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TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-10, Appendix E
Rule Title: American Association for Accreditation of Ambulatory Facilities, Inc., Guidelines for Sterilization
X New ____ Amend X 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

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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.

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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 Nancy W. Green

Date: March 16, 2017

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ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X-10, Appendix E, American Association for Accreditation of Ambulatory Facilities, Inc., Guidelines for Sterilization

INTENDED ACTION: To repeal and replace the Appendix

SUBSTANCE OF PROPOSED ACTION: To repeal and replace the Appendix with an updated version.

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments, orally or in writing, concerning the proposed new rules. For written submissions, submit to: Patricia E. Shaner, Office of General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, 848 Washington Avenue (36104), 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 Friday, May 5, 2017. Persons wishing to obtain copies of the text of this rule should contact Patricia E. Shaner, Office of General Counsel, (334-242-4116), PO Box 946, 848 Washington Avenue (36104), Montgomery, Alabama 36101-0946, email ckruger@albme.org, or obtain it from the Board's web site, www.albme.org.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: May 5, 2017

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

Norris W. Green

Norris W. Green, Executive Director

200 PROCEDURE ROOM POLICY, ENVIRONMENT AND PROCEDURES

200.30 Procedures - Sterilization

200.030.010 A,B,C-M,C

The facility has at least one autoclave which uses high pressure steam and heat, or all sterile items are single use disposable.

200 PROCEDURE ROOM POLICY, ENVIRONMENT AND PROCEDURES

200.030.015 A,B,C-M,C

Gas sterilizers and automated endoscope reprocessors (AER) must be vented as per manufacturer's specifications.

200.030.020 A,B,C-M,C

All instruments used in patient care are sterilized, where applicable.

200.030.025 A,B,C-M,C

A room with acceptable ventilation and space that is separate from the procedure room is required for reprocessing of scopes. If the facility is unable to use two separate rooms they must be able to document that they are using a closed reprocessing system with ventilation that exchanges the room air 10 -12 times per hour or an active charcoal filtration system is in place. All situations must meet requisite standards (OSHA, CDC, Federal, State, etc.) for air exchange ratios and vapor particle standards.

200.030.026 A,B,C-M,C

A written protocol is in place and followed that specifically addresses and requires enumerated steps to accomplish the below goals:
- The cleaning of the scope. The location of the manual rinsing and cleaning of endoscopes prior to HLD may be carried out in the procedure room away from the patient. Specific steps must be in place to minimize spraying and aerosolizing of the bio-burden.
- Processing of the scopes must be in the location that meets requisite standards of air exchange ratios and vapor particle standards. For example, a room that is separate from the procedure room is required for manual HLD reprocessing of endoscopes. This room must be adequate sized and segregated from patient and staff. Necessary protective equipment for personnel performing this function must be included in the protocol as well as readily available.
- Scope cleaning functions should be limited to properly trained personnel.
- If there is not a separate room (see previous standard) being utilized for processing of the scopes, then the protocol must include steps that directs that the contaminated equipment will be cleaned and placed in the re-processor prior to bringing the next patient into the room. In addition, the clean scope coming out of the re-processor is to be removed only when the room is clean and free of dirty instruments.
- Cross contamination should be avoided no matter where cleaning and processing takes place. There must always be some distinct type of separation of clean and dirty areas in any location.
- Clean (reprocessed) endoscopes should be stored in a closed cabinet exclusively dedicated for scope storage to avoid contamination prior to use.

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200 PROCEDURE ROOM POLICY, ENVIRONMENT AND PROCEDURES

200.030.030 A,B,C-M,C

High-level disinfection is used only for non-autoclavable endoscopic equipment, and in areas that are categorized as semi-critical where contact will be made with mucus membrane or other body surfaces that are not sterile. At all times the manufacturer's recommendations for usage should be followed.

200.030.035 A,B,C-M,C

Monitoring records are retained for the sterilization or other disinfection process and should be reviewed and stored for a minimum of three (3) years.

200.030.040 A,B,C-M,C

A weekly spore test, or its equivalent, is performed on each autoclave and the results filed and kept for three (3) years. The sterility of each load in the autoclave is checked with indicator tape, chemical monitors, or other effective means both on the outside and inside of the pack.

200.030.045 A,B,C-M,C

If a spore test is positive, there is a protocol for remedial action to correct the sterilization process.

AMERICAN ASSOCIATION FOR ACCREDITATION
OF AMBULATORY SURGERY FACILITIES, INC.

20 ***Sterilization*** (RG 200. 3-6)

220-010 The facility has ***at*** least one autoclave which utilizes high pressure steam and heat. (RG 200. 1) A

220-011 Alternative methods can be chemical autoclave (chemclave) or gas (ethylene oxide) sterilizer A

220-012 Gas sterilizers must be vented if appropriate for the specific sterilizer. A

220-020 All instruments used in patient care are properly sterilized where applicable. (RG 200. 1) A

220-030 High-level disinfection is used only for non-autoclavable endoscopic equipment. (RG 200. 9)(400. 4A) A

220-040 A monthly spore test is performed in a random sterilized load and the results filed for each autoclave. A

220-05 0 If a spore test is positive, there is a protocol for appropriate remedial action. A

220-060 Each load in the autoclave is checked with indicator tape, chemical monitors, or other effective means both on the outside and inside of the pack. A

22 0-070 If a sterilizer produces monitoring records, they are reviewed by appropriate personnel and stored for a minimum of 3 years. A

22 0-071 have appropriately maintained logs for all routine checks A

220-080 Sterile supplies are stored in closed cabinets/drawers or if not, away from heavy traffic areas. (RG 200. 2) A

220-081 stored away from potential contamination hazards A

220-090 Sterile supplies are appropriately labeled indicating sterility. A

220-091 appropriately packaged to prevent accidental opening A

220-092 supplies are sealed with autoclave tape A

220-093 chemical autoclaving requires notation of the expiration date A

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