John D. Rockefeller IV
Governor

L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

Notice

Legislative Rule: Trauma Center or Facility Designation, Chapter 16-1, Series XXVII (1984), West Virginia Board of Health Legislative Rules.

The above titled legislative rule is hereby submitted to the Legislative Rule Making Review Committee.

Ann M. Stottlemyer for

L. Clark Hansbarger, M. D.
Secretary
West Virginia Board of Health

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Dec. 19, 1983
Administrative Law Division
Entered

John D. Rockefeller IV
Governor

L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

Certification

Legislative Rule: Trauma Center or Facility Designation, Chapter 16-1, Series XXVII (1984), West Virginia Board of Health Legislative Rules.

The above titled legislative rule constitutes the official rule as approved by the West Virginia Board of Health on December 16, 1983 and filed pursuant to law in the Office of the Secretary of State, State of West Virginia.

L. Clark Hansbarger, M. D.
Secretary
West Virginia Board of Health

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 12-19-83
Administrative Law Division

Entered

John D. Rockefeller IV
Governor

L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

NOTICE OF PUBLIC HEARING

Pursuant to Section five, Article three, Chapter twenty-nine-A of the Code of West Virginia, one thousand nine hundred thirty-one, as amended, the West Virginia Department of Health shall convene a public hearing at 1:00 p.m. on December 2, 1983, in the first floor Conference Room 14 of the P & G Building, 2019 Washington Street, East, Charleston, West Virginia for the purpose of taking evidence pertaining to the filing of proposed Trauma Center or Facility Designation Regulations, West Virginia Board of Health Legislative Rules, Chapter 16-4D, Series 1 (198_).

Any citizen or other interested party may appear in person to present evidence. Any citizen or other interested party may submit written evidence to the Regulatory Services Program of the West Virginia Department of Health, by mail to 1800 Washington Street, East, Charleston, West Virginia 25305 or in person at Room 7, second floor , P & G Building, 2019 Washington Street, East, Charleston, West Virginia 25305 not later than 4:30 p.m., December 2, 1983. All comments, written and oral, will be made part of the public record of comments received and will be considered as a part of the public hearing. The Department requests that parties wishing to comment make an effort to submit written copies of their comments in order to facilitate review of the comments.

The issues to be heard shall be limited to the actual information contained in the proposed and abovementioned regulations. Copies of the regulations may be obtained from the address heretofore appearing or by telephoning 304-348-3956 or from the Office of the Secretary of State, Capitol Complex, Charleston, West Virginia 25305, telephone 345-4000.

L. Clark Hansbarger, M. D.
Director of Health

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Nov. 1, 1983
Administrative Law Division
Entered

FISCAL NOTE FOR PROPOSED RULES

Rule No. 16-1, Series I Subject Trauma Center or Facility Designation

Type of Rule: ☒ Legislative ☐ Interpretive ☐ Procedural

Agency Health Department Address 1800 Washington Street, East

Charleston, WV 25305

Authorized Representative _____ Phone 348-0534

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	$ NONE	$ NONE	$ NONE	$ NONE	$ NONE
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Others					

2. Explanation of above estimates.

These rules and regulations list the criteria for designation and indicate the method to be used for such designation as a trauma center of a particular level. No expenditure of funds are anticipated since the process is one of voluntary participation.

3. Date October 31, 1983 Agency Health Department

Signature of Agency Head

Alan M. Stollings for

L. Clark Hansbarger, M.D.
Director

Signature of Authorized Representative

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Nov. 1 1983
Administrative Law Division

STATEMENT OF ECONOMIC IMPACT OF PROPOSED RULES OR REGULATIONS

Agency Health Department

Rule No. 16-1, Series I Subject Trauma Center or Facility Designation

1. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of citizens.

Individual medical institutions wishing to upgrade capabilities for care of the trauma victim may incur expenditures of a moderate nature. It is not anticipated that any institution will expend more than $100,000.00 in initial costs and no more than what is being expended now for ongoing costs. Since the designation is a voluntary one, no hospital will be required to expend any additional funds.

C. Economic Impact on Citizens/Public at Large.

None

Date October 31, 1983 Agency Health Department

Signature of Agency Head

L. Clark Hansbarger, M.D.
Director

Signature of Authorized Representative

D R A F T 9/17/83

P R O P O S E D

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

TRAUMA CENTER OR FACILITY DESIGNATION

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Nov. 1, 1983
Administrative Law Division

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Trauma Center or Facility Desisnation

Chapter 16-1
Series
(1984)

INDEX

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series
(1984)

Subject: Trauma Center or Facility Desisnation

Section 1. General

1.1. Scope - These lesislative rules establish the standards, criteria and methods of desisnatins various health care facilities in the State of West Virsinia as meetins specific levels of care capability as trauma centers or facilities in order to identify those facilities best equipped and staffed to care for the critically injured patient.

1.2. Authority - These lesislative rules are issued under the authority of Chapter 16, Article 1, Section 7 (4) and are related to Chapter 16, Article 4D, Seciton 1 et seq of the West Virsinia Code of 1931, as amended.

1.3. Filins Date - These rules were promulsated on the _____ day of _____19____, and were filed on the _____ day of _____19____, in the Secretary of State's Office.

1.4. Effective Date - These lesislative rules became effective on the _____ day of _____, 19____.

Section 2. Application and Enforcement

2.1. Application - The enforcement of these lesislative rules apply to all health care institutions, facilities, hospitals, clinics, corporations, partnerships and sovernmental asencies ensased in the provision of care to critically injured patients in the state.

2.2. Enforcement - The enforcement of these lesislative rules is vested with the director of the West Virsinia Department of Health or his lawful desisnee.

Board of Health
Legislative Rule 16-1
Series

Section 3. Definitions

3.1. Level II - This means a health care facility which meets most but not all of the standards, criteria, resources and capabilities of trauma care as listed herein. (Advanced)

3.2. American College of Surgeons (ACS) Guidelines - A listing of hospital resources necessary for optimal care of the injured patient as published by the ACS in 1979 in the Bulletin of the American College of Surgeons.

3.3. Regional Emergency Medical Services Agency - One of several multicounty operational agencies established by the Office of Emergency Medical Services for the purpose of coordinating the development, implementation and planning for emergency medical services within the regional area. Each region is staffed by Area program personnel who function under a Board of Directors appointed by the several Emergency Medical Services Regions served.

3.4. Basic - This means a health care facility which meets the minimum standards, criteria, resources and capabilities of trauma care as listed herein.

3.5. Board - Means the West Virginia Board of Health

3.6. Level I - This means a health care facility which meets all of the standards, criteria, resources and capabilities of trauma care as listed herein. (Comprehensive)

3.7. Critical Care Committee - A committee established at the regional and state EMS agency level, composed of specialty physicians representing the eight critical patient care areas of trauma, cardiac, high risk infant, poisoning, drug and alcohol detoxification, behavioral, spinal and burn care for the purpose of advising the respective agency on medical care principles and

activities, including categorization of health care facilities.

3.8. Dedesignation - This means the withdrawal of a previous designation level by the West Virginia Department of Health when it is determined by review and audit of an institution that such institution no longer meets the standards, criteria, resource availability or commitment for trauma care.

3.9. Designation - This means an official notification from the West Virginia Department of Health to a particular health care facility, indicating the level of trauma care capability determined by the site visit process.

3.10. Level III - This means a health care facility that meets some of the standards, criteria, resources and capabilities of trauma care as listed herein, but does not have the specialty care capabilities to manage the more severely injured patient throughout the course of hospitalization. (Intermediate)

3.11. Levels of Care Capability - This refers to the resources, staffing, equipment and commitment that a particular health care facility evidences in the trauma care area. The terms comprehensive, advanced, intermediate and basic are used to identify the various levels.

3.12. Office of Emergency Medical Services - An official division of the West Virginia Department of Health.

3.13. Proposal - A document submitted by a health care facility which indicates the existing resources, care capability, commitments and cooperative assurances of that institution in regards to trauma care. Normally the proposal process will be used when two or more

institutions located in the same community or general area, are competing for designation at a particular level.

3.14. West Virginia Categorization Committee - A committee appointed by the director of the Office of Emergency Medical Services to periodically review and recommend changes in the West Virginia State Emergency Facility Categorization Plan. The committee shall be composed of three (3) representatives each of the West Virginia State Medical Association, the West Virginia State Hospital Association, the West Virginia regional or area EMS agencies, regional EMS Medical Directors, two (2) each from the West Virginia Chapter of the American College of Emergency Physicians, the West Virginia Nurses Association, the West Virginia Emergency Department Nurses Association and three (3) representative from the public at large, and two (2) representatives of the Committee on Trauma, West Virginia College of Surgeons.

Section 4. Site Visit - No health care facility, center, unit or hospital shall be designated in accordance with the following process without a site visit being performed by individuals authorized to perform such site visit by the West Virginia Department of Health.

Section 5. General Criteria for Determining Trauma Care Capability

5.1. Trauma

5.1.1. Basic - A facility which is capable of caring for a minimally injured patient and is able through its medical staff to stabilize patients with more severe injuries prior to transfer to a facility with higher care capability.

5.1.2. Level III - (Intermediate) An institution with approximately 100 to 250 beds which has a clear commitment to excellence of trauma care. Transfer protocols in selected specialty areas are required.

5.1.3. Level II - (Advanced trauma facility)

An institution with approximately 200 to 500 beds which treats a large volume of seriously injured patients per year.

5.1.4. Level I - (Comprehensive trauma facility)

A hospital operating in a metropolitan area and experiencing approximately one thousand (1,000) admissions per year of seriously injured patients.

Section 6. Specific Standards and Criteria for Designation of Health Care Facilities as Trauma Centers.

6.1. Trauma:

6.1.1. Basic Level Facility (No National Level Designated):

6.1.1.1. Care Capability

A. The hospital and its medical and nursing staffs are capable of treating and stabilizing patients with:

1. Closed fractures

2. Soft tissue injuries with stabilized bleeding

3. Multiple rib fractures without flail chest

4. Blunt abdominal trauma not producing hypotension

B. Required resources and equipment:

1. X-Ray facilities with adequate interpretation and laboratory facilities, both available 24 hours a day.

2. Regularly available physicians capable of caring for the patinet injuries described in A. above.

3. Experienced nurses available to care for and evaluate such patients.

4. Available stored blood

5. Cut-down trays

6. Surgical supplies for hemostasis and wound repair

7. Splints and slings

8. Oxygen supplies

9. Nasogastric tube sets

10. Suction equipment

11. Parenteral fluids and infusion equipment including dextran or similar product and blood administration sets.

12. Standard emergency drugs

13. Stretchers capable of Trendelenberg position

14. Electrocardioscope-graph-defibrillator equipment

6.1.2. Level III Trauma Center (Intermediate)

6.1.2.1. Care Capability - The hospital and its medical, nursing and administrative staffs are capable of treating and stabilizing patients with most types of traumatic injuries. Available resources include all those listed under "Basic Level Facility", plus the following:

A. Hospital organization:

1. Required departments/divisions/services or sections which are staffed by qualified physicians:

a. General Surgery

2. Surgical specialties availability. On-call and promptly available from inside or outside the hospital. (May be fulfilled by residents capable of assessing

emergency situations in their respective specialties and of providing any immediately indicated treatment. When residents are used to fulfill availability requirements, staff specialists are to be on-call and promptly available for consultation).

a. Required:

(1) General Surgery specialists

b. Recommended/Desired:

(1) Ophthalmic surgery specialists

(2) Orthopedic surgery specialists

(3) Otorhinolaryngologic surgery specialists

(4) Plastic and Maxillofacial surgery specialists

(5) Thoracic surgery specialists

(6) Urologic surgery specialists

3. Non-surgical specialties availability: (May be fulfilled by residents as before specified).

a. Required:

(1) Physician directed anesthesia department (may be physician-directed program staffed by nurse anesthetists).

(2) Internal Medicine

(3) Pathology

(4) Pediatrics

(5) Radiology

b. Recommended/Desired:

(1) Anesthesiology

(2) Cardiology

(3) Hematology

B. Special facilities, resources and capabilities

1. Emergency Department:

a. Personnel:

(1) Desisnated Medical Director

(2) Physician(s) with special competence in the care of the critically injured patient who are on duty in the Emergency Department 24 hours as day. (May be fulfilled when local conditions insure that the physician will be in the emergency department at the time of the patient's arrival).

(3) RN's, LPN's and nurses' aides in adequate numbers

b. Equipment for resuscitation and to provide life support for the critically or seriously injured patient shall include, but not be limited to the followins:

(1) Airway control and ventilation equipment, including laryngoscopes and endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen and mechanical ventilator.

(2) Suction devices

(3) Electrocardiograph-scope-defibrillator

(4) Apparatus to establish central venous pressure monitoring

(5) All standard intravenous fluids and administration devices, including intravenous catheters

(6) Sterile surgical sets for procedures standard for Emergency Departments, such as thoracotomy, cut-down trays, etc.

(7) Gastric lavage equipment

(8) Drugs and supplies necessary for emergency care

(9) Two-way radio linked with vehicles of emergency transport system and with essential on-call physicians in-hospital

(10) X-Ray capability, 24-hour coverage by technicians

(11) MAST Garmet (Medical Anti-shock Trousers)

(12) Skeletal tongs

2. Intensive Care Unit for trauma patients (may be separate specialty units):

a. Required:

(1) Designated Medical Director

(2) Nurse-patient ratio at a minimum of 1:2 on each shift

(3) Immediate access to clinical laboratory services

(4) Equipment required:

(a) Airway control and ventillation devices

(b) Oxygen source with concentration co controls

(c) Cardiac emergency cart

(d) Temporary transvenous pacemaker

(e) Electrocardiograph-scope-defibrillator

(f) Mechanical ventilator-respirator

(g) Pulmonary function measuring device

(h) Temperature control devices (patient)

(i) Pressure distribution equipment

(j) Drugs, intravenous fluids and supplies

b. Recommended/Desired:

(1) Physicians on duty in intensive care unit 24 hours a day or immediately available from in-hospital

(2) Cardiac output monitoring devices

(3) Electronic pressure monitoring devices

(4) Patient weighing devices

3. Postanesthetic Recovery Room (a surgical intensive care unit is acceptable):

a. Required:

(1) Registered nurses and other essential personnel available 24 hours a day

(2) A physician (usually an anesthesiologist) providing supervision in-hospital 24 hour a day

(3) Appropriate monitoring and resuscitation equipment

4. Radiological special capabilities:

a. Recommended/Desired:

(1) Angiography of all types

C. Operating suite special requirements, equipment and instrumentation:

1. Required:

a. Thermal control equipment for patients and blood supplies

b. X-Ray capability

c. Endoscopes, all varieties

d. Monitoring equipment

2. Recommended/Desired:

a. Operating room adequately staffed and immediately available 24 hours a day

b. Craniotome

D. Clinical Laboratory Services - required 24 hours a day

1. Standard analysis of blood, urine and other body fluids

2. Blood typing and cross-matching

3. Coagulation studies capability

4. Comprehensive blood bank or access to a community central blood bank

5. Blood gases and pH determinations

6. Serum and urine osmolality determinations

7. Microbiology

E. Programs for quality assurance:

1. Medical care evaluation, including:

a. Required:

(1) Special audits for trauma deaths

(2) Trauma morbidity and mortality reviews

(3) Medical nursing audits, utilization review and tissue review

(4) Medical records review

2. Public education program (recommended)

a. Program(s) to cover injury prevention in the home, in industry, on the highway and on athletic fields. To include programs of standard first aid, problems confronting the public, medical profession and hospitals regarding optimal care for the injured patient.

6.1.3. Level II Trauma Center (Advanced)

6.1.3.1. Care Capability - The hospital and its medical, nursing and administrative staffs are capable of treating and stabilizing patients with all but the most serious or complicated traumatic injuries. Resources include all of those required ele elements of basic and intermediate trauma facilities, plus the following:

A. Hospital organization:

1. Departments/divisions/services or sections which are staffed by qualified physicians:

a. Required:

(1) Neurologic surgery

(2) Orthopedic surgery

b. Recommended/Desired:

(1) Trauma Service

(2) Cardiothoracic surgery

(3) Obstetrics-Gynecologic surgery

(4) Ophthalmic surgery

(5) Oral surgery (dental)

(6) Otorhinolaryngologic surgery

(7) Pediatric surgery

(8) Plastic and Maxillofacial surgery

(9) Urologic surgery

2. Surgical specialties availability: (Requirement may be fulfilled by residents capable of assessing emergency situations in their respective fields and of providing any immediately indicated treatment. When residents are used to fulfill availability requirements, staff specialists are to be on-call and promptly available for consultation).

a. Required:

(1) General Surgery - in-hospital 24 hours a day: (May be fulfilled when local conditions

insure that the physician will be in the emergency department at the time of the patient's arrival.

(2) On-call and promptly available from inside or outside the hospital:

(a) Ophthalmic surgery

(b) Orthopedic surgery

(c) Otorhinolaryngologic surgery

(d) Plastic and Maxillofacial surgery

(e) Thoracic surgery

(f) Urologic surgery

b. Recommended/Desired:

(1) On-call and promptly available from inside or outside the hospital:

(a) Cardiac surgery

(b) Neurologic surgery

(c) Microsurgical capabilities

(d) Gynecologic surgery

(e) Pediatric surgery

(f) Hand surgery

(g) Oral surgery (dental)

3. Non-surgical specialties availability: (May be fulfilled by residents as specified previously).

a. Required:

(1) On-call and promptly available from inside or outside the hospital:

(a) Cardiology

(b) Hematology

b. Recommended/Desired:

(1) On-call and promptly available from inside or outside the hospital:

(a) Gastroenterology

(b) Infectious disease

(c) Nephrology

(d) Pulmonary disease

(e) Psychiatry

B. Special Facilities, Resources and Capabilities:

1. Emergency Department: As before under Level III

2. Intensive Care Unit(s):

a. Required:

(1) Cardiac output monitoring device

(2) Electronic pressure monitoring device

(3) Patient weighing devices

b. Recommended/Desired:

(1) Intracranial pressure monitoring devices

3. Postanesthetic Recovery Room: As before under level III.

4. Hemodialysis capability: Recommended/Desired

5. Radiological Special Capabilities:

a. Required:

(1) Angiography capability

b. Recommended/Desired:

(1) Sonography

(2) Nuclear scanning

(3) Computerized tomography (or equivalent)

24-hours a day availability

6. Rehabilitation Medicine: Recommended/Desired

C. Operating Suite Special Requirements, Equipment and Instrumentation:

1. Required:

a. Operating room adequately staffed and immediately available 24 hours a day

b. Craniotome

2. Recommended/Desired:

a. Cardiopulmonary bypass pump-oxygenator

b. Operating microscope

D. Clinical Laboratory Services: As before under Level III

E. Programs for Quality Assurance:

1. Medical care evaluation:

a. Required:

(1) Public education programs to cover injury prevention in the home, in industry, on the highway and on athletic fields. To include programs of standard first aid, problems confronting the public, medical profession and hospitals regarding optimal care for the injured patient.

b. Recommended/Desired:

(1) Trauma conference, multidisciplinary

(2) Outreach program with telephone and on-site consultations with physicians of the community and outlying areas.

F. Training Programs: Required

1. Formal programs in continuing education provided by the hospital for:

a. Staff physicians

b. Nurses

c. Allied Health Personnel

d. Community physicians

6.1.4. Level I Trauma Center (Comprehensive)

6.1.4.1. Care Capability - The hospital and its medical, nursing and administrative staffs are capable of treating and stabilizing patients with all types of trauma within the existing state of the art technology and knowledge. The facility or center operates as a dedicated trauma service with all of the resources and capabilities afforded to the other national level I (comprehensive) trauma centers across the nation.

The resources available to the Comprehensive Trauma Facility include all of those previously listed as required for "Basic", "Intermediate" and "Advanced" trauma facilities, plus the following:

A. Hospital organization:

1. Required departments/divisions/services or sections which are staffed by qualified physicians:

a. Trauma service

b. Cardiothoracic surgery service

c. Ophthalmic surgery service

d. Otorhinolaryngologic surgery service

e. Pediatric surgery service

f. Plastic and Maxillofacial surgery service

g. Urologic surgery service

2. Surgical specialties availability: (In-hospital 24-hours a day or resident coverage as before).

a. General surgery specialtists

b. Neurologic surgery specialists (This requirement may be fulfilled by in-hospital neurosurgeons or an in-hospital surgeon with special competence in the care of patients with nervous system trauma (as judged by the Chief of the Neurosurgical Service) and who is capable of initiating measures directed toward stabilizing the patient and initiating neurologic diagnostic procedures. An attending neurosurgeon must be promptly available and dedicated to that hospital's trauma service.

3. Surgical specialties availability: (On-call and promptly available from inside or outside the hospital)-Required:

a. Cardiac surgery specialist

b. Microsurgery capabilities

c. Gynecologic surgery specialist

d. Pediatric surgical specialist

e. Hand surgery specialist

f. Oral surgery (dental) specialist

4. Non-surgical specialties availability: (Resident services as previously indicated for levels II and III)- Required:

a. Anesthesiology

b. Gastroenterology

c. Infectious disease

d. Nephrology

e. Pulmonary disease

f. Psychiatry

g. Neuroradiology

B. Special Facilities: Resource and Capabilities:

1. Emergency Department - As before for level II

2. Intensive Care Units:

a. Required:

(1) Physician on duty in intensive care unit 24-hours a day or immediately available from in-hospital.

(2) Intracranial pressure monitoring devices

3. Postanesthetic Recovery Room: (Surgical intensive care unit is acceptable), - As before for level II

4. Hemodialysis capability required

5. Radiological Special Capabilities:

a. Required:

(1) Sonography

(2) Nuclear scanning

(3) Computerized tomography or equivalent - 24-hours a day availability.

6. Rehabilitation Medicine - Required

C. Operating Suite Special Requirements, Equipment and Instrumentation:

1. Cardiopulmonary bypass pump-oxygenator - Required

2. Operating microscope - Required

D. Clinical Laboratory Services: As before for level II

E. Programs for Quality Assurance - Required:

1. Trauma conference, multidisciplinary

2. Outreach program with telephone and on-site consultation with physicians of the community and outlying areas.

3. The qualifications of trauma care personnel are specified in writing by the applicable department.

F. Trauma Research Program: Required

1. A defined and documented program for the study of the various aspects of trauma treatment, diagnosis, management and patient response must be provided.

Section 7. Notification and Site Visit Process

7.1. The designation of health care facilities providing emergency or critical trauma care services to patients in this state shall be accomplished in a manner consistent with mutual cooperation of the facility to be evaluated and the agency performing or causing to be performed the site visit intended to obtain the necessary facts and information to facilitate such designation.

7.2. The evaluation process shall only address the resources, equipment, care capability and commitment for trauma care on the part of the institution and its medical, nursing and administrative staffs.

7.3. Notification of Intention to Perform a Site Visit - The regional EMS agency through its board of directors shall notify in writing, each health care institution within the EMS regional borders that a site visit by qualified physicians and others is to be accomplished upon acceptance in writing of such site visit by the health care facility, institution, clinic, center, unit or hospital.

7.4. The site visit team as selected by the regional EMS board of directors and approved by the West Virginia Department of Health shall include specialists in the care of traumatized patients and if necessary, other medical specialists, as well as others appointed by the board of directors to assist in the site visit process.

7.5. Each facility to be visited shall be provided a copy of these regulations as well as a copy of the evaluation form or forms to be used by the site visit team, such copies to be provided free of charge by the regional EMS agency involved.

7.6 The hospital and its medical staff shall appoint appropriate individuals to accompany the site visit team and provide access to the various clinical and administrative areas of the hospital during the site visit.

7.7 Patient confidentiality will be maintained throughout the process and names or other patient identifying information shall not be published or recorded in any form by the site visit team. Review of patient records by physician members of the team shall be permitted even though the physicians may not be members of the hospital medical staff. The hospital may require that one of their medical staff or medical records personnel accompany the site visit team physician or physicians during review of patient records.

7.8 The site visit team leader, previously appointed by the regional EMS board of directors, shall review the results of the survey prior to departing the hospital or facility in order to give the hospital administrator and the medical staff representative a preliminary judgement as to the level of trauma care determined. Such verbal reports shall not be interpreted as final, but shall be used to allow the hospital and its medical staff the opportunity of preparing a response upon official notification and to allow the re-evaluation of specific areas by the

site visit team leader or his representative(s) if significant changes are made prior to submission of the results of the site visit to the regional EMS board of Directors.

7.9. The regional EMS board of directors may delegate to its critical care committee and the regional EMS medical director the authority to carry out the entire site visit process, but the ultimate responsibility for the actions of the critical care committee and EMS medical director remains with the regional EMS board of directors.

7.10. The regional EMS board of directors or its designee shall prepare a report indicating the findings of the site visit team and recommend to the West Virginia Department of Health, Office of Emergency Medical Services the levels of trauma care capability for each health care facility, institution, clinic, center, unit or hospital so evaluated. A copy of the final recommendations related to each facility shall be sent to each facility individually with no reference to the findings on other facilities included in such report. The report to the State Office of Emergency Medical Services shall be prepared in matrix form showing the name of each facility in the left hand column and the level of care capability in rows across the top of the page. In addition, the report to the State Office shall contain the names of the individuals participating in the site visits and any other pertinent comments related to the acceptance of the verbal report by the hospital administrative or medical personnel.

7.11 Upon receipt of the recommendations from the regional EMS board of directors, the State office of Emergency Medical Services shall prepare a letter of provisional designation to each facility.

Such designation shall be limited to trauma care capability and shall not be interpreted as implying total facility care capability or expertise in other areas of health care.

Section 8. Designation Process

8.1. The West Virginia Department of Health shall have the power to designate health care facilities in the state which meet or exceed the standards and criteria listed herein as "Basic", "Intermediate", "Advanced" or "Comprehensive" trauma facilities, units or centers. Such designation will be provided in writing by the Director of the Department of Health upon determination that the appropriate standards and criteria have been met or exceeded by a health care facility.

8.2. The initial review of a particular health care facility will be accomplished by regional emergency medical service agencies utilizing the standards and criteria listed in these rules and regulations and performed in accordance with the mechanisms outlined in Sections five (5) and six (6).

8.3. Upon review and recommendation of the board of directors of the regional EMS agency, or their designated body, the proposed level of designation will be submitted to the West Virginia Department of Health, Office of Emergency Medical Services for review and action.

8.4. The Director of the West Virginia Department of Health shall issue a provisional designation to the health care facility upon determination that the information submitted by the regional EMS agency is in order and reflects compliance with these rules and regulations.

8.5. Upon granting the provisional designation, the Director or his designee, may enlist the assistance of outside reviewers to perform a site visit at the health care facility in order to confirm the original findings. If outside reviewers are not utilized, the Director or his designee will perform such site visits accompanied by specialists and others recruited from West Virginia licensed physicians practicing critical care medicine in the specialty or subspecialty related to trauma care.

8.6. Upon verification that the health care facility has met the appropriate criteria and standards, an official letter of designation will be forwarded to the hospital administrator by the Director of the West Virginia Department of Health.

8.7. Should the regional emergency medical service agency refuse of be unable to provide the initial evaluation through their own resources or from outside consultants, the Director shall arrange for such initial appraisal of the institution or institutions in question.

8.8. In areas of the state where the most likely institution for trauma care refuses to allow site visits by the regional EMS agency or the designees of the West Virginia Department of Health, and, where no other appropriate institution is located within a reasonable distance, the Director of the West Virginia Department of Health or his designee may enter such facility in order to accumulate the necessary information to evaluate the institution's trauma care capability, but no official designation will be made. The level of trauma care capability may be provided to the public and emergency ambulance squads in order to facilitate proper transportation to the most

appropriate facility for the care of a particular type of injury.

8.9. No institution, health care facility, unit, center or hospital shall hod itself out to be a trauma center, unit or facility until such time as a desisnation level is assisned by the Director of the West Virsinia Department of Health. Any public advertisement or claim of such trauma care capability on the part of a health care facility prior to receivins the appropriate desisnation may result in civil proceedinss asainst such institution.

8.10. Any institution, health care facility, unit, center or hospital havins received a desisnation as a trauma center, unit or facility from the West Virsinia Department of Health shall be exempted from the antitrust laws of this state pertainins to antitrust actions brousht as a result of such desisnation by an individual, individuals, corporation, partnership, other health care institution, or sovernmental asency.

Section 9. Review or Audit of Desisnated Facilities

9.1. The Director of the West Virsinia Department of Health or his desisnee shall have the power to periodically review or cause to be reviewed the trauma care capability of a previously desisnated health care facility. Such review or audit may include a site visit or visits to the institution in order to verify that the orisinal standards and criteria are still in palce. Such audit or review may be performed at the discretion of the Director of the West Virsinia Department of Health, but in no case more freauently than annually and with the time and date of such site visit beins mutually asreed upon by the official spokesperson of the institution and the Director of Health.

9.2. The Director may authorize qualified individuals outside state government to perform such site visits.

9.3. Should such site visit audit result in a report indicating less than acceptable levels of care capability as indicated by the standards and criteria listed herein, the institution may be dedesignated at a lower level until such time as required to meet the standards and criteria of the previous designation level.

9.4. A health care facility receiving notification from the Department of Health of its intention to lower the designation level shall be given the opportunity to respond in writing within ten working days upon receipt of such notification of dedesignation. Such response shall contain the reasons for recommending that no change in designation be made. The Director of the Department of Health may revoke the notice of dedesignation based upon factual information provided by the facility that substantially alters the results of the site visit.

Section 10. Combined Hospital Designation of Trauma Centers

10.1. General - Due to limitations in particular areas of trauma care in basically similar hospitals located in a community, there is a need to recognize the combined capabilities of these hospitals in the designation process.

10.2. Requirements - Two or more hospitals within a particular community which share a common physician attending staff and which would be eligible for a certain designation if the resources of each of the hospitals were to be combined in a trauma care plan, may be

individually designated at the combined level. In order to qualify for a combined trauma center designation the followins requirements must be met.

10.2.1 A current (annual) written plan of trauma patient care must be availble and endorsed by each hospital.

10.2.2. Specific care capabilities for all major injury types must be addressed and the plan must indicate the resources available for treatment of these major injuries, includins personnel, equipment and facilities.

10.2.3. Specific triage protocols (based upon types of injury) must be provided in writins and endorsed by each participatins hospital. The medical command center must accept these protocols and follow the triage patterns in directins patient flow.

10.2.4. The participatins hospitals must address each of the standards for designation and must as a combined effort, meet the standards upon which designation is based. All facilities may then be designated at that particular level although separately none of the facilities would be capable of meetins all of the standards for such level of care.

10.3. Minimum Care Capabilities - Each facility participatins in a combined designation process must meet certain minimum standards in order to be eligible for such combined designation.

10.3.1. Each facility participatins in a combined designation process must be capable of meetins all of the required/essential standards of a Level III (intermediate) level trauma center.

10.3.2. Each facility must meet the following level II standards individually in order to qualify for combined designation as level II.

A. All of the standards listed under "Hospital Organization" as listed under Section 6.1.3.1., A., of these rules and regulations.

B. All standards listed under "Special Facilities/Resources/ Capabilities" as listed under Section 6.1.3.1., B., of these rules and regulations.

C. All standards listed under "Operating Suite Special Requirements" as listed under Section 6.1.3.1.,C. of these rules and regulations.

10.4. Combined Designation as Level I (Comprehensive) Trauma Center - Each facility must meet as a minimum all of the minimum care capabilities as listed under Article 10.3. above, and in addition must individually meet the following standards:

10.4.1. All standards under "Special Facilities/Resources/ Capabilities", Section 6.1.4.1.,B.

10.4.2. All standards under "Program for quality assurance", Section 6.4.1.,E.

10.5. Shared Resources - Other than those requirements listed above under 10.4. and 10.5., all other human resources, specialists, equipment or facilities may be located in one or the other hospital.

10.6. Restrictions - If only a single hospital within a community meets all of the standards of a Level II or above Trauma Center, then only that hospital may be the designated Trauma Center for that

community or area. All other hospitals approaching Level II, but not meeting all of the standards as required herein for Level II designation shall not be eligible for combined designation as Level II Trauma Cent Centers.

Section 11. Proposal Method and Review Process

11.1. In those cases where it is impractical or when one or more qualified hospitals in a community insists upon designation of the trauma center through the proposal process rather than the method of combined or single designation as previously described, each hospital will be given the opportunity to present a written proposal stating the qualifications of that hospital that would indicate the resources, personnel, equipment and facilities necessary for designation at a particular level. Standard forms for this purpose to be supplied by the West Virginia Department of Health upon request. Upon receipt of the completed forms from all participating hospitals, the EMS regional board of directors will submit the entire group of proposals to the West Virginia Department of Health, Office of Emergency Medical Services for review and processing.

11.2. Submission of Proposals - Each hospital participating in the proposal process within an EMS region will submit the completed forms to the regional EMS board of directors for review as to complete-ness and proper preparation. The regional EMS board will make no judgements or decisions regarding the individual proposals, but will provide appropriate written comments as to the compatibility of the proposals with the regional trauma care strategy. Upon receipt and review of a proposal that is found to be incorrectly prepared or is

incomplete, the regional EMS board shall return such proposal to the respective hospital for corrections.

11.3. The Director of the West Virginia Department of Health, or his designee, will appoint a site visit tem composed of physicians and others familiar with trauma center designation principles to visit each facility submitting a proposal within a West Virginia Emergency Medical Service Region in order to ascertain the validity of the individual proposals and make recommendations regarding the findings of the site visit to the Director of Health.

11.4. Upon receipt of the site visit reports, the proposal and findings of the site visit team will be evaluated by the Director or his designee and outside consultants if necessary, in order to determine which facility if any will be designated as the trauma center.

11.5. Written confirmation of the receipt of all materials submitted will be sent to each hospital participating in the proposal process.

11.6. Upon review of the submitted proposals, the Director may elect to follow any of the following actions:

11.6.1. Selection of one facility to be designated as the Trauma Center.

11.6.2. Submit materials or portions of the proposal back to a hospital to obtain additional information or to properly complete the proposal.

11.6.3. Arrange for an additional site visit at one or more hospitals to verify previous findings or to evaluate additional resources.

11.6.4. Provide provisional designation based upon the upgrading or addition of standards by a hospital or hospitals.

11.6.5. Make a determination that none of the proposals meet the requirements for any level of designation.

11.6.6. Recommend that two or more facilities request combined designation.

Section 12. Appeal Mechanism

12.1. Upon receipt of official provisional designation in trauma care, a health care facility may appeal the designation through the following mechanism:

12.1.1. The facility may request a re-evaluation of any specific areas by the original site visit team. Should this review remain unchanged and the hospital continues to disagree with any part of the site visit team's findings, the hospital may request review and c recommendations by the State Critical Care Committee.

12.1.2. A request for re-evaluation may be made at any time within thirty (30) working days of receipt of the notice of provisional designation from the Director by any participating hospital. Requests may be made for re-evaluation at any future time that the hospital administration feels that the level of care has been changed due to improvements, additions or deletions from conditions or resources existing at the time of the original or subsequent site visits.

12.1.3. Requests for re-evaluation must include the specific area or areas of concern on the part of the facility and must include those facts or factors which would significantly affect the level of care previously designated.

12.1.4. A request to the State Categorization Committee for review of a site visit evaluation which has been acted upon by the Regional and State Critical Care Committees will be acted upon by the West Virginia Categorization Committee within three (3) months of such request on the part of a hospital. This action constitutes the programmatic appeals mechanism and will only be utilized when an agreement cannot be reached between the hospital and the Critical Care Committees.

12.1.5. The West Virginia Categorization Committee may follow one of several alternatives in reaching a decision:

12.1.5.1. Appointment of a special site visit team, approved by the director, to review the original report and perform an additional evaluation of specific areas of concern and report the findings to the State Categorization Committee for action.

12.1.5.2. Refer the request to the original Critical Care Committee for review and re-evaluation with specific recommendations as to the action to be taken.

12.1.5.3. Alter the level of care capability previously reported based upon results of the site visit, additional information received from the hospital and make appropriate recommendations to the Department of Health regarding designation level.

12.1.5.4. Reaffirm the re-evaluation recommended designation level as made by the Critical Care Committees.

12.1.5.5. Regardless of the alternative method chosen by the State Categorization Committee, the hospital will be informed by

letter from the chairperson of the committee as to the action taken and/or final decision.

Section 13. Administrative Due Process - Those persons adversely effected by the enforcement of these lesislative rules desirins a contested case hearins to determine any rishts, duties, interests or privileses shall do so in a manner prescribed in the West Virsinia Procedural Rules, Board of Health, Chapter 16-1, Series 1, 1981, Rules of Procedure for Contested Case Hearinss and Declaratory Rulinss. The aforementioned procedural rules are incorporated herein by reference.

Section 14. Severability - If any provisions of these rules or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not effect the provisions or the application of these rules which can be siven effect without the invalid provisions or application, and to this end the provisions of these rules are declared to be severable.