

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #2

Do Not Mark In this Box

1992 JUN -3 10:32

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Division of Health TITLE NUMBER: 64
RULE TYPE: Legislative; CITE AUTHORITY W.Va. Code §§16-4C-1 et seq.

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 27

TITLE OF RULE BEING AMENDED: Trauma Center or Facility Designation

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 3, 1992 AT Midnight *

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS. July 3, 1992.

Regulatory Development Section
Department of Health and Human Resources
Attn: Kay Howard
Room 204, Building 3
Capitol Complex
Charleston, WV 25305

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

W. Donald Weston
W. Donald Weston, M.D.
Acting Secretary

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

5.70

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Trauma Center or Facility Designation

Type of Rule: Legislative Interpretive Procedural

Agency Division of Health Address Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$ 0	\$ 0	\$ 0
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Other					

2. Explanation of above estimates.

No increase in expenditures of State funds is anticipated.

3. Objectives of these rules: The revisions are for the purpose of incorporating changes in the national system published by the American College of Surgeons.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

B. Economic Impact on Political Subdivisions; Specific Industries;
Specific Groups of Citizens.

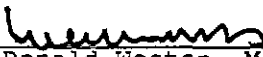
None

C. Economic Impact on Citizens/Public at Large.

None

Date April 30, 1992

Signature of Agency Head or Authorized Representative


W. Donald Weston, M.D., Acting Secretary
Department of Health and Human Resources

[PROPOSED]

TITLE 64

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

TRAUMA CENTER OR FACILITY DESIGNATION

SERIES 27

1992

RULE ABSTRACT

Agency: Department of Health and Human Resources
Rule Title: Trauma Center or Facility Designation
CSR Title & Series: 64 CSR 27 Type: Legislative

Objective/Purpose: Substantive revisions are for the purpose of incorporating changes in the national system published in November, 1990 by the American College of Surgeons. There are also some stylistic and technical revisions.

For further information contact: Fred M. Cooley, M.D., Director, Emergency Medical Services, Telephone 558-3956, Bureau of Health, Capitol Complex, Charleston, WV 25305 or Kay Howard, Director, Regulatory Development Section, Telephone 558-3223.

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH
TRAUMA CENTER OR FACILITY DESIGNATION

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[PROPOSED]
TITLE 64
WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

SERIES 27
TRAUMA CENTER OR FACILITY DESIGNATION

§64-27-1. General.

1.1. Scope - This legislative rule establishes 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 - ~~This rule is issued by the director of health under the authority of and is related to Chapter 16, Article 4C, Section 1 et seq. of the West Virginia Code. W.Va. Code §16-4C-1, et seq.~~

1.3. Filing Date -

1.4. Effective Date -

§64-27-2. Supersession and Repeal of Former Rules.

~~This rule supersedes and repeals amends and reenacts Trauma Center or Facility Designation, West Virginia Department of Health Legislative Rules, 64 CSR 27, 1986-1988.~~

§64-67-3. Application and Enforcement.

3.1. Application - ~~This rule shall apply~~ applies 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.

3.2. Enforcement - ~~The enforcement of~~ This rule is vested with enforced by the director of the West Virginia department division of health. ~~or his lawful designee.~~

§64-27-4. Definitions.

~~4.2-~~ 4.1. 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 1986 1990 in the Bulletin of the American College of Surgeons.

~~4.7--~~ 4.2. Critical Care Committee - A committee established at the regional and state emergency medical service agency level, composed of specialty physicians representing the eight (8) 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.

4-8- 4.3. Dedesignation - ~~This means~~ The withdrawal of a previous designation level by the West Virginia department division of health when it is determined by review and audit of an institution that such the institution no longer meets the standards, criteria, resource availability or commitment for trauma care.

4-9--4.4. Designation - ~~This means~~ An official notification from the West Virginia department division of health to a particular health care facility indicating the level of trauma care capability determined by the site visit process.

4-5--~~Board--Means-the-West-Virginia-board-of-health:~~

4.5. Director - The director of the West Virginia division of health or his or her lawful designee.

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

4-1- 4.7. Level II - ~~This means~~ Describes a health care facility which meets most but not all of the standards, criteria, resources and capabilities of trauma care as listed herein (Advanced).

4-10- 4.8. Level III - ~~This means~~ Describes 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).

4-11- 4.9. 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.

4-12- 4.10. Office of Emergency Medical Services (OEMS) - An official division of the West Virginia department division of health.

4-4- 4.11. Basic Primary - This means a health care facility which meets the minimum standards, criteria, resources and capabilities of trauma care as listed herein.

4-13- 4.12. 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 (2) or more institutions located in the same community or general area are competing for designation at a

particular level.

~~4.3-~~ 4.13. Regional Emergency Medical Services Agency - One (1) 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.

4.14. West Virginia Categorization Committee - A committee appointed by the director of the department West Virginia division 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 Nurses Association, one (1) from the West Virginia Society of Osteopathic Medicine and three (3) representatives from the public at large. The director of the West Virginia division of health may name additional representatives to the committee at his or her discretion.

§64-27-5. 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 division of health to perform the site visit.

§64-27-6. General Criteria for Determining Trauma Care Capability.

6.1. Basic Primary - 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.

6.2. Level III (Intermediate) - ~~An institution with approximately one hundred to two hundred fifty beds which has a clear commitment to excellence of trauma care.~~ A rural institution with the resources necessary to provide trauma care commensurate with those resources and demonstrates a commitment to excellence of trauma care. Transfer protocols in selected specialty areas are required.

6.3. Level II (Advanced) - ~~An institution with approximately two hundred to five hundred beds which treats approximately three hundred fifty to six hundred urgent or severely injured patients~~

per-year: A community institution which has the resources necessary to provide trauma care to all injured patients except those requiring sophisticated trauma care.

6.4. Level I (Comprehensive trauma facility) - A hospital operating in a metropolitan area and experiencing approximately six hundred (600) to one thousand (1,000) admissions per year of seriously injured patients, or the treatment of approximately fifty (50) immediately life-threatening and/or urgent and--severely injured patients per year for each surgeon taking trauma call.

§64-27-7. Specific Standards and Criteria for Designation of Health Care Facilities as Trauma Centers.

7.1. Primary Basic Level Facility (No National Level Designated)

7.1.1. Care Capability

A. The hospital and its medical and nursing staffs, having met minimum standards as adopted from the American College of Emergency Physicians guidelines for emergency departments and included in the West Virginia Emergency Facility Categorization Plan, 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 twenty-four (24) hours a day.
2. Regularly available physicians capable of caring for the patient injuries described in A Section 7.1.1.A above of this rule.
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

7.2. Level III Trauma Center (Intermediate)

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

a. Required: General surgery

~~(1) -- General surgery~~

~~(2) -- Trauma service~~

b. Recommended/Desired: Trauma service

2. Surgical specialties availability. On-call and promptly available from inside or outside the hospital ~~(May be fulfilled by residents capable of assessing emergency situations in their respective specialties and of providing any immediately indicated treatment. -- When residents are used to fulfill availability requirements, staff specialists are to be on call and promptly available for consultation.)~~ (The staff specialists on call are immediately advised and promptly available. This capability is continuously monitored by the trauma quality assurance program.)

a. Required:

- (1) General surgery specialists: (Communication is such that the general surgeon is present in the emergency department at the time of arrival of the trauma patient.)

b. Recommended/Desired:

- (1) Ophthalmic surgery specialists
(2) Orthopedic surgery specialists
(3) Otorhinolaryngologic surgery specialists
~~(4) Plastic and maxillofacial surgery specialists~~
(5 4) Thoracic surgery specialists
(6 5) Urologic surgery specialists
(7 6) Neurological surgery specialists

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

a. Required: (In-hospital twenty-four (24) hours a day)

- (1) Emergency medicine: (This requirement may be fulfilled by a physician who is credentialed by the hospital to provide emergency medical services.)

~~(2) Anesthesia department (May be physician-directed program staffed by nurse anesthetists)~~

~~(3) Internal medicine~~

~~(4) Pathology~~

b. Required: (On call and promptly available from inside or outside the hospital):

- (1) Anesthesiology
(2) Internal medicine

b. c. Recommended/Desired:

- (1) Cardiology

tor, sources of oxygen and mechanical ventilator

- (2) Suction devices
 - (3) Electrocardiograph-scope-defibrillator
 - (4) Apparatus to monitor establish central venous pressure
 - (5) All standard intravenous fluids and administration devices, including intravenous catheters
 - (6) Sterile surgical sets for procedures standard for emergency departments, such as thoracostomy, cutdown--trays,--etc. venesection, lavage
 - (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, twenty-four (24) hour coverage by in-hospital technician - (Desired/Recommended)
 - (11) MAST-garment--(Medical-Anti-shock-Trousers)--Swan-Ganz and arterial catheters
 - (12) Skeletal tongs traction device for cervical injuries
 - (13) Thermal control equipment for patient, blood and
2. Intensive care unit for trauma patients (May be separate specialty units.):
- a. Required:
 - (1) Designated medical surgical director
 - ~~(2)--Physician-on-duty-or-immediately-available-from-inside-the-hospital~~
 - (2 3) Nurse-patient ratio at a minimum of 1:2 on each shift

- (2) Hematology
- (3) Nephrology
- (4) Pediatrics
- (5) Radiology
- (6) Family Medicine (The patient's primary care physician is notified at an appropriate time.)
- (7) Pathology

4. Emergency Department/Division/Service/Section: The emergency department staff should ensure immediate and appropriate care for the trauma patient. The emergency department physician should--function functions as a designated member of the trauma team. The relationship between emergency department physicians and other participants of the trauma team must-be is established on an individual hospital basis, consistent with resources but adhering to established standards that ensure optimal care.

B. Special facilities, resources and capabilities

1. Emergency department:

a. Personnel - Required

- (1) Designated medical physician director
- (2) Physician(s) with special competence in the care of the critically injured patient and who is a designated member of the trauma team and is physically present are-on-duty in the emergency department twenty-four (24) hours a day
- (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: (Required)

- (1) Airway control and ventilation equipment, including laryngoscopes and endotracheal tubes of all sizes, bag-mask resuscita-

(3 4) Immediate access to clinical laboratory diagnostic services

(4 5) Equipment required: Appropriate monitoring and resuscitation equipment

{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

{k)--Patient-weighing-devices

b. Recommended/Desired:

(1) Physician Surgeon, credentialed in critical care by the trauma director, on duty in the intensive care unit (ICU) twenty-four (24) hours a day or immediately available from inside the hospital

{2)--Cardiac-output-monitoring-devices

{3)--Electronic-pressure-monitoring-devices

{4)--Intracranial-pressure-monitoring-devices

3. Postanesthetic recovery room (a surgical intensive care unit is acceptable):

a. Required:

(1) Registered nurses and other essential

personnel available twenty-four (24) hours a day

- (2) Appropriate monitoring and resuscitation equipment

4. Hemodialysis

a. Recommended/Desired:

- (1) Acute hemodialysis capability or transfer agreements in place

5. Organized Burn Care

a. Essential - Required

- (1) Physician-directed burn center staffed by nursing personnel trained in burn care and equipped properly for care of the extensively burned patient, or
- (2) Transfer agreement with nearby burn center or hospital with a burn unit.

6. Acute Spinal Cord/Head Injury Management Capability

a. Essential - Required

- (1) In circumstances where a designated spinal cord injury rehabilitation center exists in the region, early transfer should be considered; transfer agreements should be in effect.
- (2) In circumstances where a head injury center exists in the region, transfer should be considered in selected patients; transfer agreements should be in effect.

7. Radiological Special Capabilities

a. Recommended/Desired

- (1) Angiography of all types
- (2) Sonography
- (3) Nuclear scanning
- (4) Computed tomography
- (5) In-hospital computerized technology (CT)

technician twenty-four (24) hours

8. Rehabilitation Medicine
 - a. Essential
 - (1) Physician-directed rehabilitation service staffed by nursing personnel trained in rehabilitation care and equipped properly for care of the critically ill patient, or
 - (2) Transfer agreement when medically feasible to a nearby rehabilitation service.
- C. Operating suite special requirements, equipment and instrumentation:
 1. Required:
 - a. Thermal control equipment for patients, fluids 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 twenty-four (24) hours a day
 - b. Craniotome
 - c. X-ray capability including c-arm image intensifier with technologist available twenty-four (24) hours a day
- D. Clinical laboratory services ~~---required---twenty-four (24)-hours-a-day~~
 1. Required twenty-four (24) hours a day
 1. a. Standard analysis of blood, urine and other body fluids
 2. b. Blood-typing and cross-matching
 3. c. Coagulation studies capability
 4. d. Comprehensive blood bank or access to a commu-

nity central blood bank and adequate hospital storage facilities

- 5- e. Blood gases gas level and pH determinations
- 6- f. Microbiology
 - 1. Recommended/Desired
 - 1- a. Serum and urine osmolality determinations
 - 2- b. Drug and alcohol screening (Toxicology screens need not be immediately available but are desirable. If available, results are included in all quality assurance reviews.)

E. Programs for quality assurance --required

- 1. Required:
 - 1- a. Organized quality assurance program
 - 2- b. Special audits for trauma deaths
 - 3- c. Trauma morbidity and mortality reviews
 - 4- d. Medical nursing audits, utilization review and tissue review
 - 5- e. Trauma registry review (Documentation is made of severity of injury by trauma score, age, injury severity score (ISS) and outcome by survival, length of stay, intensive care unit length of stay, with monthly review of statistics.)
 - 6- ~~Review of pre-hospital and regional systems of trauma care (desired)~~

1. Desired/Recommended:

- a. Trauma conference, multidisciplinary (Regular and periodic multidisciplinary trauma conferences that include all members of the trauma team are held for the purpose of quality assurance through critiques of individual cases.)
- b. Review of prehospital and regional systems of trauma care

F. Public education program - Recommended/Desired

- a- 1. 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.

G. Trauma Research Program - Desired

H. Training Program (desired)

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

- a. Staff physicians - Desired/Recommended
- b. Nurses - Required
- c. Allied health personnel - Required
- d. Community physicians - Desired/Recommended

7.3. Level II Trauma Center (Advanced)

7.3.1. 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 primary and intermediate Level III 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
 - (3) Trauma Service
- b. Recommended/Desired:
 - (1) Cardiothoracic surgery
 - (2) Obstetrics-gynecologic surgery
 - (3) Ophthalmic surgery
 - (4) Oral surgery (dental)

- (5) Otorhinolaryngologic surgery
- (6) Pediatric surgery
- (7) Plastic and maxillofacial surgery
- (8) 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 twenty-four (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.)~~ (Evaluation and treatment may be started by a team of surgeons that includes, at a minimum, a senior fourth year (PGY 4) general surgical resident who is a member of the hospital's surgical residency program. The trauma attending surgeon's participation in major therapeutic decisions and presence at operative procedures are mandatory and are monitored by the hospital's trauma quality assurance program. Local criteria may be established, where warranted, that allow the general surgeon to take call from outside the hospital, but with a clear commitment on the part of the hospital and the surgical staff, that the general surgeon will be present in the emergency department at the time of arrival of the trauma patient and is available to care for trauma patients in the ICU.)
- (2) Neurologic surgery - In-hospital twenty-four (24) hours a day. An attending neurosurgeon ~~must be~~ is promptly available and dedicated to that hospital's trauma service. The in-house requirement may be fulfilled by an in-house neurosurgeon or surgeon ~~(or physician in Level II facilities)~~ who has special competence, as

judged by the chief of neurosurgery, in the care of patients with neural trauma, and who is capable of initiating measures directed toward stabilizing the patient and initiating diagnostic procedures.

(3) Orthopedic surgery - In-hospital twenty-four (24) hours a day. An attending orthopedic surgeon must be promptly available and dedicated to that hospital's trauma service. The in-hospital requirement may be fulfilled by an in-hospital orthopedic surgeon or a surgeon who has special competence, as judged by the chief of orthopedic surgery, in the care of patients with orthopedic trauma, and who is capable of initiating measures directed toward stabilizing the patient as well as initiating diagnostic procedures.

(3 4) On-call and promptly available from inside or outside the hospital: (The staff specialists on call are immediately advised and are promptly available. This capability is continuously monitored by the trauma quality assurance program.)

(a) Ophthalmic surgery

(b) ~~Orthopedic surgery~~

(e b) Otorhinolaryngologic surgery

(d) ~~Plastic and maxillofacial surgery~~

(e c) Thoracic surgery

(f d) Urologic surgery

b. Recommended/Desired:

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

(a) Cardiac surgery

(b) Microsurgical capabilities

(c) Obstetric-Gynecologic surgery

(d) Pediatric surgery

- (e) Hand surgery
- (f) Oral surgery (dental)

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

a. Required:

(1) In hospital twenty-four (24) hours a day:

(a) Emergency medicine (Requirements may be fulfilled by emergency medicine chief residents. When chief residents are used to fulfill availability requirements, the staff specialist on call is advised and is promptly available.)

(b) Anesthesiology ~~(may-be-physician-directed-program-staffed-by-n-u-r-s-e-anesthetist).~~ (Requirements may be fulfilled by anesthesiology chief residents capable of assessing emergent situations in trauma patients and of providing any indicated treatment, including initiation of surgical anesthesia. When anesthesiology chief residents are used to fulfill availability requirements, the staff anesthesiologist on call is advised and is promptly available.) (Requirements may be fulfilled when local conditions assure that the staff anesthesiologist will be in the hospital at the time of or shortly after the patient's arrival. During the interim period, prior to the arrival of the staff anesthesiologist, a certified nurse anesthetist (CRNA) capable of assessing emergency situations in trauma patients and of initiating and providing any indicated treatment is available.)

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

- (a) Cardiology
- (b) Hematology

- (c) Nephrology
- (d) Pathology
- (e) Pediatrics: (The patient's primary care physician is notified at an appropriate time.)
- (f) Radiology
- (g) Internal Medicine: (The patient's primary care physician is notified at an appropriate time.)

b. Recommended/Desired

- (1) On-call and promptly available from inside or outside the hospital:
 - (a) Gastroenterology
 - (b) Infectious disease
 - (c) Psychiatry
 - (d) Chest Medicine
 - (e) Family Medicine: (The patient's primary care physician is notified at an appropriate time.)

B. Special facilities, resources and capabilities:

- 1. Emergency department: As before under Level III
- 2. Intensive care unit(s): (As before under Level III, plus):

a. Required:

- ~~(1) --Physician--on--duty--in--ICU--twenty-four hours--a--day--or--immediately--from--in--hospital~~
- ~~(2) --Cardiac--output--monitoring--device~~
- ~~(3) --Electronic--pressure--monitoring--device~~
- ~~(4) --Patient--weighing--devices~~
- ~~(5) --Intracranial--pressure--monitoring--devices~~
- (1) Surgeon, credentialed in critical care by

the trauma director, on duty in intensive care unit twenty-four (24) hours a day or immediately available in hospital (Local criteria may be established that allow the general surgeon to take call from outside of the hospital, but with the clear commitment on the part of the hospital and the surgical staff, that the general surgeon will be present in the emergency department at the time of arrival of the trauma patient and be available to care for trauma patients in the intensive care unit.)

3. Postanesthetic recovery room: As before under level III.
 4. Acute Hemodialysis capability - Recommended/Desired
 5. Radiological special capabilities:
 - a. Required:
 - (1) Angiography capability of all types
 - (2) Computed tomography
 - ~~(2) -- In-hospital computerized tomography -- (or equivalent), with technicians~~
 - b. Recommended/Desired:
 - (1) Sonography
 - (2) Nuclear scanning
 - (3) In-hospital computerized tomography technician twenty-four (24) hours
 6. Rehabilitation Medicine: As before for Level III
- C. Operating suite special requirements, equipment and instrumentation:
1. Required:
 - a. Operating room adequately staffed and immediately available twenty-four (24) hours a day
 - b. Craniotome
 - c. Thermal control equipment for patient, blood and fluids

- d. X-ray capability including c-arm image intensifier with technologists available twenty-four (24) hours a day
- e. Endoscopes, all varieties
- f. Monitoring equipment
- 2. Recommended/Desired:
 - a. Cardiopulmonary bypass capability
 - b. Operating microscope
- D. Clinical laboratory services: As before under Level III
 - 1. Required:
 - a. Drug and alcohol screening
 - b. Serum and urine osmolality
- E. Quality assurance: Same as Level III, Plus:
 - 1. Trauma conference, multidisciplinary - Required
 - 2. Quality assurance personnel who are dedicated to and specific for the trauma program - Required
- F. 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. Required
- G. Outreach program with telephone and on-site consultations with physicians of the community and outlying areas. Desired/Recommended
- H. Training program: As before for Level III, Plus:

Required

- 1. Formal program in continuing education provided by the hospital for:
 - a. Staff physicians - Required
 - b. --Nurses
 - c. --Allied-health-personnel

d- b. Community physicians - Required

I. Trauma Research Program - desired Required

7.4. Level I Trauma Center (Comprehensive)

7.4.1. 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 Primary," "Intermediate Level III," and "Advanced Level II" trauma facilities, plus the following:

A. Hospital organization:

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

- a. Cardiothoracic surgery service
- b. Ophthalmic surgery service
- c. Otorhinolaryngologic surgery service
- d. Pediatric surgery service
- e. Plastic and maxillofacial surgery service
- f. Urologic surgery service
- g. Oral Surgery-Dental

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

- a. Required:
 - (1) Cardiac surgery specialist
 - (2) Microsurgery capabilities
 - (3) Obstetric/Gynecologic surgery specialist
 - (4) Pediatric surgery specialist
 - (5) Hand surgery specialist
 - (6) Oral surgery (dental) specialist

3. Non-surgical specialties availability: (~~Resident services-as-previously-indicated-for-Levels-II-and-III~~)

a. Required:

- (1) Gastroenterology
- (2) Infectious disease
- (3) Nephrology
- (4) Chest medicine
- (5) Psychiatry
- (6) Anesthesiology - (Requirements may be fulfilled by anesthesiology chief residents who are capable of assessing emergent situations in trauma patients and of providing any indicated treatment, including initiation of surgical anesthesia. When anesthesiology chief residents are used to fulfill availability requirements, the staff anesthesiologist on call is advised and is promptly available.)

b. Recommended/Desired:

- (1) Family Medicine (Notification as before)

B. Special facilities; resources and capabilities:

1. Emergency department - As before for Level II plus:
 - a. Swan-Gantz and arterial catheters required
2. Intensive care unit(s): As before for Level II except:
 - a. Surgeon, credentialed in critical care by the trauma director is on duty in intensive care unit twenty-four (24) hours a day or immediately available in the hospital.
3. Postanesthetic recovery room: (Surgical intensive care unit is acceptable) - As before for Level II
4. Acute Hemodialysis capability required
5. Radiological special capabilities:
 - a. Required:

- (1) Sonography
- (2) Nuclear scanning
- (3) Computerized-tomography or equivalent In-hospital computerized technology (CT) technician twenty-four (24) hours a day availability.

6. Rehabilitation medicine - Required

- a. Physician-directed rehabilitation and service staffed by personnel trained in rehabilitation care and equipped properly for care of the critically injured patient.

C. Operating suite special requirements, equipment and instrumentation:

1. Cardiopulmonary bypass capability - Required
2. Operating microscope - Required

D. Clinical laboratory services: As before for Level II

E. Programs for quality assurance - Required

1. Review of pre-hospital and regional systems of trauma care.

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

G. 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~~ is provided.

§64-27-8. Notification and Site Visit Process.

8.1. 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 the designation.

8.2. 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 division of health office of emergency medical services.

8.3. 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 the site visit by the health care facility, institution, clinic, center, unit or hospital.

8.4. The site visit team as selected by the regional emergency medical services board of directors and approved by the West Virginia department division 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.

8.5. Each facility to be visited shall be provided a copy of this rule 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.

8.6. 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.

8.7. Patient confidentiality ~~will~~ shall 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 (1) of ~~their~~ its medical staff or medical records personnel accompany the site visit team physician or physicians during review of patient records.

8.8. The site visit team leader, previously appointed by the regional emergency medical services board of directors, and approved by the director of the West Virginia division of health office of emergency medical services, 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 judgment as to the level of trauma care determined. Such The 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 or her 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.

8.9. 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, upon approval of the director of the West Virginia division of health office of emergency medical services, but the ultimate responsibility for the actions of the critical care committee and emergency medical services medical director remains shall remain with the regional emergency medical services board of directors.

8.10. 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 division of health office of emergency medical services the levels of trauma care capability for each health care facility, institution, clinic, center, unit or hospital so evaluated. A copy of the final recommendations related to each facility shall be sent to each facility individually with no reference to the findings on other facilities. ~~included in such report.~~ The report to the state West Virginia division of health 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 West Virginia division of health office of emergency medical services 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.

8.11. Upon receipt of the recommendations from the regional emergency medical services board of directors, the state West Virginia division of health office of emergency medical services shall prepare a letter of provisional designation to each facility. ~~Such This~~ designation shall be is limited to trauma care capability and shall not be interpreted as implying total facility care capability or expertise in other areas of health care.

§64-27-9. Designation Process.

9.1. The West Virginia department division 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 Primary," "Intermediate Level III," "Advanced Level II" or "Comprehensive Level I" trauma facilities, units or centers. Such A designation ~~will~~ shall be provided in writing by the director of the West Virginia department division of health upon determination that the appropriate standards and criteria have been met or exceeded by a health care facility.

9.2. The initial review of a particular health care facility

will may be accomplished by regional emergency medical service agencies utilizing the standards and criteria listed in this rule and performed in accordance with the mechanisms outlined in Sections 5 and 6 of this rule.

9.3. Upon review and recommendation of the board of directors of the regional emergency medical services agency, or their its designated body, the proposed level of designation will shall be submitted to the West Virginia department division of health office of emergency medical services for review and action.

9.4. The director of the West Virginia department division 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 this rule.

9.5. Upon granting the provisional designation, the director of the West Virginia division of health ~~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 of the West Virginia division of health ~~or his designee~~ will shall perform such the 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.

9.6. Upon verification that the health care facility has met the appropriate criteria and standards, an official letter of designation will shall be forwarded to the hospital administrator by the director of the West Virginia department division of health.

9.7. Should the regional emergency medical service agency refuse or be unable to provide the initial evaluation through their its own resources or from outside consultants, the director of the West Virginia division of health shall arrange for such the initial appraisal of the institution or institutions in question.

9.8. 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 director of the West Virginia department division of health, and, where no other appropriate institution is located within a reasonable distance, the director of the West Virginia department division of health ~~or his designee~~ may enter such the facility in order to accumulate the necessary information to evaluate the institution's trauma care capability, but no official designation will shall 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.

9.9. 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 division 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 the institution.

9.10. 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 division 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.

§64-27-10. Review or Audit of Designated Facilities.

10.1. The director of the West Virginia department division 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 The 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 The audit or review may be performed at the discretion of the director of the West Virginia department division of health, but in no case more frequently than annually and with the time and date of such the site visit being mutually agreed upon by the official spokesperson of the institution and the director of the West Virginia division of health.

10.2. The director of the West Virginia division of health may authorize qualified individuals outside state government to perform such site visits.

10.3. Should such a 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 institution meets the standards and criteria of the previous designation level.

10.4. A health care facility receiving notification from the department West Virginia division of health of its intention to lower the designation level shall be given the opportunity to respond in writing within ten (10) working days upon receipt of such the notification of dedesignation. Such The response shall contain the reasons for recommending that no change in designation be made. The director of the department West Virginia division 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.

§64-27-11. Combined Hospital Designation of Trauma Centers.

11.1. 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.

11.2. Requirements - Two (2) 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 shall be met:

11.2.1. A current (annual) written plan of trauma patient care must shall be available and endorsed by each hospital.

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

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

11.2.4. The participating hospitals must shall address each of the standards for designation and must shall, 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 that level of care.

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

11.3.1. Each facility participating in a combined designation process must shall be capable of meeting all of the required/essential standards of a Level III (Intermediate) trauma center.

11.3.2. Each facility must shall meet the following Level II (Advanced) 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 7.3.1.A of this rule.
- B. All standards listed under "Special facilities, resources,

and capabilities," as-listed-under Section 7.3.1.B of this rule.

- C. All standards listed under "Operating suite special requirements equipment and instrumentation," as-listed-under Section 7.3.1.C of this rule.

11.4. Combined Designation as Level I (Comprehensive) Trauma Center - Each facility must shall meet as a minimum all of the minimum care capabilities as listed under Section 11.3 above of this rule, and in addition, must shall individually meet the following standards:

11.4.1. All standards listed under "Special facilities, resources, and capabilities," Section 7.4.1.B of this rule.

11.4.2. All standards listed under "Programs for quality assurance," Section ~~7-4-1-B~~ 7.4.1.E of this rule.

11.5. Shared Resources - Other than those requirements listed above under Sections 11-4 11.3 and 11-5 11.4 of this rule, all other human resources, specialists, equipment or facilities may be located in one (1) or the other hospital.

11.6. 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~~ are not eligible for combined designation as Level II trauma centers.

§64-27-12. Proposal Method and Review Process.

12.1. In those cases where it is impractical or when one (1) 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~~ shall 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 ~~will~~ shall be supplied by the West Virginia department division of health upon request. Upon receipt of the completed forms from all participating hospitals, the emergency medical services regional board of directors ~~will~~ shall submit the entire group of proposals to the West Virginia department division of health, office of emergency medical services for review and processing.

12.2. Submission of Proposals - Each hospital participating in the proposal process within an emergency medical services region ~~will~~ shall submit the completed forms to the regional emergency

medical services board of directors for review as to for completeness and proper preparation. The regional emergency medical services board ~~will~~ shall make no judgments or decisions regarding the individual proposals, but ~~will~~ shall provide appropriate written comments ~~as to~~ regarding 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 the proposal to the respective hospital for corrections.

12.3. The director of the West Virginia department division of health ~~or his designee, will~~ shall appoint a site visit team composed of physicians and others familiar with trauma center designation principles to visit each facility submitting a proposal within a West Virginia emergency medical service region in order to ascertain the validity of the individual proposals and make recommendations regarding the findings of the site visit to the director of the West Virginia division of health.

12.4. Upon receipt of the site visit reports, the proposal and findings of the site visit team ~~will~~ shall be evaluated by the director of the West Virginia division of health ~~or his designee~~ and outside consultants if necessary, in order to determine which facility, if any, ~~will~~ shall be designated as the trauma center.

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

12.6. Upon review of the submitted proposals, the director of the West Virginia division of health may elect to follow any of the following actions:

12.6.1. Selection of one (1) facility to be designated as the trauma center.

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

12.6.3. Arrange for an additional site visit at one (1) or more hospitals to verify previous findings or to evaluate additional resources.

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

12.6.5. Recommend that two (2) or more facilities request combined designation.

§64-27-13. Appeal Mechanism.

13.1. Upon receipt of official designation action, a health

care facility may appeal the designation through the following mechanism:

13.1.1. 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.

13.1.2. 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 of the West Virginia division of health by any participating hospital. Requests may be made for re-evaluation at any future time that the hospital administration feels that the level of care has been changed due to improvements, additions or deletions from conditions or resources existing at the time of the original or subsequent site visits.

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

13.1.4. A request to the State West Virginia categorization committee for review of a site visit evaluation which has been acted upon by the regional and State critical care committees ~~will~~ shall 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~~ shall only be utilized when an agreement cannot be reached between the hospital and the critical care committees.

13.1.5. The West Virginia categorization committee may follow one (1) of several alternatives in reaching a decision:

13.1.5.1. Appointment of a special site visit team, approved by the director of the West Virginia division of health, to review the original report and perform an additional evaluation of specific areas of concern and report the findings to the state West Virginia categorization committee for action.

13.1.5.2. Refer the request to the original critical care committee for review and re-evaluation with specific recommendations as to the action to be taken.

13.1.5.3. 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 West Virginia division of health regarding designation level.

13.1.5.4. Reaffirm the re-evaluation recommended designation level as made by the critical care committees.

13.1.5.5. Regardless of the alternative method chosen by the state West Virginia categorization committee, the hospital will shall be informed by letter from the chairperson of the committee as-to of the action taken and/or final decision.

§64-27-14. Administrative Due Process.

Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West-Virginia-Department-of-Health-Procedural-Rules, 64 CSR 1. ~~The-aforementioned-procedural-rules-are-incorporated-by-reference.~~

§64-27-15. Severability.

~~If-any-provisions-of-this-rule-or-the-application-thereof-to any-person-or-circumstance-shall-be-held-invalid,-such-invalidity shall-not-affect-the-provisions-or-the-application-of-this-rule which-can-be-given-effect-without-the-invalid-provisions-or application,-and-to-this-end-the-provisions-of-this-rule-are declared-to-be-severable.~~ The provisions of this rule are severable. If any provision of this rule is held invalid, the remaining provisions shall remain in effect.