

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	04/14/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 5/16/2014

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
30	09	12	.02, .04.-.07

3. Name of Promulgating Authority

Maryland Institute for Emergency Medical Services Systems

4. Name of Regulations Coordinator	Telephone Number
Sarah M Sette	(410)706-8514

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Baltimore	MD	21201

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5. Name of Person to Call About this Document	Telephone No.
Sarah M. Sette	(410)706-8514

Email Address
ssette@miemss.org

6. Check applicable items:
 New Regulations

X- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: November 2013.

- Repeal of Existing Regulations
- Recodification
- Incorporation by Reference of Documents Requiring DSD Approval
- Reproposal of Substantively Different Text:

: Md. R
(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes **X-** No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

X- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Sarah M. Sette, Assistant Attorney General, (telephone #(410)706-8514) on November 12, 2013. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Richard Alcorta, MD

Title

Acting Co-Executive Director

Telephone No.

(410)706-5074

Date

November 12, 2013

MARYLAND INSTITUTE FOR EMERGENCY MEDICAL SERVICES SYSTEMS (MIEMSS)

Subtitle 09 COMMERCIAL AMBULANCE SERVICES

30.09.12 Neonatal Ambulance Service

Authority: Education Article Section 13-515

Notice of Proposed Action

□

The Maryland Emergency Medical Services Board proposes to amend Regulations .02, .04-.07 in COMAR 30.09.12.

This action was considered and approved by the State Emergency Medical Services Board at its regular meeting on November 12, 2013, notice of which was given by publication on the Maryland Institute for Emergency Medical Services Systems website, www.miemss.org, pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to clarify requirements for transport of neonates by ambulance, improve the quality assurance process and update required equipment.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

Improved quality assurance process, staffing and training requirements may increase expenses while improving quality of service. Streamlining equipment may decrease expenses.

II. Types of Economic Impact.

- A. On issuing agency:
- B. On other State agencies:
- C. On local governments:

Revenue (R+/R-)

Expenditure (E+/E-)

Magnitude

NONE

NONE

NONE

Benefit (+)

Cost (-)

Magnitude

D. On regulated industries or trade groups:	NONE	
(1) Staffing	(-)	Unknown
(2) Training	(-)	Minimal
(3) Equipment	(+)	Unknown
(4) Quality Assurance	(-)	Unknown
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	
(1) Improved Quality Assurance	(+)	Unknown

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

D(1). Currently almost all neonatal ambulance services staff at the level contemplated in the regulation. All are planning for the new staffing levels. Staffing requirements allow for flexibility.

D(2). Additional training required. Agency currently offering multiple free courses to increase access.

D(3). Updating required equipment to avoid unnecessary or duplicative equipment may reduce costs.

D(4). Improved quality assurance process may increase expenses but is expected to improve outcomes.

F(1). Improved Quality Assurance process is expected to improve outcomes.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Bill Adams, Director State Office Commercial Ambulance Licensing and Regulation, Maryland Institute for Emergency Medical Services Systems, 653 West Pratt Street, Baltimore, Maryland 212101, or call 410-706-8511, or email to badams@miemss.org, or fax to 410-706-7552. Comments will be accepted through June 16, 2014. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2015

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

The Commercial Ambulance Service Fund.

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

Increased expenses may be offset by decreased costs and improved service.

G. Small Business Worksheet:

Attached Document:

CHAPTER 12. NEONATAL AMBULANCE SERVICE

.01 Scope.

This chapter governs the operations of neonatal ambulance services and neonatal ambulances.

.02 Requirements for a Neonatal Commercial Ambulance Service.

A. A commercial ambulance service wishing to provide neonatal ambulance services shall comply with the requirements of this chapter in addition to the other applicable requirements of this subtitle.

B. An ambulance service transporting neonates shall obtain a neonatal commercial ambulance service license.

C. An applicant for a neonatal commercial ambulance service license shall submit an application to SOCALR on the required form.

D. A completed application form shall be accompanied by documentation which states to SOCALR's satisfaction that the commercial ambulance service has retained:

(1) Two or more registered nurses who:

(a) Meet the requirements of the Board of Nursing to provide nursing care to neonates during interfacility transport, and

(b) Agree to assume responsibility for patient care during the transport process; and

(2) One or more physicians who are board certified or are active candidates for board certification in neonatology who:

(a) Possess current knowledge of the Maryland EMS System as required in COMAR 30.03.03(B)(4), as well as current knowledge of:

(i) The effects of transport on the neonate, and

(ii) The operation of neonatal transport equipment and ambulance communications equipment; and

(b) Working with a neonatal or perinatal center, agree to:

(i) Serve as medical director for the neonatal service,

(ii) Provide medical direction to the commercial ambulance service's personnel-related neonatal care,

(iii) Provide training as required in neonatal care, and

(iv) Participate in a quality assurance program.

E. A licensed neonatal commercial ambulance service shall immediately advise SOCALR of any change in the medical director named in § D(2) of this regulation.

F. A licensed neonatal commercial ambulance service may not transport a neonate from one hospital to another for a higher level of care unless the admitting hospital:

(1) Is a perinatal center;

(2) Is a neonatal center;

(3) Before designation of perinatal centers by the EMS Board, has a certificate of need issued by the Maryland Health Resources Planning Commission for its neonatal intensive care unit or approval from Maryland Health Resources Planning Commission for a neonatal intensive care unit; or

(4) Before the EMS Board has completed the process of entering into an agreement with an out-of-State hospital to serve as an out-of-State perinatal referral center, possesses all government approvals required to operate a neonatal intensive care unit under the laws of the jurisdiction in which it is located including, if required, a certificate of need and all necessary licenses.

(G) Neonates being transported to a perinatal center or pediatric unit or pediatric intensive care unit or being transferred from one neonatal intensive care unit to another may be transported by a specialty care transport team with age appropriate competencies and equipment or neonatal transport team,

(H) Neonates who have been discharged to home and are returning to a neonatal or pediatric intensive care unit from a referring hospital may be transported by a specialty care transport team with age appropriate competencies and equipment or neonatal transport team,

(I) Neonates being transported from a neonatal or pediatric intensive care unit to another acute care hospital or rehabilitation hospital or long term care shall be screened by a specialty care transport team with age appropriate competencies and equipment or neonatal transport team prior to being transported.

.03 Additional Requirements for Neonatal Ambulances.

A. An applicant for a neonatal commercial ambulance license shall submit an application to SOCALR.

B. To be eligible for a neonatal commercial ambulance license, a commercial ambulance service shall:

- (1) Have a current, valid neonatal commercial ambulance service license; or
- (2) Be simultaneously applying for a neonatal commercial ambulance service license.

C. A licensed neonatal commercial ambulance service may not provide neonatal transport service with a BLS or ALS licensed commercial ambulance unless:

- (1) It uses a BLS or ALS licensed commercial ambulance for less than 30 days for reasons related to routine maintenance or mechanical failure of a neonatal commercial ambulance;
- (2) It has notified SOCALR of the proposed use before its occurrence and has been issued a confirmation number verifying authorization;
- (3) The BLS or ALS licensed commercial ambulance has in place all required equipment listed in Regulation .06 of this chapter; and
- (4) The BLS or ALS licensed commercial ambulance has onboard piped oxygen and piped air which meet the requirements in COMAR 30.09.10.09.

.04 Staffing.

A. A neonatal licensed commercial ambulance, when providing neonatal service, shall be staffed by:

- (1) A driver who meets the requirements in COMAR 30.09.07.02A(4)(a); and
- (2) At least two individuals, in addition to the driver:

(a) At least one of those two individuals shall be a registered nurse or physician with advanced training in the care of neonates; and

(b) As of July 1, 2014, the second individual shall be a Maryland licensed health care provider, including a physician, registered nurse, respiratory therapist, or paramedic, who is medically qualified to care for the patient and has additional training needed to care for neonatal patients during interfacility transport including:

- (i) Knowledge of the Maryland EMS System,
- (ii) The effects of transport on the neonate, and
- (iii) The operation of neonatal transport equipment and ambulance communications equipment.

B. When more than one patient is transported simultaneously in the same ambulance:

- (1) There shall be at least one registered nurse or physician with advanced training in the care of neonates present for each neonatal patient; and
- (2) Each patient shall be secured in a separate patient restraint device appropriate for the patient's age and weight.

C. All personnel attending to neonatal patients shall:

- (1) Successfully complete:
 - (a) The Neonatal Resuscitation Program prior to transporting neonatal patients, and
 - (b) The S.T.A.B.L.E. Program prior to transporting neonatal patients; \
- (2) Maintain a current:
 - (a) Neonatal Resuscitation Program Provider Course Completion Card; and
 - (b) S.T.A.B.L.E. Program Completion Certificate; and
- (3) If a physician, maintain board certification in neonatology.

.05 Additional Record-Keeping and Quality Assurance Requirements.

A. In addition to the information required in COMAR 30.09.08, the following information shall be documented on the patient runsheet:

- (1) Mother's name;
- (2) Name of the referring hospital;
- (3) Name of the referring physician;
- (4) Name of the receiving hospital;
- (5) Name of the receiving physician;

- (6) Date of birth;
- (7) Time of birth;
- (8) Gestational age of the patient;
- (9) Weight of the patient;
- (10) Primary reason for transport;
- (11) Names and license or certification level of the commercial ambulance driver and all personnel;
- (12) Time the request for transport was received by the commercial ambulance service;
- (13) Time the transport team departed from base;
- (14) Time the transport team arrived at the referral hospital;
- (15) Time the transport team departed from the referral hospital;
- (16) Time the transport team arrived at the receiving hospital; and
- (17) Care provided during the transport.

B. A copy of the runsheet shall be forwarded to SOCALR on a monthly basis by the 15th day of each subsequent month.

C. A licensed neonatal commercial ambulance service shall have a quality assurance program required by COMAR 30.03.04 which shall include:

- (1) A review by registered nurses and physicians of patient care provided during neonatal transport;
- (2) A review by the program medical director of each specialty care transport:
 - (a) Requiring a change in the plan of care during transport;
 - (b) In which the patient's condition worsened during transport;
 - (c) Requiring a change in destination during transport; or
 - (d) During which there was an unexpected outcome or event;
- (3) Written documentation of reviews of neonatal transports which shall be available to SOCALR upon request;

and

- (4) A quality assurance process for call-taking, call-screening, and dispatch.

.06 Equipment Requirements.

A. (1) A licensed neonatal commercial ambulance shall comply with COMAR 30.09.10.

B. There shall be a written maintenance plan for all medical devices used on neonatal commercial ambulances approved by SOCALR, which shall provide that:

- (1) All specialized medical devices used during transport shall:
 - (a) If provided by the hospital, be maintained by the hospital; or
 - (b) If provided by the licensed commercial ambulance services be maintained as recommended by the manufacturer; and

(2) The licensed commercial service providing specialized medical devices used during transport shall maintain records documenting maintenance and repair services.

C. All on-board medical devices shall be secured.

D. If the ambulance is also licensed as a specialty care ambulance under COMAR 30.09.14, the vehicle does not need to carry duplicates of required items.

E. The following equipment shall be carried in a neonatal ambulance:

- (1) Onboard piped oxygen that meets the criteria in COMAR 30.09.10.09;
- (2) Onboard piped air that meets the criteria in COMAR 30.09.10.09;
- (3) One onboard suction unit which meets the criteria in COMAR 30.09.10.06A;
- (4) One electrically powered portable suction that meets the criteria in COMAR 30.09.10.06B;
- (5) One neonatal transport incubator for each patient which:
 - (a) Is powered by internal batteries and alternating current; and
 - (b) Meets the U.S. General Services Administration standard for ambulance litter fasteners and anchorages;
- (6) One patient thermometer;
- (7) Four infant blankets;
- (8) Two infant caps;
- (9) Two chemically activated heat packs;
- (10) One cardiorespiratory monitor for each patient with neonatal electrodes and leads;
- (11) One pulse oximeter with neonatal sensor;
- (12) One oxygen analyzer;
- (13) One neonatal stethoscope;
- (14) Ventilation and airway maintenance equipment including:

- (a) One neonatal bag and mask equipment, including peep valve, capable of delivering 90% to 100% oxygen,

with:

- (i) A manometer, and
- (ii) Face masks, newborn and premature sizes (cushion rim preferred);
- (b) One intubation kit with:
 - (i) One size 0 Miller laryngoscope blade,

- (ii) One size 1 Miller laryngoscope blade,
- (iii) One pediatric laryngoscope handle,
- (iv) Spare batteries and bulbs for laryngoscope,
- (v) Two of each size 2.5, 3.0, 3.5, and 4.0 millimeter uncuffed endotracheal tubes,
- (vi) One stylette, and
- (vii) One meconium aspirator; and
- (c) Suction catheters 5F or 6F, 8F, 10F, 12F or 14F;
- (d) One portable mechanical ventilator for each patient as age appropriate;
- (15) Two infusion pumps for each patient as appropriate;
- (16) One blood pressure monitor with 5 neonatal size cuffs;
- (17) One umbilical vessel catheterization tray with two of each size 3.5 and 5 French umbilical artery catheters;
- (18) Four three-way stopcocks;
- (19) Two of each size 5 and 8 French oral gastric tubes and 20 ml syringe;
- (20) Site preparation materials;
- (21) Venipuncture needles and catheters sizes 25, 21, 18 gauge, or puncture device for needleless system;
- (22) Syringes sizes 1, 3, 5, 10, 20, and 50 ml, along with sterile gloves, scalpel or scissors, and antiseptic solution;
- (23) Two syringes size 25 cubic centimeters or larger;
- (24) One of each size 10 and 12 French Salem sump tubes;
- (25) One 10 French repogle tube;
- (26) One sterile bowel bag;
- (27) Protective skin barrier;
- (28) Two one-way flutter valves;
- (29) Four neonatal armboards;
- (30) Two blood product infusion sets;
- (31) Four intravenous infusion sets;
- (32) Two sterile gauze pads, maximum 2 inches by 2 inches;
- (33) Medications including:
 - (a) All ALS medications listed in the Maryland Medical Protocols for Emergency Medical Service Providers;

and

(b) Additional medications approved for use by the neonatal service medical director to meet the needs of the types of patients being transported.

F. A list of the additional medications used by the neonatal service shall be provided to SOCALR and shall be available on each ambulance when in use for a neonatal transport.

G. SOCALR shall be notified in writing of any changes to the list of additional medications used by the neonatal transport service within 7 days of the change.

H. There shall be sufficient quantities of medications to care for one neonatal patient for the longer of:

- (1) 1 hour; or
- (2) Two times the estimated time of transport.