

CR 84-199

CERTIFICATE

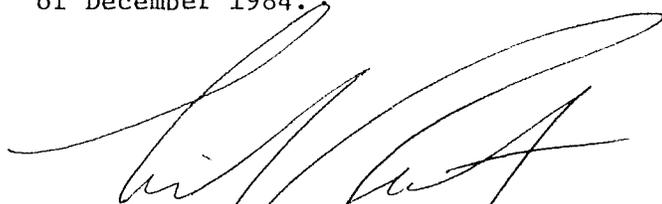
STATE OF WISCONSIN )  
 ) SS  
DEPARTMENT OF HEALTH AND SOCIAL SERVICES)

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Linda Reivitz, Secretary of the Department of Health and Social Services and custodian of the official records of said Department, do hereby certify that the annexed rules relating to defibrillation of patients by ambulance attendants were duly approved and adopted by this Department on December 7, 1984.

I further certify that this copy has been compared by me with the original on file in this Department and that the same is a true copy thereof, and of the whole of such original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department at the State Office Building, 1 W. Wilson Street, in the city of Madison, this 7th day of December 1984.

  
\_\_\_\_\_  
Linda Reivitz, Secretary  
Department of Health and Social Services

SEAL:

RECEIVED

DEC 7 1984

Revisor of Statutes  
Bureau

2-1-85

ORDER OF THE  
DEPARTMENT OF HEALTH AND SOCIAL SERVICES  
ADOPTING RULES

To create HSS 110.10, relating to defibrillation of patients by ambulance attendants.

Analysis Prepared by the Department of Health and Social Services

Ambulance attendants licensed under s. 146.50, Stats., and ch. H 20, Wis. Adm. Code, are not now authorized to administer defibrillation to a patient whose heart is in ventricular fibrillation. Limited studies in other states, however, indicate that ambulance attendants can be trained to defibrillate patients in prehospital emergency care and that the application of that training can result in an increased survival rate for patients found in ventricular fibrillation. To determine the feasibility of such training in Wisconsin, the department will allow a limited number of demonstration projects in which licensed ambulance attendants will be trained to administer defibrillation under medical control in prehospital emergency care and the impact of this training on patient outcomes will be evaluated.

HSS 110.10 defines key terms related to ambulance attendant defibrillation demonstration projects, identifies the required elements of a project proposal and training program, and establishes the general parameters within which an approved project must operate.

The Department of Health and Social Services intends to use the data and findings provided by these demonstration projects as one element in making future decisions regarding proposals for licensure or certification of ambulance attendants to administer defibrillation. Legislation may be proposed as a result of these projects which will address the issue of formal licensure or certification of this type of emergency care personnel.

Pursuant to authority vested in the Department of Health and Social Services by s. 146.50(3), Stats., the Department of Health and Social Services hereby adopts rules interpreting s. 146.50, Stats., as follows:

SECTION 1. HSS 110.10 is created to read:

HSS 110.10 AMBULANCE ATTENDANT DEFIBRILLATION DEMONSTRATION PROJECTS. (1) PURPOSE. This section sets forth conditions and procedures for approval by the department of a limited number of demonstration projects which allow ambulance attendants to be trained in and administer defibrillation, under medical control, in the prehospital setting. The data gathered by the projects will be used to evaluate the feasibility, safety, effectiveness and costs of ambulance attendant defibrillation training and service provision.

(2) APPLICABILITY. The section applies to any person involved in emergency medical services supervision, training or provision who seeks to provide training for, be trained in, or engage in defibrillation by ambulance attendants.

(3) DEFINITIONS. In this section: (a) "Ambulance attendant" means a person licensed under s. 146.50, Stats., and ch. H 20 [HSS 110], who is responsible for the administration of emergency care procedures and proper handling and transporting of sick, disabled or injured persons.

(b) "Ambulance attendant defibrillation demonstration project" or "project" means a program, limited in its duration, in which ambulance attendants are selected, trained and allowed to use defibrillation in a prehospital setting, under medical control, as described in an approved ambulance attendant defibrillation proposal and for the purpose of gathering data to assess the feasibility, safety, effectiveness and costs of defibrillation by ambulance attendants.

(c) "Ambulance attendant defibrillation proposal" or "proposal" means a proposal submitted by or for one or more acute care hospitals and one or more physicians intending to implement an ambulance attendant defibrillation demonstration project which details the training and utilization of ambulance attendants to administer defibrillation, as well as the study design and the evaluation methodology to be used.

(d) "Defibrillation" means the administration of an electrical impulse to an individual's heart for the purpose of stopping ventricular fibrillation.

(e) "Medical control" means direction, through verbal orders or a protocol, supervision and quality control by the medical director or a physician-designee of the medical director, of the activities of an ambulance attendant administering defibrillation in the prehospital emergency care of a patient.

(f) "Medical control hospital" means an acute care hospital named in the ambulance attendant defibrillation proposal which accepts responsibility to serve as a base for the system of communication, medical control and direction for ambulance attendant defibrillation personnel.

(g) "Medical director" means the physician licensed under ch. 448, Stats., who accepts responsibility in the project for the medical control, direction and supervision of ambulance attendants utilizing defibrillation, the establishment of standard operating procedures for these personnel, and the designation of specific physicians for day-to-day medical control.

(h) "Monitor and defibrillator" means a device capable of monitoring an individual's heart, by means of electrodes, and displaying the electrical activity of the individual's heart on a screen; providing a permanent paper record of the electrical activity and an audio tape recording of the treatment provided; and delivering a regulated electrical impulse to the individual's heart.

(i) "Prehospital setting" means a location at which emergency medical care is administered to a patient prior to the patient's arrival at a hospital and which is not within a facility or institution providing health services.

(j) "Project director" means the person designated by the medical director to be responsible for day to day recordkeeping for the project and for reports to be submitted to the department which will enable the department to review and evaluate the demonstration project.

(k) "Protocol" means a written statement, signed by the medical director, which lists and describes the steps an ambulance attendant is to follow in assessing and treating a patient suffering from a specific medical condition.

(l) "Training center" means the acute care hospital named in the ambulance attendant defibrillation proposal which will train ambulance attendants to administer defibrillation.

(m) "Training program coordinator" means the person designated by the medical director and training center who is responsible for coordinating and administering the training of ambulance attendants in defibrillation.

(n) "Ventricular fibrillation" means a disturbance in the normal rhythm of the heart which is characterized by rapid, irregular and ineffective twitching of the lower chambers (ventricles) of the heart.

(4) GENERAL REQUIREMENTS. (a) Defibrillation by ambulance attendants. 1. No person may implement a program which makes use of ambulance attendants to perform defibrillation on any individual without the prior approval of the department.

2. No person licensed only as an ambulance attendant may perform defibrillation on any individual unless the attendant is a participant, under medical control, in an ambulance attendant defibrillation project approved by the department.

3. No ambulance attendant may participate in an approved ambulance attendant defibrillation demonstration project unless the ambulance attendant has successfully completed the defibrillation training specified in an approved proposal and the medical director of the project has certified to the department that the ambulance attendant is competent to administer defibrillation to patients in the prehospital setting.

4. No ambulance attendant may continue to use defibrillation in the treatment of any individual after the expiration or cancellation of the ambulance attendant defibrillation project in which he or she is a participant.

5. No ambulance attendant trained to administer defibrillation in a project may function as an emergency medical technician - advanced (paramedic) as defined in s. 146.35 (1), Stats., in the provision of ambulance service nor may any ambulance service provider operating under an emergency medical technician - advanced (paramedic) plan approved by the department under s. 146.35 (3), Stats., substitute an ambulance attendant trained in administering defibrillation for an emergency medical technician - advanced (paramedic) required by the plan.

(b) Application. 1. One or more physicians and one or more acute care hospitals may submit an ambulance attendant defibrillation proposal to the department for an ambulance attendant defibrillation project. That proposal shall contain all the information required under sub. (5) (a).

2. All proposals to establish an ambulance attendant defibrillation project shall be submitted to the department for review within 90 days after the effective date of this section. Only complete proposals received during this acceptance period will be considered for approval.

Note: Proposals should be sent to the Emergency Medical Services (EMS) Section, Division of Health, P.O. Box 309, Madison, Wisconsin 53701.

(c) Review and decision. 1. The department shall review each complete proposal received during the 90-day acceptance period and shall, within 60 days following the expiration of the acceptance period, approve or disapprove of it and notify the applicant accordingly, in writing.

2. In reaching an approval or disapproval decision on any proposal, the department shall consult with physicians experienced in emergency medical services and medical research regarding the quality and feasibility of the proposal. Approval decisions on competing proposals shall be made in consultation with a panel of these physicians selected by the department.

3. Before approving a project, the department shall ensure that the protocol to be used, data to be collected and methods of evaluation to be employed are compatible with all other approved projects to the extent necessary to make possible comparison and aggregation of data and findings among projects.

4. Approval of a project shall be for a period not to exceed 18 months which shall be stated in the approval notice.

(d) Implementation. Following approval by the department of an ambulance attendant defibrillation proposal, all persons named in the proposal may implement the program as described for the time period specified in the approval.

(5) AMBULANCE ATTENDANT DEFIBRILLATION PROPOSAL. (a) A proposal for an ambulance attendant defibrillation project shall include, at a minimum, the following information:

1. Identification and qualifications of the medical director, medical control hospital or hospitals, project director, training program coordinator and designated physicians providing day to day medical control and quality assurance;

2. Identification and qualifications of the training center to be used and its relationship to the medical control hospital or hospitals;

3. Identification and description of the licensed ambulance service provider or providers planning to use ambulance attendant personnel trained in defibrillation;

4. A description of the educational, training and experience prerequisites to be used in the selection of ambulance attendants for inclusion in the project;

5. A description of the training course for the project, including content, behavioral objectives, clock hours, competency testing standards and procedures, and training methods. Required training course content areas are specified in sub. (6);

6. A description of the manner in which each ambulance service provider included in the project will use the ambulance attendants who are trained in defibrillation, including the number of ambulance attendants to be trained, hours of coverage to be provided, and service area to be affected;

7. A list of the equipment to be used by ambulance attendants participating in the project to administer defibrillation, including the brand name, capabilities and technical specifications of each piece of equipment. Minimum equipment requirements are identified in sub. (7);

8. A description of the operating policies and procedures to be used in medical control, implementation and quality assurance of the ambulance attendant defibrillation demonstration project;

9. A copy of any protocol to be used by ambulance attendants in determining the need for defibrillation and in administering defibrillation;

10. A description of the communications system to be used in medical control and direction of the ambulance attendants who are trained to administer defibrillation;

11. A description of the methods by which continuing education will be provided to ambulance attendants and the continuing competency of ambulance attendants participating in the project will be assured. Required continuing education shall include maintenance of certification from the American heart association or American national red cross in cardiopulmonary resuscitation;

12. A description of the relationship of the project to other emergency and public safety services in the project area, including how the project will be coordinated with and secure assistance in emergency care of a patient from any emergency medical technician - advanced (paramedic) services existing in the project area;

13. A copy of the research design for the project, detailing, at minimum, the data to be collected; the methods to be used for gathering, storing and retrieving data; the methods to be used for evaluating project data and reaching conclusions regarding the feasibility, effectiveness, safety and costs of training and using ambulance attendants to administer defibrillation in prehospital emergency patient care; the contents of reports which will be generated and available from the project; and the methods which will be used to address any medical, legal or ethical issue that arises in the implementation of the project;

14. A copy of agreements or letters of commitment from all parties to the project, indicating their willingness to participate in the project and adhere to the requirements of this section and to the statements made in the ambulance attendant defibrillation proposal;

15. Evidence that there is insurance available that will be in effect when the project begins which provides coverage to all parties involved in the ambulance attendant defibrillation project for any liability they incur in implementing the project; and

16. A budget for the proposed project and identification of the sources of financing the project.

(b) An ambulance attendant defibrillation proposal is not considered complete for review until all materials noted in par. (a) have been received by the department.

(6) AMBULANCE ATTENDANT DEFIBRILLATION TRAINING. (a) The ambulance attendant defibrillation training course which is part of an ambulance attendant defibrillation proposal shall include theory and practice in at least the following content areas:

1. Patient assessment and examination;
2. Use and maintenance of a cardiac monitor/defibrillator;
3. Cardiac rhythm interpretation;
4. Cardiac defibrillation;
5. Cardiopulmonary resuscitation; and,
6. Standard operating procedure for patient assessment, examination and defibrillation.

(b) Training program content shall be the same for all participants in the ambulance attendant defibrillation project.

(c) Each ambulance attendant shall, as a prerequisite to successful completion of an ambulance attendant defibrillation training course, present to the medical director proof of current certification in cardiopulmonary resuscitation issued by the American heart association or American national red cross.

(d) The medical director shall, upon completion of the ambulance attendant defibrillation training course, submit to the department records of student performance for each ambulance attendant who participated in the course and a list of the ambulance attendants who satisfactorily completed the course and are considered qualified to administer defibrillation in the project under medical control.

(7) MONITOR AND DEFIBRILLATOR EQUIPMENT. (a) The monitor and defibrillator used in an ambulance attendant defibrillation demonstration project shall include, at a minimum, an oscilloscope monitor, monitoring electrodes for placement on a patient's chest, a paper strip recorder for production of a permanent record of the electrical activity of the heart, an audio tape recorder and microphone for recording the ambulance attendant's voice activity during the resuscitation attempt, and a manually triggered defibrillator and paddles for delivery of defibrillation.

(b) During any prehospital emergency care effort in which the monitor and defibrillator is used, monitoring electrodes shall be attached to the patient and paper strip and audio tape recorders shall be in operation.

(8) PROGRAM RESPONSIBILITIES. The medical director is responsible for overall supervision and control of the ambulance attendant defibrillation demonstration project and adherence of the project to the approved proposal.

(9) REPORTS. (a) The project director of an approved project shall submit to the department, at least quarterly, a report on the progress and findings of the project. In addition, a final report shall be submitted to the department within 90 days following the conclusion or cancellation of the project. The report shall include the data specified in the research design approved with the proposal, including at least the following:

1. A summary of training courses and continuing education programs conducted during the period covered by the report, including clock hours and subject matter involved;

2. The names of ambulance attendants participating in the training courses and continuing education programs and the grades or other performance evaluation results achieved by each individual;

3. Statistical data, cumulative since project initiation and for the period covered by the report, detailed for the total project and individual ambulance services and attendants, including:

- a. The total number of patients contacted;
- b. The number of patients monitored with a monitor and defibrillator;
- c. The number of cases of ventricular fibrillation encountered;

d. The number of defibrillation attempts carried out;

e. The number of successful and unsuccessful defibrillations; and

f. Specific information on the history and the medical course and disposition of each patient on whom defibrillation was attempted; and

4. A description of the findings and actions taken, if any, as a result of retrospective analysis of paper strip and audio tape recordings produced in the project.

(b) The department shall have access on request to all data gathered by an ambulance attendant defibrillation demonstration project.

(10) APPROVAL AGREEMENT. (a) Departmental approval of an ambulance attendant defibrillation proposal shall be incorporated in an agreement signed by all parties to the proposal and a representative of the department which details the obligations of each party to the approval.

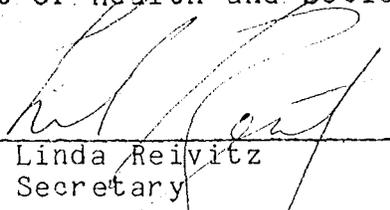
(b) Implementation of the project may not begin until the agreement is signed by all parties.

(11) CANCELLATION. The department may, at any time during the project period, cancel its approval of a project, if project participants fail to adhere to the approved proposal or approval agreement or there is evidence that the project, either in its implementation or its results, presents a danger to the health and safety of patients or the general public.

The rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in s. 226.026(1), Stats.

Department of Health and Social Services

Dated: 12-7-84

By:   
Linda Reivitz  
Secretary

SEAL:



State of Wisconsin

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

1 West Wilson Street, Madison, Wisconsin 53702

Anthony S. Earl  
Governor

Linda Reivitz  
Secretary

December 7, 1984

RECEIVED

DEC 7 1984

Mailing Address:  
Post Office Box 7850  
Madison, WI 53707

Revisor of Statutes  
Bureau

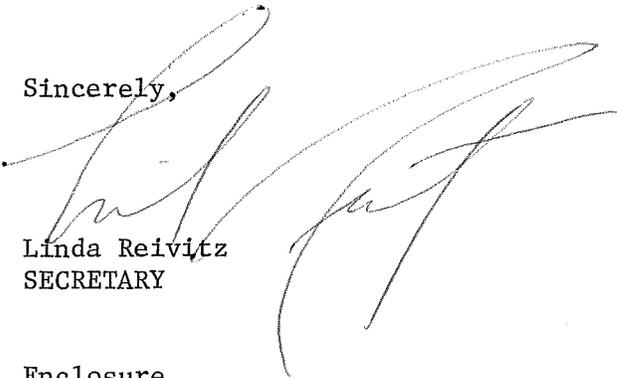
Mr. Orlan Prestegard  
Revisor of Statutes  
411 West, State Capitol  
Madison, Wisconsin 53702

Dear Mr. Prestegard:

As provided in s. 227.023, Stats., there is hereby submitted a certified copy of HSS 110.10, administrative rules relating to defibrillation of patients by ambulance attendants.

These rules are also being submitted to the Secretary of State as required by s. 227.023, Stats.

Sincerely,

  
Linda Reivitz  
SECRETARY

Enclosure