

**APPLICATION FOR PETITION FOR
ADDITION/CHANGE/REMOVAL
OF DRUG/EQUIPMENT TO/FROM THE EMS INVENTORY**

This form should be filled out and submitted to the Health District OEMSTS Office by the 15th of the month prior to the next scheduled Medical Advisory Board Committee meeting for consideration. Please attach any materials that you consider useful in this discussion.

Specify one: Addition Change Removal

Agency requesting: _____

Name of drug/device: _____

What is the classification/action of the drug? _____

What is the type of device? _____

What is the proposed change, if applicable? _____

What is the proposed benefit of the addition/change/removal of this drug/device? _____

Specify the number of Patient encounters this change would affect: _____

What drug/device is currently being used to manage this problem? (Provide supporting statistical data) _____

Are you aware of any other EMS system using this drug/device in the prehospital setting? Yes _____ No _____

EMS System: _____ Contact person: _____

Summarize their experience/use of the drug/device: _____

Manufacturer(s)/Supplier(s): _____

Is training required? Yes _____ No _____ If yes, explain education program in detail on separate sheet, including projected cost of program. (Refer to back of page for "Cost Calculations".)

Is an IRB required? Yes _____ No _____

Please disclose any past or present affiliation/relationship with the vendor/supplier.

ATTACH:

1. DRAFT PROTOCOL
2. LIST OF OTHER AGENCIES USING DRUG/ITEM
3. DOCUMENTATION, ARTICLES AND/OR STATISTICAL DATA ON PRODUCT EFFECTIVENESS FOR EVIDENCE-BASED REVIEW
4. ADDITIONAL COMMENTS ON A SEPARATE SHEET

Medical Director

EMS Operations Director

COST CALCULATIONS

INITIAL COST

Cost per Dose/Device	\$ _____ x	
Proposed Number of Doses/Devices per Vehicle	\$ _____ x	
Number of Vehicles (per SNHD)	_____ =	
Total Initial Cost		\$ _____

ANNUAL COST

Cost per Dose/Device	\$ _____ x	
Estimated Number of Doses/Devices Used Annually	_____ =	
Total Annual Cost		\$ _____

TRAINING COST

Number of Personnel to Train (per SNHD)	_____ x	
Number of Man-Hours	_____ x	
Estimated Cost per Hour	\$ _____ x	
Estimated Cost of Materials	\$ _____ =	
Estimated Training Cost		\$ _____

Drug/Device/Protocol Evaluation for the MAB

Does the issue need to be studied?

NO

YES

System-wide Implementation?
Complete "Application for Petition for Addition/Removal of Drug/Equipment To/From the EMS Inventory"

Review by OEMSTS and MAB Chairman

Item placed on MAB agenda to be sent to Drug/Device/Protocol Committee

Drug/Device/Protocol Committee:

1. Review/edit protocol
2. Determine endorsement of protocol
3. Coordination with:
 - a. Education Committee
 - b. QI Directors Committee
4. Make final recommendation to MAB once QA process, educational plan and final protocol completed

Address the need to revise/update the following:

- 1) Protocol Manual (effective date/review all affected protocols)
- 2) Inventory lists (equipment/drug)
- 3) Inspection form
- 4) Website posting

1. Complete "Application for Petition for Addition/Removal of Drug/Equipment To/From the EMS Inventory"
2. Review by OEMSTS and MAB Chairman

Item placed on MAB agenda:

1. Endorse moving forward with study
2. Send study to QI Directors Committee for coordination and oversight

QI Directors Committee Review:

1. Objective – to determine:
 - a. Ethical/safe
 - b. Is the study question narrow and precise?
 - c. Primary outcome measure
 - i. Secondary measures
 - d. Study protocol (recommend changes)
 - i. Sample size calculations
 - e. Timeline to report results back to QI Directors Committee

QI Directors Committee Presentation:

1. Agency/Investigator presents study results in writing, along with a 10-minute presentation to QI Directors Committee
2. QI Directors Committee determines:
 - a. Final answer to study question
 - b. Report back results and make recommendation to MAB

MAB votes to endorse for EMS system

DRUG/DEVICE/PROTOCOL COMMITTEE EVIDENCE-BASED GUIDELINES

1. Gather available evidence from credible sources and predetermined criteria (e.g. human studies only) and assess the power of methodology:
 - a. Level 1 – Large randomized clinical trials
 - b. Level 2 – Smaller randomized clinical trials
 - c. Level 3 – Prospective, controlled, nonrandomized cohort studies
 - d. Level 4 – Historic, non-randomized cohort, or case-controlled studies
 - e. Level 5 – Case series, no control group
 - f. Level 6 – Animal or mechanical model
 - g. Level 7 – Extrapolations from existing data, theoretical analyses
 - h. Level 8 – Rational conjecture (common sense); common practice

2. Assess quality of evidence and execution of methodology:
 - a. Excellent
 - b. Good
 - c. Fair
 - d. Poor

3. Determine the proposal class/recommendation based on available information:
 - a. Class I: Definite, excellent Level 1 evidence
 - b. Class II: Acceptable and useful; no harm
 - c. Class IIa: good supportive evidence
 - d. Class IIb: Fair supportive evidence
 - e. Class IIg: Historical precedent or consensus
 - f. Class III: Not acceptable; may be harmful
 - g. Indeterminate: Insufficient data