Alabama Rules and Laws - Use of Controlled Substances for Weight Reduction

Alabama State Board of Medical Examiners

INTRODUCTION

Alabama physicians utilizing controlled substances for the treatment of patients with obesity or for weight reduction are required to do so in compliance with all Board rules and state and federal laws. Here we will discuss the applicable Board rules and state laws affecting these practices.

In January 2012, the Alabama State Board of Medical Examiners promulgated rules regulating the use by physicians of controlled substances for the treatment of obesity or for the purpose of weight reduction.

In 2017, rules were adopted requiring physicians to utilize medically appropriate risk and abuse mitigation strategies when prescribing controlled substances.

The Board also has rules concerning prescribing medications for patients whom the physician has not personally examined and rules describing the requirements for medical records management.

Lastly, the Alabama Legislature in 2022 enacted laws regulating the practice of telemedicine.

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GUIDELINES AND STANDARDS FOR THE UTILIZATION OF CONTROLLED SUBSTANCES FOR WEIGHT REDUCTION (ALA. ADMIN. CODE R. 540-X-17)

540-X-17-.01 Preamble.

(1) The purpose of these rules is to provide guidelines, and in some instances standards, for licensed medical doctors (M.D.s) and doctors of osteopathy (D.O.s) who determine that the use of a controlled substance as an adjunct for a weight reduction regimen is medically appropriate for a patient.

(2) The Board of Medical Examiners is obligated under the laws of the state of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including those used for the purpose of weight reduction, may lead to drug diversion and abuse by individuals who seek drugs for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(3) Prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity should be based on accepted scientific knowledge and sound clinical grounds. All such prescribing and dispensing should be in compliance with applicable state and federal law.

(4) Each case of prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines and standards, if good cause is shown for such deviation. Whether the drug used is medically and/or pharmacologically recognized to be appropriate for the patient's individual needs will be considered by the Board in evaluating individual cases. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation.

540-X-17-.02 Schedule II Controlled Substances. A physician shall not order, prescribe, dispense, supply, administer or otherwise distribute any Schedule II amphetamine or Schedule II amphetamine-like anorectic drug, or Schedule II sympathomimetic amine drug or compound thereof or any salt, compound, isomer, derivative or preparation of the foregoing which is chemically equivalent thereto or other non-narcotic Schedule II stimulant drug, which drugs or compounds are classified under Schedule II of the Alabama Uniform Controlled Substances Act, to any person for the purpose of weight control, weight loss, weight reduction or treatment of obesity.

540-X-17-.03 Schedule III, IV and V Controlled Substances.

(1) Only a doctor of medicine or doctor of osteopathy licensed by the Medical Licensure Commission of Alabama may order, prescribe, dispense, supply, administer or otherwise distribute a controlled substance in Schedule III, IV or V to a person for the purpose of weight control, weight loss, weight reduction, or treatment of obesity, except that a Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife may prescribe non-controlled drugs for such purpose. If a Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife prescribes non-controlled drugs for weight reduction or the treatment of obesity, the prescriber shall comply with the guidelines and standards of this Chapter which apply to M.D.s and D.O.s.

(2) A written prescription or a written order for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity shall be signed by the prescribing physician on the date the medication is to be dispensed or the prescription is provided to the patient. If an electronic prescription is issued for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity, the prescribing physician must sign and authorize the transmission of the electronic controlled substance prescription in accordance with federal law and must comply with all applicable requirements for Electronic Prescriptions for Controlled Substances (See 21 CFR Parts 1300, 1304, 1306 and 1311, as amended effective June 1, 2010). Such prescriptions or orders shall not be called in to a pharmacy by the physician or an agent of the physician.

(3) The prescribing/ordering physician shall be present at the facility when he or she prescribes, orders or dispenses a controlled substance for a patient for the purpose of weight reduction or treatment of obesity.

540-X-17-.04 Initial Requirements.

(1) Before initiating treatment for weight reduction or obesity utilizing any Schedule III, IV or V controlled substance, a physician should comply with the following:

(a) An initial evaluation of the patient should be conducted by and recorded by the prescribing physician prior to the prescribing, ordering, dispensing or administering of any drug. Such evaluation should include an appropriate physical and complete history; appropriate tests related to medical treatment for weight reduction; and appropriate medical referrals as indicated by the physical, history, and testing; all in accordance with general medical standards of care. Relative contraindications to the use of anorectic drugs should be addressed prior to prescribing or dispensing these medications.

(b) The patient should have a Body Mass Index (BMI) of 30 or above, or a BMI of greater than 25 with at least one comorbidity factor, or a measurable body fat content equal to or greater than 25% of total body weight for male patients or 30% of body weight for female patients, or an abdominal girth of at least 40 inches for male patients or an abdominal girth of at least 35 inches for female patients. BMI is calculated by use of the formula BMI=kg/m2.

(c) The prescribing physician should assess and document the patient's freedom from signs of drug or alcohol abuse and the presence or absence of contraindications and adverse side effects.

540-X-17-.05 Continued Use of a Controlled Substance for the Purpose of Weight Reduction or Treatment of Obesity.

(1) A physician should not prescribe, order or dispense a controlled substance for the purpose of weight reduction or treatment of obesity in an amount greater than a thirty-five (35) day supply.

(2) Within the first thirty-five (35) days following initiation of a controlled substance for the purpose of weight reduction or treatment of obesity, the patient should be seen by the prescribing physician, a physician assistant supervised by the prescribing physician, or a certified registered nurse practitioner collaborating with the prescribing physician, and a recording should be made of weight, blood pressure, pulse, and any other tests which may be necessary for monitoring potential adverse effects of drug therapy.

(3) Continuation of the prescribing, ordering, dispensing or administering of a controlled substance to a patient for the purpose of weight reduction or treatment of obesity should occur only if the patient has continued progress toward achieving or maintaining medically established goals and has no significant adverse effects from the medication.

(4) A patient continued on a controlled substance for the purpose of weight reduction or treatment of obesity should undergo an in-person re-evaluation at least once every thirty-five (35) days. Once medically established goals have been met for an individual patient, it is strongly recommended that reduced dosing and drug holidays be implemented for those patients who need maintenance medication.

(5) If the re-evaluation is delegated to a physician assistant or certified registered nurse practitioner, then the prescribing physician should personally review the resulting medical records prior to the continuance of the patient on a controlled substance for the purpose of weight reduction or treatment of obesity.

(6) For the prescribing of only non-controlled drugs for weight reduction or the treatment of obesity, the following applies:

(a) Five (5) refills of non-controlled drugs for weight reduction or the treatment of obesity are allowed after an initial prescription and one follow up visit for an in-person re-evaluation. The five (5) refills shall not extend past a period of six (6) months from the date of issue of the original prescription.

(b) Continued prescribing/refills of non-controlled drugs for weight reduction or the treatment of obesity must occur in accordance with any Risk Evaluation and Mitigation Strategy (REMS) required by the Federal Food and Drug Administration (FDA).

(c) Refills allowed pursuant to this rule are specific for non-controlled drugs for weight reduction or the treatment of obesity. This rule in no way amends, alters, or applies to the refilling of individual prescriptions for controlled substances.

540-X-17-.06 Medical Records.

(1) Every physician who prescribes, orders, dispenses or administers a controlled substance to a patient for the purpose of weight reduction or treatment of obesity should maintain medical records in compliance with the provisions of this Chapter and Medical Licensure Commission Rule 545-X-4-.09, Minimum Standards for Medical Records.

(2) The treatment of obesity should be based on evidence based medicine1.The Board considers the promotion and use for weight reduction of controlled and non-controlled substances which have not been scientifically validated to be of questionable benefit (e.g., HCG, etc.). The promotion and use of these substances is under scrutiny by the Board for possible sanctions for non-legitimate medical use violations. Adequate medical documentation should be kept so that progress as well as the success or failure of any modality is easily ascertained.

(3) At a minimum, every thirty-five (35) days when a controlled substance is being provided to a patient for the purpose of weight reduction or treatment of obesity, the physician or PA or CRNP should record in the patient record, information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

540-X-17-.07 Conditions Warranting Discontinuance of a Controlled Substance.

(1) A physician should not initiate or should discontinue utilizing a controlled substance for the purpose of weight reduction or treatment of obesity of a patient immediately upon ascertaining or having reason to believe:

(a) That the patient has failed to progress toward medically established goals while under treatment with the controlled substance over a period of seventy (70) days, which determination should be made by assessing the patient with regard to previously established goals at least every thirty-five (35) days.

(b) That the patient has developed tolerance to the anorectic effects of the controlled substance being utilized.

(c) That the patient has a history of or shows a propensity for alcohol or drug abuse or has made any false or misleading statement to the physician or PA or CRNP relating to the patient's use of drugs or alcohol.

(d) That the patient has consumed or disposed of a controlled substance other than in compliance with the treating physician's directions.

(e) That the patient has repeatedly failed to comply with the physician's treatment recommendations.

(f) That the patient is pregnant.

RISK AND ABUSE MITIGATION STRATEGIES (ALA. ADMIN. CODE R. 540-X-4-.09)

(1) The Board recognizes that all controlled substances, including but not limited to, opiates, benzodiazepines, stimulants, anticonvulsants, and sedative hypnotics, have a risk of addiction, misuse, and diversion. It is the opinion of the Board that the best practice when prescribing controlled substances shall include medically appropriate risk and abuse mitigation strategies, which will vary from patient to patient. Additional care should be used by practitioners when prescribing medication to a patient from multiple controlled substance drug classes.

(2) Every practitioner shall provide his or her patient with risk education prior to initiating controlled substances therapy and prior to continuing the controlled substances therapy initiated by another practitioner.

(3) Every practitioner shall utilize medically appropriate risk and abuse mitigation strategies when prescribing controlled substances. Examples of risk and abuse mitigation strategies include, but are not limited to:

(a) Pill counts;

(b) Urine drug screening;

(c) PDMP checks;

(d) Consideration of abuse-deterrent medications;

(e) Monitoring the patient for aberrant behavior;

(f) Using validated risk-assessment tools, examples of which shall be maintained by the Board; and

(g) Co-prescribing naloxone to patients receiving opioid prescriptions when determined to be appropriate in the clinical judgment of the treating practitioner.

(4) The Board recognizes that the best available research demonstrates that the risk of adverse events occurring in patients who use controlled substances to treat pain increases as dosage increases. The Board adopts the "Morphine Milligram Equivalency" ("MME") daily standard as set out by the Centers for Disease Control and Prevention ("CDC") for calculating the morphine equivalence of opioid dosages. The Board further adopts the “Lorazepam Milligram Equivalency” (“LME”) daily standard for calculating sedative dosing when using the Alabama Prescription Drug Monitoring Program.

(5) For the purpose of preventing controlled substance diversion, abuse, misuse, addiction, and doctor-shopping, the Board sets forth the following requirements for the use of Alabama's Prescription Drug Monitoring Program (PDMP):

(a) For controlled substance prescriptions totaling less than 30 MME or 3 LME per day, physicians are expected to use the PDMP in a manner consistent with good clinical practice.

(b) When prescribing to a patient controlled substances of more than 30 MME or 3 LME per day, physicians shall review that patient's prescribing history through the PDMP at least two (2) times per year, and each physician is responsible for documenting the use of risk and abuse mitigation strategies in the patient's medical record.

(c) Physicians shall query the PDMP to review a patient's prescribing history every time a prescription for more than 90 MME or 5 LME per day is written, on the same day the prescription is written.

(6) Exemptions: The Board's PDMP requirements do not apply to physicians writing controlled substance prescriptions for:

(a) Nursing home patients;

(b) Hospice patients, where the prescription indicates hospice on the physical prescription;

(c) When treating a patient for active, malignant pain; or

(d) Intra-operative patient care.

(7) Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, physicians should reconsider a patient's existing benzodiazepine prescriptions or decline to add one when prescribing an opioid and consider alternative forms of treatment.

(8) Effective January 1, 2018, each holder of an Alabama Controlled Substances Certificate (ACSC) shall acquire two (2) credits of AMA PRA Category 1™ continuing medical education (CME) in controlled substance prescribing every two (2) years as part of the licensee's yearly CME requirement. The controlled substance prescribing education shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.

(9) A violation of this rule is grounds for the assessment of a fine and for the suspension, restriction, or revocation of a physician's Alabama Controlled Substances Certificate or license to practice medicine.

CONTACT W/ PATIENTS BEFORE PRESCRIBING (ALA. ADMIN. CODE R. 540-X-9-.11)

(1) It is the position of the Board that prescribing drugs to an individual the prescriber has not personally examined is usually inappropriate. Before prescribing a drug, a physician should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the physician personally perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription. This process must be documented appropriately.

(2) Prescribing for a patient whom the physician has not personally examined may be suitable under certain circumstances. These may include, but not be limited to, admission orders for a patient newly admitted to a health care facility, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment. Established patients may not require a new history and physical examination for each new prescription, depending on good medical practice.

MEDICAL RECORDS MANAGEMENT (ALA. ADMIN. CODE R. 540-X-9-.10)

(1) Definitions.

(a) ACTIVE PATIENTS. Active patients are any patients treated by the physician one or more times during the immediately preceding thirty-six (36) months.

(b) NOTIFICATION. Notification shall be conducted by US Mail in a form letter to the active patients at their last known address or an electronic message sent via a HIPAA compliant electronic record system or HIPAA-compliant electronic health record system that provides a means of electronic communication to the patient and is capable of sending the patient a notification that a message is in the patient's portal.

(c) PERSONAL REPRESENTATIVE. The executor, administrator, or such other person as may be authorized under Title 43 to act as a fiduciary and to settle and distribute the estate of a decedent. The trustee of a trust established as a substantial part of the estate plan of a deceased physician or any other person having legal control over the medical records of the patients of a deceased physician shall also be responsible for compliance with these rules in the same manner as a personal representative.

(2) General Guidelines.

(a) Medical records serve important patient interests for present health care and future needs, as well as for insurance, employment, and other purposes. Medical records management encompasses not only managing the records of current patients, but also retaining old records against possible future need, and providing copies or transferring records to a third party as requested by the patient or the patient's authorized representative when the physician leaves a practice, sells his or her practice, retires, or dies. Medical records should be maintained by the treating physician for such period as may be necessary to treat the patient, in compliance with these rules, and for such additional time as may be indicated for medical and legal purposes.

(b) Access. On a legally compliant request of a patient or a patient's legal representative, a physician or his or her practice shall provide a copy of the medical record to the patient or to another physician, attorney, or other person designated by the patient or the patient's legal representative. A patient or his or her legal representative may authorize a physician or his or her practice, at the physician's or practice's discretion, to provide a copy of a specific portion or a summary of the medical record when the medical record is in non-electronic form and the patient or his or her legal representative knowingly waives his or her right to a copy of the full record. The cost of reproduction shall not exceed what is authorized under state and federal law. Records subpoenaed by the State Board of Medical Examiners are exempt from this subsection. Physicians charging for the cost of reproduction of medical

records should give primary consideration to the ethical and professional duties owed to other physicians and their patients and waive copying charges when appropriate.

(c) Retention of Medical Records. Medical records shall be retained for a period of not less than seven (7) years from the physician's (and/or other providers within his or her practice) last professional contact with the patient except for the following:

1. Immunization records which have not been transmitted to the immunization registry maintained by the State Board of Health shall be retained for a period of not less than two (2) years after the minor reaches the age of majority or seven (7) years from the date of the physician's (and/or other providers within his or her practice) last professional contact with the patient, whichever is longer.

2. X-rays, radiographs, and other imaging products shall be retained for at least five (5) years after which if there exist separate interpretive records thereof, they may be destroyed. However, mammography imaging and reports shall be maintained for ten (10) years.

3. Medical records of minors shall be retained for a period of not less than two (2) years after the minor reaches the age of majority or seven (7) years from the date of the physician's (and/or other providers within his or her practice) last professional contact with the patient, whichever is longer.

4. Notwithstanding the foregoing, no medical record involving services which are under dispute shall be destroyed until the dispute is resolved, so long as the physician has formal notice of the dispute prior to the expiration of the retention requirement.

(d) Destruction of Medical Records.

1. No medical record shall be singled out for destruction other than in accordance with the established office operating procedures.

2. Records shall be destroyed only in the ordinary course of business according to established office operating procedures that are consistent with these rules and state and federal privacy requirements.

3. Records may be destroyed by burning, shredding, permanently deleting, or other effective methods in keeping with the confidential nature of the records.

4. When records are destroyed, the time, date and circumstances of the destruction shall be recorded and maintained for not less than four (4) years. The record of destruction need not list the individual patient medical records that were destroyed but shall be sufficient to identify which group of destroyed records contained a particular patient's medical records.

(e) Retention and Access by Physicians Practicing Telemedicine. Physicians who practice medicine via telemedicine have the same duty as all other physicians to adhere to

these rules relating to medical records. Physicians who provide care via telemedicine must retain access to the medical records which document their delivery of health care services via telemedicine. A physician who is unable to access and produce the medical records documenting his or her practice of medicine via telemedicine upon demand for inspection or review by the Board of Medical Examiners or Medical Licensure Commission shall be in violation of Ala. Code §§ 34-24-360(2) and (23).

(3) Minimum Requirements for Patient Notification. The retirement, death, license suspension or revocation, and the departure of a physician from a practice group all create conditions under which patients must be notified of the triggering event. At a minimum, the notification to patients shall identify the physician who treated the patient, the general reason for the patient to be notified, an explanation of how the patient may obtain his or her medical records, a HIPAA authorization for the patient to complete, how long the medical records will be made available to the patient, and the intended disposition of the medical records if no instructions are received within the time provided.

(4) Disposition of Patient Medical Records. All physicians shall plan for the disposition of patient medical records in accordance with this rule.

(a) Disposition of Patient Medical Records upon Physician's Death. When a physician dies while in active medical practice, notification shall be sent by the physician's practice if in a group practice within thirty (30) days following the death of the physician. If the physician is not a member of a group practice, the notice shall be sent by the personal representative of the physician's estate within thirty (30) days of appointment of an executor or administrator by the probate court to all his or her active patients. The notification to active patients shall contain a HIPAA-compliant form for the patient to sign to authorize copies of the patient's records be sent to a new physician, the patient, or the patient's representative, and shall include clear directions to the patient for submission of the form to effectuate the timely transfer of records. The party sending the notice shall bear the costs of notifying the physician's patients.

1. For physicians who are in solo practice, the physician should include compliance with these rules as part of his or her estate planning.

2. In addition to the notice requirement stated above, the personal representative of a physician's estate should take reasonable steps for all medical records to be transferred either to the custody of another physician or to a HIPAA-compliant entity that agrees in writing to act as custodian of the records. Medical records shall be maintained in custody in their original or legally reproduced form for the retention periods specified above, during which time the personal representative shall make the medical records available for transfer to the deceased physician's active patients. After the expiration of the retention period, the personal representative may dispose of or destroy the medical records in compliance with state and federal law.

(b) Disposition of Medical Records upon Physician's Retirement. When a physician retires, it is his or her, if in solo practice, or his/her group practice's responsibility to send notification of retirement not less than thirty (30) days prior to retirement to all active patients. The physician must take reasonable steps for all medical records to be transferred to the custody of his or her active patients, to another physician, or to a HIPAA-compliant entity that agrees in writing to act as custodian of the records. Medical records shall be maintained in custody in their original or legally reproduced form in compliance with the retention periods set forth in (2)(c). The notification to active patients shall contain a HIPAA-compliant form for the patient to sign to authorize copies of the patient's records to be sent to a new physician, the patient, or the patient's representative, and shall include clear directions to the patient for submission of the form to effectuate the timely transfer of records.

(c) Disposition of Medical Records upon Physician's License Suspension or Revocation. When a physician's medical license is suspended or revoked, the physician or his or her practice shall send notification of the suspension or revocation within thirty (30) days of the suspension or revocation to all active patients. The cost of sending the patient notifications shall be borne by the physician whose license is suspended or revoked. The notification must contain a copy of the Medical Licensure Commission's Order of Suspension or Revocation. The physician must take reasonable steps for all medical records to be transferred either to the custody of the physician's active patients, to another physician, a physician practice group, or to a HIPAA-compliant entity that agrees in writing to act as custodian of the records. Medical records shall be maintained in custody in their original or legally reproduced form in compliance with the retention periods set forth in (2)(c). The notification to active patients shall contain a HIPAA-compliant form for the patient to sign in order to authorize copies of the patient's records to be sent to a new physician, the patient, or the patient's representative, and shall include clear directions to the patient for submission of the form to effectuate the timely transfer of records.

(d) Disposition of Medical Records upon Departure from the Group. The responsibility for notifying patients and paying for the cost of the notification of a physician who leaves a group practice but continues to practice medicine shall be governed by the physician's employment contract with the group practice. If no contractual provision exists pertaining to medical records upon departure, and the group does not elect to notify the patients, then the departing physician shall be responsible for notifying all active patients and be responsible for the cost of such notification. Absent a contractual provision to the contrary, the party who notifies the patients of the departure shall bear the costs of notification and reproducing or transferring medical records. Patient notification, records retention, and record dispersal shall be accomplished in accordance with this rule.

1. Any provision of the physician's employment contract notwithstanding, the departing physician's active patients shall be notified of the physician's new address and offered the opportunity to have copies of their medical records forwarded to the departing physician at his or her new practice.

2. A group shall not withhold the medical records of any patient who has authorized their transfer to the departing physician or any other physician. The patient's freedom of choice in choosing a physician shall not be interfered with, and the choice of physician in every case should be left to the patient. The patient shall be informed that upon authorization, his or her records will be sent to the physician of the patient's choice.

3. Absent a contractual provision to the contrary, when the group or medical practice undertakes to notify patients of the physician's departure, the group shall bear the cost of notifying patients and reproducing or transferring medical records. When the departing physician is responsible for notifying patients of his or her departure, the practice shall cooperate with the physician by providing the physician a list of the active patients and their last known mailing address and contact information, and the physician shall bear the cost of notifying his or her patients and reproducing or transferring medical records.

(e) Sale of a Medical Practice. A physician, a physician group practice, or the estate of a deceased physician may sell the elements that comprise his or her practice, one of which is its goodwill, i.e., the opportunity to take over the patients of the seller by purchasing the physician's medical records. Notwithstanding the above, the sale of a physician owner's equity in a medical practice that continues to operate, and which does not constitute the sale of the entire practice, does not constitute a medical sale for the purposes of this rule. Therefore, the transfer of records of patients is subject to the following:

1. The selling physician, his or her estate, or group practice must take reasonable steps for all medical records to be transferred to another physician or covered entity or business associate operation on its behalf. Medical records shall be maintained in custody in their original or legally reproduced form in compliance with the retention periods set forth in (2)(c).

2. All active patients shall be notified within thirty (30) days of the transfer that the physician, his or her estate, or group practice is transferring the practice to another physician, group practice, or entity who will retain custody of their records, and that at their written request the copies of their records will be sent to another physician, the patient, or the patient's representative.

(f) Disposition of Medical Records when a Physician is Unavailable. When a physician goes on vacation, goes on sabbatical, takes a leave of absence, leaves the United States, or is otherwise voluntarily unavailable to his or her patients, the physician shall arrange to provide his or her patients access to their medical records.

(g) Abandonment of Records. It shall be a violation of Ala. Code §§ 34-24-360(2) and (23) for a physician to abandon his or her practice without his or her practice making provision for the maintenance, security, transfer, or to otherwise establish a secure method of patient access to their records.

(5) Violations. Violation of any provision of these rules is grounds for disciplinary action pursuant to Ala. Code §§ 34-24-360(2) and (23).

TELEMEDICINE ACT OF 2022 (ALA. CODE §§ 34-24-400 THROUGH 707)

Section 34-24-700 - Legislative intent

It is the intent of the Legislature to expand access to safe, effective health care services for the residents of this state through the use of various electronic devices and technologies. The Legislature finds and declares the following:

(1) Telehealth has proven to be a viable tool to supplement traditional, in-person services and provides additional ways for individuals to access medical care.

(2) Allowing physicians to utilize telehealth medical services and other electronic devices to provide care will positively impact residents of this state.

(3) Telehealth should be promoted as sound public policy and should be available to every Alabama resident, irrespective of their race, identity, age, income, socioeconomic class, or geographic location.

Section 34-24-701 - Definition

For the purposes of this article, the following terms shall have the following meanings:

(1) ASYNCHRONOUS. The electronic exchange of health care documents, images, and information that does not occur in real time, including, but not limited to, the collection and transmission of medical records, clinical data, or laboratory results.

(2) BOARD OF MEDICAL EXAMINERS. The Alabama Board of Medical Examiners established pursuant to Section 34-24-53.

(3) CONTROLLED SUBSTANCE. The same meaning as defined in Section 20-2-2. This term includes an immediate precursor, as defined in Section 20-2-2.

(4) DIGITAL HEALTH. The delivery of health care services, patient education communications, or public health information via software applications, consumer devices, or other digital media.

(5) DISTANT SITE. The physical location of a physician at the time in which telehealth medical services are provided.

(6) HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA). The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, §264, 110 Stat. 1936.

(7) LEGEND DRUG. Any drug, medicine, chemical, or poison bearing on the label the words, "Caution, federal law prohibits dispensing without prescription" or other similar wording

indicating that the drug, medicine, chemical, or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

(8) MEDICAL LICENSURE COMMISSION. The Alabama Medical Licensure Commission established pursuant to Section 34-24-310.

(9) MEDICAL SUPPLIES. Non-drug medical items, including durable medical equipment, which may be sold or dispensed only upon the prescription of a licensed medical practitioner.

(10) ORIGINATING SITE. The physical location of a patient at the time in which telehealth medical services are provided.

(11) PHYSICIAN. Either a doctor of medicine who is licensed to practice medicine or a doctor of osteopathy who is licensed to practice osteopathy in a state, commonwealth, district, or territory of the United States.

(12) PRESCRIBER. Any person who possesses an active Alabama controlled substance certificate or a Qualified Alabama Controlled Substances Registration Certificate issued by the Board of Medical Examiners.

(13) SYNCHRONOUS. The real-time exchange of medical information or provision of care between a patient and a physician via audio/visual technologies, audio only technologies, or other means.

(14) TELEHEALTH. The use of electronic and telecommunications technologies, including devices used for digital health, asynchronous and synchronous communications, or other methods, to support a range of medical care and public health services.

(15) TELEHEALTH MEDICAL SERVICES. Digital health, telehealth, telemedicine, and the applicable technologies and devices used in the delivery of telehealth. The term does not include incidental communications between a patient and a physician.

(16) TELEMEDICINE. A form of telehealth referring to the provision of medical services by a physician at a distant site to a patient at an originating site via asynchronous or synchronous communications, or other devices that may adequately facilitate and support the appropriate delivery of care. The term includes digital health, but does not include incidental communications between a patient and a physician.

Section 34-24-702 - Physicians must be licensed

(a) Physicians who engage in the provision of telehealth medical services to any individual in this state must possess a full and active license to practice medicine or osteopathy issued by the Medical Licensure Commission.

(b) Notwithstanding subsection (a), a physician who engages in the provision of telehealth medical services to any individual in this state is not required to possess a license issued by the Medical Licensure Commission, if either of the following apply:

(1) The services are provided on an irregular or infrequent basis. The term "irregular or infrequent" refers to telehealth medical services occurring less than 10 days in a calendar year or involving fewer than 10 patients in a calendar year.

(2) The services are provided in consultation, as further provided by Section 34-24-74, with a physician licensed to practice medicine or osteopathy in this state.

(c) A violation of this article shall constitute the unauthorized practice of medicine.

(d) Nothing in this article shall be interpreted to limit or restrict the Board of Medical Examiners' or Medical Licensure Commission's authority to regulate, revoke, suspend, sanction, or otherwise discipline any physician licensed to practice in this state who violates the provisions of this chapter, the provisions relating to the regulation of manufacture and distribution of controlled substances, as provided by Sections 20-2-50 through 20-2-58, or the administrative rules of the Board of Medical Examiners or the Medical Licensure Commission while engaging in the practice of medicine within this or any other state.

(e) Nothing in this article shall be construed to apply to or to restrict the provision of health-related services via telehealth by a health care provider other than a physician, provided that those health-related services are within the scope of practice of the health care professional licensed in Alabama.

Section 34-24-703 - Duties of physician providing telehealth medical services

(a) A physician providing telehealth medical services shall owe to the patient the same duty to exercise reasonable care, diligence, and skill as would be applicable if the service or procedure were provided in person. Telehealth medical services shall be governed by the Medical Liability Act of 1987, codified in Sections 6-5-540 through 6-5-552, and shall be subject to the exclusive jurisdiction and venue of the circuit courts of the State of Alabama, regardless of the citizenship of the parties.

(b) A physician practicing telemedicine shall do all of the following, if such action would otherwise be required in the provision of the same service if delivered in-person:

(1) Establish a diagnosis through the use of acceptable medical practices, which may include, but not be limited to, taking a patient history, a mental status examination, a physical examination, disclosure and evaluation of underlying conditions, and any diagnostic and laboratory testing.

(2) Disclose any diagnosis and the evidence for the diagnosis, and discuss the risks and benefits of treatment options.

(3) Provide a visit summary to the patient and, if needed, inform the patient of the availability of, or how to obtain, appropriate follow-up and emergency care.

(c) The provision of telehealth medical services is deemed to occur at the patient's originating site within this state. A licensed physician providing telehealth medical services may do so at any distant site.

(d) Telehealth medical services may only be provided following the patient's initiation of a physician-patient relationship, or pursuant to a referral made by a patient's licensed physician with whom the patient has an established physician-patient relationship, in the usual course of treatment of the patient's existing health condition. The physician-patient relationship may be formed without a prior in-person examination.

(e) Prior to providing any telehealth medical service, the physician, to the extent possible, shall do all of the following:

(1) Verify the identity of the patient.

(2) Require the patient to identify his or her physical location, including the city and state.

(3) Disclose to the patient the identity and credentials of the physician and any other applicable personnel.

(4) Obtain the patient's consent for the use of telehealth as an acceptable mode of delivering health care services, including, but not limited to, consent for the mode of communication used and its limitations. Acknowledgment of consent shall be documented in the patient's medical record.

(f)

(1) If a physician or practice group provides telehealth medical services more than four times in a 12-month period to the same patient for the same medical condition without resolution, the physician shall do either of the following:

a. See the patient in person within a reasonable amount of time, which shall not exceed 12 months.

b. Appropriately refer the patient to a physician who can provide the in-person care within a reasonable amount of time, which shall not exceed 12 months.

(2)

a. For the purposes of this section, each pregnancy for a woman shall be considered a separate or new condition.

b. For the purposes of this subsection, the term "practice group" shall mean, at a minimum, a group of providers who have access to the same medical records.

c. The Board of Medical Examiners, by rule or otherwise, may provide for exemptions to the requirement contained in subdivision (1) that are no more restrictive than the provisions of this article.

(3) The provision of telehealth medical services that includes video communication to a patient at an originating site with the in-person assistance of a person licensed by the Board of Medical Examiners or by the Board of Nursing pursuant to Chapter 21 of Title 34 of the Code of Alabama 1975, shall constitute an in-person visit for the purposes of this subsection.

(4) This section does not apply to the provision of telehealth medical services provided by a physician in active consultation with another physician who is providing in-person care to a patient.

(5) This section shall not apply to the provision of mental health services as defined in Section 22-50-1.

Section 34-24-704 - Prescriptions

(a) A prescriber may prescribe a legend drug, medical supplies, or a controlled substance to a patient as a result of a telehealth medical service if the prescriber is authorized to prescribe the drug, supplies, or substance under applicable state and federal laws. To be valid, a prescription must be issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her professional practice.

(b)

(1) A prescription for a controlled substance may only be issued as a result of telehealth medical services if each of the following apply:

a. The telehealth visit includes synchronous audio or audio-visual communication using HIPAA compliant equipment with the prescriber responsible for the prescription.

b. The prescriber has had at least one in-person encounter with the patient within the preceding 12 months.

c. The prescriber has established a legitimate medical purpose for issuing the prescription within the preceding 12 months.

(2) This subsection shall not apply in an in-patient setting.

(c) A physician shall be exempt from the requirements of subsection (b) and may issue a prescription for a controlled substance to a patient if the prescription is for the treatment of a patient's medical emergency, as further defined by rule by the Board of Medical Examiners and the Medical Licensure Commission.

Section 34-24-705 - Compliance with all federal and state laws and regulations; records; rules

(a) A physician who provides a telehealth medical service shall comply with all federal and state laws and regulations applicable to the provision of telehealth medical services, including the Health Insurance Portability and Accountability Act (HIPAA), and shall use devices and technologies in compliance with these laws, rules, and regulations. A physician who provides telehealth medical services shall also take reasonable precautions to protect the privacy and security of all verbal, visual, written, and other communications involved in the delivery of telehealth medical services.

(b) A physician who provides a telehealth medical service shall maintain complete and accurate medical records in accordance with rules of the Board of Medical Examiners and the Medical Licensure Commission, must have access to the patient's medical records, and must be able to produce the records upon demand by the patient, the Board of Medical Examiners, or the Medical Licensure Commission.

(c) Rules adopted by the Board of Medical Examiners and the Medical Licensure Commission shall set standards for the creation, retention, and distribution of medical records pursuant to the delivery of telehealth medical services.

Section 34-24-706 - Board of Medical Examiners and the Medical Licensure Commission may adopt rules

(a) The Board of Medical Examiners and the Medical Licensure Commission may adopt rules regulating the provision of telehealth medical services by physicians in this state, even if the rules displace competition.

(b) Rules adopted by the Board of Medical Examiners and the Medical Licensure Commission shall promote quality care, prevent fraud, waste, and abuse, and ensure that physicians provide adequate supervision of health professionals who aid in providing telehealth medical services.

(c) Other than as set forth in this article, the authority of the Board of Medical Examiners and the Medical Licensure Commission to regulate physicians providing telehealth medical services shall be the same as the authority of the Board of Medical Examiners and the Medical Licensure Commission to regulate physicians providing services in person.

Section 34-24-707 - Applicability

(a) This article, and the rules adopted by the Board of Medical Examiners and the Medical Licensure Commission, shall apply only to the provision of telehealth medical services by physicians to individuals located in this state.

(b) The Board of Medical Examiners, the Medical Licensure Commission, and its officers, agents, representatives, employees, and directors thereof, shall be considered to be

acting pursuant to clearly expressed state policy as established in this act and under the active supervision of the state. The boards, agencies, and individuals in this section shall not be subject to state or federal antitrust laws while acting in the manner provided in this section.