STATE OF MAINE
DEPARTMENT OF PUBLIC SAFETY
MAINE EMERGENCY MEDICAL SERVICES
152 STATE HOUSE STATION
AUGUSTA, MAINE 04333

Maine EMS Policy/Procedure			
Medical Direction and Practices Board			
Policy #	**Title**		**Date Issued**
010.04.01	**MDPB APPROVED ALTERNATE EQUIPMENT**		**2022-07-25**
Policy Superseded	**Next Review Date**	**Author**	**Pages**
N/A	**2027-07-25**	C. Azevedo, M. Minkler	4
Approved By:	MDPB on 20 Jul 2022; J. Sam Hurley, Director, Maine EMS		

I. Scope

A. This policy is designed to provide a process for approval of alternate medical equipment which may benefit and improve patient care by Maine EMS services and clinicians. It is not designed to replace protocols or other rules, but to address the dynamic changes and updates that may occur to devices and equipment, provide clarity of device specifications, and other application of devices to existing procedures and care principles.

II. Applicability

A. This policy is applicable to all medical devices and EMS equipment which:
   i. Are designed/intended to treat and care for EMS patients, AND
   ii. Are not included in the current Maine EMS Rules Chapter 17 "Equipment Lists for Maine EMS Services" chapter, OR are variations of the equipment and specifications listed
   iii. Are FDA approved
   iv. Are applicable to existing and current Maine EMS Prehospital Care Protocols
   v. Are ***not*** for medication/pharmacy change requests

III. Review

A. This policy should be reviewed every five years from date of approval.
B. The Approved Alternate Equipment list should be reviewed bi-annually with the Maine EMS Prehospital Treatment Protocols, and as needed.

IV. Definitions

A. **Peer-reviewed published literature:** An author's scholarly work which has been published and has been subject to the process of review and scrutiny of others who are experts in the same field.
B. **MDPB:** Maine EMS Medical Direction and Practices Board
C. **Current Maine EMS Rules & Statutes:** Copies of the current Maine EMS Rules and pertinent statutes can be found on the Maine EMS Website at www.maine.gov/ems
D. **Current Maine EMS Prehospital Treatment Protocols**: A copy of the most current version can be found on the Maine EMS Website at www.maine.gov/ems
E. **Presentation Submission to the Regional Medical Director and MDPB**
   i. Written submission shall be electronic, and in a PDF or other widely accessible document format.
   ii. Presentations done via PowerPoint or other method will also be submitted electronically in an accessible format.
   iii. Audio and/or video presentations will be made available in an accessible format
   iv. Equipment/Device samples do not need to be submitted but must be made available for the presentation

V. Policy

A. Eligible persons or organizations interested in submitting alternate equipment or devices for approval by MDPB and Maine EMS shall follow the procedure outlined in this policy.

B. Services are expected to adhere to current Maine EMS Rules and Maine EMS Prehospital Treatment Protocols, with consideration of approved alternate equipment and devices as approved by the Maine EMS Medical Direction and Practices Board.

C. Eligibility for submission
   i. Personnel and organizations eligible for submission of proposals for alternate equipment and/or devices is limited to:
      1. Maine EMS licensed clinicians, who are representing themselves or a Maine EMS licensed EMS service or agency
      2. Maine EMS licensed services who may be represented by an operational or administrative official of that agency
      3. Maine EMS Regional & State Medical Directors and members of the MDPB
      4. Maine EMS Regional Offices
      5. Maine EMS Staff
   ii. The following are NOT eligible for submission of proposals for alternate equipment and/or devices:
      1. Equipment or device manufacturers or their representatives
      2. Equipment or device vendors

D. Approved Alternate Equipment list
   i. A current list of alternate equipment or devices, which have been approved by the MDPB, shall be maintained, published, and be made available by Maine EMS.

E. Changes in approval status for alternate equipment and devices
   i. In the normal course of periodic review of approved equipment and devices, it is possible an approval may not be renewed for one or more issues. In these cases, upon completion of the review, the MDPB and Maine EMS shall publish a list of any affected items, along with the reasons the item was not re-approved or no longer requires approval, as applicable.

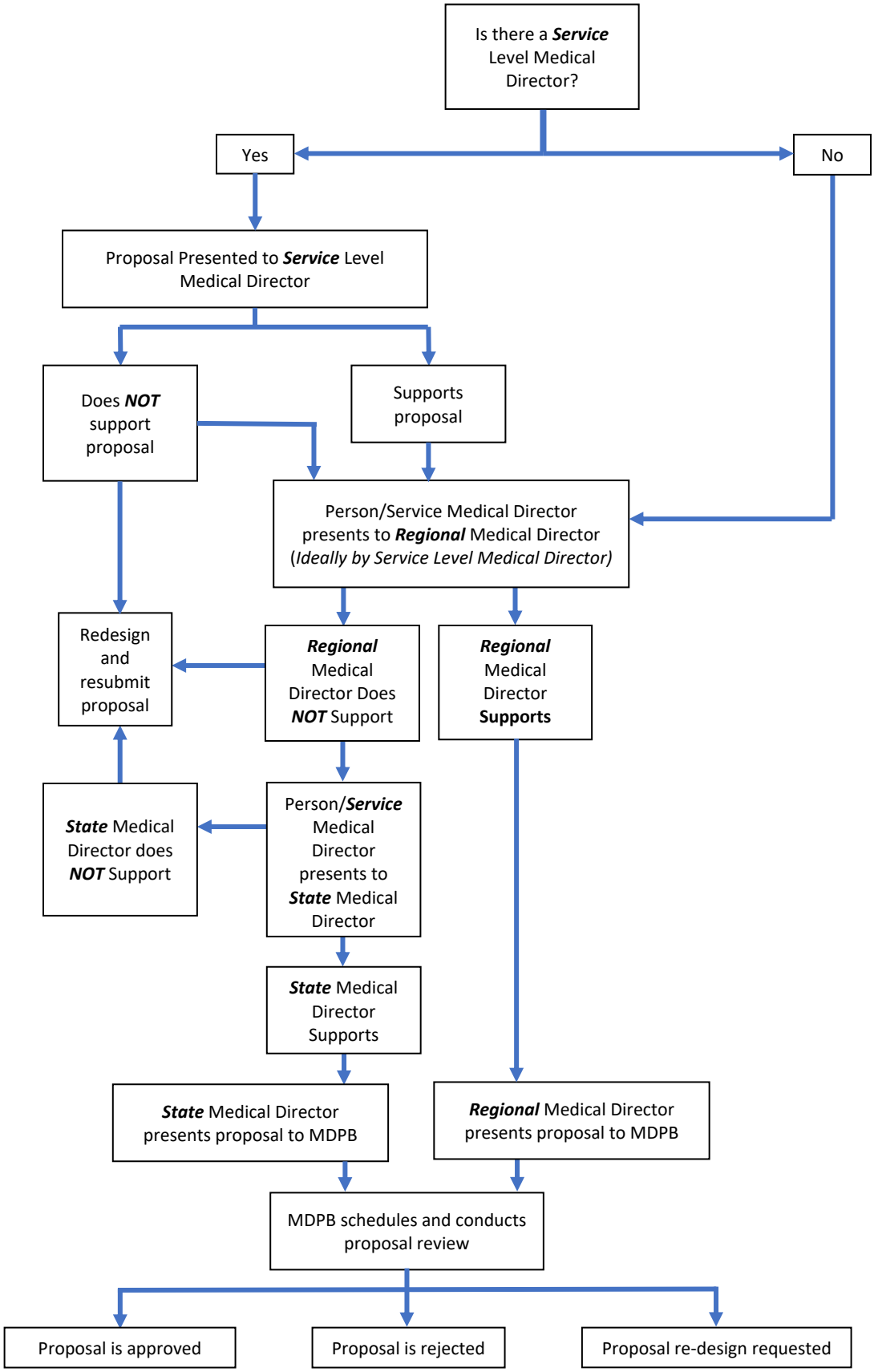
VI. Procedure

A. Eligible persons or agencies wishing to present a device for approval by MDPB will use the following procedure:
   i. Device proposals should be presented
      1. First to the Service Medical Director
         a. If Service Medical Director supports the proposal, the service medical director brings the proposal to the Regional Medical Director.
         b. If Service Medical Director does not support the proposal, you may proceed to the Regional Medical Director
         c. If no Medical Director, or not from a Service, start with the Regional Medical Director
      2. Proposal is presented to the Regional Medical Director
         a. If Regional Medical Director does not support the proposal, you may proceed to the State Medical Director.
      3. If approved for further consideration by the Regional Medical Director or State Medical Director, the proposal will be presented to the Maine EMS Medical Direction and Practices Board (MDPB) as an agenda item scheduled by the MDPB Chair.
         a. Documentation of support for a device, listed below, must be submitted to the MDPB Chair 30 days in advance of the proposal presentation, and will be considered in review of the proposal by the MDPB.
         b. Additional documentation for support may be requested of persons submitting proposals.
         c. Manufacturers, sales representatives, and/or company stakeholders are not allowed to present the proposal but may be considered for technical questions at the discretion of the MDPB.
      4. Proposals must be in written form with the following supporting documentation:
         a. **Rationale** – this is the reason why the device is being submitted for approval consideration
         b. **The Maine EMS Incidence of the underlying condition in which use of the device is intended to address** – this means the frequency of occurrence of the condition for which use of the device might be applied
         c. **Supporting Evidence –** This is evidence described in peer reviewed, published literature which supports the implementation of the proposed device.

d. **Expected Impact of Implementation –** This is a measurement of the expected and/or potential effect that implementation of the device will have upon EMS clinicians, services, and patient care including, but not limited to:
    i. Cost of equipment
    ii. Training – extent, cost of development and delivery
    iii. Operational changes
    iv. Protocol changes
    v. Communication within the healthcare system
    vi. Quality improvement considerations
e. **Anticipated outcome** – expected results of implementing the device, including, but not limited to:
    i. Is this a service specific, regional, or statewide change?
    ii. Improved patient care
    iii. Improved patient outcomes
    iv. Efficiency
    v. Improved cost of care

ii. Once a decision has been reached regarding approval, the person and/or organization submitting the proposal shall be notified in writing by Maine EMS/MDPB within 15 days of the decision.
    1. In cases wherein proposed equipment was rejected, reasons and circumstances for rejection should be made clear and include as applicable:
        a. Lack of sufficient evidence of efficacy
        b. Practices and treatment paradigms that are either in conflict with existing Maine EMS Prehospital Treatment Protocols or otherwise do not support implementation of the device
        c. Cost and/or lack of cost efficiency
        d. Other factors
    2. Maine EMS will maintain a list of devices that were presented to the MDPB and NOT approved.

MAINE EMS
ALTERNATE DEVICE APPROVAL
PROCESS FLOWCHART



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