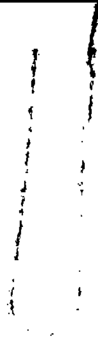

[P R O P O S E D]

WEST VIRGINIA LEGISLATIVE RULES

BOARD OF HEALTH

TRAUMA CENTER OR FACILITY DESIGNATION

Chapter 16-1
Series XXVII
(1984)

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

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Trauma Center or Facility Designation

Chapter 16-1
Series XXVII
(1984)

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John D. Rockefeller IV
Governor

L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

Notice

The Health Department has discovered a typographical error in the proposed rule Trauma Center or Facility Designation, Chapter 16-1, Series XXVII (1984), West Virginia Board of Health Legislative Rules as filed with the Legislative Rule-Making Review Committee on December 18, 1983 and with the Office of the Secretary of State on December 19, 1983. Since the error is significant in that it involves the action of related Code for the rule, we are hereby filing a corrected page one of this proposed rule with the Legislative Rule-Making Review Committee and with the Secretary of State.

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

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Jan. 26, 1984
Administrative Law Division

Entered

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WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series XXVII
(1984)

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 10-27/1984
Administrative Law Division

Subject: Trauma Center or Facility Designation

Section 1. General

1.1. Scope - These legislative rules establish the standards, criteria and methods of designating various health care facilities in the State of West Virginia as meeting 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 legislative rules are issued under the authority of Chapter 16, Article 1, Section 7 (4) and are related to Chapter 16, Article 4D, Section 1 et seq of the West Virginia Code of 1931, as amended.

1.3. Filing Date - These rules were promulgated 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 legislative rules became effective on the ________ day of ________ 19___.

Section 2. Application and Enforcement

2.1. Application - The enforcement of these legislative rules shall apply to all health care institutions, facilities, hospitals, clinics, corporations, partnerships and governmental agencies engaged in the provision of care to critically injured patients in the state.

2.2. Enforcement - The enforcement of these legislative rules is vested with the director of the West Virginia department of health or his lawful designee.

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), and as may be modified by the West Virginia Categorization Committee.

3.2. American College of Surgeons Guidelines - A listing of hospital resources necessary for optimal care of the injured patient as published by the American College of Surgeons in 1979 in the Bulletin of the American College of Surgeons, and as may be modified by the West Virginia Categorization Committee.

3.3. Regional Emergency Medical Services Agency - One of several multi-county 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, and as may be modified by the West Virginia Categorization Committee.

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), and as may be modified by the West Virginia Categorization Committee.

3.7. Critical Care Committee - A committee established at the regional

and state emergency medical service agency level, composed of specialyy physicians representating the eight critical patient care areas of trauma, cardiac, high risk infant, poisoning, drug and alcohol detoxification, behavioral, spinal and burn 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 hospitilization (Intermediate), and as may be modified by the West Virginia Categorization Committee.

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 department of health 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 Emergency Medical Service agencies, regional Emergency Medical Service 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, one (1) from the West Virginia Society of Osteopathic Medicine and three (3) representatives from the public at large. The director of health may name additional representatives to the committee at his discretion.

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) 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 patient 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 situtations 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) Designated 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 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).

(3) Registered nurses, licensed practical nurses 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 following:

(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 Garment (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 ventilation devices

(b) Oxygen source with concentration 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 hours 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

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:

(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 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. Recommened/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)

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 Program: Required

1. Formal program 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 specialists

   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 specialities availability: (Resident services as previously indiciated 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; Resources 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, as recommended by the West Virginia Categorization Committee and published by the West Virginia department of health office of emergency medical services.

7.3. Notification of Intention to Perform a Site Visit - The regional emergency medical services agency through its board of directors shall notify in writing each health care institution within the emergency medical services 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 emergency medical services 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 emergency medical services 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 emergency medical services 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 emergency medical services board of directors.

7.9. The regional emergency medical services board of directors may delegate to its critical care committee and the regional emergency medical services 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 emergency medical services medical director remains with the regional emergency medical services board of directors.

7.10. The regional emergency medical services 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 emer-

gency 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 emergency medical services 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 ac-

complished 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 5 and 6 of these rules.

8.3. Upon review and recommendation of the board of directors of the regional emergency medical services 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 emergency medical services 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 or 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 emergency medical services 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 hold itself out to be a trauma center, unit or facility until such time as a designation level is assigned by the director of the West Virginia department of health. Any public advertisement or claim of such trauma care capability on the part of a health care facility prior to receiving the appropriate designation may result in civil proceedings against such institution.

8.10. Any institution, health care facility, unit, center or hospital having received a designation as a trauma center, unit or facility from the West Virginia department of health shall be exempted from the antitrust laws of this state pertaining to antitrust actions brought as a result of such designation by an individual, individuals, corporation, partnership, other health care institution, or governmental agency.

Section 9. Review of Audit of Designated Facilities

9.1. The director of the West Virginia department of health or his designee shall have the power to periodically review or cause to be reviewed the trauma care capability of a previously designated health care facility.

Such review or audit may include a site visit or visits to the institution in order to verify that the original standards and criteria are still in place. Such audit or review may be performed at the discretion of the director of the West Virginia department of health, but in no case more frequently than annually and with the time and date of such site visit being mutually agreed 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 following requirements must be met.

10.2.1. A current (annual) written plan of trauma patient care must be available 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, including personnel, equipment and facilities.

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

10.2.4. The participating 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 meeting all of the standards for such level of care.

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

10.3.1. Each facility participating in a combined designation process must be capable of meeting all of the required/essential standards of a Level III (Intermediate) 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 6.1.4.1., B.

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 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 emergency medical services 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 emergency medical services region will submit the completed forms to the regional emergency medical services board of directors for review as to completeness and proper preparation. The regional emergency medical services 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 Emergency Medical Services 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 team composed of physicians and others familiar with trauma center designation principles to visit each facility sub-

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

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

Section 12. Appeal Mechanism

12.1. Upon receipt of official designation action, 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 continue to disagree with any part of the site visit team's findings,

the hospital may request review and 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 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 perfrom 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 legislative rules desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the West Virginia procedural rules, Board of Health, Chapter 16-1, Series 1, 1983, Rules of Procedure for Contested Case Hearings and Declaratory Rulings. The aforementioned procedural rules are incorporated 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 given effect without the invalid provisions or application, and to this end the provisions of these rules are declared to be severable.

Summary of Comments Received at
Public Hearing in re

Title, Type and Number: Trauma Center or Facility Designation
Legislative, Chapter 16-1, Series I, 198-
Date and Location: Friday, December 2, 1983
P & G Building, Room 10, 2019 Washington Street, East
Charleston West Virginia

Fifteen individuals attended the public hearing. Several offered comments at the hearing, and several written comments were received (See attached lists.) During the hearing, some individuals asked specific questions about the regulation as it might be applied to their facility in particular; the questions were answered but are not included here because they did not constitute comments about the regulation. A compilation of comments received, discussion and proposed changes appears below. This compilation constitutes minutes of the hearing. The changes noted have been incorporated into the regulation as filed with the Legislative Rule-Making Review Committee. Strike-throughs indicate language that has been stricken from the rule; underscoring indicates new language that has been added subsequent to the hearing. Copies of actual documents received are on file in the Health Department.

1. Comment: Several commenters attending the hearing stated they were quite pleased with the regulation. Some written comments also supported the regulation stating that it appeared that all the criteria and essentials of a good trauma center had been addressed sufficiently.

2. Comment: It is the position of the West Virginia Hospital Association that a designation process is an example of the kind of regulatory overkill that the nation's health care system has been subject to for many years. Currently there is a nationwide effort to reduce regulation and increase competition in order to provide additional incentives for cost containment.

Response: The Board of Health feels that a public process of designation according to an approved and authorized regulatory process is in the best interest of the public.

Proposed: No change

3. Comment: There should be some clarification in the regulation as to whether or not trauma centers are to be considered a new service even though the service has been provided in the past, and whether or not a Certificate of Need would be required in either the case of a new service or an existing one.

Response: This topic would not be an appropriate topic for the regulation in question which is not a Certificate of Need regulation. Any needed clarification would be a topic for a different regulation.

Proposed: No change.

4. Comment: One commenter stated that emergency medical service issues were not being addressed by these commenters. That the pre-hospital system is limited in its ability to deal with trauma victims [choice of facilities]. Without a prearranged agreement with a hospital they have no legal basis to do more than deliver a victim to the nearest facility, which may not be the best. However, the commenter felt that trauma center designation would at least give emergency medical service personnel a basis for rational decision about where a victim should be taken. The commenter strongly supported the promulgation of this regulation.

5. Comment: The regulation should perhaps address whether there is a cost to the institution that is making application and whether there is a cost associated with the designation.

Response: There is no fee for either the site visit or the designation; the regulation only needs to specify a fee if there is one.

Proposed: No change.

6. Comment: The West Virginia Committee on Trauma of the American College of Surgeons recommended that Sections 3.1, 3.2, 3.4, 3.6 and 3.10, be amended to add to the end of each section: "and as may be modified by the West Virginia Categorization Committee." That Section 7.2 add at the end of the paragraph: "as recommended by the West Virginia Categorization Committee and published by the West Virginia Department of Health, Office of Emergency Medical Services." They stated they felt these changes would allow for revisions in the standards by a public body in order to adjust to future changes in the national consensus on the requirements for optimal care of the trauma victim and recommended the promulgation of the regulation with these changes.

Response: The Board of Health agrees that there should be provision in this regulation for revision in this manner. In this critical area of optional care of trauma victims, it is urgent to keep current with the most recent developments in the field. Since participation in this designation program is voluntary, such changes will not constitute the <u>imposition</u> of standards without public hearing and legislative approval.

Proposed:

3.1. <u>Level II</u> - 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), <u>and as may be modified by the West Virginia Categorization Committee</u>.

3.2. <u>American College of Surgeons Guidelines</u> - a listing of hospital resources necessary for optimal care of the injured patient as published by the American College of Surgeons in 1979 in the Bulletin of the American College of Surgeons, <u>and as may be modified by the West Virginia Categorization Committee</u>.

3.4. Basic - This means a health care facility which meets the minimum standards criteria, resources and capabilities of trauma care as listed herein, and as may be modified by the West Virginia Categorization Committee.

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), and as modified by the West Virginia Categorization Committee.

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) and as modified by the West Virginia Categorization Committee.

7.2. This 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, as recommended by the West Virginia Categorization Committee and published by the West Virginia department of health, office of emergency medical services.

7. Comment: The Categorization Committee (Section 3.14) should include a representative from the West Virginia Society of Osteopathic Medicine.

Response: The Board concurs that the important representative should be included. The Department also feels that there should be provision for the addition of additional professional groups from time to time. Such additions should be placed at the discretion of the Director of Health rather than at the divisional level.

Proposed:

3.14. West Virginia Categorizaiton Committee - A committee appointed by the director of the ~~office of emergency medical services~~ department of health 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 emergency medical service agencies, regional emergency medical service medical directors, two (2) each from the West Virginia Nurses Association, the West Virginia Emergency Department Nurses Association, one (1) representative from the West Virginia Society of Osteopathic Medicine, and three (3) representatives from the public at large. The director of health may name additional representation to the committee at his discretion.

8. Comment: A nurse representing emergency practice should be added to the categorization committee as defined in Section 3.14.

Response: The comment apparently relates to an earlier draft. The committee does include two members each from the West Virginia Nurses Association and the West Virginia Emergency Nurses Association in the draft filed for hearing and as submitted to the legislature.

Proposed: No change.

9. Comment: This regulation should include definition of clinic, health care facility, etc. For example, does it include a group of private physicians. Suggested either definitions or specific references to other State regulations or laws.

Response: Definitions of these items are not pertinent for this regulations since the rule specifies the criteria for trauma center or facility desgination.

Proposed: No change.

10. Comment: Delete "required" or following "Required" add "or transfer agreement with nearby facility" in Section 6.1.4.1.C.1. Interviews and site visits to Level I Trauma Centers indicate no use of cardiopulmonary bypass. Consultant Dr. David Boyd has stated that this criteria is being deleted from Level I requirements due to: (a) lack of demonstrated need; and (b) patients with traumatic cardiac perforations and tears requiring immediate bypass support do not survive to be treated in trauma centers. The standard should consider criteria related to auto-transfusions.

Response: This suggested change is one of a number of recent changes in national standards. This change would be accomplished by the changes proposed in Comment discussion #7.

Proposed: No change.

11. Comment: Several comments were offered regarding Section 10 on Combined Hospital Designation. Some commenters were opposed to the combined designation; others were in favor. One commenter felt that there should be no limit to the number of designated trauma centers if all facilities meet standards. Some commenters requested that the Department provide leadership and assistance with respect to combined designation.

Arguments against combined designation were as follows: In order for a facility to meet the requirement for Trauma Center Designation, a major commitment is required by the hospital's Board of Directors, Administration and Medical Staff, not only in expenditure of manpower but dollars in materials resources. Issues relating to pre-hospital care, emergency services, operating rooms, intensive care (post-trauma services) and rehabilitation comprise the programming in a designated institution. To duplicate such services in a single community is a monumental waste.

It is easy to see that clinical division of services <u>will</u> require duplication. Communities with two or more hospitals that have potential for Trauma Center Designation should provide proposals that can be objectively evaluated. It seems that this section was written because the interest in resource consumption and programming in our free enterprise system was subordinated to political expediency.

John D. Rockefeller IV
Governor

L. Clark Hansbarger, M.D.
Director

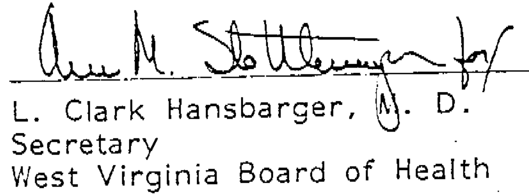
State of West Virginia

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.



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

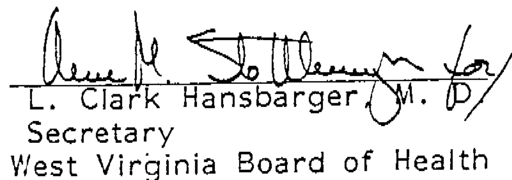
DEPARTMENT OF HEALTH

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

1800 WASHINGTON STREET, EAST
OFFICE OF THE DIRECTOR
CHARLESTON, WEST VIRGINIA 25305
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[P R O P O S E D]

WEST VIRGINIA LEGISLATIVE RULES

BOARD OF HEALTH

TRAUMA CENTER OR FACILITY DESIGNATION

Chapter 16-1
Series XXVII
(1984)

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

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Trauma Center or Facility Designation

Chapter 16-1
Series XXVII
(1984)

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John D. Rockefeller IV
Governor

L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH

CHARLESTON 25305

Notice

The Health Department has discovered a typographical error in the proposed rule Trauma Center or Facility Designation, Chapter 16-1, Series XXVII (1984), West Virginia Board of Health Legislative Rules as filed with the Legislative Rule-Making Review Committee on December 18, 1983 and with the Office of the Secretary of State on December 19, 1983. Since the error is significant in that it involves the action of related Code for the rule, we are hereby filing a corrected page one of this proposed rule with the Legislative Rule-Making Review Committee and with the Secretary of State.

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

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Jan. 26, 1984
Administrative Law Division

Entered

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-1
Series XXVII
(1984)

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Jan. 26, 1984
Administrative Law Division

Subject: Trauma Center or Facility Designation

Section 1. General

1.1. Scope - These legislative rules establish the standards, criteria and methods of designating various health care facilities in the State of West Virginia as meeting 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 legislative rules are issued under the authority of Chapter 16, Article 1, Section 7 (4) and are related to Chapter 16, Article 4D, Section 1 et seq of the West Virginia Code of 1931, as amended.

1.3. Filing Date - These rules were promulgated 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 legislative rules became effective on the ___________ day of ________ 19___.

Section 2. Application and Enforcement

2.1. Application - The enforcement of these legislative rules shall apply to all health care institutions, facilities, hospitals, clinics, corporations, partnerships and governmental agencies engaged in the provision of care to critically injured patients in the state.

2.2. Enforcement - The enforcement of these legislative rules is vested with the director of the West Virginia department of health or his lawful designee.

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), and as may be modified by the West Virginia Categorization Committee.

3.2. American College of Surgeons Guidelines - A listing of hospital resources necessary for optimal care of the injured patient as published by the American College of Surgeons in 1979 in the Bulletin of the American College of Surgeons, and as may be modified by the West Virginia Categorization Committee.

3.3. Regional Emergency Medical Services Agency - One of several multi-county 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, and as may be modified by the West Virginia Categorization Committee.

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), and as may be modified by the West Virginia Categorization Committee.

3.7. Critical Care Committee - A committee established at the regional

and state emergency medical service agency level, composed of specialyy physicians representating the eight critical patient care areas of trauma, cardiac, high risk infant, poisoning, drug and alcohol detoxification, behavioral, spinal and burn 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 hospitilization (Intermediate), and as may be modified by the West Virginia Categorization Committee.

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 department of health 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 Emergency Medical Service agencies, regional Emergency Medical Service 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, one (1) from the West Virginia Society of Osteopathic Medicine and three (3) representatives from the public at large. The director of health may name additional representatives to the committee at his discretion.

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) 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 patient 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 situtations 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) Designated 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 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).

(3) Registered nurses, licensed practical nurses 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 following:

(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 Garment (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 ventilation devices

(b) Oxygen source with concentration 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 hours 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

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:

(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 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. Recommened/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)

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 Program: Required

1. Formal program 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 specialists

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 specialities availability: (Resident services as previously indiciated 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; Resources 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, as recommended by the West Virginia Categorization Committee and published by the West Virginia department of health office of emergency medical services.

7.3. Notification of Intention to Perform a Site Visit - The regional emergency medical services agency through its board of directors shall notify in writing each health care institution within the emergency medical services 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 emergency medical services 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 emergency medical services 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 re-corded 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 emergency medical services 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 emergency medical services board of directors.

7.9. The regional emergency medical services board of directors may delegate to its critical care committee and the regional emergency medical services 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 emergency medical services medical director remains with the regional emergency medical services board of directors.

7.10. The regional emergency medical services 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 emer-

gency 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 emergency medical services 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 ac-

complished 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 5 and 6 of these rules.

8.3. Upon review and recommendation of the board of directors of the regional emergency medical services 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 emergency medical services 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 or 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 emergency medical services 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 hold itself out to be a trauma center, unit or facility until such time as a designation level is assigned by the director of the West Virginia department of health. Any public advertisement or claim of such trauma care capability on the part of a health care facility prior to receiving the appropriate designation may result in civil proceedings against such institution.

8.10. Any institution, health care facility, unit, center or hospital having received a designation as a trauma center, unit or facility from the West Virginia department of health shall be exempted from the antitrust laws of this state pertaining to antitrust actions brought as a result of such designation by an individual, individuals, corporation, partnership, other health care institution, or governmental agency.

Section 9. Review of Audit of Designated Facilities

9.1. The director of the West Virginia department of health or his designee shall have the power to periodically review or cause to be reviewed the trauma care capability of a previously designated health care facility.

Such review or audit may include a site visit or visits to the institution in order to verify that the original standards and criteria are still in place. Such audit or review may be performed at the discretion of the director of the West Virginia department of health, but in no case more frequently than annually and with the time and date of such site visit being mutually agreed 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. <u>Combined Hospital Designation of Trauma Centers</u>

10.1. <u>General</u> - 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 following requirements must be met.

10.2.1. A current (annual) written plan of trauma patient care must be available 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, including personnel, equipment and facilities.

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

10.2.4. The participating 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 meeting all of the standards for such level of care.

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

10.3.1. Each facility participating in a combined designation process must be capable of meeting all of the required/essential standards of a Level III (Intermediate) 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 6.1.4.1., B.

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 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 emergency medical services 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 emergency medical services region will submit the completed forms to the regional emergency medical services board of directors for review as to completeness and proper preparation. The regional emergency medical services 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 Emergency Medical Services 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 team composed of physicians and others familiar with trauma center designation principles to visit each facility sub-

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

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

Section 12. Appeal Mechanism

12.1. Upon receipt of official designation action, 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 continue to disagree with any part of the site visit team's findings,

the hospital may request review and 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 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 perfrom 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 legislative rules desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the West Virginia procedural rules, Board of Health, Chapter 16-1, Series 1, 1983, Rules of Procedure for Contested Case Hearings and Declaratory Rulings. The aforementioned procedural rules are incorporated 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 given effect without the invalid provisions or application, and to this end the provisions of these rules are declared to be severable.

Summary of Comments Received at
Public Hearing in re

Title, Type and Number: Trauma Center or Facility Designation
Legislative, Chapter 16-1, Series I, 198-
Date and Location: Friday, December 2, 1983
P & G Building, Room 10, 2019 Washington Street, East
Charleston West Virginia

Fifteen individuals attended the public hearing. Several offered comments at the hearing, and several written comments were received (See attached lists.) During the hearing, some individuals asked specific questions about the regulation as it might be applied to their facility in particular; the questions were answered but are not included here because they did not constitute comments about the regulation. A compilation of comments received, discussion and proposed changes appears below. This compilation constitutes minutes of the hearing. The changes noted have been incorporated into the regulation as filed with the Legislative Rule-Making Review Committee. Strike-throughs indicate language that has been stricken from the rule; underscoring indicates new language that has been added subsequent to the hearing. Copies of actual documents received are on file in the Health Department.

1. Comment: Several commenters attending the hearing stated they were quite pleased with the regulation. Some written comments also supported the regulation stating that it appeared that all the criteria and essentials of a good trauma center had been addressed sufficiently.

2. Comment: It is the position of the West Virginia Hospital Association that a designation process is an example of the kind of regulatory overkill that the nation's health care system has been subject to for many years. Currently there is a nationwide effort to reduce regulation and increase competition in order to provide additional incentives for cost containment.

Response: The Board of Health feels that a public process of designation according to an approved and authorized regulatory process is in the best interest of the public.

Proposed: No change

3. Comment: There should be some clarification in the regulation as to whether or not trauma centers are to be considered a new service even though the service has been provided in the past, and whether or not a Certificate of Need would be required in either the case of a new service or an existing one.

Response: This topic would not be an appropriate topic for the regulation in question which is not a Certificate of Need regulation. Any needed clarification would be a topic for a different regulation.

Proposed: No change.

4. Comment: One commenter stated that emergency medical service issues were not being addressed by these commenters. That the pre-hospital system is limited in its ability to deal with trauma victims [choice of facilities]. Without a prearranged agreement with a hospital they have no legal basis to do more than deliver a victim to the nearest facility, which may not be the best. However, the commenter felt that trauma center designation would at least give emergency medical service personnel a basis for rational decision about where a victim should be taken. The commenter strongly supported the promulgation of this regulation.

5. Comment: The regulation should perhaps address whether there is a cost to the institution that is making application and whether there is a cost associated with the designation.

Response: There is no fee for either the site visit or the designation; the regulation only needs to specify a fee if there is one.

Proposed: No change.

6. Comment: The West Virginia Committee on Trauma of the American College of Surgeons recommended that Sections 3.1, 3.2, 3.4, 3.6 and 3.10, be amended to add to the end of each section: "and as may be modified by the West Virginia Categorization Committee." That Section 7.2 add at the end of the paragraph: "as recommended by the West Virginia Categorization Committee and published by the West Virginia Department of Health, Office of Emergency Medical Services." They stated they felt these changes would allow for revisions in the standards by a public body in order to adjust to future changes in the national consensus on the requirements for optimal care of the trauma victim and recommended the promulgaticn of the regulation with these changes.

Response: The Board of Health agrees that there should be provision in this regulation for revision in this manner. In this critical area of optional care of trauma victims, it is urgent to keep current with the most recent developments in the field. Since participation in this designation program is voluntary, such changes will not constitute the imposition of standards without public hearing and legislative approval.

Proposed:

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), and as may be modified by the West Virginia Categorization Committee.

3.2. American College of Surgeons Guidelines - a listing of hospital resources necessary for optimal care of the injured patient as published by the American College of Surgeons in 1979 in the Bulletin of the American College of Surgeons, and as may be modified by the West Virginia Categorization Committee.

3.4. Basic - This means a health care facility which meets the minimum standards criteria, resources and capabilities of trauma care as listed herein, and as may be modified by the West Virginia Categorization Committee.

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), and as modified by the West Virginia Categorization Committee.

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) and as modified by the West Virginia Categorization Committee.

7.2. This 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, as recommended by the West Virginia Categorization Committee and published by the West Virginia department of health, office of emergency medical services.

7. Comment: The Categorization Committee (Section 3.14) should include a representative from the West Virginia Society of Osteopathic Medicine.

Response: The Board concurs that the important representative should be included. The Department also feels that there should be provision for the addition of additional professional groups from time to time. Such additions should be placed at the discretion of the Director of Health rather than at the divisional level.

Proposed:

3.14. West Virginia Categorizaiton Committee - A committee appointed by the director of the ~~office of emergency medical services~~ department of health 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 emergency medical service agencies, regional emergency medical service medical directors, two (2) each from the West Virginia Nurses Association, the West Virginia Emergency Department Nurses Association, one (1) representative from the West Virginia Society of Osteopathic Medicine, and three (3) representatives from the public at large. The director of health may name additional representation to the committee at his discretion.

8. Comment: A nurse representing emergency practice should be added to the categorization committee as defined in Section 3.14.

Response: The comment apparently relates to an earlier draft. The committee does include two members each from the West Virginia Nurses Association and the West Virginia Emergency Nurses Association in the draft filed for hearing and as submitted to the legislature.

Proposed: No change.

9. Comment: This regulation should include definition of clinic, health care facility, etc. For example, does it include a group of private physicians. Suggested either definitions or specific references to other State regulations or laws.

Response: Definitions of these items are not pertinent for this regulations since the rule specifies the criteria for trauma center or facility desgination.

Proposed: No change.

10. Comment: Delete "required" or following "Required" add "or transfer agreement with nearby facility" in Section 6.1.4.1.C.1. Interviews and site visits to Level I Trauma Centers indicate no use of cardiopulmonary bypass. Consultant Dr. David Boyd has stated that this criteria is being deleted from Level I requirements due to: (a) lack of demonstrated need; and (b) patients with traumatic cardiac perforations and tears requiring immediate bypass support do not survive to be treated in trauma centers. The standard should consider criteria related to auto-transfusions.

Response: This suggested change is one of a number of recent changes in national standards. This change would be accomplished by the changes proposed in Comment discussion #7.

Proposed: No change.

11. Comment: Several comments were offered regarding Section 10 on Combined Hospital Designation. Some commenters were opposed to the combined designation; others were in favor. One commenter felt that there should be no limit to the number of designated trauma centers if all facilities meet standards. Some commenters requested that the Department provide leadership and assistance with respect to combined designation.

Arguments against combined designation were as follows: In order for a facility to meet the requirement for Trauma Center Designation, a major commitment is required by the hospital's Board of Directors, Administration and Medical Staff, not only in expenditure of manpower but dollars in materials resources. Issues relating to pre-hospital care, emergency services, operating rooms, intensive care (post-trauma services) and rehabilitation comprise the programming in a designated institution. To duplicate such services in a single community is a monumental waste.

It is easy to see that clinical division of services <u>will</u> require duplication. Communities with two or more hospitals that have potential for Trauma Center Designation should provide proposals that can be objectively evaluated. It seems that this section was written because the interest in resource consumption and programming in our free enterprise system was subordinated to political expediency.

Arguments for combined designation were as follows: Bluefield Community Hospital supports the combined designation concept. They feel that the best interests of the state would be served at this time by combined designation of Bluefield Community Hospital and Princeton Community Hospital as a trauma center. The hospitals are basically similar in makeup, size and capability, while the communities of Bluefield and Princeton together form a population unit which would not be best served by the designation of either hospital as a trauma center. Most of the physicians in Bluefield and Princeton are members of the attending staff of both hospitals. They feel that, should one or the other hospital be designated a trauma center, a competitive race would be initiated which would inevitably result in wasted community resources and would not result in the shared objective of good patient care in either hospital. They are prepared to enter into appropriate agreements with Princeton Community Hospital if they receive joint designation with them as a trauma center.

Response: The Board feels that combined designation is a reasonable and cost-efficient alternative in that specialized trauma care is a viable alternative.

Proposed: No change.

12. Comment: One commenter suggested that there could be problems in several communities with two or more hospitals, such as, Charleston, Huntington, Parkersburg, and perhaps others, where two or more meet the necessary standards. The regulations should mandate combined designation or no designation in this instance.

Response: The Board feels that the regulation is sufficiently clear.

Proposed: No change.

13. Comment: Section 11.6.4 states that the Director of the Department of Health may "provide provisional designation based upon the upgrading or addition of standards by a hospital or hospitals." This makes it unclear as to whether two or more hospitals in the same community can be designated, and suggested that it be made more specific.

Response: Upon consideration, the Board agreed that provision was unnecessary and confusing and has deleted the provision. The remainder of Section 11.6 has been renumbered in accordance with the deletion of this provision. Certain technical changes were also necessitated in Section 12.1 as shown.

Proposed:

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

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