

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

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2019 JUL 31 A 11:47

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Form #3

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

AGENCY: DIIIR - BUREAU FOR PUBLIC HEALTH TITLE NUMBER: 64

CITE AUTHORITY: WV Code §§16-1-4 and 16-4C-23

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 27

TITLE OF RULE BEING AMENDED: STATEWIDE TRAUMA AND EMERGENCY CARE SYSTEM

IF NO, SERIES NUMBER OF 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.


Authorized Signature

FISCAL NOTE FOR PROPOSED RULES

Rule Title: STATEWIDE TRAUMA / EMERGENCY CARE SYSTEM

Type of Rule: X Legislative Interpretive Procedural

Agency: Health and Human Resources - Bureau for Public Health

Address: One Davis Square
Suite 100, East
Charleston, WV 25301

Phone Number: 304 558-2971 Email: ann.a.goldberg@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

This amendment to the Trauma rule will have no impact on costs or revenues of state government.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2014 Increase/Decrease (use "-")	2015 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Buildings			
Equipment			
Land			
Other Assets			
2. Estimated Total Revenues	0	0	0

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

[Empty box for explanation of above estimates]

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

[Empty box for memorandum]

Date

7/30/14

Agency

Department of Health and Human Resources

Authorized Representative

Karen L. Bowling

Karen L. Bowling
Cabinet Secretary

Legislative Rule, 64CSR27
Department of Health and Human Resources
Bureau for Public Health
Statewide Trauma / Emergency Care System

BRIEF SUMMARY

This rule was last updated in 2004. The guidelines published by the American College of Surgeons, Committee on Trauma have been updated since the last promulgation of the rule and those updates are adopted in this rule. In particular, the standards and criteria for designation as a West Virginia Trauma Center are outlined in the newest version of the "Resources for Optimal Care of the Injured Patient", written by the American College of Surgeons, Committee on Trauma (ACS-COT).

The rule also extends the time period for a probationary designation from 1 year to 2 years, with a possible extension. Throughout the rule an effort has been made to give the Commissioner of the Bureau for Public Health greater flexibility and discretion with respect to trauma designation status in order to assure the continuation of services and to allow the Commissioner and the Bureau staff to work with the institutions to assist them in compliance with the requirements of the statute and this rule.

STATEMENT OF CIRCUMSTANCES

In the past year it has come to the attention of the Commissioner of the Bureau for Public Health that the rule is written in such a way as to be too restrictive on the Commissioner's power to work with a Trauma Center on meeting their requirements to maintain the designation status that is assigned. Therefore, a greater degree of flexibility and discretion is the main objective of this amendment.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: _____

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) DHHR Bureau for Public Health
350 Capitol Street, Room 702
Charleston, WV 25301
(304) 558-2971

LEGISLATIVE RULE TITLE: Statewide Trauma/Emergency Care System

1. Authorizing statute(s) citation WV Code §§ 16-1-4, and 61-4C-23

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

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

c. Date of Public Hearing(s) or Public Comment Period ended:
N/A

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

Attached N/A No comments received X

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

N/A

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Ann Goldberg, Director
Public Health Regulations
350 Capitol Street, Room 702
Charleston, WV 25301
Phone(304) 558-2971
Fax (304) 558-1035
ann.a.goldberg@wv.gov

- g. **IF DIFFERENT FROM ITEM 'f'**, please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Dr. Michael Mills, Medical Director
Office of Emergency Services
350 Capitol Street, Room 425
Charleston, WV 25301
Phone (304) 558-7124
Fax (304) 558-7125
michael.r.mills@wv.gov

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 or comment period:

N/A

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH

FILED

SERIES 27
STATEWIDE TRAUMA / EMERGENCY CARE SYSTEM

2004 JUL 31 A 11:47

OFFICE WEST VIRGINIA
SECRETARY OF STATE**§64-27-1. General.**

1.1. Scope. -- This legislative rule establishes the standards, criteria, and methods for designating various health care facilities in the State of West Virginia as meeting specific levels of care capability as trauma and emergency care centers or facilities in order to identify those facilities best equipped and staffed to care for patients experiencing emergency injuries or illnesses. It also establishes the responsibilities, powers, and authority of certain trauma / EMS committees or councils, and establishes the organizational structure of a statewide trauma / emergency care system including medical review committees for system quality. This rule should be read in conjunction with W. Va. Code §§16-4C-1 et seq. and 55-7B-9c. The W. Va. Code is available in public libraries and on the Legislature's web page, <http://www.legis.state.wv.us/>.

1.2. Authority -- W. Va. Code §§16-1-4 and 16-4C-23 and ~~55-7B-9c(k)~~.

1.3. Filing Date. -- ~~April 29, 2004~~.

1.4. Effective Date. -- ~~April 29, 2004~~.

~~1.5. Repeal and Replacement of Former Rule. -- This rule repeals and replaces, "Trauma Center or Facility Designation," 64 CSR 27, effective June 11, 1993.~~

§64-27-2. Application and Enforcement.

2.1. Application -- This rule applies to all health care institutions, facilities, hospitals, clinics, agencies, corporations, partnerships, and governmental agencies engaged in the provision of emergency care to injured or ill patients in the state.

2.2. Enforcement -- This rule is enforced by the Commissioner of the Bureau for Public Health.

§64-27-3. Definitions.

3.1. American College of Surgeons, Committee on Trauma Guidelines -- The guidelines published by the American College of Surgeons, Committee on Trauma, outlining the listing of resources for optimal care of the injured patient in the current edition entitled of "Resources for the Optimal Care of the Injured Patient: ~~1999~~".

3.2. Bureau -- The West Virginia Bureau for Public Health within the Department of Health and Human Resources.

3.3. Categorization Process -- The process in which the Office of Emergency Medical Services (OEMS) determines the level of care capability of emergency facilities in various categories of emergency care to assist medical command in determining the most appropriate facility to which an emergency patient should be transported.

3.4. Commissioner -- The Commissioner of the Bureau for Public Health or his or her designee.

3.5. Designated Facility -- A facility that has been officially designated as a West Virginia trauma center by the Bureau through the Office of Emergency Medical Services.

3.6. Designation -- An official notification by the Commissioner to a particular health care facility indicating the level of trauma care capability determined through the verification process.

3.7. Emergency Medical Services (EMS) -- Emergency medical services as defined in W. Va. Code §16-4C-3(d).

3.8. Emergency Medical Services Advisory Council (EMSAC) -- The Emergency Medical Services Advisory Council created pursuant to W. Va. Code §16-4C-5.

3.9. Medical Policy and Care Committee (MPCC) -- The committees established by OEMS at the regional and state levels as outlined in the "Emergency Medical Services" rule, 64CSR48, that serve as the primary advisory committees to the regional and state EMS medical director on all medical issues involving the EMS System.

3.10. Medical Review Committees (MRC) -- The committees established by OEMS at the local, regional and state levels to provide medical peer review and quality assurance for the state trauma / emergency care system.

3.11. Office of Emergency Medical Services (OEMS) -- The Office of Emergency Medical Services within the Bureau.

3.12. OEMS Medical Direction System -- The system established within OEMS that has the primary responsibility for the establishment of the policies and procedures governing all aspects of the operation of the on-line and off-line medical direction for all EMS activities in West Virginia. This system includes, but is not limited to, state, regional, and agency medical directors, committees, and medical command centers.

3.13. Revocation of Designation -- The removal of designation from a health care facility requiring the complete re-application process before designation can be reinstated.

3.14. State Trauma Advisory Council (STAC) -- The primary advisory council to the state EMS medical director and OEMS on all trauma-related matters.

3.15. Suspension of Designation -- The temporary removal of designation from a health care facility pending further review and evaluation by the Commissioner.

3.16. Trauma and Emergency Medical Information System (TEMIS) -- The information system developed and maintained by OEMS to collect and maintain the necessary trauma and emergency care information to assure system quality and accountability, as well as to provide data for use in system design and operations. This system includes, but is not limited to, the State Trauma Registry (STR), the State Medical Command Record (SMCR), and the EMS Patient Care Record (EPCR).

§64-27-4. Powers of Designation and Categorization.

4.1. The Bureau through OEMS has the power to designate health care facilities in the state that meet the criteria set forth in this rule. The Commissioner shall provide a designation in writing to the health care facility upon determination that the standards and criteria for that designation have been met. Facilities designated as trauma centers shall enjoy all of the rights and privileges provided by the W. Va. code and this rule including limits of liability pursuant to W. Va. Code §55-7B-9c.

4.2. An institution, health care facility, unit, center or hospital shall not represent itself as a trauma center, unit, or facility until a designation level is assigned by the Commissioner. Any public advertisement or claim of trauma care capability by a facility prior to receiving the appropriate designation may result in civil proceedings against the institution or facility.

4.3. Any institution, health care facility, unit, center or hospital that received designation as a trauma center from the Commissioner is exempt from the antitrust laws of this state pertaining to antitrust actions brought as a result of the designation by an individual, individuals, corporation, partnership, other health care institution, or governmental agency.

§64-27-5. Types of Designation.

5.1. General. The Bureau shall use the following general categories when granting trauma center designation status to facilities:

5.1.a. Permanent, when a facility meets all the requirements as referenced in this rule. Permanent designation may be granted for a maximum of three (3) years.

5.1.b. Provisional, when a facility substantially meets the requirements ~~at the time of application~~ and has outlined in writing clear plans and progress toward full compliance with all requirements. Provisional designations may be granted for not less than six (6) months ~~or nor longer than one (1) year~~ two (2) years with a possible extension of six (6) months.

5.1.c. Probational, when the Commissioner determines that it is in the best interest of the public health and safety for a permanently designated facility to remain designated while identified non-compliance issues are being corrected. The facility shall provide written evidence of active progress in correction of non-compliance areas. Probational designation may be granted for not less than six (6) months a maximum of one (1) year nor longer than two (2) years, with a possible extension at the discretion of the Commissioner.

5.1.d. Emergency, when the Commissioner determines that it is in the best interest of the public health and safety to temporarily designate a facility to meet a particular emergency need. Emergency designation shall not exceed six (6) months, with a possible extension of six (6) months at the discretion of the Commissioner.

5.2. Levels. The standards and criteria for designation as a West Virginia trauma center are those standards outlined in the current edition of "Resources for Optimal Care of the Injured Patient-1999", by the American College of Surgeons, Committee on Trauma (ACS-COT) with any variations as outlined in this subsection. The following levels of care designations will be used when granting trauma center designation status to facilities:

5.2.a. Level I. The facility meets at a minimum the ACS-COT standards for a level I center as determined by OEMS.

5.2.b. Level II. The facility meets at a minimum the ACS-COT standards for a level II center as determined by OEMS.

5.2.c. Level III. The facility meets at a minimum the ACS-COT standards for a level III center as determined by OEMS.

5.2.d. Level IV. The facility meets at a minimum the ACS-COT standards for a level IV center as determined by OEMS.

~~5.2.e. Level V. The facility meets at a minimum the characteristics of a "trauma receiving facility" as described in the ACS-COT guidelines. The level V center is not required to be open twenty-four (24) hours a day, but shall comply with minimal hours of operation as established by OEMS.~~

§64-27-6. Criteria for Designation.

6.1. The standards and criteria for designation as a West Virginia trauma center are those standards outlined in the current edition of "Resources for Optimal Care of the Injured Patient: 1999", by the American College of Surgeons, Committee on Trauma (ACS-COT) with any specific modifications or additions set forth in Subsection 6.2 of this rule.

6.2. Facilities at all levels shall meet and maintain the following additional specific requirements in order to be designated and maintained as a West Virginia trauma center. The facilities shall:

6.2.a. Participate and submit information to the State Trauma / Emergency Medical Information System (TEMIS);

6.2.b. Meet all benchmarks of timely submission of data and information into the State Trauma Registry (STR) as established by OEMS;

6.2.c. Actively participate in the state trauma / emergency care quality assurance performance improvement and medical review process as outlined in Section 10 of this rule;

6.2.d. Provide and maintain appropriate hardware and software at the local site in order to participate in the state trauma and emergency medical information system. This includes internet access to OEMS central site;

6.2.e. Actively participate and abide by medical command guidelines including adherence to all policies and procedures established which govern the statewide facility resource tracking mechanisms as established by the OEMS Medical Direction System;

6.2.f. Provide facility representatives to all required committees of the statewide trauma / emergency care system as outlined by OEMS and assure that appropriate attendance is maintained;

6.2.g. Maintain compliance with state and federal laws, rules, and regulations concerning confidentiality of patient information and participation in the medical review process;

6.2.h. Maintain written trauma team policies and procedures, including activation guidelines and operational guidelines for all members of the trauma team including physicians, nurses, EMS personnel, and other ancillary staff. At no time may a trauma team member exceed the scope of practice established by his or her respective certifying or licensing authority; and

6.2.i. Participate and abide by all policies and procedures of the statewide trauma / emergency care system including the facility categorization guidelines in Section 8 of this rule.

§64-27-7. Process of Designation.

7.1. The chief executive officer of a facility seeking to apply for trauma center designation shall request in writing from the medical director of OEMS an application for initial provisional trauma center designation. The application and other required materials shall be completed and submitted to OEMS with the initial provisional non-refundable designation fee.

7.2. Site visits. The following two (2) types of site visits are used in the designation process:

7.2.a. Consultation site visit. A consultation site visit shall be conducted early in the provisional designation process to identify areas of non-compliance and provide specific recommendations to assist facilities in fully meeting the designation requirements.

7.2.a.1. All facilities seeking designation as a level I, II, or III center shall obtain an official American College of Surgeons, Committee on Trauma consultation site visit as outlined in Subdivision 7.3.c. of this rule, except as provided in Subdivision 7.3.i. of this rule. OEMS may waive this consultation site visit if the facility has undergone an official ACS-COT consultation site visit in the past year.

7.2.a.2. All facilities seeking designation as a level IV ~~or V~~ center shall obtain a consultation site visit by a State site visit team as outlined in Subdivision 7.3.c. of this rule.

7.2.a.3. The team composition, format, and nature of a level IV ~~or V~~ consultation shall be determined by OEMS based on discussions and information from the specific facility as to the need for clarification of guidelines and degree of assistance needed to meet the standards and criteria of designation. In certain situations, the consultation may be done by telecommunication or other electronic or written means.

7.2.b. Verification site visit. A verification site visit shall be conducted during the provisional designation period or prior to re-certification of a permanently designated facility, in order to verify compliance with trauma center designation requirements.

7.2.b.1. All facilities seeking permanent designation as a level I, II, or III center shall obtain an official American College of Surgeons, Committee on Trauma verification site visit as outlined in Subdivision 7.4.b. of this rule, except as provided in Subdivision 7.3.i. of this rule.

7.2.b.2. All facilities seeking designation as a level IV ~~or V~~ center shall obtain a verification site visit by a West Virginia site visit team as outlined in Subdivision 7.4.c. of this rule.

7.3. Initial Provisional Designation. -- After the effective date of this rule, any facility seeking designation as a trauma center shall apply for initial provisional designation status as outlined in this rule. This requirement also includes those trauma centers designated prior to the effective date of this rule. At the discretion of the Commissioner, a facility holding an active trauma center designation prior to the effective date of this rule may maintain that designation for no longer than six (6) months from the effective date of this rule or until the new initial provisional designation is granted or denied, whichever of the three (3) circumstances occur first. The Commissioner may grant provisional status to facilities which meet or substantially meet the requirements as outlined in this rule, and provide evidence of committed progress toward meeting all standards and criteria for permanent designation status. The process for obtaining provisional designation and required activities during the provisional designation are as follows:

7.3.a. Upon receiving a correctly completed application and other required materials, OEMS shall review and evaluate the information provided and make a preliminary assessment as to the facility's ability to meet the requirements of the designation level requested. If, in the opinion of OEMS, the facility appears to substantially meet the requirements and shows evidence of committed progress toward meeting all standards and criteria for permanent status, the facility will be notified in writing of the intent to grant provisional designation status to the facility.

7.3.b. If OEMS determines that the facility does not have the ability to substantially meet the requirements for provisional designation at the requested level, OEMS shall deny the application and may recommend that the facility seek provisional designation at a different level and/or suggest to the facility additional modifications before re-applying for provisional designation status.

7.3.c. Upon receiving notification from OEMS of the intent to grant provisional status, the facility shall provide to OEMS evidence of the scheduling of a consultation site visit as outlined in Subsection 7.2. of this rule to occur within ninety (90) days of the notification except as outlined in Paragraph 7.2.a.1. of this rule. The cost of the consultation site visit is at the facility's own expense.

7.3.d. After receiving written evidence from the facility of the scheduled consultation site visit, the Commissioner shall grant the facility official provisional designation status. The provisional designation letter shall outline any known non-compliance areas discovered during the preliminary review conducted under Subdivision 7.3.a. of this rule. OEMS may establish specific time frames for correction of deficiencies or other activities, including expected progress toward complete compliance. Facilities shall respond to all inquiries and requirements as outlined by OEMS. Provisional status remains valid for no longer than ~~one (1) year~~ two (2) years, except as outlined in Subdivision 7.3.e. of this rule.

7.3.e. The Commissioner may grant a facility a one-time only six (6) month extension of provisional status, upon submission by the facility of a written request for extension, accompanied by a detailed explanation and plan of action to fulfill the requirements for permanent trauma center designation. If, at the end of the six (6) month extension period, the facility has not been designated as a permanent trauma center, the provisional designation expires.

7.3.f. Facilities shall use the information provided in the consultation site visit report to assist in correction of non-compliance areas in preparation for the permanent verification site visit. Facilities shall send OEMS a written copy of the consultation report within ten (10) days of receipt of the report by the facility.

7.3.g. Provisionally designated facilities seeking permanent designation shall complete the permanent designation process as outlined in Subsection 7.4. of this rule, no sooner than six (6) months nor longer than ~~one (1) year~~ two (2) years after the date of official provisional designation.

~~7.3.h. Except as outlined in Subsection 7.3. of this rule, the category of provisional designation is only used in cases where a facility has never been previously designated or designation has lapsed for at least one (1) year. A provisional facility may not be placed on probation.~~

~~7.3.i~~ 7.3.h. If a facility applying for initial provisional designation status has a valid ACS-COT verification certificate issued within the previous two (2) years, OEMS may waive the requirement for a consultation site visit and grant the facility provisional designation status. The facility may then apply for permanent designation status by completing the permanent designation application and materials and paying the appropriate permanent designation fee. If after six (6) months of provisional status the facility continues to meet or exceed all standards and criteria established in this rule, the Commissioner may waive the requirement for a verification site visit, and grant the facility permanent designation as outlined under the permanent designation guidelines in Subsection 7.4. of this rule.

7.4. Permanent designation. Provisional centers seeking permanent designation shall complete the following process during their provisional designation period no sooner than six (6) months nor greater than ~~one (1) year~~ two (2) years after their official date of provisional designation:

7.4.a. All facilities seeking permanent designation shall complete and submit an official permanent designation application and other required materials to OEMS, along with the non-refundable permanent designation fee. This permanent designation application shall be submitted ninety (90) days prior to expiration and prior to the scheduling of the verification site visit.

7.4.b. All facilities seeking permanent designation as a level I, II, or III center shall obtain an official American College of Surgeons, Committee on Trauma verification site visit. This visit shall be conducted no later than ~~twelve (12) months~~ two (2) years after granting of provisional designation, except

as outlined in Subdivision ~~7.3.i~~ 7.3.h of this rule. The cost of the ACS-COT verification site visit is at the facility's own expense.

7.4.c. All facilities seeking designation as a level IV ~~or V~~ center shall obtain a verification site visit by a state site visit team. This visit shall be conducted no later than ~~twelve (12) months~~ two (2) years after the official provisional designation date. The state verification site visit team shall be appointed by the state EMS medical director from a pool of names developed by the State Trauma Advisory Council (STAC). The site visit team shall consist of a minimum of two (2) persons, one of which is a licensed physician who practices in emergency medicine or trauma surgery and one who is a registered nurse with trauma system care experience. The credentials of this pool shall be developed by the State Trauma Advisory Council.

7.4.d. Verification site visit reports shall be sent to the medical director of OEMS. The facilities shall assure that ACS-COT site visit reports are received by OEMS within ten (10) days of receipt of the report by the facility. In extreme situations where a delay in receipt of a report is beyond the control of the facility, OEMS may accept the report if the circumstances for a reasonable delay are explained in writing. State site visit reports shall be sent by the site visit team to the medical director of OEMS ~~within thirty (30) days of the visit~~ in a timely manner.

7.4.e. OEMS shall use the information from the verification site visit report and other information, including activities during the facility's provisional status, to determine the permanent designation status of the facility. OEMS may take into account any special situations relating to the state system when rendering a final decision including, but not limited to: the need for trauma or emergency care in a particular geographic area; the number of facilities applying for designation within a particular locale or area; and resources available within a specific area. OEMS may require facilities to develop joint facility designation plans according to specific guidelines established by OEMS in situations where multiple facilities are seeking similar designation status in the same general location. Nothing in this rule shall be interpreted to require OEMS or the Commissioner to designate or not designate a facility based solely on the recommendation of the verification site visit report.

7.4.f. OEMS may visit the facility or make further inquiries to confirm information in the application or site visit report in order to determine the final disposition of the facility.

7.5. Granting of designation.

7.5.a. The Commissioner shall review the site visit report, application, and any additional materials and, within thirty (30) days after receipt of the site visit report, shall determine the designation status of the facility.

7.5.b. The Commissioner shall issue the official designation letter and certification to the facility. The effective date of the permanent designation shall be the date of the official designation letter.

7.6. Authority to inspect. Any facility designated or seeking designation may be inspected at any time by OEMS in order to determine compliance with the standards and criteria outlined in this rule.

7.6.a. Facilities shall make available any requested information and cooperate fully with OEMS during a compliance inspection. Failure to cooperate as determined by OEMS shall be grounds for immediate suspension of designation status pending further review and investigation.

7.6.b. If information obtained during an inspection visit indicates substantial non-compliance with standards or criteria, OEMS shall provide written notification to the facility of intent to change the designation status of the facility. This written notification shall include detailed descriptions of the areas of non-compliance as well as the proposed action by OEMS concerning the designation status of the

facility.

7.6.c. If the facility disagrees with the findings outlined in the notification referenced in Subdivision 7.6.b. of this rule, the facility may respond in writing to the state EMS medical director, within ten (10) working days, and present clear and convincing evidence as to why the facility is not subject to the proposed action. Specific steps proposed to correct the deficiencies shall also be included. The Commissioner shall consider this information and make a decision within thirty (30) days of receipt of the facility's written response, and shall send written notification to the facility of the decision regarding the request and the final status of the facility. The facility may then request a contested case hearing pursuant to Section 11 of this rule.

7.6.d. If information is obtained by inspection or other means that OEMS concludes is a situation or condition at a facility that could pose an immediate threat to the public health or safety, the OEMS medical director may immediately suspend the designation status of a facility pending further review and evaluation by the Commissioner.

7.7. Designation Fees. Pursuant to W. Va. Code §55-7B-9c(b)(2), OEMS may collect reasonable fees for designation of trauma centers.

7.7.a. Fees for designation:

7.7.a.1. Shall accompany the application for initial provisional designation, the application for permanent designation, and the application for re-certification of permanent designation;

7.7.a.2. Shall be the following: initial provisional designation fee per facility, two thousand dollars (\$2000.); permanent designation fee, two thousand dollars (\$2000.); level I, II, and III re-certification designation fee, five thousand dollars (\$5000.); and level IV ~~and V~~ re-certification designation fee, two thousand five hundred dollars (\$2500.); and

7.7.a.3. Are non-refundable and shall be deposited in accordance with W. Va. Code §16-4C-6b and expended in accordance with the duties imposed in this rule.

7.8. Re-certification of Designation Status. Permanent designation status is valid for three (3) years from the date of the official permanent designation letter from the Commissioner.

7.8.a. Within the last year of certification, all level I, II, and III trauma facilities shall undergo an ACS-COT verification site visit and file the report of that visit with a re-certification application supplied by OEMS. The application and site visit report shall be submitted to OEMS with the appropriate non-refundable designation fee, no less than ninety (90) days prior to the expiration of the designation certification of the facility.

7.8.b. Within the last year of certification, all level IV ~~and V~~ trauma facilities shall undergo a re-verification site visit by a West Virginia site visit team. The facility shall schedule the visit with OEMS so as to ensure its completion no less than ninety (90) days prior to the expiration of the designation certification of the facility. The re-certification application, materials, and appropriate non-refundable designation fee must be received by OEMS prior to scheduling of the state site visit.

7.8.c. OEMS may grant an extension of the re-certification time limits of up to ~~sixty (60)~~ one hundred twenty (120) days if the facility submits in writing clear and convincing evidence of extraordinary circumstances which prevent the completion of the re-certification process on schedule.

7.9. Probational Designation. The Commissioner may place a permanently designated facility on probational status ~~for a period not to exceed one (1) year~~, if it is determined to be in the best interest of

the public health and safety for the facility to remain designated during the time it is in the process of correcting deficiencies identified by OEMS either during the re-certification process or during an inspection of the facility.

7.9.a. In the event that a facility is placed on probational status, OEMS shall provide written notification to the facility outlining the specific deficiencies requiring correction. OEMS may at its discretion establish time frames for correction of deficiencies or other activities.

7.9.b. If a facility does not meet the standards and criteria for permanent designation ~~after the one (1) year probational period~~ within a reasonable time, but not less than one (1) year, the facility designation ~~shall be~~ may continue on probation, be changed to provisional, be downgraded or revoked.

7.9.c. A facility whose designation has been revoked may reapply for designation and complete all the requirements outlined in this rule. Facilities may not reapply sooner than one (1) year after the date of official revocation.

7.10. Downgrading, Suspension, or Revocation of Designation. A facility's designation status may be downgraded, placed on probation, suspended, or revoked at any time by the Commissioner for failure of the facility to substantially comply with any of the standards and criteria outlined in this rule. The Commissioner may also downgrade, place on probation, suspend, or revoke the designation status of a facility any time continued designation poses a threat to the public health or safety, as determined by the Commissioner.

7.10.a. In the event a facility's designation is downgraded, suspended, or revoked, OEMS shall provide written notification to the facility outlining the specific reasons for the action.

7.10.b. If a facility disagrees with the findings leading to the action taken under Subdivision 7.10.a. of this rule, it may respond as outlined in Subdivision 7.6.c. of this rule.

§64-27-8. Categorization of Facilities For Emergency Care Capabilities.

8.1. Pursuant to W. Va. Code §16-4C-18, emergency medical services personnel under the direction of medical command shall determine the appropriate facility to which a patient shall be transported. In order to provide the necessary information to medical command, OEMS may develop and implement policies and procedures to categorize the emergency care capability of all facilities receiving emergency medical patients.

8.2. Specific Categories of Care. OEMS may require facilities applying for designation as a trauma center to provide additional information in order to determine the categorization of level of care capability of the facility in other areas of emergency care including, but not limited to, cardiac care, general emergency care, stroke and neurological conditions, pediatric emergencies, burns, psychiatric emergencies, respiratory conditions, poisoning and toxicology, and obstetrics and gynecology.

8.3. Guidelines for Categorization Process. Policies and procedures for the process, criteria for categories of care, and level of care capabilities shall be developed by the State Medical Policy and Care Committee, pursuant to the "Emergency Medical Services" rule, 64CSR48.

8.3.a. OEMS may conduct a verification site visit to confirm the categorization information in order to determine the resources and level of care capability of a facility to assist medical command with appropriate facility destination decisions.

8.3.b. If a facility fails to cooperate and participate in the categorization process, the Commissioner may revoke the facility's trauma center designation. OEMS may enter the facility in order

to accumulate necessary information to evaluate the facility's care capability.

8.3.c. Using the categorization information in this subsection, the OEMS Medical Direction System shall develop triage policies and procedures for use by medical command in determining the most appropriate destination to which a patient should be transported.

8.3.d. Facilities shall notify the state EMS medical director in writing of any changes to the level of care within each category. OEMS may then obtain additional information or conduct a site visit to confirm the changes and notify the facility and medical command of any change in the categorization of a facility.

8.3.e. Facility categorization shall be updated during a facility's trauma designation recertification process or any time information is obtained by OEMS which may indicate a change in categorization is warranted.

§64-27-9. Trauma / Emergency Care System Organization and Operation.

9.1. Pursuant to W. Va. Code §55-7B-9c, the organization and operation of the state trauma / emergency care system shall be integrated with the existing emergency medical services system.

9.2. The lead agency for the trauma / emergency care system is OEMS within the Bureau. As the lead agency for the system, OEMS shall develop and implement policies and procedures necessary to carry out the operation and management of the state trauma/emergency care system, including but not limited to: trauma center designation; facility categorization; system design and operation; medical review and audit for performance improvement and quality assurance; development and enforcement of triage, transfer, and emergency procedures guidelines.

9.3. The advisory councils for the trauma / emergency care system shall be the Emergency Medical Services Advisory Council (EMSAC) and the State Trauma Advisory Council (STAC). Their duties are to advise OEMS and the Commissioner in all matters relating to the trauma /emergency care system as follows:

9.3.a. The Emergency Medical Services Advisory Council shall continue to function pursuant to W. Va. Code §16-4C-5;

9.3.b. The State Trauma Advisory Council shall advise OEMS in all trauma- related matters concerning the state trauma and emergency care system and its members shall:

9.3.b.1. Include at a minimum: the Chair and Vice-chair of the West Virginia State Committee of the American College of Surgeons, Committee on Trauma (WV ACS-COT); the immediate past chair of the WV ACS-COT; the trauma medical director of all designated level I, II, and III facilities; a physician from the West Virginia Chapter of the American College of Emergency Physicians; a hospital administrator; ~~a Healthnet~~ an aeromedical medical director; a medical director and an additional representative of a level IV ~~or V~~ designated trauma center; a rural hospital representative; a registered nurse trauma program manager; a trauma registrar; a pediatric surgeon; a paramedic with trauma care experience; a consumer member from the general public; and other members as recommended by STAC and appointed by the state EMS medical director; and

9.3.b.2. Be appointed by the state EMS medical director from a list of potential appointees submitted by the State Trauma Advisory Council. The State Trauma Advisory Council shall solicit potential appointees from the various agencies or organizations who have representation on the State Trauma Advisory Council and then recommend appointments to the state EMS medical director from those names. A list of potential appointees for the hospital administrator and rural hospital representative

may be submitted to the State Trauma Advisory Council by the West Virginia Hospital Association; and

9.3.b.3. Be appointed for a term of three (3) years. Members may be reappointed if recommended by the State Trauma Advisory Council to the state EMS medical director;

9.3.c. The State Trauma Advisory Council shall:

9.3.c.1. Recommend procedures and guidelines for the formation and administration of a state trauma / emergency care system;

9.3.c.2. Recommend policies and procedures governing the evaluation, designation, and re-designation of state trauma centers;

9.3.c.3. Establish the credentials and serve as the central resource pool of individuals for appointment by the state EMS medical director to serve on site visit teams;

9.3.c.4. Recommend and evaluate data collection needs for quality improvement, medical review, and planning purposes for the system;

9.3.c.5. Serve as the main liaison for activities between the West Virginia Committee of the ACS-COT and OEMS;

9.3.c.6. Explore and seek additional funding sources to continue the development and maintenance of the state trauma / emergency care system;

9.3.c.7. Recommend policies and procedures necessary to carry out its duties; and

9.3.c.8. Undertake other duties as assigned by the OEMS director or medical director;

9.3.d. The council shall meet a minimum of twice a year.

9.4. Trauma and Emergency Care Regions. OEMS may establish policies and procedures governing the design, implementation, and operation of trauma and emergency care regions as part of the state trauma / emergency care system. The policies and procedures governing these regions shall include, but are not be limited to: administration and support within the region; funding and operation; establishment of lead trauma hospitals; and coordination and development of funding mechanisms.

9.5. Medical Direction. The OEMS Medical Direction System shall provide medical direction for all aspects of the state trauma /emergency care system.

9.5.a. The state EMS medical director may appoint additional members to the state Medical Policy and Care Committee as may be necessary to assure proper input from specific specialists or agencies and to assure proper integration of the trauma and EMS system statewide, as required in W. Va. Code §55-7B-9c.

9.5.b. The OEMS medical direction system in conjunction with facilities supporting medical command and interested designated trauma centers shall establish a centralized resource center to coordinate and manage the resources necessary for efficient, effective, and accurate triage, transfer, and treatment of the seriously injured or ill patients in the state. The resource center shall at a minimum:

9.5.b.1. Monitor and manage a statewide tracking system of facility resources and diversion status to ensure proper patient triage and appropriate destination decisions;

9.5.b.2. Provide for the coordination of urgent and emergent interfacility transfers of trauma and seriously ill patients within the system including aeromedical and critical care ground transport;

9.5.b.3. Coordinate the resources necessary for effective triage and transfer of injured or ill patients from the scene of an incident or from health care facilities throughout the state to the closest appropriate facility, based on established triage and transfer guidelines developed by the medical direction system;

9.5.b.4. Develop the capability to assist or provide on-line medical command to EMS field units as may be requested or required by OEMS medical direction system;

9.5.b.5. Assist in the collection and management of patient care information for purposes of public health operation and monitoring including the performance improvement and quality assurance medical review process as outlined Section 10 of this rule;

9.5.b.6. Collaborate with health care providers, facilities, and other interested parties to identify and seek funding to support the medical command system and resource center components of the trauma / emergency care system; and

9.5.b.7. Develop policies and procedures necessary to carry out its duties.

9.5.c. The state Medical Policy and Care Committee shall develop and recommend written protocols specifying the standards for triage and emergency health care procedures for the trauma / emergency care system pursuant to W. Va. Code §§55-7B-9c(f) and (g).

§64-27-10. Trauma / Emergency Care System Accountability.

10.1. Policies and procedures. To ensure system accountability, OEMS shall develop policies and procedures governing the components necessary to collect and analyze information within the trauma / emergency care system including patient care information. These policies and procedures shall include guidelines for medical review and audit to assure system quality as required in W. Va. Code §55-7B-9c(k).

10.2. Trauma and Emergency Medical Information System (TEMIS). OEMS shall develop and maintain a Trauma and Emergency Medical Information System in order to provide the necessary information to assure system quality and accountability as well as to provide data for use in system design and operations.

10.2.a. The three (3) major components of the Trauma and Emergency Medical Information System shall be the State Trauma Registry (STR), the State Medical Command Record (SMCR), and the EMS Patient Care Record (EPCR). Other components may be added as needed to facilitate effective operation and management of the trauma /emergency care system.

10.2.b. All designated trauma centers, medical command centers, and licensed EMS agencies shall collect and provide information to the Trauma and Emergency Medical Information System as required in the policies and procedures governing the operation of the system.

10.2.c. OEMS shall ensure the security and confidentiality of protected information within the Trauma and Emergency Medical Information System according to state and federal guidelines. All designated trauma centers, medical command centers, and licensed EMS agencies and their personnel shall follow all policies and procedures governing the system including the confidentiality of the information submitted to the Trauma and Emergency Medical Information System.

10.3. Medical Review and Quality Improvement. The medical review and quality improvement process for the trauma / emergency care system shall consist of medical review committees (MRC) at the local, regional, and state level. OEMS shall develop policies and procedures for the operation of these committees. Pursuant to WV Code §55-7B-9c these committees and the providers shall qualify for all the rights and protections established in WV Code §§30-3C-1 et seq.

10.3.a. Each designated trauma center and each licensed EMS agency shall develop a local Medical Review Committee that follows guidelines established by OEMS.

10.3.b. The regional Medical Review Committee shall consist of the following members:

10.3.b.1. The regional EMS medical director, who shall serve as the co-chair of the committee;

10.3.b.2. A trauma surgeon representative from each level I, II, and III designated trauma center within the region, one of which shall be elected by the regional Medical Review Committee as the co-chair;

10.3.b.3. A physician representing all level IV designated trauma centers within the region. This physician will be appointed by the regional medical director from a list of nominees submitted by the centers;

~~10.3.b.4. A physician representing all level V designated trauma centers within the region. This physician will be appointed by the regional medical director from a list of nominees submitted by the centers;~~

~~10.3.b.5.~~ 10.3.b.4. Two (2) EMS agency medical directors appointed by the regional medical director;

~~10.3.b.6.~~ 10.3.b.5. Two (2) paramedics from licensed EMS agencies within the region appointed by the regional medical director. The paramedics shall not be from the same agency as the medical directors on the committee; and

~~10.3.b.7.~~ 10.3.b.6. A registered nurse with trauma and emergency care experience appointed by the regional medical director.

10.3.c. The state Medical Review Committee shall consist of the following members:

10.3.c.1. The state EMS medical director, who shall serve as the co-chair of the committee;

10.3.c.2. A trauma surgeon appointee from the membership of the State Trauma Advisory Committee, who shall serve as the co-chair of the committee;

10.3.c.3. A regional medical director appointed by the state Medical Policy and Care Committee;

10.3.c.4. A practicing emergency physician appointed by the state EMS medical director;

10.3.c.5. A registered nurse with trauma and emergency care experience appointed by the State Trauma Advisory Council; and

10.3.c.6. A paramedic appointed by the state Medical Policy and Care Committee;

10.3.d. The Medical Review Committee may make recommendations to OEMS or to the state and regional Medical Policy and Care Committee concerning disciplinary actions or system policy issues as outlined in Medical Review Committee operational guidelines established by OEMS.

10.3.e. The chair of a Medical Review Committee may, with the approval of the committee, temporarily appoint certain specialists to the committee as may be required to adequately and appropriately review a particular case. The temporary members shall follow all policies and procedures established by the committee and OEMS.

10.3.f. If a designated facility or a licensed EMS agency fails to participate and abide by the policies and procedures governing the operation of the Medical Review Committees, the Commissioner may suspend or revoke the designation status or license of the facility or EMS agency.

§64-27-11. Administrative Due Process.

11.1. The provisions of W. Va. Code §16-4C-10 apply.

11.2. 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 the Bureau for Public Health's procedural rule, "Rules of Procedure for Contested Case Hearings and Declaratory Rulings,"² 64CSR1, ~~and the provisions of this rule.~~