope of practice for a physician assistant is determined pursuant to Ala. Code §§ 34-24-290 through 306 and the Rules of the Alabama Board of Medical Examiners.

(2) The scope of practice of a CRNP or a CNM is determined pursuant to Ala. Code §§ 34-21-80 through 93, the Rules of the Alabama Board of Medical Examiners and the Rules of the Alabama Board of Nursing

(3) Nothing in these rules shall be interpreted to limit the scope of practice of a healthcare practitioner who is practicing pursuant to a license issued by a state licensing board or authority and who is practicing within the scope of such license.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.04 Exemptions. Telehealth home care services prescribed by a

provider, as defined in these rules, and delivered by a licensed home care agency are exempt from these rules.

540-X-15-.05 Definitions. The following words and terms, when used in this Chapter, shall have the following meanings unless context indicates otherwise.

- (1) Provider.
 - (a) Medical Doctor (M. D.) or Doctor of Osteopathy (D. O.).
 - (b) A Physician Assistant (P. A.), Certified Registered Nurse Practitioner (CRNP), or Certified Nurse Midwife (CNM) in a supervisory or collaborative relationship with an M. D. or D. O.
- (2) Distant site provider. A medical doctor, doctor of osteopathy, Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife who uses telehealth to provide healthcare services to a patient in Alabama. A distant site provider must have a current and unrestricted Alabama license.
- (3) Established medical site. A location where a patient would present to seek medical care, where there is a patient site presenter, and where there are sufficient technology and medical equipment to allow for an adequate physical evaluation which is appropriate for the patient's presenting complaint. A defined provider-patient relationship is required. A patient's private home is not considered an established medical site, except for emergent conditions.
- (4) Face-to-face visit. An evaluation performed on a patient where the provider and patient are both at the same physical location, or where the patient is at an established medical site.
- (5) In-person evaluation. A patient evaluation conducted by a provider who is

at the same physical location as the location of the patient.

(6) Patient site location. The site where the patient is physically located.

(7) Patient site presenter. The individual at the patient site location who introduces the patient to the distant site provider for examination and to whom the distant site provider may delegate tasks and activities. A patient site presenter must be:

(a) Licensed or certified in the state of Alabama to perform healthcare services; and

(b) Delegated only tasks and activities within the scope of the individual's licensure or certification.

(8) Person. An individual unless otherwise expressly made applicable to a partnership, association or corporation.

(9) Provider-patient messaging. An interactive communication via a secure interactive electronic text messaging system between a provider (or medical staff member) and a patient within a professional relationship in which the provider has taken on an explicit measure of responsibility for the patient's care.

(10) Telehealth medical service. The practice of medical care delivery initiated by a distant site provider who is physically located at a site other than the site where the patient is located, for the purposes of evaluation, diagnosis, consultation or treatment which requires the use of appropriate telecommunication technology.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.06 Telehealth Medical Services.

(1) A provider who uses telehealth medical services in his or her medical practice shall adopt protocols to prevent fraud and abuse through the use of telehealth medical services.

(2) In order to establish that a provider has made a good faith effort in the provider's practice to prevent fraud and abuse through the use of telehealth medical services, the provider must implement written protocols which address the following:

- (a) Authentication and authorization of users;
- (b) Authentication of the origin of information;
- (c) The prevention of unauthorized access to the system or information;
- (d) System security, including the integrity of health information which is collected, program integrity, and system integrity;
- (e) Maintenance of documentation concerning system and information usage;
- (f) Information storage, maintenance and transmission; and
- (g) Synchronization and verification of patient profile data.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.07 Notice to Patients.

- (1) Privacy practices.
 - (a) A provider who communicates with a patient by electronic communication other than telephone, facsimile or text must provide the patient with written notification of the provider's privacy practices prior to evaluation or treatment. In addition, a good faith effort must be made to obtain the patient's written acknowledgment, including by

provider-patient messaging, of the notice.

(b) The notice of privacy practices shall include language which is consistent with federal standards under 45 CFR Parts 160 and 164 relating to privacy of individually identifiable health information.

(2) Limitations of telehealth. A provider who uses telehealth medical services must, prior to providing services, give patients notice regarding telehealth medical services, unless the patient is unconscious or otherwise incapable of consenting, and harm from failure to treat is imminent. The notice must include the following: the risks and benefits of being treated pursuant to telehealth; how to receive follow-up care or assistance in the event of an adverse reaction to the treatment; and how to receive follow-up care or assistance in the event of an inability to communicate as a result of a technological or equipment failure. A signed and dated notice, including an electronic acknowledgment, by the patient establishes a presumption of notice.

(3) Necessity of in-person evaluation. When, for any reason, the telehealth modality in use for a particular patient encounter is unable to provide all pertinent clinical information which a healthcare provider exercising ordinary skill and care would deem reasonably necessary for the practice of medicine at an acceptable level of safety and quality in the context of that particular medical encounter, then the distant site provider must make this known to the patient prior to the conclusion of the live telehealth encounter. The distant site provider must advise and counsel the patient, prior to the conclusion of the live telehealth encounter, regarding the need for the patient to obtain an additional, in-person medical evaluation reasonably able to meet the patient's needs.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.08 Telehealth Medical Services Provided at an Established Medical Site.

(1) Telehealth medical services provided at an established medical site may be used for all patient visits, including initial evaluations to establish a proper provider-patient relationship between a distant site provider and a patient.

(2) For new conditions, a patient site presenter must be reasonably available on site at the established medical site to assist with the provision of care. The distant site provider has discretion to determine if a patient site presenter is necessary for follow-up evaluation or treatment of a previously diagnosed condition.

(a) A distant site provider may delegate tasks and activities to a patient site presenter during a patient encounter.

(b) A distant site provider delegating tasks to a patient site presenter shall ensure that the patient site presenter to whom delegation is made is properly trained and supervised or directed.

(3) If the only services provided are related to mental health, a patient site presenter is not required except in cases where the patient may be a danger to himself/herself or others.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.09 Telehealth Medical Services Provided at a Site Other than an Established Medical Site.

(1) A distant site provider who provides telehealth medical services at a site other than an established medical site for a patient's previously diagnosed condition must either:

(a) See the patient one time in a face-to-face visit before providing telehealth medical care; or

(b) See the patient without an initial face-to-face visit, provided the patient has received an in-person evaluation by another provider who has referred the patient for additional care, and the referral is documented in the medical record.

(2) A patient site presenter is not required for a pre-existing condition previously diagnosed by a provider through a face-to-face visit.

(3) If the only services provided are related to mental health, a patient site presenter is not required except in cases where the patient may be a danger to himself/herself or others.

(4) Each patient must be seen for an in-person evaluation at least once a year.

(5) Telehealth medical services may not be used to treat non-malignant pain with scheduled drugs, with the exception of patients who are enrolled in a qualified multidisciplinary hospice or a palliative care program.

(6) A distant site provider may treat an established patient's new symptoms which are unrelated to the patient's pre-existing condition, provided that the patient is advised to see a provider in a face-to-face visit within 72 hours. A distant site provider

may not provide continuing telehealth medical services for these new symptoms to a patient who is not seen by a provider in a face-to-face visit within 72 hours.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.10 Evaluation and Treatment of the Patient.

(1) Evaluation of the patient. A distant site provider who utilizes telehealth medical services must ensure that a proper provider-patient relationship is established.

At a minimum, this provider-patient relationship includes the following:

(a) Establishing that the person requesting the treatment is in fact the person he/she claims to be;

(b) Establishing a diagnosis through the use of acceptable medical practices, including patient history, an appropriate physical examination, and indicated diagnostic studies;

(c) Discussing with the patient the diagnosis, the evidence for it, and the risks and benefits of various treatment options; and

(d) Ensuring the availability of appropriate coverage of the patient for follow-up care.

(2) Treatment. Treatment and consultation recommendations made in a telemedicine setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate medical practice applied to traditional in-person clinical settings.

(3) An online or telephonic evaluation solely by questionnaire does not

constitute an acceptable standard of care.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.11 Technology and Security Requirements.

(1) Appropriate communication technology must be used for all patient evaluation and treatment conducted via telehealth.

(2) Adequate security measures must be implemented to ensure that all patient communications, recordings and records remain confidential.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.12 Medical Records for Telehealth Medical Services.

For all telehealth medical services, the distant site provider must maintain medical records in HIPAA compliant (45 CFR Parts 160 and 164) electronic health record format. This provision will become effective 36 months from the effective date of these rules.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.13 On Call Services. Physicians who are of the same specialty and provide reciprocal services, may provide on call telehealth medical services for each others' active patients.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.14 State Licensure. Distant site providers who treat and prescribe through telehealth services are practicing medicine and must comply with all applicable laws and rules in all jurisdictions where their patients reside or seek medical care.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.15 Special Purpose Licenses to Practice Medicine or Osteopathy Across State Lines.

(1) This rule is promulgated to establish standards for the provision of telehealth medical services by physicians who are issued certificates of qualification by the Alabama Board of Medical Examiners and who are issued special purpose licenses to practice medicine or osteopathy across state lines by the Medical Licensure Commission of Alabama, pursuant to Ala. Code § 34-24-502.

(2) The telehealth rules and standards governing full certificates of qualification and licenses found in Board Rules 540-X-15-.05 through .14 are applicable to special purpose licensees except where they conflict with Ala. Code §§ 34-24-500 through 34-24-508; Commission Rules, Chapter 545-X-6; Board Rules, Chapter 540-X-16; and this rule. In the event of a conflict, Ala. Code §§ 34-24-500 through 34-24-508; Commission Rules, Chapter 545-X-6; Board Rules, Chapter 540-X-16; and this rule are controlling.

(3) A special purpose licensee is prohibited from entering into a collaborative

practice with a Certified Registered Nurse Practitioner or a Certified Nurse Midwife and is prohibited from acting as a covering physician in a collaborative practice.

(4) A special purpose licensee is prohibited from supervising a Physician Assistant either as the physician to whom a Physician Assistant is registered or as a covering physician.

(5) A special purpose licensee is prohibited from utilizing a Certified Registered Nurse Practitioner, a Certified Nurse Midwife, or a Physician Assistant as a patient site presenter.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.

540-X-15-.16 Certificates of Qualification and Licenses Issued without Examination: "Limited" Certificates of Qualification and Licenses for Teaching Physicians, Residents, and Physicians at State Penal and Mental Institutions.

(1) This rule is promulgated to establish standards for the provision of telehealth medical services by physicians who are issued certificates of qualification without examination by the Alabama Board of Medical Examiners ("limited" certificates of qualification) and who are issued licenses without examination by the Medical Licensure Commission of Alabama ("limited" licenses) pursuant to Ala. Code § 34-24-75(a), (b) and (c).

(2) The telehealth rules and standards governing full certificates of qualification and licenses found in Board 540-X-15-.05 through .14 are applicable to "limited" licensees except where they conflict with Ala. Code § 34-24-75; Board Rules

540-X-3-.15 through 540-X-3-.17; any Medical Licensure Commission rule applicable to “limited” licenses; and this rule. In the event of a conflict, Ala. Code § 34-24-75; Board Rules 540-X-3-.15 through 540-X-3-.17; Medical Licensure Commission rules applicable to “limited” licenses; and this rule are controlling.

(3) Teaching Physicians.

(a) A full-time employed physician teaching in a medical college in Alabama who holds a certificate of qualification and license pursuant to Ala. Code § 34-24-75(a) (“limited” license) must limit his or her medical practice to the confines of the medical center of which the medical college is a part, and as an adjunct to his or her teaching functions in that college.

(b) The Teaching Physician may include in his or her medical practice the provision of telehealth services which are external to the medical college; provided that the telehealth services are rendered from the medical college and are rendered as an adjunct to the physician’s teaching functions at that school.

(4) Residents.

(a) A physician enrolled in a residency training program approved by the Board (Resident) who holds a certificate of qualification and license pursuant to Ala. Code § 34-24-75(c) (“limited” license) must limit his or her medical practice to the confines of the institution in which he or she is placed pursuant to his or her training program.

(b) The Resident may include in his or her medical practice the provision of telehealth services which are external to the training program institution, provided that the telehealth services are rendered from the training program institution and are

rendered pursuant to his or her training program.

(5) Physicians at state penal and mental institutions.

(a) A physician employed full-time at a state penal or mental institution who holds a certificate of qualification and license issued pursuant to Ala. Code § 34-24-75(b) ("limited" license) must limit his or her medical practice to the confines of the institution in which he or she is employed.

(b) The limited license physician who provides medical services for state mental institutions may include in his or her medical practice the provision of telehealth medical services; provided that the telehealth services are rendered to patients served in facilities owned and operated by the Alabama Department of Mental Health or patients served by regional mental health programs and facilities created pursuant to Ala. Code §§ 22-51-1 through 22-51-14 (Act 310 corporations).

(c) A limited license physician who provides medical services for a state penal institution may include in his or her medical practice the provision of telehealth services, provided that the telehealth services are rendered to patients incarcerated in Alabama Department of Corrections facilities.

(d) A physician employed full-time at a state penal or mental institution who holds a certificate of qualification and license issued pursuant to Ala. Code § 34-24-75(b) ("limited" license) is prohibited from providing telehealth services to patients in Alabama from a location outside of the state of Alabama.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 34-24-53 and 34-24-508

History: Adopted/Approved: January 16, 2013. Amended/Approved: April 11, 2013.