

**New York State
Department of Health
Bureau of Emergency Medical Services**

POLICY STATEMENT

No.	93-10
Date	12/1/93
Re:	EMS Service Operating Authority Approvals
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**POLICY FOR THE DETERMINATION OF NEED FOR NEW
OR EXPANDING EMS SERVICES
IN ACCORDANCE WITH PHL ARTICLE 30**

**Adopted – May 11, 1990
Revised – November 18, 1993**

**Authorized by: NY State Emergency Medical Services Council &
Bureau of Emergency Medical Services**

NYS-EMS POLICY 93-10
EMS SERVICE OPERATING AUTHORITY APPROVALS

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INTRODUCTION

There are five distinct steps that can be identified in the Article 30 process for determining public need for a proposed ambulance service. Every new EMS service or any seeking to expand its primary service territory must, by statute, receive the approval of the appropriate Regional EMS Council through this process prior to the Department's issuing operating authority. These steps are:

1. The Application
2. Public Notice
3. The Public Hearing and Application Review
4. Regional Council Determination
5. Certificate Issuance or Appeal

Each step has to be successfully completed in order to move to the next.

This document defines a logical approach to the five steps and establishes a framework for Regional EMS Councils to use when processing ambulance service applications under PHL 3008.

This document shall serve as a policy guideline for all Regional Councils until such time as rules and regulations are adopted.

'PUBLIC NEED'

Definition

THE DEMONSTRATED ABSENCE, REDUCED AVAILABILITY OR AN INADEQUATE LEVEL OF CARE IN AMBULANCE OR EMERGENCY MEDICAL SERVICE AVAILABLE TO A GEOGRAPHICAL AREA WHICH IS NOT READILY CORRECTABLE THROUGH THE REALLOCATION OR IMPROVEMENT OF EXISTING RESOURCES.

Variables in considering "Public Need"

Geography
Population – size, density, projections
Level of care – existing, available
Quality, reliability and response of existing services
Type of service – emergency, non-emergency
Special Need (i.e. Air, Industrial or Facility)
Service effectiveness, cost and operational
Other defined local factors

Each Regional EMS Council shall prepare a statement which is reviewed annually and is made available to each applicant that provides regional definitions and or minimum standards, alone or in combination, for these variables and any other local criteria that are appropriate to the development and review of an application.

The Regional Council has an obligation to determine if the issues identified are truly ones of public need/necessity or as an alternative if an improvement in existing resource allocation or coordination within a specific time frame can solve the problem. Inherent in this review is a determination as to why appropriate measures were not taken by existing providers prior to the submission of the new application.

THE APPLICATION

* It is the applicant's responsibility to verify that, prior to submission, the application is properly completed and that all necessary attachments are submitted in accordance with all policies, rules and/or regulations.

* All applications shall be complete, submitted on the prescribed form, be notarized and affirmed, be accompanied by all required attachments, endorsements, evidence and other supporting and explanatory material the applicant wishes the Regional Council to consider and any necessary fees. At least 2 original¹ applications shall be provided to the REMSC upon determination that the application is complete.

* A completed Application for New EMS Service..., (DOH 3777) will be submitted.

* The *complete* application is the basis for the determination of need. In the public hearing the applicant **may be** restricted to corroborating and/or explaining the data therein.

* The application and narrative shall describe the proposed area of service, level of service, hours of operation, service location and other pertinent operational aspects of the new service to allow for a reasonable and comprehensive review of the proposed service.

* The application shall describe the initial source of funds, the adequacy of sources of future revenue and shall provide a first year budget for the proposed service in enough detail to allow a reasonable assessment of the financial stability for the applicant to provide the proposed service and the financial feasibility of the proposal.

* The application shall attest to the competency and fitness of the applicant(s) and/or officers of the corporation. An Affirmation of Competency and Fitness (DOH 3778) shall be provided.

* All applications shall focus on the definition of public need. The narrative and endorsements shall respond to and document issues related to this definition. Statements of want, desire, feeling or other unsubstantiated sentiment are not acceptable.

* The applicant bears the burden of proof for the demonstration of public need.

* The applicant shall have sufficient knowledge of the EMS system in the area to be able to describe the **positive and negative** impact the proposed agency shall have on the area and providers. The applicant shall submit a narrative to be appended to the application detailing this impact on the following:

- 1) All existing ambulance and or emergency medical services within the proposed area in terms of but not limited to: response time, staffing, level of service, call volume for the past 12 months and the first 12 months of

¹ An original may be a first generation copy in original format with original signatures.

operation, mutual aid, quality assurance, medical direction, protocols, ability and quality of existing services, financial impact, and any adverse impact the proposed service will have on existing services.

- 2) The EMS system in the area – in terms of a description of the system, all existing EMS agencies, hospitals and other institutions that generate calls, participation agreements, mutual aid, actual and projected response times for the proposed agency and existing ones for the past and next 12 months, communications system interface, medical direction and control and any possible economies and improvements in service to be anticipated from the applicants operation.

The applicant shall demonstrate the ability to meet the definition of public need within the variable and any other standards defined by the Regional Council. In addition the fourteen items of evaluation¹ found in Appendix 1 shall be addressed in the application and or any attachments thereto.

* It is the intent of the public application and hearing process to obtain input from all who use, provide, pay for or compete in the EMS arena. Therefore, applicants shall solicit letters of endorsement from, but not limited to, the following agencies or organizations within the proposed service area and those with service areas or influence areas (i.e. adjacent ambulance primary service areas or hospitals with bordering patient catchment areas) bordering:

All EMS and ALSFR agencies licensed to provide service in the area.

EMS Medical Director(s) in the region.

The chairperson of any County EMS organization and county EMS coordinator.

All hospital CEO's and emergency department directors.

The CEO's of all municipalities.

* All letters of solicitation shall include a general description of the new service, the type and level of service to be provided, the definition of public need and a request for response by a specified date.

* All letters in response to the applicant's solicitation shall be signed by the CEO of the organization or authorized designee, can be no more than 6 months old and shall include an acknowledgement of receipt of the definition of public need.

* The application shall include a copy or sample of the letter of solicitation, a list of the agencies/individuals to which it was sent and any response received.

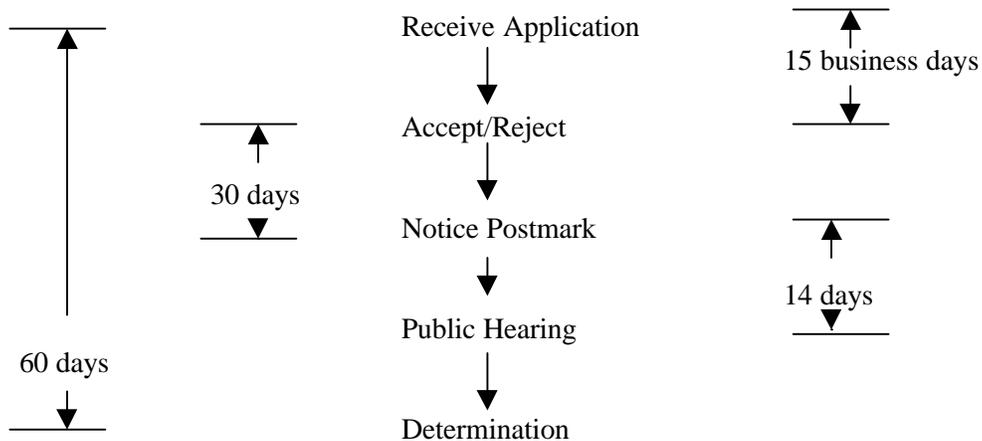
* The Regional EMS Council may establish a *uniform and non-waivable* fee to be

received with each application that reflects the **direct and real costs** of the application review, the process of public notice and the hearing. The fee shall be reviewed and re-approved annually by the Council and be made available at the normal place of council business.

* The application shall be received by the Regional Council at a designated location. Upon receipt, it shall be reviewed for completeness by designated “staff”. The application shall be accepted if it is deemed to be complete in accordance with these policies. If found to be incomplete, it shall be returned by certified mail or personal service to the applicant within one week, along with an explanation of the grounds for the rejection. When deemed complete and accepted, the time frames established by Public Health Law, Section 3008 begin. The applicant may request that any hearing and the final determination be made using the original application.

* The designated Regional Council shall begin action immediately upon of receipt and acceptance of a complete application, including scheduling a hearing date, sending public notice and establishing a Council meeting date at which to make a determination to comply with the 60 day limit.

* Applicants shall provide copies of the application accepted by the Council for each Council member, unless otherwise determined by local Council policy.



PUBLIC NOTICE

* The Regional EMS Council shall establish a date, time and location for a public hearing(s) to review the application and receive all comments.

* The hearing(s) shall be held within 30 days of accepting a complete application and the notice shall be postmarked at least 14 days prior to the hearing date.

* The hearing(s) shall be established at a time and place(s) logical to the application, preferably in the county or central to the proposed service area.

* More than one public hearing may be held if it is in the best interest of the application and so

long as *the same application and information is presented by the applicant at each* and they are held within the appropriate time frames.

- * One public hearing can be held to serve the needs of several Regional Councils if it is in the best interest of the applicant and appropriate representation from each of the Regional Councils is in attendance.

- * Letters of notice shall be sent in accordance with PHL 3008; certified return receipt to:

“The chief executive officers of all general hospitals, ambulance services, and municipalities operating within the same county or counties where the service seeks to operate...”

Hospitals adjoining the proposed service area and ambulance agencies with adjoining primary service areas and the local health systems agency shall also be included in the notice.

- * The letter of notice shall include the date, time and location of the hearing session, the definition of public need, a solicitation of response to the application by a specific date and provide a mechanism for any interested party to obtain and/or review the application.

- * The council shall maintain a copy of the letter of notice, a list of recipients, and all postal receipts until final disposition of the application is made.

- * The information contained in the letter of notice shall be published in the newspaper designated by the Regional Council to receive legal notices. As necessary this shall include newspapers designated by counties in the area of the Regional Council.

THE REGIONAL PUBLIC HEARING

- * The Regional Council shall establish a committee to hear each application. The Committee will **usually** consist of five members. Normally one shall be from the county or area the applicant proposes to serve, and one shall represent the majority of the ambulance constituency in the area proposed to be served.

- * The Regional Council may use a hearing officer designated by the Council and charged with finding fact and preparing a report for the Council. Regional Councils can utilize individuals who are authorized by various state agencies (DEC, State, etc.) as hearing officers or other individuals with similar training and experience. A hearing officer may also be utilized as a facilitator for the hearing committee to moderate and insure the hearing process follows generally accepted procedures. In this case the committee renders its decision following the hearing and does not utilize a report.

- * The purpose of the hearing is to provide a technical review and objective evaluation of the applicant's statement of need as well as any other testimony presented.

- * The committee may hear witnesses, receive written statements, ask questions and accept testimony in any form that will lend credibility to the hearing and the ultimate determination.

- * The Regional Council shall complete and maintain a record of the proceeding of

any and all hearings. This may be in stenographic or tape form. It is recommended that a record be transcribed and considered along with all other evidence in making the determination, especially pertinent are all discussions relating to public need.

* A written summary of the hearing shall be prepared that includes a finding of fact and a recommendation to support or deny the motion to approve the application and detailed justification for the recommendation made. Any other pertinent findings for presentation to the Regional Council are also included. If a hearing officer's report is the principle process, the committee should review the report and prepare the recommendation for the Council following a similar outline. It is recommended that the committee meet at a time other than immediately prior to the Council meeting for its deliberations.

REGIONAL COUNCIL DETERMINATION OF NEED

* At the designated Regional Council meeting, the chairperson of the hearing committee shall present the application, committee report, including the summary, any technical review, finding of fact and a specific recommendation.

* The recommendation of the hearing committee comes to the floor of the Council as a seconded motion for debate.

* Opportunity shall be provided for Council members present to make inquiry and ask questions prior to making a determination. No opportunity is to be given to non-council members to speak at this time as the public hearing(s) constituted the appropriate forum.

* One responsibility of the application process is to insure a high quality of ownership and management of an ambulance service to the degree of attempting to identify any issues of character that would be detrimental to this highly personal service.

With this as a purpose, the Regional Council shall address issues relative to the competency and fitness of the applicant and/or officers of the corporation as prescribed in PHL 3005(5).

The determination may include factors such as the individual's standing in the community, a demonstration of experience in the industry and an evaluation of any dubious history, including any convictions for any crime or crimes involving moral turpitude including, but not limited to, murder, manslaughter, assault, sexual abuse, theft, robbery, drug abuse or sale of drugs or fraud.

* The applicant shall submit a completed Affirmation of Fitness and Competency (DOH 3778). The Regional EMS Council shall conduct a review of the applicant's fitness and competency in accordance with the provisions of PHL Section 3005 and described in DOH Policy 93-09.

* The Regional EMS Council may place binding contingencies on the approval of an application as long as the conditions are in the best interest of the EMS system and are not in conflict with any State law, regulation or policy. The applicant may amend the application at any time during the process.

* Each Regional Council shall establish a policy within the framework mandated by NYS Ethics Rules and established by the State EMS Council regarding members abstaining from voting in cases of conflict of interest.

This policy shall address members who have a pecuniary interest in a competing service and those who serve as an officer in an organization deemed to be in direct competition with the applicant.

* Each Regional Council has the obligation to discuss and record in the record, all pertinent points and issues of the application relating to need, the definition of public need, and specific reasons and rationale for and against the application based on the application, evidence presented and testimony from the public hearing.

* A motion **approving** the application is the proper form. The motion is supported by a recommendation from the committee for or against the application and shall contain rationale and justification, positive and negative, for the recommendation presented.

* The Regional Council shall make its determination by a roll call ballot of the members present to accept or reject the recommendation of the committee. A majority of the voting members of the Council is required to make a determination. A statement shall be entered into the record that clearly defines the authority of alternates to vote in the procedure and a statement of the needed majority to pass the motion. The record of the roll call ballot shall list all voting members of the Council include at least:

- Member name, affiliation and status as member or alternate
- Present or absent for ballot
- Voting for, against or abstaining
- Declarations and/or decisions of conflict of interest

ISSUANCE OF OPERATING AUTHORITY

* The Regional Council shall provide written notice of its determination to the applicant within seven (7) working days and shall forward to the Department a copy of this notice along with an original copy¹ of the complete and accepted application.

* The applicant or any other party directly involved has the right to appeal by filing notice with the Executive Secretary of the State EMS Council at the Department. This notice must be received by the Department, **using receipted delivery, within thirty (30) calendar days** of the date of the Regional Council's determination.

* If the Regional Council's determination was to grant operating authority, and no notice of appeal is filed within the 30 days, the Department shall issue the Ambulance Service Certificate or Certificate of Registration.

* If the Regional Council's determination was to grant operating authority, and a notice

¹ An original may be a first generation copy in original format with original signatures.

of appeal is filed within the 30 days, the Department shall not issue the registration or ambulance service certificate. This shall stand until the conclusion of all legal processes.

- * The Department's Regional EMS representative shall obtain other application paperwork, conduct any necessary inspections, and collect any necessary fee for a new service.

- * In the event of an appeal the Department shall request the assignment of an Administrative Law Judge (ALJ) to hear the appeal and make a finding of fact and recommendation to the State EMS Council.

- * State EMS Council meetings and considerations of service application appeals are not *dunovo* hearings of the application, therefore discussion will be limited to State EMS Council members and the record.

- * The State EMS Council's Systems Committee shall review any appeal and the recommendation of the ALJ and shall make a recommendation to the State Council. The complete application and pertinent record and the ALJ's report shall be provided to the Council prior to their consideration of the appeal and a decision in accordance with PHL 3002(3).

CONTINUING EXISTING SERVICES (GRANDFATHERING)

* Ambulance services in bone fide operation prior to April 1, 1975, and Advanced Life Support First Response (ALFRS) services in bone fide operation prior to January 1, 1993, except those ALSFR service providing only "Defibrillation" level of care as of July 1, 1993, are considered eligible to be grandfathered without the burden of proving public need under the provisions of Public Health Law 3005.

* ALSFR services are required to hold a valid EMS service operating certificate as of July 1, 1993.

* ALSFR service apply for grandfathering as follows:

To be considered in bone fide operation by the Department and Regional EMS Council an ALS agency must submit an application to the Department that includes:

1. A completed new EMS service application (DOH 3777);
2. Evidence of having been available and dispatched to calls for assistance at the ALS level on or before January 1 or July 1, 1993 as appropriate;
3. Evidence of having provided ALS care at an approved level on or before January 1 or July 1, 1993 as appropriate;
4. A statement from the regional and or agency medical director that the agency and its personnel were authorized by the MD to provide ALS service on or before January 1, or July 1, 1993 as appropriate;
5. Written acknowledgement of the existence and provision of service by the agency and any remarks by the Regional Council;
6. A description of the exact geographical area being applied for as a primary operating territory **using existing** political subdivision boundary definitions **and** includes an endorsement from the CEO of all named political subdivisions.

* After January 1, 1995, any ambulance service or ALSFR service will be required to apply to the appropriate Regional Council for approval under the provisions of Public Health Law sections 3003.5 and 3010.2.

ADVANCED LIFE SUPPORT FIRST RESPONSE (ALSFR) SERVICE APPROVALS

It is recognized that a modified review and approval policy will be followed for ALSFR services wishing to provide defibrillation only, to facilitate making this modality of care available to local EMS systems and communities in accordance with recognized national standards.

ALSFR – DEFIBRILLATION

* At this time defibrillation by CFR and EMT First responder units is considered ALS care. First Responder services wishing to provide this level are required to apply and receive approval from a Regional EMS Council under PHL section 3005, before an operating certificate will be granted.

* The definition of public need for a service projecting to provide defibrillation is considered for this process to be the lack of available early defibrillation and the willingness of the agency to commit to provide the service as demonstrated by the approvals and testimony contained within the application. The most recent ECC/CPR national guidelines demonstrate the visibility and need for this level of care being readily and rapidly available.

* Agency submit to REMSC:

- Application for New EMS Service..., (DOH 3777).
- Affirmation of Fitness and Competency (DOH 3778).
- Letter of authority from governing authority.
- Letter of authority from system and/or agency medical director.
- Protocols for patient care, response and dispatch.
- Transport agency written agreement pursuant to 800.30.
- A narrative describing how defibrillation service is to be provided specifying in detail the nature of the dispatch, availability, service, staffing, equipment, ambulance dispatch, etc.
- Letter of agreement for dispatch and transport from the ambulance service agreeing to transport ALSFR service members and the patient in their care.
- A written stipulation which state the agency's understanding and agreement to the limitation that this CON proceeding is limited to the provision of Defibrillation only. Any expansion of service in scope or level requires a new CON approval from the REMSC for the new service.

* REMSC send notice to in accordance with PHL 3008 and the Public notice section of this policy.

* The time frames established by Article 30 and this policy apply.

* The public notice will provide a date by which any opposition to the application from certificate holders in the territory to be served or any receiving hospital for the proposed service must be declared.

* If no opposition is heard/received, the council may make its determination following an open discussion period at the next scheduled council meeting.

* If significant opposition is received, as determined by council reviewers/staff, a public hearing should be scheduled at least 2 weeks prior to the scheduled council meeting.

**ALSFR SERVICES PROPOSING INTERMEDIATE, CRITICAL CARE OR
PARAMEDIC LEVEL OF CARE**

* Review and complete an application in accordance with the process in this policy statement. Direct the content of the application to describe the service type and level to be offered.

UPGRADING OR CHANGING ALS LEVEL OF SERVICE

* Any ambulance or ALSFR service is referred to the Regional Medical Advisory Committee (REMAC) for policy, application and approval procedures. The Article 30 CON process does not govern in this case.

Appendix I¹

GUIDELINES FOR ESTABLISHING AMBULANCE SERVICES

Many states have specific guidelines that they use to evaluate ambulance-service license applications. Although some states license the service to operate in any part of the state, others require separate authorization for each specific service area. The following information was adapted from regulations which guide Missouri's Department of Health in granting ambulance licenses. EMS managers throughout the nation should find this information helpful in considering the viability of any new service area.

When considering a request for licensure of an ambulance service, the Missouri Bureau of Emergency Medical Services employs the following 14-factor analysis in making the difficult decision on whether or not a new service should be licensed. Typically, a convenience and necessity hearing is held to evaluate the 14 criteria. Following the hearing, and upon further review, a formal determination is made on the need for the service.

1. What is the population of the jurisdiction requesting the ambulance service, including tourism and traffic flow through the area? Does the area have a large enough population base to support a new ambulance service?
2. How many calls for service and how many emergency calls are made in the proposed area? What is the average daily rate of calls for this area? Would the area have a large enough demand to maintain a full-time service?
3. What is the average response time for all calls and emergency calls during a recent time period? Is the average response time reasonably prompt or under response-time specifications?
4. What is the quality of existing services and how do the present conditions affect public convenience? Do the nearby ambulance services adequately cover the emergency medical needs of the area? Would a newly licensed ambulance service be an improvement to public convenience?
5. Do mutual-aid ambulance agreements exist among the area under consideration and the nearby ambulance, police, and fire units? Are these agreements necessary for adequate coverage of this particular area?
6. Would the employees of the proposed ambulance service have a sufficient level of clinical experience for maintaining emergency care?
7. Would opportunities exist for personnel to maintain their level of skill? If an additional ambulance service was added, would the dilution of service calls between the ambulance services cause a decay in skills due to inactivity?
8. Are the existing communications capabilities adequate for maintaining medical control and directing paramedics? Would the proposed facilities be an improvement?
9. How will the ambulance service be financed? Are the financial resources available to the proposed ambulance service sufficient for maintaining a full-time service?

10. How will the ambulance service be organized and administered? Does management seem willing to support an ambulance service and is management capable of performing its duties?
11. What will be the total cost of the new ambulance service? Are the benefits that the proposed area would receive worth the expense?
12. Does public opinion in the proposed area favor the establishment of a new ambulance service?
13. Do the local government planning agencies favor establishment of a new ambulance service?
14. Are there any viable alternative other than licensing a new ambulance service? For example, in some cases volunteer EMTs or firefighters can respond in a non-licensed vehicle and call in an existing service for transport.

Before embarking on a program of licensure, an EMS leader should review the above questions and then objectively decide if there's a legitimate need for an ambulance service in the area.

¹ Excerpt taken