# WEST VIRGINIA
# SECRETARY OF STATE
**KEN HECHLER**
# ADMINISTRATIVE LAW DIVISION
Form #3

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## NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §16-4C-1, et seq.

AMENDMENT TO AN EXISTING RULE: YES X 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: ___

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

W. Donald Weston, M.D.
Acting Secretary

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Trauma Center or Facility Designation

Type of Rule: X Legislative ____ Interpretive ____ Procedural

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

| 1. Effect of Proposed Rule | ANNUAL Increase | ANNUAL Decrease | FISCAL YEAR Current | FISCAL YEAR Next | FISCAL YEAR 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.

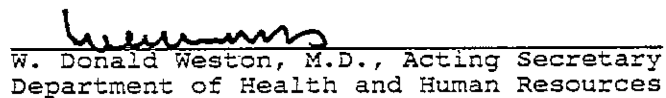
None

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

DATE: September 16, 1992

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: DIVISION OF HEALTH

LEGISLATIVE RULE TITLE: TRAUMA CENTER OR FACILITY DESIGNATION

1. Authorizing statute(s) citation W. Va. Code §16-4C-1, et seq.

2. a. Date filed in State Register with Notice of Hearing:

   June 3, 1992

   b. What other notice, including advertising, did you give of the hearing?

   Notice was sent to hospitals, county health departments and concerned professional associations.

   c. Date of hearing(s): Public comment period ended July 3, 1992

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached X No comments received ________

   e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

   ________

   f. Name and phone number of agency person to contact for additional information:

   Kay Howard - 558-3223

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

   a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

      N/A

   b. Date of hearing: ____________

   c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

      ____________

   d. Attach findings and determinations and reasons:

      Attached ____________

[PROPOSED]

TITLE 64

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

# TRAUMA CENTER OR FACILITY DESIGNATION

SERIES 27

199_

For Submission to the Legislative
Rule-Making Review Committee

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.

64 CSR 27

# 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

RECEIVED
1992 SEP 18 AM 11:57
OFFICE OF WEST VIRGINIA
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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~~ primary 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.~~ An 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

~~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. ~~Basic~~ Primary 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~~ Primary 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 (May be physician directed program staffed by nurse anesthetists)

(2) Internal medicine

~~b.~~ c. Recommended/Desired:

(1) Cardiology

(2) Hematology

(3) Nephrology

(4) Pediatrics

(5) Radiology

<u>(6) Family Medicine (The patient's primary care physician is notified at an appropriate time.)</u>

<u>(7) Pathology</u>

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~~ <u>functions</u> as a designated member of the trauma team. The relationship between emergency department physicians and other participants of the trauma team ~~must be~~ <u>is</u> 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~~ <u>physician</u> director

(2) Physician(s) with special competence in the care of the critically injured patient <u>and</u> who <u>is a designated member of the trauma team and is physically present</u> ~~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-

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

(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 written 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) Written 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; written transfer agreements ~~should~~ shall 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.~~ b. Endoscopes, all varieties

~~d.~~ c. 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 is 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~~

(c 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 judgements 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 Virginina 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.

Discussion of Public Comments Received
Concerning the Proposed Rule,
Trauma Center or Facility Designation, 64 CSR 27

The proposed revisions are for the purpose of incorporating changes in the national system published in November, 1990 by the American College of Surgeons.

A public comment period was held from June 3, 1992 to July 3, 1992. Eight sets of comments were received. Copies of the comments are attached.

General

1. Comment: St. Mary's Hospital requested that "no action be taken on these proposed rules and regulations until the State Trauma Categorization Advisory Committee has had the opportunity to review and discuss the impact of the proposed regulations on existing trauma centers in our State." The West Virginia Hospital Association stated that "while the proposed standards by the American College of Surgeons may be a good beginning point, modifications are needed based on West Virginia's special needs including its rural nature." The Association recommended that the proposed standards "be reviewed by the state's hospital categorization committee to determine if standards are applicable to West Virginia's unique problems and opportunities."

Response: The West Virginia Categorization Committee approved the changes in the rule at the meeting held July 21, 1992.

Section 4

2. Comment: Section 4.9. WRMS EMS, Inc. believes the word "basic" in line 4 should be replaced with "primary".

Response: Agreed.

Section 6

3. Comment: Section 6.2. Cabell Huntington Hospital stated that "rural" is not specified in the definition of a Level III facility in Section 4.2; suggested a definition of a "rural institution" and clarification on whether a small "urban" hospital can obtain a Level III designation. The West Virginia Hospital Association stated that it believes the criteria for the Level III Category are reasonable with two (2) exceptions, which are noted separately at appropriate points in this discussion.

Response: Except for a few metropolitan areas, West Virginia is generally defined as "rural" under the federal census. The word "rural" has been deleted from Section 6.2 as it appeared to cause some confusion.

## Section 7

4. Comment: Section 7.1.1.A. Cabell Huntington Hospital stated that "The concept of determining 'care capability' for Primary Level Facilities based on the West Virginia Emergency Facility Categorization Plan is to be commended in the context of categorization by participating institutions who know well their capabilities and available resources."

Response: The Department acknowledges the comment.

5. Comment: Section 7.2.1. Cabell Huntington Hospital stated that Basic Level Facility should read Primary Level Facility.

Response: Agreed.

6. Comment: Sections 7.2.1.A.1.a, 7.3.1.A.1.a and 7.4.1.A.1.a. West Virginia University Hospital recommended that Emergency Medicine be added to all three sections.

Response: The Department will take this recommendation under consideration in the next revision.

7. Comment: Section 7.2.1.A.2. Cabell Huntington Hospital stated that requiring surgical specialists on-call and "promptly available" is impractical in some Level III centers. This commenter questioned whether the proposed changes "preclude the use of residents to provide immediate treatment if staff specialists are on-call and promptly available for consultation". United Hospital Center stated that this provision would essentially exclude all hospitals without a general surgical training program from designation as a Level III facility. The hospital believes that a more fitting requirement for general surgery backup in a Level III facility would be a general surgeon qualified to provide trauma care on-call and promptly available from inside or outside the hospital (within 30 minutes), and that a designation as a Primary Level Facility instead of a Level III facility would under-rate its capabilities.

Response: Wording in this section is "Recommended/Desired" and does not preclude the use of residents since Level II facilities permit resident use to meet the standard.

8. Comment: Section 7.2.1.A.2.a.(1). West Virginia University Hospital suggested that this section should more clearly state how the general surgeon is to be notified so that he/she is present in the Emergency Department at the time of the arrival of the trauma patient.

Response: This is a question best answered by each individual facility depending upon local circumstances.

9. Comment: Section 7.2.1.A.3.b. West Virginia University Hospital, West Virginia Hospital Association and Summersville Memorial Hospital objected to the requirement for an anesthesiol-

ogist to be promptly available from inside or outside the hospital. The commenters stated that this is impractical and will be impossible for many hospitals to meet. The West Virginia Hospital Association stated that "Most small rural hospitals do not have anesthesiologists on call and, in fact, do not employ anesthesiologists. Rural America does not use anesthesiologists; rather, the certified registered nurse anesthetist is the standard of care and is recognized as a national standard of care by the JCAHO and by Medicare." Summersville Memorial Hospital stated that this requirement "will prevent us from becoming such a designated trauma center." The commenters suggested returning to the previous language which included certified registered nurse anesthetists.

Response: The phrase "May be physician directed program staffed by nurse anesthetists" was inadvertently omitted when the requirement for the anesthesia department was moved from in-hospital to on call and promptly available. This has been corrected.

10. Comment: Section 7.2.1.A.3.c.(6). Cabell Huntington Hospital stated that the inclusion of the patient's primary care physician among those recommended to be notified is to be commended.

Response: The Department acknowledges the comment.

11. Comment: Section 7.2.1.B.1.b.(10). WRMS EMS, Inc. stated that X-ray capability with twenty-four hour coverage by an in-house technician should be "required". "Allowing the x-ray technician to be called in seems unrealistic for any trauma center designation level."

Response: Requiring twenty-four hour coverage by an in-house x-ray technician is not in accordance with the American College of Surgeons guidelines.

12. Comment: Section 7.2.1.B.1.b.(11). West Virginia University Hospital stated that substituting Swan-Ganz and arterial catheters for MAST garments makes no sense. The commenter stated that many seriously injured rural trauma patients have the MAST garment inflated during transport to their Level I trauma facility. "Swan-Ganz and arterial catheters have little use in emergency departments unless there are sophisticated monitoring devices available."

Response: The change in this section was not intended to "substitute" catheters for MAST garments. MAST garments are primarily a prehospital device for assisting in the management of shock. Arterial or Swan-Ganz catheters are an added equipment item as suggested by the American College of Surgeons.

13. Comment: Section 7.2.1.B.2.b.(1). Summersville Memorial Hospital suggested that the language be changed to allow call from outside the hospital as opposed to placing a surgeon on call inside the hospital twenty-four hours a day.

Response: This is a "Recommended/Desired" item, not a requirement.

14. Comment: Section 7.2.1.B.4.a.(1). WRMS EMS, Inc. stated that the word "written" should be inserted before "transfer" in line 1.

Response: Agreed.

15. Comment: Section 7.2.1.B.5.a.(2). WRMS EMS, Inc. stated that the word "written" should be inserted before "transfer" in line 1.

Response: Agreed.

16. Comment: Section 7.2.1.B.6.a.(1) and (2). WRMS EMS, Inc. stated that the word "written" should be inserted before "transfer" in line 4 and the word "shall" should replace "should" in line 5 in both sections. "Transfer agreements for head/spinal injuries should be required, not optional, for any designated facility that does not provide such care."

Response: Agreed.

17. Comment: Sections 7.2.1.B.7.a.(4) and 7.3.1.B.5.a.(2). Cabell Huntington Hospital stated that the "certification of need standards for CT scanners should take into consideration that CT capabilities are recommended for Level III centers and required for Level II and I centers." Summersville Memorial Hospital stated that "as long as someone is on call within a reasonable period of time, it is unnecessary to have someone in-house for CT procedures twenty-four hours a day". Summersville Memorial Hospital also suggested that the Health Care Planning Commission's proposed Certificate of Need regulations will effectively eliminate the majority of CT scanners within the next ten years as the current machines need to be replaced.

Response: The Department notes the comment but has no authority over regulations of the Health Care Planning Commission.

18. Comment: Section 7.2.1.H.1. WRMS EMS, Inc. suggested that the phrase "in trauma care shall be" should follow the word "education" on line 1. This commenter further suggested that any trauma center must be required to provide specific trauma education for its staff.

Response: The Department believes the item is clear.

19. Comment: Section 7.2.1.H.1.a. WRMS EMS, Inc. stated that this section should be changed from "desired/recommended" to "required". This commenter stated that if ancillary and allied health personnel are required to have specific trauma education, the physicians should also.

Response: This would be inappropriate for this rule. Individual

hospitals set physician training standards in their staffing requirements.

20. Comment: Section 7.3.1.A.2.a.(1). West Virginia University Hospital stated that this section is vague and needs to be re-written to clarify whether the intent is that the general surgeon attending is to be present at the arrival of the trauma patient in the emergency department or if the upper level resident is considered sufficient. Wheeling Hospital stated that: "With the exception of hospitals which have surgical residents, this is a very impractical requirement for hospitals attempting to attain Level II status". This commenter felt that making a surgeon available within 10-15 minutes of arrival of the patient is more than adequate for trauma patient care, and that the "immediate evaluation and resuscitation can be handled adequately by skilled emergency physicians boarded in emergency medicine or trained in ATLS".

Response: The Department agrees in principle, but believes that establishing specific time requirements is not acceptable or necessary.

21. Comment: Section 7.3.1.A.2.a.(2) and (3). West Virginia Hospital Association and Cabell Huntington Hospital both requested retaining the previous language, which required an orthopedic surgeon be "on call and promptly available from inside or outside of the hospital" instead of the new language which requires the orthopedic surgeon to be "in-hospital twenty-four (24) hours a day" at Level II centers. Cabell Huntington Hospital stated that the previous requirement for orthopedic surgery being available on call and promptly available from inside or outside the hospital was sufficient.

Response: The language permits the chief of orthopedic surgery to designate an in-house surgeon to meet in-hospital requirement and permits Level II facilities to continue on-call practices for the orthopedic surgeon.

22. Comment: Section 7.4.1.B.2.a. Cabell Huntington Hospital questioned the practicality of requiring a critical care surgeon to be on duty in the ICU of a Level I center twenty-four hours per day or immediately available in the hospital.

Response: The Department agrees with the American College of Surgeons standards which require Level I centers to have a critical care surgeon on duty in the ICU twenty-four hours per day or immediately available in the hospital.

23. Comment: Section 7.4.1.B.4. Cabell Huntington Hospital stated that a definition of "acute" hemodialysis is not included and questioned the practicality of the requirement.

Response: "Acute" refers to the patient (e.g. as opposed to chronic dialysis).

CABELL HUNTINGTON HOSPITAL

June 26, 1992

Ms. Kay Howard
Regulatory Development Section
Department of Health and Human Resources
Room 204, Building 3
Capitol Complex
Charleston, West Virginia 25305

Re: Proposed Trauma Center Rules

Dear Ms. Howard:

Thank you for the opportunity to comment on the proposed Trauma Center Rules. My comments are attached. Each comment is prefaced by the referenced (Ref) section of the proposed rule to which it applies.

If you have any questions, please call.

Sincerely,

C. Keith Biddle

C. Keith Biddle
Vice President Planning and
Guest Services

/bjj

cc: W. Don Smith
President

RECEIVED
JUN 29 1992
REGULATORY DEVELOPMENT SECTION

1340 Hal Greer Boulevard, Huntington, West Virginia 25701-0195 304/526-2000

Ref. Sect 64-27-6.2, p.3

Does a Level III designation necessarily require that the hospital be "rural"? What is the definition of a "rural institution"? Can a small urban hospital obtain a Level III designation? "Rural" is not specified in the definition provided in 4.8 on p.2.

Ref. Sect 7.1.1.A., p.4

The concept of determining "care capability" for Primary Level Facilities based on the West Virginia Emergency Facility Categorization Plan is to be commended in the context of categorization by participating institutions who know well their capabilities and available resources.

Ref. Sect 7.2.1, p.5

Reference is made under "Care Capability" to "Basic Level Facility". To be consistent with the change in terminology, it should read "Primary Level Facility".

Ref. Sect 7.2.1.A.2., p.5

What is the basis for the proposed change requiring surgical specialists on-call and "promptly available"? Do the proposed changes preclude the use of residents to provide immediate treatment if staff specialists are on-call and promptly available for consultation? If so, won't this proposed change in requirements be impractical in some Level III centers?

Ref. Sect 7.2.1.A.3.c(6)., p.7

This inclusion of the patient's primary care physician is among those recommended and notified is to be commended.

Ref. Sect 7.2.1.B.7.a.(4)., p.10;
Sect 7.3.1.B.5.a.(2)., p.18

The certification of need standards for CT scanners should take into consideration that CT capabilities are recommended for Level III centers and required for Level II and I centers.

Ref. Sect 7.3.1.A.2.a(2) and (3), pp.14-15

What is the basis for the proposed changes requiring that an attending neurosurgeon and an attending orthopedic surgeon be "in-hospital twenty-four (24) hours a day" at a Level II center? These proposed changes in requirements may be impractical in Level II centers in the state. Were these proposed changes made in consultation with the Trauma Advisory Board? The previous requirement for orthopedic surgery being available "on-call and promptly available from inside or outside the hospital" was sufficient.

Ref. Sect. 7.4.1.B.2.a., p.21

What is the basis for requiring a critical care surgeon to be on duty in the ICU of a Level I center twenty-four (24) hours per day or immediately available in the hospital? Is this practical?

Ref. Sect. 7.4.1.B.2.4., p.21

What is the definition of "acute" hemodialysis? Is this requirement practical?

JUNE 26, 1992

REGULATORY DEVELOPMENT SECTION
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

DEAR SIRS,

I'm concerned about the Trauma Center Legislation page 14, wherein there is a requirement for General Surgery in hospitals 24 hours a day. With the exception of hospitals which have Surgical Residents, this is a very impractical requirement for hospitals attempting to attain Level II status.

I feel that a Surgeon available within 10-15 minutes of arrival of the patient is more than adequate for Trauma patient care. The immediate evaluation and resuscitation can be handled adequately by skilled Emergency Physicians boarded in Emergency Medicine or trained in ATLS.

Sincerely,

C. David Burkland, M.D.FACEP
CHIEF OF EMERGENCY MEDICINE

CDB/pk

RECEIVED
JUN 30 1992
REGULATORY DEVELOPMENT SECTION

Medical Park, Wheeling WV 26003
Member: Health First Alliance, Voluntary Hospitals of America, Inc.

St. Mary's Hospit[illegible]
2900 First Avenue Huntington, West Virginia 25702 (304) 526-[illegible]

June 23, 1992

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

Dear Ms. Howard:

I am writing to comment on the Proposed Amendments to the Rules for Trauma Centers or Facility Designation.

I would strongly urge that the proposed amendments not be adopted at this time. The State of West Virginia has a State Trauma Categorization Advisory Committee which is chaired by Fred Cooley, M.D. Membership on this committee is made up of physician, nursing, hospital, EMS and other interested individuals to provide input and guidance to the state with regard to trauma designation. The proposed amendments have not been presented to or discussed by the Trauma Advisory Committee. Further, it my opinion that the proposed regulations could have a significant impact on existing trauma facilities in our state.

I would request that no action be taken on these proposed rules and regulations until the State Trauma Categorization Advisory Committee has had the opportunity to review and discuss the impact of the proposed regulations on existing trauma centers in our state.

If you have any questions, please do not hesitate to contact me.

Sincerely,

J. Thomas Jones
Executive Director/CEO

RECEIVED
JUN 25 1992
REGULATORY DEVELOPMENT
SECTION

SMH SUMMERSVILLE MEMORIAL HOSPITAL
400 Fairview Heights Road • Summersville, West Virginia 26651 • 872-2891

June 15, 1992

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

Re: Proposed Trauma Center Rules

Dear Ms. Howard:

I am writing in regards to the proposed trauma center rules which were presented to me by EMSOR on June 12. My comments will be brief and to the point. I'm writing my comments from the perspective of a rural hospital administrator whose hospital has the busiest Emergency Department in a five county area.

Summersville Memorial Hospital, because of its central location and the large volume of patients it sees in it's Emergency Department, would like to be classified as a Level III (Intermediate) trauma center. In reviewing the proposed regulations, there was one particular item which will prevent us from becoming such a designated trauma center.

On page 6 - Item 3B (1), an anesthesiologist is required to be on call for the Level III trauma designation. Like the majority of rural hospitals in our state, we do not have an anesthesiologist on our medical staff. Instead, we rely strictly upon nurse anesthetists for the provision of all anesthesia. Based upon the continued growth of our facility, we anticipate that we will indeed recruit an anesthesiologist within the next five years, however, I'm certain that there are a number of other rural hospitals which serve a wide geographic area which do not have any immediate plans or hopes of recruiting an anesthesiologist. I would hope that the proposed regulations could be loosened to afford the survey team flexibility to override the requirement for an anesthesiologist.

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JUN 18 1992

REGULATORY DEVELOPMENT
SECTION

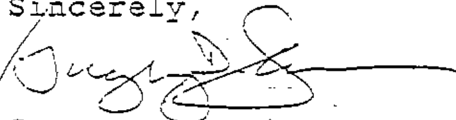
Even though the following two concerns are under "Recommended/Desired" categories, I have some concerns that these criteria are too strict and perhaps unrealistic for Level 3 trauma designation. On page 9, the proposed regulations encourage the presence of a surgeon inside the hospital at all times. I would suggest that this language be changed to allow call from outside the hospital as opposed to placing a surgeon on call inside the hospital 24 hours a day.

Likewise, on page 10, the proposed criteria encourage the presence of an in-house CT technician 24 hours a day. In this regard, I feel that as long as someone is on call within a reasonable period of time, it is unnecessary to have someone in-house for CT procedures 24 hours a day.

In terms of CT services, I would hope that EMSOR and others who are working on the proposed trauma designations would take into account that the Health Care Planning Commission's proposed Certificate of Need regulations will effectively eliminate the majority of CT scanners within the next 10 years as the current machines need to be replaced. The proposed CON regulations are based strictly upon volume criteria and do not take into account the wide geographic areas that certain hospitals, such as my own, serve. Nonexistence of basic diagnostic services, such as CT scanning, in certain hospitals is going to tax the Emergency Medical Transportation system across the state and unnecessarily place victims of accidental and medical emergencies at unnecessary risk.

Thank you for this opportunity to comment. Please feel free to call or contact me if you need additional clarification on my comments.

Sincerely,



Gregory D. Johnson
Administrator

GDJ:ss

cc: F. M. Cooley, MD
Bob Whitler, WVHA

UNITED HOSPITAL CENTER

Post Office Box 1680 ▪ Clarksburg, West Virginia 26302-1680 ▪ Telephone 304/624-2[illegible]

July 1, 1992

Kay Howard
Regulatory Development Section
Department of Health and Human Resources
Building 3, Room 304
State Capitol Complex
Charleston, West Virginia 25305

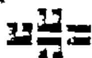
Dear Ms. Howard:

This letter is in response to the proposed trauma center rules for West Virginia (proposed - Title 64, West Virginia Administrative Rules, Division of Health, Trauma Center or Facility Designation, Series 27, 1992).

The area of concern for United Hospital Center and other similar hospitals is the general surgery backup requirement under 7.2.1.A.2.a.(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.)* This provision would essentially exclude all hospitals without a general surgical training program from designation as a Level III or Intermediate facility.

I believe designation as a Primary Level Facility would belie our true capabilities. Level III designation of a facility such as ours would be a more accurate reflection of our capabilities. United Hospital Center is a 383 bed full-service community hospital. Our active medical staff includes 9 general surgeons, 4 ophthalmologists, 2 orthopedists, 2 otorhinolaryngologists, 3 thoracic/vascular surgeons, 4 urologists and 2 neurosurgeons. Our facility has a new, well equipped and appropriately staffed Emergency Department, as well as, the full array of ancillary services in-house 24 hours a day.

United Hospital Center has approximately 100 trauma admissions per year. Some of our trauma patients are seriously injured while others have relatively minor injuries. Some require early surgical intervention while others require mainly observation. The initial evaluation and stabilization of these patients can be properly accomplished by qualified emergency physicians with prompt surgical consultation as indicated by the patient's condition. A more fitting requirement for general surgery backup in a Level III facility would be *a general surgeon qualified to provide trauma care on-call and promptly available from inside or outside the hospital (within 30 minutes).* This would allow us and others like us to provide good trauma care within our capabilities while not under-rating those capabilities.



UNITED HOSPITAL CENTER

Post Office Box 1680 ▪ Clarksburg, West Virginia 26302-1680 ▪ Telephone 304/624-2:: 

Thank you for your favorable consideration of this issue.

Sincerely,

J. Hermel, M.D.

J. Hermel, MD, FACEP, ABQAURP
Medical Director and Chairman, Department of Emergency Medicine

S. Smith

S. Smith, DO, FACOEP
Assistant Medical Director, Department of Emergency Medicine

cc: Bruce Carter, CEO
Saad Mossallati, MD, Chief of Surgery

600 D Street, Second Level
South Charleston, West Virginia 25303
(304) 744-9842 FAX (304) 744-9889

July 2, 1992

Ms. Kay Howard
Regulatory Development Section
Department of Health and Human Resources
Room 204, Building 3
Capitol Complex
Charleston, West Virginia 25305

RE: WV Code §16-4C-1 et seq.

Dear Kay:

The West Virginia Hospital Association on behalf of its 64 member hospitals appreciates the opportunity to review and comment on the proposed trauma center or facility designation rules. The proposed rule changes have been made based on a 1990 publication of the American College of Surgeons. The Hospital Association's Board of Trustees and its Emergency Medical Services (EMS) Task Force believes that while the proposed standards by the American College of Surgeons may be a good beginning point, modifications are needed based on West Virginia's special needs including its rural nature.

We would recommend that the proposed trauma center standards could be reviewed by the state's hospital categorization committee to determine if standards are applicable to West Virginia's unique problems and opportunities.

We have the following comments on specific standards for Level III and Level II centers:

Level III (Intermediate) Trauma Center

Under 6.2., a Level III Trauma Center is defined as "a rural institution with the resources necessary to provide trauma center commensurate with those resources and demonstrates a commitment to excellence of trauma care. Transfer protocols in selected specialty areas are required."

Many of our rural hospitals have recently made major commitments to improve their emergency department capabilities and have, indeed, made arrangements for 24-hour in-hospital physician coverage and have made major investments in equipping the emergency department. These particular hospitals were fully expecting that they would be able to move from the basic category to an intermediate or Level III category.

The West Virginia Hospital Association's EMS Task Force has reviewed the proposed standard and basically believes that the criteria is reasonable with two exceptions which are outlined below:

1. Requirement that an anesthesiologist be promptly available from inside or outside the hospital.

-more-

Most small rural hospitals do not have anesthesiologists on call and, in fact, do not employ anesthesiologists. Rural America does not use anesthesiologists; rather, the certified registered nurse anesthetist (CRNA) is the standard of care and is recognized as a national standard of care by the Joint Commission on the Accreditation of Health Care Organization (JCAHO) and by Medicare. A standard requiring hospitals to employ anesthesiologists is, in our opinion, not a cost-effective requirement, especially when national accrediting organizations recognize that quality care can be given by CRNAs.

Level II Trauma Center

The proposed standard requires that an attending orthopedic surgeon be in-hospital 24 hours a day. We recommend that an orthopedic surgeon on call and promptly available from inside or outside the hospital is sufficient.

Please feel free to call if you have any questions.

Sincerely,

Robert D. Whitler
Vice President
Public Policy Development

RDW/tlm

c Fred Cooley, M.D.

Health Sciences Center
West Virginia University
Emergency Medicine Service
WVU Hospitals
Morgantown, WV 26506
304 598-4160

July 7, 1992

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

Dear Ms. Howard:

Please find enclosed my comments on the proposed trauma center rules for West Virginia. I apologize for the lateness of this letter but given the importance of this matter I hope the committee will take these comments into consideration.

Most of the rules and proposed changes are straightforward. However, there are several areas for concern. The most important of these are as follows:

Page 6: Section 7.2.1.A.3.b. "Required: (On call and promptly available from inside or outside the hospital): (1) Anesthesiology." From a practical standpoint, this new requirement will be an impossible one for many capable rural hospitals to meet. Certified nurse anesthetists are a fact of life for rural hospitals, there simply are not enough anesthesiologists. Hospitals which would otherwise receive the Level III designation would be arbitrarily forced to accept a lower designation for failure to meet this requirement. I strongly advise you support the old wording which included nurse anesthetists.

Listed below are other areas of concern/questions:

Page 5: Section 7.2.1.A.1.a. I recommend that Emergency Medicine be added here and in each of the following sections (7.3.1.A.1.a. and 7.4.1.A.1.a) which are designated as required under Hospital Organization.

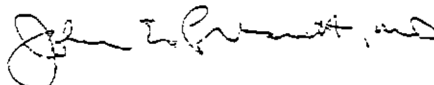
Page 6: Section 7.2.1.A.2.a. (1). This is a very vague statement and does not spell out how the general surgeon is to be notified so that he/she is present in the ED at the time of the arrival of the trauma patient.

Page 7: Section 7.2.1.B.1.b.(11). In this statement, the MAST garment is deleted and Swan-Ganz and arterial catheters are substituted. This makes no sense. Many seriously injured rural trauma patients have the MAST garment inflated during transport to our Level I trauma facility. (Recent studies have shown that it is not very useful in urban environments and patients with penetrating trauma. But I am not familiar with any study that comes to the same conclusion for rural patients suffering from blunt trauma.) Furthermore, Swan-Ganz and arterial catheters have little use in emergency departments unless there are sophisticated monitoring devices available.

Page 14: Section 7.3.1.A.2.a.(1). This statement is somewhat vague and may have purposefully been written that way. After reading it several times, I'm still not sure if the intent of this statement is that the general surgery attending is to be present at the arrival of the trauma patient in the ED or if the upper level resident is considered sufficient. This may need to be rewritten to reflect the wishes of the State.

Please contact me at (304) 598-4180 if you have any questions regarding these comments.

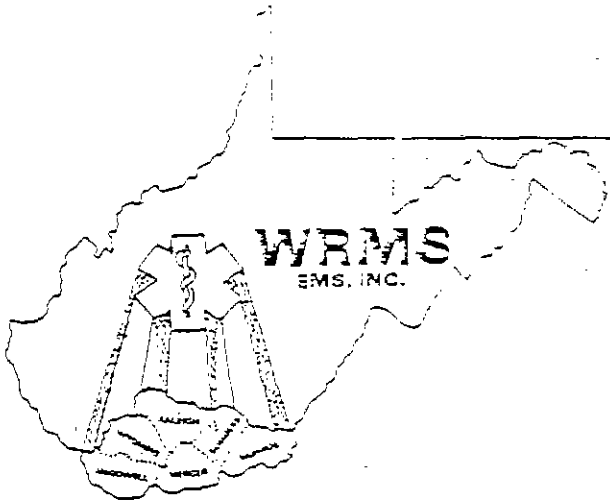
Sincerely,



John E. Prescott, MD, FACEP
Chief, Emergency Medicine

Director,
Center for Rural Emergency Medicine
(CREM)

JEP/cl




RECEIVED
JUL 10 1992
REGULATORY DEVELOPMENT
SECTION

June 29, 1992

Kay Howard
Regulatory Development Section
West Virginia Department of Health & Human Resources
Room 204, Building 3
Capitol Complex
Charleston, West Virginia 25305

RE: 64 CSR 27, Trauma Center or Facility Designation

Dear Ms. Howard:

Please accept these comments related to revision of the referenced rule.

In general, the revisions are appropriate for use in West Virginia and will improve the trauma center designation process. I do have specific comments or have found apparent errors in some sections. Specific comments as follows:

1. 4.9.: The word "basic" in the line 4 should be replaced with "primary". This will bring this wording into line with current facility categorization plans.

2. 7.2.1.B.1.b.(10): X-ray capability, 24 hour coverage by in-house technician should be "required". Significant delays in patient treatment can and will occur if this is left as "desired/recommended". Level III centers in southern West Virginia will be getting critical patients that should go to a higher level facility but cannot due to time/distance/weather constraints. Allowing the x-ray technician to be called-in seems unrealistic for <u>any</u> trauma center designation level.

3. 7.2.1.B.4.a.(1): The word "written" should be inserted before "transfer" in line 1. In evaluating a facility, only the existence of a current written document is proof that such agreements exist.

P.O. BOX 959 • BEAVER, WEST VIRGINIA 25813
PHONE (304) 253-8469
1-800-321-3216

4. 7.2.1.B.5.a.(2): The word "written" should be inserted before "transfer" in line 1. In evaluating a facility, only the existence of a current written document is proof that such agreements exist.

5. 7.2.1.B.6.a.(1): The word "written" should be inserted before "transfer" in line 4. The word "shall" ought to replace "should" in line 5. In evaluating a facility, only the existence of a current, written document is proof that such agreements exist. Transfer agreements for head/spinal injuries should be required, not optional for any designated facility that does not provide such care.

6. 7.2.1.B.6.a.(2): The word "written" should be inserted before "transfer" in line 4. The word "shall" ought to replace "should" in line 4. Same reason as 5. above.

7. 7.2.1.H.1.: The phrase "in trauma care shall be" should follow the word "education" on line 1. Any facility that holds itself out to be a trauma center must be required to provide specific trauma education for it's staff.

8. 7.2.1.H.1.a.: Should be changed from "desired/ recommended" to "required". There is no reason that ancillary and allied health personnel should be required to have trauma education and the physicians not. Trauma is a surgical disease best treated by skilled physicians. How can a physician staff at any designated trauma center be considered to have special competence in trauma care if specific trauma care education is not required?

Thank you for the opportunity to comment on these rules.

Sincerely,

Gerald L. Kyle
Program Director