ent, guardian, and staff member on the pesticide notification list that a pesticide was applied for emergency pest control.

(3) Notification shall include:

(a) Common name of the pesticide applied;

(b) Approximate location of the application;

(c) Date of the application; and

(d) Reason for the emergency application.

(4) Notification may be made by:

(a) Telephone call;

(b) Direct contact; or

(c) Written notice delivered to a staff member or sent home with a student.

H. Pesticide Application in a Public School or on School Property.

(1) A pesticide licensee, permittee, or certificate holder may not apply a pesticide in a school or on school property until notification is provided by the school in accordance with §§E and F of this regulation, unless notification is provided in accordance with §G of this regulation.

(2) A pesticide may not be applied if a staff member, student, or other unauthorized individual is present in the area to be treated.

(3) A licensee, permittee, or certificate holder may not allow an individual to enter the treated area until the pesticide has dried or as directed by the pesticide label.

(4) An individual who applies a pesticide in a school or on school property shall be a certified applicator or a registered employee working under the supervision of a certified applicator.

(5) A licensee, permittee, or certificate holder shall provide the school with a record of each pesticide application. The application record shall:

(a) Include information required by Regulation .12 of this chapter; and

(b) Be provided to the school at the time of the pesticide application.

LEWIS R. RILEY
Secretary of Agriculture

Title 22
STATE RETIREMENT AND PENSION SYSTEM

Subtitle 01 GENERAL REGULATIONS

22.01.06 Payment of Allowance

Authority: State Personnel and Pensions Article, §21-110, Annotated Code of Maryland

Notice of Proposed Action

[97-009-P]

The Board of Trustees of the State Retirement and Pension System proposes to amend Regulation **.04** under **COMAR 22.01.06 Payment of Allowance**.

Statement of Purpose

The purpose of this action is to give the Executive Director the authority to accept or deny requests for payment of the monthly allowance directly to the retiree instead of by electronic fund transfer to the retiree's bank without the need for Board of Trustee approval.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed regulation.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Opportunity for Public Comment

Written comments may be sent to J. Howard Pleines, Director of Legislation and Research, State Retirement Agency of Maryland, 300 West Preston Street, Room 706, Baltimore, Maryland 21201, or call (410) 767-4052. Comments must be received by February 3, 1997.

.04 Payment by Check.

A. — B. (text unchanged)

C. The Executive Director may grant the request and, in the Executive Director's discretion, set forth terms and conditions for the payment of the participant's monthly allowance by check. [The Executive Director shall report all payments by check to the Board of Trustees for ratification.]

D. The Executive Director may deny the request. The Executive Director shall [report the denial to the Board of Trustees for review.

E. A majority of the Board of Trustees may:

(1) Affirm the Executive Director's decision; or

(2) Direct the Executive Director to pay the participant's monthly allowance by check, specifying any terms or conditions for the payment.] *notify the participant of the denial in writing and advise the participant of the participant's right to request a hearing under COMAR 22.03.04.*

PETER VAUGHN
Executive Director
State Retirement Agency

Title 30
MARYLAND INSTITUTE FOR EMERGENCY MEDICAL SERVICES SYSTEMS (MIEMSS)

Subtitle 08 DESIGNATION OF TRAUMA AND SPECIALTY CENTERS

Authority: Education Article, §13-509, Annotated Code of Maryland

Notice of Proposed Action

[97-007-P]

The State Emergency Medical Services Board proposes to adopt new Regulations **.01 — .04** under a new chapter, **COMAR 30.08.01 General Provisions**; new Regulations **.01 — .10** under a new chapter, **COMAR 30.08.02 Designation of Trauma and Specialty Centers**; new Regulations **.01 — .03** under a new chapter, **COMAR 30.08.03 Requirements for Designated Trauma or Specialty Centers**; new Regulations **.01 — .06** under a new chapter, **COMAR 30.08.04 Data Collection and Quality Man-**

agement; new Regulations **.01 — .19** under a new chapter, **COMAR 30.08.05 Trauma Center Standards**; new Regulations **.01 — .17** under a new chapter, **COMAR 30.08.06 Burn Center Standards**; new Regulations **.01 — .16** under a new chapter, **COMAR 30.08.12 Perinatal and Neonatal Center Standards**; and new Regulations **.01 — .06** under a new chapter, **COMAR 30.08.13 Disciplinary Action for Violation of Subtitle**.

The proposed action was considered and approved by the State Emergency Medical Services Board at its regular meetings on July 9, 1996 (Trauma Center Designation) and September 10, 1996 (Perinatal and Burn Center Designation).

Statement of Purpose

This subtitle is intended to replace the informal designation process under the uncodified "Echelons of Care" document with procedures in COMAR for designating a hospital as a trauma or specialty center, establishing standards for a designated center to provide trauma or specialty care service, disciplinary action to be taken if a trauma or specialty center fails to comply with this subtitle, and collecting and using trauma or specialty care data by the Institute to monitor and evaluate the trauma and specialty care systems.

The "Echelons of Care" document was originally issued in 1978 and revised in 1983 by the Maryland Institute for Emergency Medical Services Systems (MIEMSS) as an uncodified document exempt from the regulatory promulgation process by virtue of Education Article, §12-104(h)(2), Annotated Code of Maryland. As a result of the creation of the State EMS Board in 1993 (Ch. 592, Acts of 1993) and the removal of MIEMSS from under the University of Maryland System umbrella, this exemption no longer applies. The echelons must now be updated and formalized in COMAR in accordance with the promulgation requirements in the State Government Article. There have been no official site visits of the existing centers under the "Echelons" since 1985, and the proposed regulations would allow site visits to resume in accordance with the State EMS Plan adopted by the State EMS Board and the 1991 National Highway Traffic Safety Administration assessment recommendations.

After the adoption of the proposed regulations, MIEMSS shall solicit applications for designation via the Maryland Register. Hospitals designated under the "Echelons of Care" document on the effective date of the regulations shall have 6 months from the publication of the solicitation to apply for designation under the codified regulations. During this 6-month period, hospitals may continue to function as designated under the "Echelons of Care". If application is made within the 6-month window, hospitals designated under the "Echelons" on the effective date of the regulation may continue to function under their "Echelons" designation pending action on their application.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed regulation.

Estimate of Economic Impact

I. Summary of Economic Impact. The economic impact on the issuing agency is anticipated to be approximately $95,635 during the first year after adoption. This represents an average of $4,554 per center ($95,625 ÷ 21 centers rather than 23 centers; burn centers are required to be Level II or higher level trauma centers, and therefore burn center verification can be accomplished in the same site visit by the trauma site-visit team).

MIEMSS is funded through the Emergency Medical System Operations Fund established by the Legislature in Transportation Article, §13-955, Annotated Code of Maryland. At the inception of designation under COMAR, funds from the current MIEMSS budget will have to be reallocated to cover the initial costs of site visits and validation of existing trauma and specialty referral centers.

Concurrent with this regulatory proposal, MIEMSS will be proposing legislation to allow for the recovery of designation expenses directly from the hospitals being designated. This is the practice nationally, and the benefits of state-sanctioned designation far outweigh the nominal costs involved. Since application for designation is voluntary, these expenses would only be recovered from hospitals seeking designation.

Because the proposed regulations follow substantially the preexisting, uncodified designation standards, the economic impact on hospitals is anticipated to be minimal and well understood by those affected. Those hospitals who previously committed to serving as a designated trauma or specialty referral center have already allocated the resources necessary to function at their designated status. Designation as a perinatal center includes a requirement that the designated hospital operate or contract for a licensed neonatal service. While this can be an expensive service to operate, it is critical that newborns, especially those that are high risk, be transported by specially trained teams. Hospitals currently accepting neonatal transfers already have neonatal transport service arrangements. These proposed regulations also require designated perinatal centers to provide the transport, even if the family is unable to pay for the transport. It is anticipated that this will be a small number. The additional cost of operating or contracting for a neonatal transport service should be offset by those able to pay for transport and by the income generated by the subsequent hospital stay of all admissions.

There are no anticipated impacts on other State agencies, local governments, other industries or trade groups, or small businesses.

The effects on the public will be overwhelmingly positive as a result of adopting the highest possible standard of care, mandating prevention activities to reduce the incidence and severity of traumatic injury, assuring reliable and coordinated access to trauma and specialty care facilities, reducing preventable death and disability through rapid transport to definitive care, improving medical outcomes through highly specialized medical intervention, and maximizing function after traumatic injury through rehabilitation, while at the same time controlling costs of care by efficient resource allocation.

II. Types of Economic Impact	Revenue (R+/R−) Expenditure (E+/E−)	Magnitude
A. On issuing agency:	(E+)	$95,635
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (−)	**Magnitude**
D. On regulated industries or trade groups:	(−)	Minimal
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Not quantifiable

III. Assumptions. (Identified by Impact Letter and Number for Section II).

A. The agency will be proposing legislation for the 1997 legislative session to allow the agency to recoup the cost of conducting site surveys for trauma or specialty referral center designation from the facilities being surveyed. The issuing agency does not currently have this authority. This practice is typical in states with highly developed trauma designation systems, such as Pennsylvania, California, Oregon, and New Mexico, and is advocated in the following national standards: "Resources for Optimal Care of the Injured Patient" (American College of Surgeons, Committee on Trauma, 1993), and the "Model Trauma Care System Plan" (Health Resources and Services Administration, September 30, 1992).

The American College of Surgeons charges hospitals for verification to recover the cost of honoraria, travel, and office expenses involved in the verification of trauma centers.

In the interim, the issuing agency shall have to bear the costs associated with this legislative mandate out of its existing budget allocation. Some of the costs associated with this activity include:

(a) reallocation of salary expense for a senior staff person to oversee the hospital designation program, provide consultation to hospitals during the application process, review applications for designation, coordinate and support the functions of the site survey teams, monitor compliance with standards for designation;

(b) need for 0.5 secretarial FTE ($13,000) to support the senior staff person;

(c) increased workload on MIEMSS Information Services staff associated with management of the existing Trauma Registry;

(d) the costs of honoraria and associated expenses for independent professional experts used as members of the site survey team to ensure objectivity and impartiality;

(e) duplication and postage expenses to prepare and distribute applications for designation, handout materials, and correspondence associated with the designation activities;

(f) telephone expenses;

(g) travel, meals, and lodging expenses for MIEMSS staff coordinating site surveys and supporting site survey teams; and

(h) additional equipment needed such as computers and telecommunications equipment.

The major costs will be associated with the required site visits and are estimated as follows:

Primary Adult Resource Center & Level I Center
(1 day per center times 2 centers)

Honorarium	$750 x 3 Surveyors =	$2,250 x 2 days =	$4,500
Meals	$30 x 3 Surveyors =	$90 x 2 days =	$180
Lodging	$95 x 3 Surveyors =	$285 x 2 days =	$570
Airfare	$1,000 x 3 Surveyors =	$3,000 =	$3,000
SUBTOTAL			$8,250

Level II Centers (1 day per center times 4 centers)

Honorarium	$750 x 3 Surveyors =	$2,250 x 4 days =	$9,000
Meals	$30 x 3 Surveyors =	$90 x 4 days =	$360
Lodging	$95 x 3 Surveyors =	$285 x 4 days =	$1,140
Airfare	$500 x 2 Surveyors =	$1,000 =	$1,000
Private Auto Mileage Reimbursement =			$30
SUBTOTAL			$11,530

Level III Centers (1 day per center times 3 centers)

Honorarium	$750 x 3Surveyors =	$2,250 x 3 days =	$6,750
Meals	$30 x 3Surveyors =	$90 x 3 days =	$270
Lodging	$95 x 3Surveyors =	$285 x 3 days =	$855
Private Auto Mileage Reimbursement =			$120
SUBTOTAL			$7,995

Burn Centers (0 day per center times 2 centers)

SUBTOTAL	$ 0**

**Burn centers are required to be Level II or higher level trauma centers and therefore burn center verification can be accomplished in the same site visit by the trauma site visit team. Furthermore, both burn centers are currently American Burn Association verified burn centers which will be accepted for purposes of designation.

Perinatal Centers (1 day per center times 12 centers)

Honorarium	$750 x 3 Surveyors =	$2,250 x 12 days =	$27,000
Meals	$30 x 3 Surveyors =	$90 x 12 days =	$1,080
Lodging	$95 x 3 Surveyors =	$285 x 12 days =	$3,420
Airfare	$1,000 x 3 Surveyors =	$3,000 x 12 days =	$36,000
Private Auto Mileage Reimbursement =		$30 x 12 days =	$360
SUBTOTAL			$67,860

PAR Center & Level I Center	$8,250
Level II Centers	$11,530
Level III Centers	$7,995
Burn Centers	$ 0**
Perinatal Centers	$67,860
TOTAL	$95,635

D. Required participation in the trauma registry will require additional resources which have already been committed to but not expended by some trauma centers. However, participation in the registry will allow a more favorable consideration in rate setting by the Health Services Cost Review Commission for each participating facility.

Additional data collection expenditures are needed to meet the information requirements of new regulations.

The staff education requirements in the standards may impact some of the hospitals by increasing their education expenditures due to the mandated education time. The education standards are important requirements to ensure current standards of practice are provided that result in quality health care to the citizens of Maryland requiring trauma and specialty care.

The requirement for a neonatal transport service will impact all hospitals seeking perinatal center designation. Neonatal transport is a very specialized type of transport requiring special equipment and well trained personnel. Referring hospitals in Maryland expect the receiving center to send a neonatal transport team to stabilize the patient before transport and to accompany and monitor the baby during transport. Hospitals currently operating as perinatal centers already have neonatal transport service arrangements. The revenue generated from the admissions to the perinatal centers via the neonatal transport service should offset the operating cost of the transport service.

F. In addition to creating the State EMS Board, Chapter 592, Acts of 1993, also charged the Emergency Medical Services Board with developing a state Emergency Medical System plan that included "criteria for the designation of trauma and specialty referral facilities". The EMS Plan developed by the EMS Board includes the following goals:

(1) Provide an adequate number of designated trauma centers which are accessible and which collectively provide quality services on a continuous basis; and

(2) Ensure that patients with potentially life threatening injuries are transported to the appropriate level of care in an appropriate time.

The EMS Board also adopted the following principles which directly affect the quality, accessibility, and timeliness of trauma care that citizens and transients in this State can receive:

(1) Trauma and specialty care will reflect national standards;

(2) Hospital trauma programs will be designated based on system need and the ability to meet standards;

(3) MIEMSS and the hospital trauma centers will work collaboratively with health care planners and regulators to transition to new models of health care delivery;

(4) Quality monitoring will cover all phases of trauma care and quality improvement processes will be the mechanism for enhancing and maintaining a cutting edge trauma system.

The adoption of these regulations will directly benefit citizens by:

(1) Updating standards of care to the most current national standards so the patients will benefit directly by receiving the highest standard of care possible.

(2) Reducing preventable death and disability and improving outcomes of injured patients thereby providing direct benefits to patients and their families by saving patients' lives, minimizing their injuries, and returning them as soon as possible to the greatest level of function possible;

(3) Mandating injury prevention activities which have been shown to reduce the incidence and severity of traumatic injury;

(4) Improving delivery and cost effectiveness of trauma care and movement of trauma patients through the system; and

(5) Reducing the cost of trauma care by making the most efficient use of available resources through coordination of the trauma and specialty care system within the State.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Opportunity for Public Comment

Comments on the proposed action will be accepted by mail, telephone, facsimile, or e-mail through February 17, 1997. Address your comments to Mary Beachley, Director of Hospital Programs, MIEMSS, 636 West Lombard Street, Baltimore, Maryland 21201-1528, via telephone at (410) 706-3932, via facsimile at (410) 706-4768, or via e-mail to MBEACHLEY@MDEMS.AB.UMD.EDU.

A public hearing will be held on February 5, 1997, at 10 a.m., at which time oral comments will be heard. Written summaries of any oral comments made at the hearing would be appreciated at that time. If a closure of UMBC due to inclement weather is announced on WBAL radio, the hearing will held on February 12, 1997, at 10 a.m. The hearing will be held at the UMBC Technology Center (former Lockheed Martin Building), 1450 South Rolling Road (off of Gun Road), Catonsville, Maryland. A direction sheet can be obtained from the contact person listed above.

30.08.01 General Provisions

.01 Purpose.

This subtitle establishes:

A. Procedures for designating a hospital as a trauma or specialty center;

B. Standards for a designated center to provide trauma or specialty care service;

C. Procedures for disciplinary action to be taken if a trauma or specialty center fails to comply with this subtitle; and

D. Procedures for the collection and use of trauma or specialty care data by the Maryland Institute for Emergency Medical Services Systems to monitor and evaluate the trauma and specialty care systems.

.02 Definitions.

A. In this subtitle, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Advanced Burn Life Support (ABLS™)" means a course developed and approved by the American Burn Association.

(2) "Advanced Trauma Life Support (ATLS™)" means a course developed and approved by the American College of Surgeons.

(3) "Appropriately trained" means a health care provider who has received the necessary training to develop the knowledge and skills needed for the appropriate care of the trauma or specialty care patient.

(4) "Approved" means a formal process of review and acceptance by the appropriate authority.

(5) "Attending" means a physician with practice privileges delineated by the hospital's medical staff.

(6) "Attending staff surgeon" means a surgical member of the burn team appointed by the burn center director with credentials and privileges appropriate to the burn service.

(7) "Base station" means a facility designated by the Maryland Institute for Emergency Medical Services Systems to provide on-line medical direction to emergency medical services personnel.

(8) "Board certified" means a physician certified by an appropriate specialty board recognized by the American Board of Medical Specialties.

(9) "Board eligible" means a physician qualified to take the examination to complete the certification process as specified by an appropriate specialty board that is recognized by the American Board of Medical Specialists.

(10) "Burn care director" means a surgeon designated by the institution and medical staff to coordinate the activities of the burn center.

(11) "Burn care system" means a coordinated component of an emergency medical services system which encompasses one or more burn centers and features communication links to, and triage-transfer protocols between, health care facilities, prehospital personnel, and transportation services.

(12) "Burn center" means:

(a) An in-State hospital designated by the Maryland Institute for Emergency Medical Services Systems to provide comprehensive burn treatment services; or

(b) An out-of-State hospital that has entered into an agreement with the Maryland Institute for Emergency Medical Services Systems to provide comprehensive burn treatment services.

(13) "Burn center hospital" means an institution which meets the criteria specified in COMAR 30.08.06.

(14) "Burn service" means a clinical service established by the medical staff which has responsibility for burn patients.

(15) "Burn team" means a group of health care professionals organized to provide care to the burn patient in a coordinated system of care.

(16) "Burn unit" means a specific area within the burn center hospital that:

(a) Has committed the resources necessary to meet the criteria for a burn center; and

(b) Contains beds and other physical equipment related to care of the patient with burn injury.

(17) "Bypass" means a request by a trauma or specialty center to an emergency medical service that a patient be directed to another hospital, usually due to a shortage or unavailability of beds, equipment, personnel, or other resources.

(18) "Continuing medical education (CME)" means training approved by the Accreditation Council of Continuing Medical Education or accredited by a state medical society recognized by this Council.

(19) "Credentialing" means a hospital's process for granting practice privileges to health care providers.

(20) "Data quality guideline" means a written procedure for ascertaining the accuracy and completeness of data.

(21) "Dedicated" means a designated resource whose primary use is for a specific trauma or specialty care program.

(22) "Definitive care" means a level of therapeutic intervention capable of providing comprehensive services for the patient's particular injuries, or associated conditions, or both.

(23) "Designation" means a process by which a hospital is identified by the Maryland Institute for Emergency Medical Services Systems as an appropriate facility to receive patients with particular injuries or illnesses.

(24) "Desirable" means a component of the standards whose presence or availability is encouraged but not required for designation.

(25) "Emergency department (ED)" means a department or patient care area within a hospital which:

(a) Is organized to provide emergency medical care 24 hours a day; and

(b) Meets the applicable standards in COMAR 30.08.05.

(26) Emergency Medical Services.

(a) "Emergency medical services (EMS)" means a comprehensive system of emergency medical care that starts with prevention and continues through rehabilitation.

(b) "Emergency medical services (EMS)" includes:

(i) Comprehensive EMS, trauma, and specialty care system legislation, regulations, and policies;

(ii) Medical oversight and physician involvement;

(iii) Trained volunteer, career, and commercial personnel;

(iv) State and local government resource management and administration;

(v) Integrated communications system including 911 centers, medical consultation centers, ambulances, and receiving hospitals;

(vi) Medical ground, air, and water transportation systems;

(vii) Cooperating facilities including hospitals, trauma centers, and specialty centers;

(viii) Public information, education, and prevention programs; and

(ix) Data collection, evaluation, quality improvement, and research.

(27) "EMS Board" means the Emergency Medical Services Board, as established by Education Article, §13-509, Annotated Code of Maryland.

(28) "EMS Plan" means the plan to ensure effective coordination and evaluation of emergency medical services delivered in the State, as developed and approved by the EMS Board.

(29) "EMS provider" means an individual certified or licensed by a state to provide out-of-hospital emergency medical services.

(30) "Essential" means a component of the standards that is required for designation.

(31) "Executive Director" means the Executive Director of the Maryland Institute for Emergency Medical Services Systems.

(32) "Expanded trauma registry" means those trauma registry database elements, as defined by the EMS Board, that must be collected by designated trauma centers and submitted on a regular basis to the Maryland Institute for Emergency Medical Services Systems.

(33) "Fellowship" means formal, advanced, postresidency, specialty training.

(34) "Geographic proximity" means that distance, which is optional for Level III perinatal centers and mandatory for Level III+ perinatal centers, so that patients requiring Level IV services may be transported from a Level III or Level III+ sending facility to the Level IV perinatal center in less than 30 minutes by nonemergency transport.

(35) "Geographic service area" means the area defined by the EMS Board that is normally served by a designated hospital for patients with a particular illness or injury.

(36) "Immediately available" means a source available as soon as it is requested.

(37) "Immediate response" means reacting at once to a patient care need.

(38) "In-house" means physically present in the hospital.

(39) "Injury surveillance" means routine monitoring of the type of injury and incidence for a specific population.

(40) "Inpatient discharge data" means certain information from inpatient hospital records that is submitted by the hospital to the Health Services Cost Review Commission as required by law.

(41) "Institute" means the Maryland Institute for Emergency Medical Services Systems.

(42) "Interfacility transfer" means the transfer of a patient from one hospital to another hospital.

(43) "Learning outcomes" means an individual's performance, which can be measured by objective means, that results from the individual's participation in an educational program.

(44) "Level I trauma center" means a university-affiliated hospital with a comprehensive residency program in trauma care and trauma research which meets the Level I trauma center standards in COMAR 30.08.05.

(45) "Level II trauma center" means a hospital with 24-hour, in-house, surgical coverage, with a defined trauma program and trauma services, which meets the Level II trauma center standards in COMAR 30.08.05.

(46) "Level III perinatal center" means a hospital that:

(a) Meets the Level III perinatal center standards in COMAR 30.08.12; and

(b) Is designated by the Maryland Institute for Emergency Medical Services Systems as capable of providing medical intensive care to newborns greater than:

(i) 26 weeks gestational age, or

(ii) 800 grams.

(47) "Level III+ perinatal center" means a hospital that:

(a) Meets the Level III+ perinatal center standards in COMAR 30.08.12;

(b) Is geographically near a Level IV perinatal center; and

(c) Is designated by the Maryland Institute for Emergency Medical Services Systems as capable of providing medical intensive care to newborns of all:

(i) Gestational ages, and

(ii) Birth weights.

(48) "Level III trauma center" means a community hospital with a trauma program which meets the Level III trauma center standards in COMAR 30.08.05.

(49) "Level IV perinatal center" means a hospital that:

(a) Meets the Level IV perinatal center standards in COMAR 30.08.12; and

(b) Provides comprehensive neonatal and obstetrical services, including all subspecialty services.

(50) "Maryland Ambulance Information System (MAIS©)" means the prehospital patient care record for Maryland, otherwise known as a runsheet.

(51) "Maryland EMS Quality Leadership Council" means the quality management council appointed by the Executive Director to coordinate, develop, and utilize resources to improve the State's emergency medical system.

(52) "Maternal-fetal medicine" means a subspecialty recognized by the American Board of Obstetrics and Gynecology which addresses the medical care of high-risk pregnant women and their fetuses.

(53) "Minimal trauma registry" means an abbreviated set of trauma registry database elements, as defined by the EMS Board, that are:

(a) Collected by hospitals not designated as trauma centers; and

(b) Submitted on a regular basis to the Institute.

(54) "Multidisciplinary committee" means a group of health care professionals from two or more professional disciplines within a trauma or specialty center that reflects the multidisciplinary nature of trauma or specialty care.

(55) "Multiple casualty" means two or more injured people requiring emergency care simultaneously.

(56) "Neonatal center" means an out-of-State facility that has entered into an agreement with the Institute to accept transfers in order to provide neonatal care.

(57) "Neonate" means a patient who:

(a) Is less than 28 days old; or

(b) Has been an inpatient since birth.

(58) "Neonatologist" means a pediatrician certified by the American Board of Pediatrics in neonatology.

(59) "Nurse manager" means a registered nurse who has a full-time commitment to a specific patient care unit and is administratively responsible for the nursing service of that unit.

(60) "Office of Administrative Hearings (OAH)" means the unit within Maryland's Executive Branch responsible for scheduling and conducting administrative hearings.

(61) "Office of Hospital Programs" means the office within the Institute that is responsible for the designation, verification, and reverification of the trauma and specialty care programs.

(62) "On-call" means committed for a specific time period to be available and respond within an agreed amount of time to provide care for a patient in the hospital.

(63) On-Site Review Record.

(a) "On-site review record" means any record of the on-site visit and of the on-site review team.

(b) "On-site review record" includes, but is not limited to:

(i) Proceedings;
(ii) Records;
(iii) Files;
(iv) Notes;
(v) Deliberations;
(vi) Reports;
(vii) Documents;
(viii) Statements;
(ix) Minutes; and
(x) Any other oral or written communication.

(64) "Optional" means a component of the standards that may be present or available but is not required for designation.

(65) "Outcome" means a measurable health status that follows as a result of an injury or illness.

(66) "Patient care log" means a list of patients' names and other information that is recorded by hospitals or prehospital care agencies.

(67) "Patient care record" means a record that contains information regarding the assessment and the care provided to a patient by any health care provider in any practice setting.

(68) "Patient discharge summary" means an abbreviated narrative, created after discharge from a health care facility, of a patient's record during that hospitalization.

(69) "Patient identifier" means a unique number that is assigned to only one patient in order to identify records pertaining to the evaluation and care of that particular patient.

(70) "Pediatric Advanced Life Support (PALS™)" means a pediatric resuscitation course developed and approved by the American Heart Association.

(71) "Perinatal center" means:

(a) An in-State hospital designated by the EMS Board to provide comprehensive obstetrical and neonatal services; or

(b) An out-of-State hospital that has entered into an agreement with the Institute to provide comprehensive obstetrical and neonatal services.

(72) "Person" means:

(a) An individual or group of individuals;

(b) A State or federal agency; or

(c) A business entity.

(73) "Physical plant" means a building and associated structures.

(74) "Postgraduate year (PGY)" means a classification system for residents indicating the year of post-medical school residency.

(75) "Prehospital service" means a service that is provided from the time of injury or illness until the patient arrives in the hospital.

(76) "Preliminary investigation" means fact finding and information gathering to enable the Institute to determine whether justification exists to initiate disciplinary action or to conduct a further investigation.

(77) "Primary Adult Resource Center (PARC)" means a comprehensive trauma program including a dedicated trauma care facility, dedicated staff and services, and designated, specialized, advanced training and research programs which meets the PARC standards in COMAR 30.08.05 and which, in Maryland, is legislated to be the R Adams Cowley Shock Trauma Center.

(78) "Promptly available" means a resource available within 30 minutes of the time it was requested.

(79) "Protocol" means a written procedure to ensure standardization of a process.

(80) "Quality management plan" means a written plan for the quality management of trauma and specialty care services.

(81) "Quality management program record" means a documented record related to quality management activities.

(82) "Readily available" means a resource available for use a short time after it is requested.

(83) "Resuscitation" means the phase of trauma or specialty care where emergency life support treatment is provided to sustain vital body functions.

(84) "Reverification" means the process by which the Institute renews a trauma or specialty center's designation status.

(85) "Sonologist" means a physician with special training in ultrasonography.

(86) "Specialty center" means:

(a) An in-State hospital that has been designated by the EMS Board to provide care for a specific patient population with special care needs; or

(b) An out-of-State facility that has entered into an agreement with the Institute to provide specialty care.

(87) "State trauma registry" means a database of information, submitted to the Institute by hospitals, relating to the care of trauma patients that is used to evaluate the quality of care provided.

(88) "SYSCOM" means the Systems Communications Center, an EMS communications center located within the Institute, that is used for coordination of medical communication on a Statewide basis.

(89) "Transfer agreement" means a formal agreement between hospitals for the transfer and acceptance of patients.

(90) "Transporting service" means an agency or entity providing patient care transport.

(91) "Transport vehicle" means a vehicle or other conveyance used to transport patients.

(92) "Trauma" means a major single system or multisystem injury or mechanism of injury which has a reasonable probability of disability or death.

(93) Trauma Center.

(a) "Trauma center" means a hospital that has been designated by the Institute to provide care to trauma patients.

(b) "Trauma center" includes an out-of-State facility that has entered into an agreement with the Institute to provide care to trauma patients.

(94) "Trauma Network (TraumaNet)" means an organization of representatives of trauma centers which includes trauma surgeons, trauma coordinators, and hospital administrators.

(95) "Trauma panel" means the group of physicians within a specific trauma center credentialed by the trauma center hospital to provide trauma care.

(96) "Trauma patient care resource" means the physical facilities, equipment, supplies, and medical personnel that are:

(a) Used to provide care to trauma patients; and

(b) Identified as immediately available, readily available, or promptly available.

(97) "Trauma resuscitation team" means a group of health care providers organized to provide trauma care to the trauma patient in a coordinated and timely fashion.

(98) "Trend" means a tendency towards a particular conclusion or end point, usually determined by an analysis of data.

(99) "Triage" means the sorting of patients in terms of priority, treatment, transportation, and destination, so that the patient can be transported to the appropriate hospital according to triage protocols.

(100) "Unit of care" means the hospital subunit where the patient is receiving care at any point in time.

(101) "Verification" means the process by which the Institute determines that a hospital, which is applying for a particular designation status, is in substantial compliance with the standards for the designation requested.

.03 System Administration.

A. The EMS Board is the State administrative agency responsible for the coordination, evaluation, and regulation of all emergency medical services.

B. The Institute shall:

(1) With the approval of the EMS Board, designate and verify hospitals to be trauma or specialty centers;

(2) Establish standards for trauma and specialty care, triage, and transfer protocols for injured patients;

(3) Establish and manage the State trauma registry and specialty care data bases;

(4) Facilitate the establishment of Statewide, inclusive trauma and specialty care systems by encouraging all hospitals to participate:

(a) In the Statewide data collection process, and

(b) In prevention programs;

(5) Develop a quality management and improvement program to:

(a) Monitor compliance with this subtitle by hospitals in the Statewide trauma and specialty care systems, and

(b) Identify areas for enhancement;

(6) With the consultation and advice of appropriate persons, develop and periodically review:

(a) Prehospital trauma and specialty center triage criteria guidelines,

(b) Interfacility transfer criteria for adult and pediatric patients,

(c) Trauma and specialty center standards, and

(d) Trauma registry and specialty center data;

(7) Annually evaluate the effectiveness of the Statewide trauma and specialty care systems and its component subsystems by using trauma registry and other appropriate data to identify and analyze system and patient care trends and outcomes;

(8) Periodically conduct special studies of the Statewide trauma and specialty care systems to evaluate:

(a) System access,

(b) Capacity,

(c) Quality,

(d) Patient care outcomes, and

(e) The financial condition of the system components;

(9) Consult with appropriate persons in determining the need for trauma or specialty care services;

(10) Facilitate and, where necessary, develop and maintain, public information, education, and prevention programs as an integral component of the trauma and specialty care systems;

(11) As necessary, recommend to the EMS Board additional regulations to ensure the quality of the Statewide trauma and specialty care systems;

(12) Provide technical assistance and support to hospitals and providers as necessary to implement the components of the EMS Plan; and

(13) As necessary, verify compliance with trauma and specialty care standards by:

(a) Reviewing, inspecting, evaluating, and auditing trauma and specialty care patient records, trauma and specialty care quality improvement committee minutes, and any other documents relevant to trauma and specialty care in any trauma or specialty center, and

(b) Inspecting a trauma or specialty center's physical plant.

C. With the approval of the EMS Board, the Institute may enter into agreements with out-of-State trauma and specialty center hospitals where necessary to ensure access of patients to appropriate levels of trauma and specialty care. Such agreements are tantamount to designation by the EMS Board.

.04 Confidentiality of Records.

The Institute shall maintain the confidentiality of records referred to in this subtitle in accordance with:

A. Health Occupations Article, Title 14, Subtitle 5, Annotated Code of Maryland; and

B. State Government Article, Title 10, Subtitle 6, Part III, Annotated Code of Maryland.

30.08.02 Designation of Trauma and Specialty Centers

.01 Trauma Care Levels and Specialty Care Centers.

A. The Institute shall designate a hospital by level of care capability as set forth for:

(1) Trauma centers, in COMAR 30.08.05; or

(2) Specialty care centers, in the appropriate specialty care standards within COMAR 30.08.06 — 30.08.12.

B. The levels of trauma care are:

(1) Primary Adult Resource Center;

(2) Level I trauma center;

(3) Level II trauma center; or

(4) Level III trauma center.

C. The specialty care centers are:

(1) Burn center;

(2) Pediatric trauma center;

(3) Eye center;
(4) Hand center;
(5) Head/spinal center;
(6) Hyperbaric center;
(7) Perinatal and neonatal centers; and
(8) Such other specialty centers as the EMS Board determines are necessary.

.02 Criteria for Designation.

A. The EMS Board shall:

(1) Establish criteria for the number and level of trauma and specialty care centers to be designated; and

(2) For specialty centers that require a certificate of need from the Health Resources Planning Commission, establish the criteria for the number of specialty centers in coordination with the Health Resources Planning Commission.

B. For each region, the criteria shall address:

(1) Access to trauma or specialty care;
(2) Level of care;
(3) Capacity to provide the care; and
(4) Timeliness of care received.

C. The Institute may consult with appropriate State agencies in determining the need for trauma or specialty services for a hospital's geographic service area.

D. To be eligible for consideration by the EMS Board as a designated trauma or specialty center, a hospital shall meet the following standards:

(1) For trauma centers, the trauma center standards in COMAR 30.08.05 for the respective level of trauma center designation;

(2) For burn centers:

(a) Meet the burn center standards in COMAR 30.08.06,

(b) Be designated as a Level II or higher trauma center,

(c) Be verified as a burn center by the American Burn Association Committee for Burn Center Verification and the American College of Surgeons Committee on Trauma,

(d) Have pediatric intensive care capabilities or transfer children 16 years old and younger who require critical care to a pediatric trauma center, and

(e) If an in-State hospital, have a certificate of need issued by the Health Resources Planning Commission; or

(3) For perinatal centers, the perinatal center standards in COMAR 30.08.12.

.03 Initial Application Process.

A. A hospital that is currently functioning as a trauma or specialty center may continue to function as a trauma or specialty center until the Institute has completed the designation process under this subtitle with respect to that hospital, if the hospital makes application for designation. The application must be received complete within 6 months of the publication date of the initial solicitation in the Maryland Register in accordance with §B of this regulation.

B. The Institute shall solicit applications for trauma and specialty center designation from any interested hospital, including all current trauma and specialty centers, by publication of the solicitation in the Maryland Register.

C. The Institute may periodically solicit applications for trauma and specialty center designation, as needed, by publication of the solicitation in the Maryland Register.

D. The Institute shall provide the applicant with an appropriate application packet for trauma or specialty center designation.

E. An applicant for trauma or specialty center designation shall submit an application to the Office of Hospital Programs in a form specified by the Institute, which shall include, but not be limited to, submitting evidence of the applicant's financial capability to provide this care.

F. The Institute shall review each application submitted for completeness.

G. The Institute shall notify an applicant if an application is incomplete, and the applicant shall be afforded the opportunity to complete the application within 30 business days of the date of the notification.

H. As necessary, the Institute shall provide technical assistance to a hospital throughout the designation process by answering questions about this subtitle and the designation process.

I. An applicant's designation application is the property of the Institute and is confidential information in accordance with:

(1) Health Occupations Article, Title 14, Subtitle 5, Annotated Code of Maryland; and

(2) State Government Article, Title 10, Subtitle 6, Part III, Annotated Code of Maryland.

.04 Denial of Application for Designation.

A. The Institute may deny an application for designation without conducting an on-site review if it finds that the hospital:

(1) Would add unnecessary duplication of services to a geographic service area where there is not a sufficient need for additional trauma or specialty services;

(2) Is unable to meet the requirements of this subtitle for the level of designation sought;

(3) Makes a false statement or omits a material fact in the hospital records, documentation, or materials required to be submitted that pertain to the designation process;

(4) Is less qualified than another applicant hospital in the same geographic service area;

(5) Is applying for designation as a specialty center that requires a certificate of need from the Health Resources Planning Commission but does not have the required certificate of need; or

(6) Should not be designated for any other relevant reason.

B. Notice of Denial of Application for Designation.

(1) The Institute shall issue a written notice of denial to the hospital.

(2) The notice of denial shall conform to State Government Article, §10-207, Annotated Code of Maryland.

(3) The Institute shall send the notice of denial to the chief executive officer of the hospital.

(4) The Institute shall notify the EMS Board of the action taken.

C. A hospital may file an appeal with the EMS Board, in accordance with Regulation .08 of this chapter, if the Institute denies its application for designation.

D. If the EMS Board overturns the Institute's decision to deny the application for designation, the Institute shall continue the application process by scheduling an on-site review of the hospital.

E. If the hospital does not timely appeal the Institute's decision to deny the application for designation, the Institute's decision is the final agency decision and is not subject to judicial review.

.05 On-Site Review for Initial Trauma Center Designation.

A. After a hospital's application for designation has been accepted, the Institute shall conduct an on-site review of a hospital that has applied to be a Primary Adult Resource Center, or a Level I, II, or III trauma center.

B. On-Site Review Teams.

(1) The Institute shall establish multidisciplinary on-site review teams composed of individuals knowledgeable in trauma or specialty care and trauma or specialty care systems.

(2) The composition of the team shall be appropriate to the level of designation sought.

(3) For trauma center designation, the Institute shall select a team, which shall include Institute staff and representatives from three of the following categories:

(a) Trauma surgeon;

(b) Emergency physician;

(c) Trauma nurse coordinator;

(d) Administrator.

(4) A staff person from the Institute shall accompany and coordinate the functions of the review team.

(5) A team shall consist of professionals who do not have any conflict or competitive interest with the applicant.

(6) If a hospital can demonstrate a reasonable basis for concern, the Institute shall consider allegations that conflicts of interest exist between an on-site reviewer and an applicant.

(7) Contact with Members of On-Site Review Team.

(a) Except as authorized by the Institute, an applicant's administration, faculty, medical staff, employees, and representatives may not have any contact with an on-site review team member relating to the review process after the team members are announced and before the on-site review is conducted.

(b) A violation of §B(7)(a) of this regulation may be grounds for denial by the Institute of the hospital's application.

(8) The on-site review team shall:

(a) Evaluate the appropriateness and capability of the applicant to provide trauma care services, according to the designation standards described in COMAR 30.08.05;

(b) Verify the hospital's ability to meet the:

(i) Responsibilities of, and the resources, equipment, and performance standards for, the level of designation sought, and

(ii) Overall needs of the trauma system in that region;

(c) Familiarize themselves with the hospital's application and the designation standards;

(d) Inspect the hospital's physical plant;

(e) Interview trauma team members and management personnel;

(f) Examine the hospital's trauma-related documents, including patient care records;

(g) Review other materials considered appropriate by the Institute;

(h) Provide an exit interview of preliminary findings to the applicant upon completion of the on-site review; and

(i) Provide a brief written summary of preliminary findings upon completion of the on-site review.

(9) Confidentiality of On-Site Review Records.

(a) The Institute shall require and maintain confidentiality of an on-site review record.

(b) An on-site review record is confidential and exempt from public disclosure under State Government Article, Title 10, Subtitle 6, Part III, Annotated Code of Maryland.

(c) Except as provided in Health Occupations Article, Title 14, Subtitle 5, Annotated Code of Maryland, an on-site review record is not discoverable or admissible in evidence.

(d) A member of the on-site review team may not divulge, and may not be compelled to divulge, any information obtained or included in on-site review records submitted to the Institute relating to the on-site review, including in any civil action resulting from the Institute's designation process.

C. Notwithstanding §§A and B of this regulation, instead of conducting an on-site review, the Institute may take into consideration or coordinate with verification surveys by the American College of Surgeons or other specialty medical organizations.

.06 On-Site Review for Initial Specialty Center Designation.

A. At the Institute's discretion, the Institute may accept verification of a specialty center by a nationally recognized medical specialty organization, without conducting an on-site review.

B. The on-site review process for initial designation of specialty centers shall be conducted in accordance with Regulation .05 of this chapter, with the following exceptions:

(1) The on-site review team shall consist of Institute staff, as well as medical, administrative, and nursing professionals having expertise in the specialty being designated;

(2) The Executive Director may appoint additional staff from other State agencies to the on-site review team when those agencies have shared regulatory oversight in the specialty center;

(3) The Institute shall select a team, which, at a minimum, shall include Institute staff and three representatives from the following categories:

(a) Specialty physician;

(b) Emergency physician;

(c) Specialty nurse;

(d) Administrator;

(4) The on-site review team members shall:

(a) Evaluate the appropriateness and capability of the applicant to provide specialty care services, according to the designation standards for that particular specialty, as described at COMAR 30.08.06 — 30.08.12;

(b) Verify the hospital's ability to meet the:

(i) Responsibilities of, and the resources, equipment, and performance standards for, the type of specialty care designation sought, and

(ii) Overall needs of that particular specialty system in that region;

(c) Familiarize themselves with the hospital's application and the designation standards;

(d) Inspect the hospital's physical plant;

(e) Interview team members and management personnel;

(f) Examine the hospital's specialty care-related documents, including patient care records;

(g) Review other materials considered appropriate by the Institute;

(h) Provide an exit interview of preliminary findings to the applicant upon the completion of the on-site review; and

(i) Provide a brief written summary of preliminary findings upon the completion of the on-site review.

.07 Designation Decision by Institute.

A. As soon as practicable, but not later than 45 business days after completion of the on-site review, the Institute shall provide written notice to a hospital of its designation status.

B. The Institute may:

(1) Approve a hospital's designation as a trauma or specialty center as proposed by the applicant;

(2) Approve a hospital at a level of designation lower than the applicant proposed, if the on-site review determined that the hospital does not meet the standards for the level of designation proposed;

(3) Adjust the level of an applicant's designation based on system needs and the hospital's ability to meet those needs; or

(4) Deny designation as a trauma center at any level or as a specialty center.

C. Provisional or Full Designation.

(1) The Institute may initially designate a trauma or specialty center as provisional for a term not to exceed 1 year.

(2) The Institute shall require each provisional trauma or specialty center to:

(a) Have a written work plan to rectify deficiencies; and

(b) Demonstrate progress on the work plan throughout the provisional period.

(3) At the end of the provisional period, the Institute may:

(a) Grant full designation to the trauma or specialty center; or

(b) Deny the trauma or specialty center's designation under §D of this regulation.

(4) The Institute may grant full designation to a hospital in full compliance with this chapter for a period not to exceed 5 years, excluding an extension during the reverification process as set forth in Regulation .10 of this chapter.

D. Denial of Designation. The Institute may deny a hospital's designation as a trauma or specialty center if it finds that the hospital:

(1) Does not meet the requirements of this subtitle for the level of designation or specialty;

(2) Has engaged in unauthorized contact with an on-site review team member, as prohibited by Regulation .05B(7) of this chapter;

(3) Made a false statement or omitted a material fact in the hospital records, documentation, or materials required to be submitted that pertain to the designation process;

(4) Is less qualified than another applicant hospital in the same geographic service area; or

(5) Should not be designated for another relevant reason.

E. Notice of Denial of Designation.

(1) The Institute shall issue a written notice of denial of designation to a hospital.

(2) The notice of denial of designation shall conform to State Government Article, §10-207, Annotated Code of Maryland.

(3) The Institute shall send the notice of denial of designation to the chief executive officer of the hospital.

(4) The Institute shall notify the EMS Board of the action taken.

F. If the Institute approves a hospital's designation as a trauma or specialty center as proposed by the applicant, the Institute shall require the hospital to accept or decline the proposed designation within 30 business days from the date the hospital receives the notice.

G. A hospital may file an appeal with the EMS Board in accordance with Regulation .08 of this chapter if the Institute:

(1) Approves the hospital at a level of designation lower than the applicant proposed; or

(2) Denies designation as a trauma center at any level or as a specialty center.

H. If the EMS Board overturns the Institute's decision, the Institute shall designate the hospital as a trauma or specialty center as directed by the EMS Board.

I. If the hospital does not timely appeal the Institute's decision, the Institute's decision is the final agency decision.

.08 Appeal to the EMS Board.

A. Procedures for Appeal by Hospital.

(1) Not later than 20 business days from the date a hospital receives the Institute's decision, the hospital may appeal the Institute's decision by filing written exceptions with the Executive Director for consideration by the EMS Board.

(2) For the written exceptions to be considered timely, a hospital shall file the written exceptions with the Executive Director within 20 business days from the date the hospital receives the Institute's decision.

(3) The exceptions shall state with specificity the reasons why the Institute's decision should be overturned.

(4) The hospital shall mail a copy of the exceptions to the Institute by first class mail, postage prepaid.

B. Institute's Response.

(1) Not later than 20 business days from the date the exceptions are filed with the Executive Director, the Institute may file a response.

(2) The Institute shall mail a copy of its response to the hospital by first class mail, postage prepaid.

C. Decision of EMS Board.

(1) Not later than 90 calendar days from the date of the filing of the hospital's exceptions or the Institute's response, whichever is later, the EMS Board shall issue a written decision granting or denying the exceptions.

(2) If the EMS Board denies the exceptions, the proposed decision, as affirmed by the EMS Board, is the final agency decision.

(3) If the EMS Board grants the exceptions, in whole or in part, the EMS Board shall modify the proposed decision accordingly and the modified decision is the final agency decision.

(4) An appeal to the EMS Board is not a contested case as defined in State Government Article, §10-202(d), Annotated Code of Maryland, and the decision of the EMS Board is the final agency decision and is not subject to judicial review.

.09 Change in Designation Status of Trauma or Specialty Center.

A. A designated trauma or specialty center:

(1) Has the right to relinquish its designation as a trauma or specialty center or to request a designation lower than its current level of designation; and

(2) Shall provide the Office of Hospital Programs with 90 calendar days advance written notice of its request to change its designation status.

B. If the designated trauma center applies for a lower level of designation, the Institute:

(1) At its discretion, may repeat all or part of the designation process set forth in this chapter; and

(2) Shall consider the request based upon the criteria described in Regulation .02 of this chapter.

C. Temporary Inability to Comply with Standards.

(1) A designated trauma or specialty center shall notify the Office of Hospital Programs within 5 business days if it is temporarily unable to comply with the requirements for designated trauma or specialty centers as set forth in COMAR 30.08.03.

(2) The notice shall be in writing and shall specify the reasons for and the anticipated duration of the temporary inability to comply with the standards.

(3) The Institute shall determine whether the temporary inability to comply with the standards warrants disciplinary action under COMAR 30.08.13.

.10 Reverification of Trauma or Specialty Center Designation.

A. A designated trauma or specialty center shall repeat the designation process, as set forth in this chapter, every 5 years.

B. If a designated trauma or specialty center is in good standing, the:

(1) Institute shall send written notice to the chief executive officer of the trauma or specialty center requesting that the trauma or specialty center submit, within 60 calendar days, a request for reverification of its designation status; and

(2) Designated trauma or specialty center shall retain its current designation status until the reverification process is completed.

C. At the time of the reverification process, the Institute shall publish a notice in the Maryland Register that:

(1) Lists the trauma and specialty centers that have requested reverification of their designation status;

(2) Requests a person with knowledge of any reason why a designated trauma or specialty center should not have its designation status reverified to submit a written statement of the reason to the Institute within 20 business days following publication of the notice; and

(3) Requests that a hospital not designated that wishes to be considered for designation as a trauma or specialty center submit a written application to the Office of Hospital Programs in accordance with Regulation .03 of this chapter within 60 calendar days following publication of the notice.

30.08.03 Requirements for Designated Trauma or Specialty Centers

.01 Requirements for Trauma or Specialty Centers.

A. A hospital designated as a trauma or specialty center shall:

(1) Comply with the applicable standards for trauma or specialty care as developed by the Institute and set forth in COMAR 30.08.05 — 30.08.12;

(2) Receive all trauma or specialty patients, regardless of race, color, religion, age, sex, marital status, national origin, ancestry, physical or mental disability, or ability to pay;

(3) Upon the Institute's request, provide data to the Institute related to trauma or specialty care programs;

(4) Allow the Institute to monitor compliance with applicable regulations and standards as set forth by the Institute, including providing the Institute with access to:

(a) Patient discharge summaries,

(b) Patient care logs,

(c) Patient care records,

(d) Hospital trauma or specialty care quality management program records, including minutes, and

(e) Other documents that the Institute determines to be relevant; and

(5) Require confidentiality of information relating to an individual patient, provider, and hospital care outcomes in accordance with:

(a) Health Occupations Article, Title 14, Subtitle 5, Annotated Code of Maryland, and

(b) State Government Article, Title 10, Subtitle 6, Part III, Annotated Code of Maryland; and

B. In addition to the requirements set forth in §A of this regulation, a burn center shall transfer children younger than 15 years old who require critical care to a pediatric trauma center, if the center does not have pediatric intensive care capability.

C. Emergency Standards.

(1) The Institute may impose additional requirements on a trauma or specialty center if it determines that the requirements are necessary for the immediate protection of trauma or specialty patients.

(2) The Institute shall provide the designated trauma or specialty center with advance written notice of an additional emergency standard.

(3) The designated trauma or specialty center shall have reasonable time to comply with the emergency standard.

.02 Prehospital Triage and Transport.

A. The Institute shall develop and distribute to health care providers prehospital triage and transport protocols for patients needing trauma or specialty care services to ensure that patients who meet the triage criteria established by the protocols are transported directly to an appropriate facility.

B. In the absence of extenuating circumstances, a health care provider shall transport a patient to the closest appropriate trauma or specialty care center, consistent with the triage protocols.

.03 Prohibited Acts.

A. A hospital may not represent itself to be a trauma or specialty center unless it is so designated by the Institute.

B. A designated trauma or specialty center may not advertise services or capabilities for the treatment of patients above the trauma care level or specialty for which it has been designated.

30.08.04 Data Collection and Quality Management

.01 Responsibilities of Institute.

The Institute shall:

A. Maintain a State trauma registry and specialty care data bases to collect and analyze data including, but not limited to, data concerning the incidence, severity, and causes of trauma;

B. Establish criteria to identify patients to be included in the State trauma registry and specialty care data bases;

C. Collect data about patients to be included in the State trauma registry and specialty care data bases from:

(1) EMS providers;

(2) Hospitals, both designated and nondesignated;

(3) Office of Medical Examiner reports; and

(4) Other sources outside of the trauma and specialty care systems including, but not limited to:

(a) Death certificates,

(b) Hospital inpatient discharge data,

(c) Health care provider and third-party payer billing data, and

(d) Law enforcement agency records;

D. Require hospitals to have a case specific patient identifier common to all data sources used in the State trauma registry and specialty care data bases; and

E. Establish procedures and specifications for electronic and hard copy submission of data.

.02 Trauma and Specialty Care Quality Management Plan.

A. The Institute shall design a trauma and specialty care quality management plan for continued monitoring and evaluation of the State trauma and specialty care systems.

B. The trauma and specialty care quality management plan shall include the establishment, publication, and periodic review of the data required to be submitted to provide information regarding injury, trauma and specialty care, and system operation in the following categories:

(1) Demography;
(2) Anatomy;
(3) Physiology;
(4) Severity;
(5) Epidemiology;
(6) Resource utilization;
(7) Quality improvement;
(8) Outcomes; and
(9) Finance.

C. The Institute shall establish committees for trauma and specialty care quality management as structural units of the Maryland EMS Quality Leadership Council to coordinate the trauma and specialty care systems quality management and quality improvement activities set forth in this subtitle.

D. The Institute shall develop a system and reporting mechanism for quality improvement by:

(1) Determining the data elements that constitute the State trauma registry and specialty care data bases;

(2) Establishing protocols for quality monitoring, consistent with the Institute's most current data quality guidelines;

(3) Conducting studies to assess the completeness and accuracy of case identification and data collection; and

(4) Ensuring that the data entered in the State trauma registry and specialty care data bases are complete and accurate.

.03 Trauma and Specialty Care Quality Management Programs.

A. A designated trauma or specialty care center shall have a hospital-wide quality management plan to reflect and demonstrate continuous quality improvement in the delivery of trauma and specialty care.

B. The quality management program includes, but is not limited to, the requirements for trauma and specialty care centers in COMAR 30.08.03.

C. A designated trauma and specialty care center shall have a system for continuous monitoring and trend analysis of trauma patient bypass to alternative trauma or specialty centers.

D. Designated trauma and specialty care centers shall participate in State trauma and specialty care quality management activities sponsored by the Institute.

.04 Use of State Trauma Registry and Specialty Care Data.

The Institute may use State trauma registry and specialty care data to:

A. Monitor and provide information necessary to evaluate major trauma or specialty patient care, outcome, and cost;

B. Assess compliance of EMS providers, designated trauma and specialty centers, and other hospitals with the trauma and specialty care standards, regulations, and protocols;

C. Provide information necessary for resource planning and management;

D. Provide data for injury surveillance, analysis, and prevention programs; and

E. Provide a data resource for research and education.

.05 Responsibilities of Emergency Medical Services Providers.

A. Prehospital services shall provide prehospital MAIS runsheets that include trauma or specialty care patient data about:

(1) Trauma victims dead at the scene of the trauma;

(2) Patients meeting State trauma or specialty triage criteria who are transported to a hospital;

(3) Patients transported in accordance with interfacility transfer policies to receive a higher level of care or for special resources; and

(4) Patients transported to specialty centers.

B. The transporting service is responsible for submitting patient care data designated in the MAIS runsheet to the receiving hospital.

C. Designated trauma or specialty care centers shall use the patient criteria described in Regulation .01B and C of this chapter.

.06 Access to Trauma Registry and Specialty Care Information.

A. Data that identifies individual patients, providers, and hospital outcomes is confidential.

B. The Institute may only release confidential information in accordance with:

(1) The provisions of Health Occupations Article, Title 14, Subtitle 5, Annotated Code of Maryland; and

(2) Other criteria as developed by the Institute pertaining to patient confidentiality and quality management records.

C. The Institute may approve requests for data and other information from the State trauma registry and specialty care data bases for special studies and analyses in accordance with §B of this regulation.

D. A person having access to information collected under this subtitle may use the information only for the purposes allowed under Regulation .04 of this chapter.

E. The Institute may require a person who requests data or other information from the State trauma registry and specialty care data bases to pay all or part of the reasonable costs associated with special preparation of the request.

F. The Institute may not disclose confidential information to any person, except on request:

(1) To an approved regional or State quality improvement program if the regional or State quality improvement program is subject to the same confidentiality guidelines as the Institute;

(2) To a scientific research professional associated with a scientific research organization, if:

(a) The Institute has reviewed and approved the research professional's written research proposal with respect to scientific merit and confidentiality safeguards, and

(b) The data does not identify specific hospitals or patients; and

(3) The Institute shall provide aggregate State trauma registry and specialty care data to hospitals, public or private agencies, and other interested parties for:

(a) Prevention activities,
(b) Epidemiological or demographic studies, or
(c) Education and research projects.

30.08.05 Trauma Center Designation and Verification Standards

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "E" means the standard is essential.
(2) "D" means the standard is desirable.
(3) "NA" means the standard does not apply.

.02 Types of Trauma Centers.

A. "PARC" is a Primary Adult Resource Center.
B. "I" is a Level I trauma center.
C. "II" is a Level II trauma center.
D. "III" is a Level III trauma center.
E. "ED" is an emergency department for which the indicated standards are recommended, not required.

	PARC	I	II	III	ED
.03 Organization.					
A. A hospital's board of directors, administration, and medical and nursing staffs shall demonstrate commitment to the hospital's specific level of trauma center designation and to the care of trauma patients by:					
(1) A board of director's resolution stating:	E	E	E	E	E
(a) That the hospital agrees to meet the trauma center designation standards for the hospital's specific level of designation, and					
(b) The hospital's commitment to the infrastructure and the financial, human, and physical resources necessary to support the hospital's specific level of designation;	E	NA	NA	NA	NA
(2) Establishing an identifiable organization whose dedication to the care of the injured is shown in:					
(a) Its mission statement,					
(b) The configuration of its medical, administrative, and support staffs, and					
(c) The configuration of its physical plant;	E	E	E	E	E
(3) Participating in the Statewide trauma system, including submission of patient care data to the State trauma registry for system and quality management;	E	E	E	E	E
(4) Assuring that all trauma patients receive medical care commensurate with the level of the hospital's designation; and	E	E	E	E	E
(5) Indicating the hospital's commitment to the infrastructure and financial, human, and physical resources necessary to support the hospital's level of trauma center designation by the hospital's bylaws, contracts, and budget specific to the trauma program.	E	E	E	E	E
B. A hospital shall be licensed by the Department of Health and Mental Hygiene as an acute care hospital.	E	E	E	E	E
C. A hospital shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations.	E	E	E	E	E
D. A hospital shall maintain current equipment and technology to support optimal trauma care for the level of the hospital's trauma center designation.	E	E	E	E	NA
E. A hospital shall have:					
(1) A heliport or helipad positioned so there is a limited distance from the helipad to the hospital, positioned at the closest safe location, in order to minimize the effects to the patient; or	NA	NA	NA	NA	E
(2) Access to a helicopter landing site near the hospital.					
F. To administer the trauma program, a hospital shall have a management team that includes:					
(1) A trauma medical director who:	E	E	E	E	D
(a) Has administrative authority for the trauma program;					
(b) Is responsible for the overall clinical coordination;					

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(c) Is responsible for all trauma patients through the quality management process;					
(d) Has a job description developed by the hospital;					
(e) Appears on the hospital's organizational chart where the relationship between the medical director and other hospital services is depicted; and					
(f) Participates in regional and State education, quality management, and prevention activities;					
(2) A full-time director of patient care services, who is a registered nurse, with direct authority for all nursing and ancillary trauma patient care services, operations, and the quality management associated with these services;	E	NA	NA	NA	NA
(3) An in-house trauma resource coordinator who is available 24 hours a day and is responsible for the timely coordination of trauma patient care resources, services, and patient flow;	E	NA	NA	NA	NA
(4) A trauma coordinator who, in collaboration and conjunction with the trauma medical director and nursing management, monitors and coordinates the components of the trauma program, including:	E	E	E	E	NA
(a) Patient care;					
(b) Provider education;					
(c) Public education and prevention activities;					
(d) Program management according to the trauma center's need;					
(e) Trauma registry; and					
(f) Quality management for the trauma program; and					
(5) A hospital committee that provides expert input to hospital's management on trauma program issues and has responsibility for overseeing the trauma program's quality management composed as follows:					
(a) The committee shall:	E	E	E	E	NA
(i) Be multidisciplinary, and					
(ii) Coordinate trauma patient care among hospital departments, medical and nursing staffs, and representative disciplines across the trauma care continuum; or					
(b) A subcommittee of the emergency department committee shall address trauma care issues.	NA	NA	NA	NA	E
G. The trauma resuscitation team shall:					
(1) Be present full-time in the resuscitation area and directed by an attending trauma surgeon;	E	NA	NA	NA	NA
(2) Be activated by an emergency physician or nurse by protocol;	NA	E	E	E	E
(3) Be directed by an in-house emergency physician who has experience and training in trauma resuscitation until the patient is formally transferred to the care of the trauma surgeon;	NA	E	E	E	E
(4) Be present in-house and immediately available upon notification unless otherwise covered by this subtitle;	E	E	E	E	D
(5) Be oriented to the trauma care system;	E	E	E	E	D
(6) Be required to complete annual continuing education and demonstrate competence for trauma care that is appropriate and specific to each member's specialty roles;	E	E	E	E	E
(7) Participate in:	E	E	E	E	E
(a) Trauma quality management, and					
(b) Ongoing continuing medical education or continuing education in trauma;					

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(8) Be oriented to the internal trauma patient clinical management protocols or policies;	E	E	E	E	E
(9) Be defined in writing, specifying the roles and responsibilities of each member; and	E	E	E	E	E
(10) Be accountable to the trauma surgeon who becomes the team leader upon arrival in the resuscitation area.	NA	E	E	E	NA
H. A hospital shall have written policies or procedures to direct the organized, safe, intra-hospital and inter-hospital transport of trauma patients.	E	E	E	E	E
I. A hospital shall have a multidisciplinary plan of care specific to the needs of each trauma patient and address all phases of care, including discharge, disposition, and rehabilitation needs.	E	E	E	E	NA
.04 Medical Staff.	E	E	E	E	E
A. Credentialing Process. Each physician shall be credentialed by the hospital for the appropriate specialty, including trauma care.	E	E	E	E	NA
B. Delineation or Reevaluation of Privileges.					
(1) The trauma panel shall be limited to those with demonstrated skills, commitment, experience, and interest in trauma care.	E	NA	NA	NA	NA
(2) The trauma medical director shall serve on the medical staff as the trauma chief of service.	E	E	E	E	NA
(3) Appointment and reappointment to the trauma admitting or consulting staff shall be coordinated by the trauma medical director and based on the following criteria:					
(a) Maintenance of good standing in the primary specialty;					
(b) Evidence of the required continuing medical education in trauma;					
(c) Documentation of attendance at multidisciplinary conferences, morbidity or mortality rounds, or hospital peer-review conferences that deal with the care of injured patients; and					
(d) Satisfactory performance in managing trauma patients based on performance assessment and outcome analysis.					
C. Continuing Medical Education.	E	E	E	E	NA
(1) General surgeons taking trauma calls shall have evidence of 16 hours of trauma-related CME credits a year.	E	E	D	D	NA
(2) Over a 3-year period, half of the CME hours in §C(1) of this regulation shall be obtained outside the hospital and be recognized by a national accrediting body.	E	E	E	E	NA
(3) ATLS™ may not be counted in required CME credits.	E	E	E	E	NA
(4) Physician CME credits shall be documented in accordance with hospital policy.	E	NA	NA	NA	NA
(5) There shall be a full-time director of trauma continuing education who is responsible for scheduling at least weekly medical staff CME opportunities conducted in-house and open to regional participation.					
.05 Trauma Service.					
Trauma service requirements are as follows:	E	E	E	E	NA
A. The trauma service shall be established by the medical staff and shall be responsible for the care of injured patients;	E	E	E	E	NA
B. Privileges for physicians on the trauma service shall be determined by the medical credentialing process;					

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C. Patients with injuries having a high index of suspicion, such as a significant mechanism of injury, shall be evaluated by the trauma service in compliance with hospital protocol;	E	E	E	E	NA
D. Patients with multiple system or complex single system injuries shall be evaluated by the trauma service;	E	E	E	E	NA
E. The surgeon responsible for a patient's care shall be identified;	E	E	E	E	NA
F. Current certification as ATLS™ instructors for all attending trauma surgeons;	E	NA	NA	NA	NA
G. Successful completion of an ATLS™ course for all general surgeons;	E	E	E	E	NA
H. Successful completion of an ATLS™ course for all specialists providing trauma care;	D	D	D	D	D
I. Current PALS certification for physicians providing pediatric trauma care.	D	D	D	D	D
.06 Trauma Medical Director.					
The trauma medical director shall:					
A. Be an expert in and committed to the care of the injured;	E	E	E	E	NA
B. Be board certified in general surgery or other surgical specialties;	E	E	E	E	NA
C. Have the following appropriate educational preparation and clinical experience:					
(1) Successful completion of a fellowship in trauma for at least 1 year and commitment to a full-time position as trauma medical director,	E	D	D	D	NA
(2) Demonstrated experience at a designated Level I trauma center in trauma systems management, trauma research, and quality management functions, and	E	D	NA	NA	NA
(3) Documented interest in trauma center or trauma system issues as evidenced by education, publications, professional experience, and involvement in planning and prevention efforts;	E	D	NA	NA	NA
D. Participate in local, State, or national trauma-related activities;	E	E	E	E	NA
E. Participate in trauma educational activities such as:					
(1) Trauma fellowship programs,	E	D	NA	NA	NA
(2) Undergraduate medical education,	E	E	NA	NA	NA
(3) Continuing education, and	E	E	E	E	NA
(4) ATLS™ courses;	E	E	D	D	NA
F. Participate in trauma research and publication efforts; and	E	E	D	D	NA
G. Demonstrate active participation in the resuscitation of multisystem trauma patients, or surgery of multisystem trauma patients, or both.	E	E	E	E	NA
.07 Surgery Department.					
A. General Surgery. A hospital shall have a surgery department including:					
(1) An in-house, fellowship-trained attending 24 hours a day;	E	NA	NA	NA	NA
(2) Either:	NA	E	E	NA	NA
(a) A general surgeon trained in trauma care who responds immediately upon notification according to approved hospital protocols; or					
(b) An in-house PGY4 or more senior resident who:					
(i) Is part of a formal training program, and					
(ii) Responds to all trauma code activations with an on-call attending surgeon who is available within 30 minutes of being called;					

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	NA	NA	NA	E	NA
(3) A general surgeon trained in trauma care who is on-call and available within 30 minutes of being called;	E	E	E	E	NA
(4) Trauma or general surgeons who are board certified or board eligible;	E	E	E	E	D
(5) Trauma or general surgeons who agree to actively participate in a defined continuing education program; and	E	E	E	E	NA
(6) Criteria and protocols for the notification and response of a trauma or general surgeon.					
B. Neurosurgery. Neurosurgery requirements are as follows:	E	E	NA	NA	NA
(1) In-house attending or PGY2 or higher with attending on-call within a 30-minute response;	E	NA	NA	NA	NA
(2) Dedicated in-house PGY2 or higher with attending on-call;	NA	NA	E	E	NA
(3) Attending on-call with a 30-minute response, with in-house physician capable of initiating stabilization and diagnostic procedures.					
C. Othopedic Surgery. Orthopedic surgery requirements are as follows:	E	D	NA	NA	NA
(1) Board-certified, trauma fellowship-trained attending or PGY3 in-house, dedicated 24 hours a day to trauma care with attending on call with a 30-minute response;	NA	E	NA	NA	NA
(2) Board-certified or board-eligible in-house attending or PGY2 with attending on call with a 30-minute response;	NA	NA	E	E	NA
(3) Board-certified or board-eligible on-call attending with a 30-minute response.					
.08 Nonsurgical Specialties.					
A. Anesthesia. Anesthesia requirements are as follows:	E	D	NA	NA	NA
(1) Board-certified attending in-house, dedicated 24 hours a day to trauma care;	NA	E	E	NA	NA
(2) Board-certified or board-eligible, in-house attending 24 hours a day;	NA	NA	NA	E	NA
(3) Attending on-call and promptly available with in-house PGY4 or CRNA with local criteria defining conditions requiring an immediate response.					
B. Emergency Medicine. Emergency medicine requirements are as follows:					
(1) Physician director:	NA	E	E	E	D
(a) Board certified or board eligible in emergency medicine with evidence of active participation in daily emergency care,	NA	E	E	E	D
(b) Administrative duties in the emergency department;					
(2) Emergency physicians in-house 24 hours a day:	NA	E	E	D	D
(a) Board certified or board eligible in emergency medicine,	NA	NA	NA	E	E
(b) Board certified or board eligible in an appropriate specialty with at least 7,000 hours of emergency practice and ATLS™ certification,	NA	NA	NA	NA	E
(c) Emergency physicians who have demonstrated special capabilities through commitment, continuing education, and experience.					
C. Critical Care. Critical care requirements are as follows:	E	E	NA	NA	NA
(1) Intensive care with a designated surgical director who is fellowship-trained and board certified or board eligible in critical care;					

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(2) Physician with privileges in critical care and approved by the trauma director, on duty in the ICU or in hospital 24 hours a day.	E	E	E	D	NA
.09 Additional Surgical Specialties.					
The following surgical specialties shall be on call and available with a 30-minute response time:					
A. Cardiac;	E	E	D	NA	NA
B. Hand;	E	E	D	D	NA
C. Microvascular replant or flaps;	E	E	D	D	NA
D. Obstetric and gynecologic;	E	E	E	E	NA
E. Ophthalmic;	E	E	E	D	NA
F. Oral or maxillofacial;	E	E	E	D	NA
G. Otorhinolaryngologic;	E	E	D	E	NA
H. Pediatric;	E	E	E	D	NA
I. Plastic;	E	E	E	D	NA
J. Thoracic; and	E	E	E	E	NA
K. Urologic.	E	E	E	E	D
.10 Additional Nonsurgical Specialties — Promptly Available.					
The following nonsurgical specialties shall be on-call and available within 30 minutes of being requested:					
A. Cardiology;	E	E	D	D	NA
B. Pulmonary medicine; and	E	E	E	D	NA
C. Radiology.	E	E	E	E	D
.11 Additional Nonsurgical Specialties — On-Call.					
The following nonsurgical specialties shall be on-call:					
A. Gastroenterology;	E	E	E	E	D
B. Infectious disease;	E	E	E	E	NA
C. Internal medicine;	E	E	E	E	NA
D. Nephrology;	E	E	E	D	NA
E. Neurology;	E	E	E	E	NA
F. Pathology;	E	E	E	D	NA
G. Pediatrics;	E	E	E	E	D
H. Psychiatry; and	E	E	E	E	D
I. Psychiatry.	E	E	E	E	D
.12 Nursing Services.					
A. Responsibility shall be assigned within the department of nursing for the trauma program.	NA	E	E	E	NA
B. The nursing department's plan shall include the ability to immediately mobilize qualified staff for initial resuscitation.	E	E	E	E	E
C. There shall be a plan for providing adequate and appropriate nursing staff to meet the acuity needs of trauma patients in each unit.	E	E	E	E	E
D. The nursing department shall participate in multidisciplinary quality management monitoring of trauma care.	E	E	E	E	E
E. There shall be an introductory education program for all nurses caring for trauma patients that addresses the learning outcomes approved by the EMS Board. This introductory education program shall include 16 hours of content within 1 year of hire.	E	E	E	E	E
F. After completion of the introductory education required in §E of this regulation, continuing education shall be required that meets the following criteria:	E	E	E	E	D
(1) 16 hours of trauma-related education every 2 years for emergency and critical care personnel caring for trauma patients; or					
(2) 8 hours of trauma-related education for nurses who care for trauma patients and are from other clinical areas.					

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.13 Facility or Unit Capabilities.					
A. Emergency Department. Emergency department requirements are as follows:					
(1) A designated physician director and nurse manager;	NA	E	E	E	E
(2) Board-certified or board-eligible attending physician with demonstrated competence in the care of critically injured patients in-house 24 hours a day;	NA	E	E	E	D
(3) Dedicated trauma resuscitation unit with dedicated staff, equipment, and supplies 24 hours a day;	E	D	NA	NA	NA
(4) Senior attending trauma surgeon available 24 hours a day through SYSCOM as a resource for trauma consultation Statewide;	E	NA	NA	NA	NA
(5) A sufficient number of registered nurses and other providers, who are competent to provide care during trauma resuscitation and present in sufficient numbers to manage projected case load, and a plan to reinforce the number of staff on immediate notice of multiple admissions;	E	E	E	E	E
(6) Equipment and supplies organized for trauma resuscitation present and immediately available 24 hours a day;	E	E	E	E	E
(7) Identified trauma cubicle or room for trauma resuscitation;	NA	E	E	E	E
(8) Direct communication link to prehospital providers and transport vehicles;	E	E	E	E	E
(9) Designated as base station by the Institute;	E	E	E	E	NA
(10) Sterile surgical sets located in the ED for:	E	E	E	E	E
(a) Airway control or cricothyrotomy,					
(b) Thoracotomy,					
(c) Vascular access,					
(d) Chest decompression, and					
(e) Peritoneal lavage;					
(11) Policies and protocols for trauma team response and roles in ED trauma resuscitation in accordance with Regulation .11 of this chapter;	E	E	E	E	E
(12) Drugs necessary for emergency care;	E	E	E	E	E
(13) Autotransfusion equipment and capability immediately available.	E	E	E	E	E
B. Operating Room. Operating room requirements are as follows:					
(1) Operating room or rooms adequately staffed with in-house personnel dedicated to trauma 24 hours a day;	E	D	NA	NA	NA
(2) Operating room available within 15 minutes of notification with adequate in-house staff;	NA	E	E	E	NA
(3) X-ray capability including C-arm image intensifier 24 hours a day;	E	E	E	E	NA
(4) Equipment and instrumentation appropriate for:					
(a) Neurosurgery,	E	E	E	E	NA
(b) Vascular surgery,	E	E	E	E	NA
(c) Pelvic and long-bone fracture fixation, and	E	E	E	E	NA
(d) Cardiopulmonary bypass;	E	E	D	NA	NA
(5) Blood recapturing and warming equipment;	E	E	E	E	NA
(6) Endoscopes.	E	E	E	E	NA
C. Post-Anesthesia Recovery Room. Post-anesthesia recovery room requirements are as follows:					
(1) Dedicated to trauma and staffed 24 hours a day;	E	NA	NA	NA	NA
(2) Room available to trauma patients with registered nurses and other essential staff 24 hours a day;	NA	E	E	E	NA

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(3) Equipment for continuous monitoring of temperature, hemodynamics, and gas exchange.	E	E	E	E	NA
D. Intensive Care Unit. Intensive care unit requirements are as follows:					
(1) Dedicated intensive care unit for trauma with appropriately trained registered nurse staff;	E	NA	NA	NA	NA
(2) Priority bed availability for trauma patients with appropriately trained registered nurses in sufficient numbers based on patient acuity;	NA	E	E	E	NA
(3) Written plan for triaging patients from the intensive care unit to free up beds for trauma patients when necessary or provision of alternate critical care beds for trauma patients with appropriately trained registered nurse staff;	E	E	E	E	NA
(4) Equipment for monitoring and resuscitation;	E	E	E	E	D
(5) Support services with immediate access to clinical diagnostic services such as arterial blood gases, hematocrits, and chest X-rays available within 30 minutes;	E	E	E	E	NA
(6) Acute continuous hemodialysis capability.	E	E	E	E	NA
E. Acute Spinal Cord or Head Injury Management Capability. Acute spinal cord or head injury management requirements are as follows:					
(1) Dedicated neurotrauma units with dedicated, specialty trained nursing and support staff;	E	NA	NA	NA	NA
(2) Neuro-intensive care unit with intracranial pressure capabilities for trauma patients;	NA	E	NA	NA	NA
(3) Transfer agreements with designated spinal or head injury trauma centers and spinal or head injury rehabilitation centers.	NA	E	E	E	NA
F. Burn Care. Burn care requirements are as follows:					
(1) Burn center:	E	E	E	E	E
(a) Certified by American Burn Association,					
(b) Staffed by nursing personnel trained in burn care, and					
(c) Properly equipped for the care of extensively burned patients; or					
(2) Transfer agreements with a designated burn center.	E	E	E	E	E
G. Radiological Special Capabilities. Radiological special capabilities requirements are as follows:					
(1) In-house trauma-dedicated technicians 24 hours a day;	E	NA	NA	NA	NA
(2) In-house radiology technicians 24 hours a day;	E	E	E	E	NA
(3) Dedicated computed tomography (CT) scan and angiography facilities and staff 24 hours a day;	E	NA	NA	NA	NA
(4) Angiography;	E	E	E	E	NA
(5) Sonography;	E	E	E	E	D
(6) Nuclear scanning;	E	E	E	E	NA
(7) Magnetic resonance imaging;	E	E	E	D	D
(8) Computed tomography (CT):					
(a) Computed tomography (CT) in-house and available 24 hours a day,	E	E	E	E	NA
(b) In-house CT technician 24 hours a day,	E	E	E	NA	NA
(c) CT technician on-call and available within 30 minutes, and	NA	NA	NA	E	NA
(d) Back-up CT scan capabilities.	E	E	E	E	NA
H. Rehabilitation. Rehabilitation requirements are as follows:					
(1) Rehabilitation services staffed by personnel trained in rehabilitative care and properly equipped for acute care of the critically injured patient;	E	E	D	D	NA

	PARC	I	II	III	ED
	NA	E	E	E	NA
(2) Full in-house service or transfer agreement to a rehabilitation service for long-term care;	E	NA	NA	NA	NA
(3) Ongoing continuity of care for patients with traumatic brain, musculoskeletal, and soft tissue injuries provided in an affiliated rehabilitation facility by attending trauma center specialists and subspecialists.					
I. Clinical Laboratory Service.	E	E	E	E	E
(1) A clinical laboratory service shall be available 24 hours a day capable of providing:					
(a) Standard analysis of blood, urine, and other body fluids;					
(b) Blood-typing and cross-matching;					
(c) Comprehensive blood bank or access to a central blood bank in the community and adequate storage facilities with stock minimums set by protocol for blood products;					
(d) Blood gases and pH determinations;					
(e) Coagulation studies;					
(f) Microbiology; and					
(g) Drug and alcohol screening.					
(2) A dedicated satellite lab facility shall be available near or in the trauma resuscitation area for essential lab studies.	E	E	NA	NA	NA
J. Equipment for Resuscitation. Equipment for resuscitation of patients of all ages in the emergency department, operating room, post-anesthesia care unit, or intensive care unit shall include:	E	E	E	E	E
(1) Immediately available equipment such as:					
(a) Airway control and ventilation equipment, including laryngoscopes and endotracheal tubes of all sizes, bag-mask resuscitator, pocket masks, and oxygen,					
(b) Suction devices,					
(c) Pulse oximetry,					
(d) Electrocardiograph-oscilloscope-defibrillator, and					
(e) Standard intravenous fluids and administration devices, including large-bore intravenous catheters; and					
(2) Readily available equipment such as:	E	E	E	E	E
(a) End-tidal CO_2 determination,	E	E	E	E	NA
(b) Apparatus to establish hemodynamic monitoring,	E	E	E	E	E
(c) Skeletal traction devices, including capability for cervical traction,	E	E	E	E	NA
(d) Arterial catheters,	E	E	E	E	E
(e) Thermal control equipment for patient and fluids, and	E	E	E	E	D
(f) Compartmental pressure measuring device.	E	E	E	E	E
.14 Quality Management.					
A. Ongoing quality management of the trauma program that is:					
(1) Integrated into the hospital's overall quality management program; and					
(2) Reported to the hospital's governing body.					
B. The following shall be included:	E	E	E	E	E
(1) Structure to ensure that defined program outcomes and performance measures are developed and monitored regularly;	E	E	E	E	E
(2) Trauma registry with participation in the State trauma registry;	E	E	E	E	E
(3) Special audit of all trauma deaths;	E	E	E	E	E
(4) Morbidity and mortality review;					

	PARC	I	II	III	ED
(5) Evaluation of nursing care, medical care, utilization review, tissue review, and prehospital care;	E	E	E	E	E
(6) Trauma center by-pass status including, if applicable, both medevac fly by and ground unit reroute statistics; and	E	E	E	E	NA
(7) Documentation of quality management available to demonstrate the multidisciplinary approach to the quality management program including if appropriate:	E	E	E	E	E
(a) Problem identification,					
(b) Analysis,					
(c) Action plan,					
(d) Implementation, and					
(e) Reevaluation.					
C. Monthly Review.					
(1) At one or more appropriate forums in the hospital, the trauma program shall be reviewed monthly, looking at both clinical care and administration.	E	E	E	E	E
(2) When a resource is required to be available within a specified period of time, the time the resource is requested and the time the resource is available shall be documented as part of the quality management process and the response times shall be reviewed monthly.	E	E	E	E	E
(3) The following aspects shall be addressed:	E	E	E	E	E
(a) Trends;					
(b) All deaths;					
(c) All transfers;					
(d) Morbidities;					
(e) Problem identification and solution;					
(f) Issues identified from the quality management process; and					
(g) Other trauma system issues.					
(4) Participation shall be multidisciplinary.	E	E	E	E	E
(5) The trauma medical director shall have a leadership role in trauma center quality management.	E	E	E	E	E
(6) Minutes shall be maintained for all meetings.	E	E	E	E	E
.15 Prevention and Public Education.					
A. The trauma center hospital shall:					
(1) Collaborate closely with the Institute in developing, monitoring, and evaluating the effectiveness of prevention and public education programs;	E	NA	NA	NA	NA
(2) Conduct epidemiology research concerning injury control;	E	E	NA	NA	NA
(3) Collaborate with other hospitals or agencies in research; and	E	E	E	E	D
(4) Monitor progress of prevention programs in cooperation with State quality monitoring activities.	E	E	E	E	NA
B. The trauma center shall:					
(1) Participate in continuous monitoring of the:					
(a) Expanded trauma registry, and	E	E	E	E	NA
(b) Minimal trauma registry data;	NA	NA	NA	NA	E
(2) Have a prevention program:					
(a) With a designated prevention coordinator,	E	E	D	D	NA
(b) With outreach activities and program development,	E	E	E	E	E
(c) With information resources, and	E	E	E	E	E
(d) In collaboration with existing national, regional, and State programs.	E	E	E	E	E
.16 Trauma Research.					
A. A trauma center shall have:					
(1) An organized trauma research program with a designated physician director and documented research plan;	E	E	NA	NA	NA

	PARC	I	II	III	ED
(2) Regular meetings of the research group; and					
(3) Evidence of productivity through peer review.					
B. The trauma center shall have:					
(1) Proposals reviewed by an institutional review board;	E	E	NA	NA	NA
(2) Presentations at local, regional, or national meetings;	E	E	NA	NA	NA
(3) Publications in peer-reviewed journals; and	E	E	NA	NA	NA
(4) Clinical research trials designed to enhance the trauma system's ability to resuscitate, stabilize, and treat trauma patients in the most cost-effective manner.	E	NA	NA	NA	NA
.17 Training.					
A. A trauma center shall assist the Institute with developing, monitoring, and evaluating the effectiveness of out-of-hospital training programs.	E	NA	NA	NA	NA
B. The hospital shall offer:					
(1) Trauma education for:					
(a) Staff and community physicians,					
(b) Staff and community nurses,					
(c) Prehospital personnel, and					
(d) Allied health personnel;	E	E	E	E	D
(2) A trauma fellowship training program;	E	NA	NA	NA	NA
(3) A surgical residency program accredited by the Accreditation Council for Graduate Medical Education; and	E	E	NA	NA	NA
(4) Participation in undergraduate medical education.	E	E	NA	NA	NA
.18 Continuing Education Programs.					
A. A hospital shall have:					
A. Formal internal continuing education programs concerning the treatment and care of trauma patients for:					
(1) Physicians,					
(2) Nurses, and					
(3) Allied health personnel;	E	E	E	E	D
B. Special training for personnel exclusively on trauma protocols and trauma care for all new physicians, nurses, and allied health personnel assigned to units where trauma care is provided; and	E	E	E	E	E
C. An external continuing education program concerning the care and treatment of trauma patients for physicians, nurses, and allied health personnel in the region.	E	E	E	D	NA
.19 Protocols and Agreements.					
The following patient treatment and care documents shall be written, distributed, and monitored for quality:	E	E	E	E	E
A. Resuscitation protocol;					
B. Transfusion protocol;					
C. Infection control protocol;					
D. Trauma team alert protocol;					
E. Physician call schedule and notification protocol;					
F. Inter-hospital transfer protocol;					
G. Helicopter safety protocol;					
H. Organ procurement protocol; and					
I. Transfer agreements with specialty and rehabilitation centers.					

30.08.06 Burn Center Standards

.01 Burn Care System.

A. Burn Center Hospital. A burn center hospital shall maintain a specialized unit dedicated to acute burn care.

B. Burn Center. A burn center shall:

(1) Have both a medical and administrative commitment to the care of the patient with burns;

(2) Have written guidelines for the triage, treatment, and transfer of burn patients from other facilities;

(3) Maintain current accreditation by the Joint Commission of Accreditation of Healthcare Organizations; and

(4) Be used predominantly for patients with burn injuries or those suffering from skin disorders or other injuries whose treatment requirements are similar to those of burn patients.

C. Prehospital Care. A burn center shall:

(1) Maintain access to an EMS system for the transport of patients with burns from referral sources within the geographic service area;

(2) Participate in existing regional or State EMS systems;

(3) Have a written multiple casualty plan for the triage and treatment of those patients burned in a multiple casualty incident occurring within its geographic service area that is reviewed and updated on an annual basis by EMS representatives and the burn center director; and

(4) Provide education on the current concepts in emergency and inpatient burn care treatment to prehospital and hospital care providers within its geographic service area.

.02 Organizational Structure.

A. Documentation of Policies and Procedures.

(1) A burn center hospital shall formally establish and maintain an organized burn service that is responsible for coordinating the care of the burn patient.

(2) A burn center shall maintain an organizational chart relating personnel within the burn center and relating the personnel of the burn center within the burn center hospital.

(3) A burn center shall maintain an appropriate policy and procedure manual that:

(a) Is reviewed annually by the burn center director and the nurse manager;

(b) Addresses:

(i) Administration of the burn center,

(ii) Staffing and programs of the burn center,

(iii) Criteria for admission to the burn unit by the burn service,

(iv) Usage of the burn unit beds by other medical or surgical services,

(v) Criteria for discharge and follow-up care,

(vi) Availability of beds and the transfer of burn patients to other medical or surgical units within the hospital, and

(vii) Care of patients with burns in areas of the burn center hospital other than the burn unit.

B. Consistency of Data Collected and Reported.

(1) A burn center shall maintain or participate in a registry or internal data base that is capable of providing annual statistical reports.

(2) The data base shall include all patients who are admitted to the burn center hospital for acute burn care treatment.

C. Admission and Census Levels for the Burn Center Hospital.

(1) A burn center shall admit an average of 75 or more patients with acute burn injuries annually.

(2) At least 60 patients shall meet the American Burn Association Burn Center Referral Criteria in Regulation .17 of this chapter.

(3) A burn center shall maintain an average daily census of four or more patients with acute burn injuries.

.03 Burn Center Director.

A. General.

(1) A burn center director is authorized to direct and coordinate all medical services for patients admitted to the burn service.

(2) Medical care for patients in the burn center shall be provided by the burn center director or qualified physicians approved by the director and shall conform to burn center patient care protocols.

(3) Privileges for physicians participating in the burn service shall be determined by the medical staff credentialing process and approved by the burn center director.

B. Qualifications and Activities of a Burn Center Director.

(1) A burn center shall appoint a qualified burn center director to oversee the care of patients in the burn service.

(2) A burn center director shall meet the requirements in Regulation .05 of this chapter.

C. Responsibilities of the Burn Center Director. The responsibilities of a burn center director include:

(1) Creation of policies and procedures within the burn center that specify the care of burn patients;

(2) Creation of policies and protocols for use throughout the burn care system for initial care, triage, and transport of burn patients;

(3) Cooperation with regional EMS authorities in regard to all aspects of burn treatment;

(4) Communication on a regular basis with physicians and other authorities regarding patients who have been referred;

(5) Direction of the burn center administration functions;

(6) Direction and active participation in the burn center quality management program;

(7) Liaison with adjacent and regional burn centers; and

(8) Development of and participation in both internal and external continuing medical education programs in the care and prevention of burn injuries.

.04 Appointment and Qualifications of Attending Staff Surgeons.

A. A burn center director may appoint qualified attending staff surgeons to participate in the care of patients in the burn service.

B. An attending staff surgeon shall meet the requirements in Regulation .05 of this chapter.

.05 Qualifications For Burn Center Director and Surgeons.

Category / Description	Burn Center Director	Staff Surgeons
A. Certification. Certification qualifications are as follows:		
(1) Board certified or board eligible in general or plastic surgery;	Required	Required
(2) Board certification of special qualification in critical care.	Desirable	Desirable
B. Training. Training qualifications are as follows:		
(1) 2 or more years of burn care experience during the previous 5 years; and	Required	Desirable
(2) Either:	Required	Required

Category / Description	Burn Center Director	Staff Surgeons
(a) Completion of a fellowship in burn treatment or training, or (b) Supervision in burn surgery on an active burn service at the PGY3 or higher level for at least 6 months.	Required	Required
C. Clinical Activity. The clinical activity qualification requires participation in the care of 50 or more acutely burned patients annually with 40 or more of the patients meeting the American Burn Association Burn Center Referral Criteria in Regulation .17 of this chapter.	Required	Required
D. Continuing Medical Education. The continuing medical education qualification requires annual participation in 16 hours or more of burn-related continuing medical education, which can be met by attendance at annual American Burn Association meetings or American Burn Association endorsed meetings.	Desirable	Desirable
E. Research Participation. The research participation qualification is to demonstrate a commitment to clinical or basic science burn care research, or the organization of burn care systems, which can be met by: (1) Submission of an abstract at least every 3 years to a national meeting dealing with burns, emergency medicine, or trauma; or (2) Research projects, completed or in progress.		
F. Community Education and Burn Prevention. The community education and burn prevention qualification is:	Desirable	Desirable
(1) To participate in: (a) The development or revision of community or EMS burn treatment protocols; or (b) Representation on a State or local EMS committee; and	Required	Required
(2) At least one of the following: (a) Annual participation in one or more prehospital training / certification courses in burn care which can be met by prehospital basic life support or advanced life support courses or equivalent courses; (b) Annual development or presentation of acute burn care courses or lectures which can be met by prehospital basic life support or advanced life support courses or equivalent courses; or (c) Participation in a burn prevention program.		

.06 Burn Service Physician Coverage.

A burn service shall:

A. Have at least one full-time equivalent (FTE) attending staff surgeon involved in the management of burn patients for each of 200 acute inpatient admissions annually;

B. Have an attending staff surgeon available on-call within 30 minutes, 24 hours a day;

C. Have a physician with privileges appropriate for the burn unit:

(1) Assigned to the burn service, and

(2) Available within 15 minutes, 24 hours a day;

D. Maintain an on-call schedule for residents and attending staff surgeons who are assigned to the burn service;

E. Have the following surgical specialists on-call and available for consultation within 30 minutes:

(1) General surgery,
(2) Cardiothoracic surgery,
(3) Neurologic surgery,
(4) Obstetrics / gynecology,
(5) Ophthalmology,
(6) Orthopedic surgery,
(7) Otorhinolaryngology,
(8) Plastic surgery, and
(9) Urology;

F. Have the following nonsurgical specialists on-call and available for consultation within 30 minutes:

(1) Anesthesiology,
(2) Pediatrics,
(3) Psychiatry,
(4) Pulmonology, and
(5) Radiology; and

G. Have the following nonsurgical specialists available on-call:

(1) Cardiology,
(2) Gastroenterology,
(3) Hematology,
(4) Infectious disease,
(5) Nephrology,
(6) Neurology,
(7) Pathology, and
(8) Physiatry.

.07 Nursing Personnel.

A. Nurse Manager.

(1) A burn center shall have a nurse manager who is administratively responsible for the burn unit.

(2) A nurse manager shall:

(a) Be a registered nurse;

(b) Have either a:

(i) Baccalaureate or higher degree in nursing, or

(ii) Diploma and 2 or more years of experience as nurse manager of a burn unit; and

(c) Have at least two of the following qualifications:

(i) 12 months or more of experience in acute burn care,

(ii) 2 years or more of experience in intensive care unit or equivalent training,

(iii) 6 months or more managerial experience.

(3) A burn center shall have an organizational chart relating the nurse manager to the burn service and other members of the burn team.

B. Nursing Staff. A burn center shall:

(1) Have a patient classification system to determine:

(a) Nurse staffing for each patient in the burn unit, and

(b) Daily staffing needs;

(2) Have a burn unit orientation program that documents nursing competencies specific to care and treatment of burn patients including critical care, wound care, and rehabilitation;

(3) Require each new staff nurse hired for the burn unit to complete the orientation program before assuming independent practice in the burn unit; and

(4) Provide burn center staff nurses with a minimum of two burn-related continuing education opportunities annually.

.08 Rehabilitation Personnel.

A burn center shall:

A. Have a rehabilitation program designed for the burn patient that identifies specific goals;

B. Require physical and occupational therapists to be appropriately licensed or registered in their specific disciplines;

C. Base staffing upon both inpatient and outpatient activity with at least one full-time equivalent (FTE) burn therapist for the burn unit;

D. Assign a therapist to the burn center for both inpatients and outpatients, either:

(1) Permanently, or

(2) On a rotating basis for at least 1 year;

E. Provide therapists with regular supervision from individuals with at least 1 year of experience in the treatment of burn patients;

F. Provide a competency-based burn therapy orientation program for all new therapists assigned to the burn unit; and

G. Provide burn unit therapists with a minimum of one burn-related continuing education opportunity annually.

.09 Other Personnel.

A. A burn center may use appropriately credentialed physician extenders as members of the burn team, including:

(1) Physician assistants;

(2) Surgical assistants; or

(3) Nurse practitioners.

B. A burn center shall:

(1) Have social service consultation available to the burn service; and

(2) Assign a social worker to the burn center for both inpatients and outpatients, either:

(a) Permanently, or

(b) On a rotating basis for at least 1 year.

C. A burn center shall have a dietitian available daily for consultation.

D. A burn center shall have the following personnel available 24 hours a day:

(1) A pharmacist who has at least 6 months of experience in:

(a) Critical care, and

(b) The pharmacokinetics of patients with acute burn injuries;

(2) A respiratory therapist to assess and manage patients on the burn service; and

(3) A psychiatrist or clinical psychologist for consultation.

.10 Quality Management Program.

A. Policies and Procedures.

(1) A burn service shall have a quality management program that is multidisciplinary.

(2) A burn center director is responsible for the quality management program.

(3) A burn unit multidisciplinary committee shall:

(a) Oversee the quality management program;

(b) Meet at least quarterly; and

(c) Maintain sufficient documentation to:

(i) Verify problems,

(ii) Identify opportunities for improvement,

(iii) Take corrective actions, and

(iv) Resolve problems.

B. Weekly Patient Care Conferences.

(1) A burn center hospital shall hold patient care conferences at least weekly to review and evaluate the status of each patient admitted to the burn center.

(2) Each clinical discipline shall be represented to appropriately contribute to the treatment plan for each patient.

(3) Patient care conferences shall be documented in the progress notes of each patient or in minutes of the conferences.

C. A burn center hospital shall:

(1) Hold morbidity and mortality conferences at least monthly; and

(2) Maintain appropriate documentation of morbidity and mortality conferences.

D. A burn service shall conduct audits at least annually that shall include:

(1) Severity of burns;

(2) Mortality;

(3) Incidence of complications;

(4) Length of hospitalizations; and

(5) Hospital charges for care.

.11 Other Programs.

A. Educational Program.

(1) A burn center shall have an educational program for the medical staff.

(2) If residents rotate on the burn service, a burn service director or the director's designee shall provide an orientation program for new residents.

B. Infection Control Program.

(1) A burn center shall have effective means of isolation that are consistent with principles of universal precautions and barrier techniques to decrease the risk of cross-infection and cross-contamination.

(2) A burn center shall:

(a) Provide ongoing review and analysis of nosocomial infection data and risk factors that relate to infection prevention and control for burn patients; and

(b) Make these data available to the burn service in order to assess infection risk for burn unit patients.

C. Continuity of Care Program. A burn center shall provide the following services, if needed:

(1) Recreational therapy;

(2) Education in rehabilitation;

(3) Support for family members or other significant persons;

(4) Coordinated discharge planning;

(5) Follow-up after hospital discharge;

(6) Access to community resources;

(7) Evaluation of the patient's physical, psychological, developmental, and vocational status; and

(8) Planning for future rehabilitative and reconstructive needs.

D. Burn Prevention Program. A burn center shall participate regularly in public burn awareness and prevention programs.

E. Research Program. A burn center shall participate in basic, clinical, or health sciences research.

.12 Equipment.

A burn unit shall have:

A. At least four burn unit beds with critical care capability;

B. The following equipment in the burn center:

(1) Weight measurement devices;

(2) Cardiac emergency carts with age-appropriate equipment; and

(3) Temperature control devices for:

(a) The patient,

(b) Intravenous fluids, and

(c) Blood products.

.13 Other Services.

A burn center hospital shall have available the following services for burn patients 24 hours a day:

A. Renal dialysis;

B. Radiographs;

C. Angiography;

D. Ultrasonography;

E. Nuclear medicine scanning;

F. CT scanning;

G. Clinical laboratory services; and

H. Blood bank services.

.14 Operating Suites.

A burn center hospital shall have an operating room available to the burn service 24 hours a day.

.15 Emergency Service.

An emergency department shall have written protocols for the care of acutely burned patients that are consistent with the burn service treatment protocols.

.16 Allograft Service.

A burn center hospital shall:

A. Maintain a written policy stating:

(1) That allograft tissues are to be obtained only from those tissue banks that adhere to the standards of the American Association of Tissue Banks, if applicable, and

(2) Compliance with U.S. Food and Drug Administration regulations published in 21 CFR §§1270.1 — 1270.15);

B. Maintain policies governing the handling and storage of human skin allograft, if a burn center hospital handles or stores human skin allograft;

C. Develop and implement policies and procedures related to obtaining and storing homograft and heterograft skin, if the use of biological membranes is a component of care provided by the burn center;

D. Maintain documentation records indefinitely;

E. Maintain written documentation of all allograft transplants including:

(1) The name of the tissue bank providing the tissue,

(2) The donor identification number,

(3) The recipient identification number,

(4) Documentation of storage conditions,

(5) The date of allograft transplantation and site of application,

(6) The name of the surgeon utilizing the allograft,

(7) Disposition of all allograft tissues received from the tissue bank, and

(8) Reports of any adverse reactions related to allograft skin transplantation;

F. Maintain a policy and documentation of the notification of the recipients and the tissue bank in the event of an adverse event arising from the use of allograft;

G. Name an individual to verify and oversee all functions relating to the handling and storage of human allograft skin;

H. Obtain informed consent from the recipient or appropriate legal representative before the use or transplantation of human allograft skin; and

I. Maintain a policy for the proper disposal of all unused or expired human allograft skin in order to minimize any hazards to the hospital staff or the environment.

.17 Burn Center Referral Criteria.

A burn injury requiring referral to a burn center includes:

A. A second and third degree burn greater than 10 percent total body surface area (TBSA) in patients younger than 10 years old or 50 years old or older;

B. A second and third degree burn greater than 20 percent TBSA in other age groups;

C. A second and third degree burn that involves the face, hands, feet, genitalia, perineum, and major joints;

D. A third degree burn greater than 5 percent TBSA in any age group;

E. An electrical burn including lightning injury;

F. A chemical burn;

G. An inhalation injury;

H. A burn injury in patients with preexisting medical disorders that could:

(1) Complicate management,

(2) Prolong recovery, or

(3) Affect mortality;

I. A burn injury with concomitant trauma, such as a fracture, in which the burn injury poses the greatest risk of morbidity or mortality in accordance with the following considerations:

(1) If the trauma poses the greater immediate risk, the patient may be treated initially in a trauma center until stable before being transferred to a burn center, and

(2) Physician judgment is necessary in these situations and shall be in concert with the regional medical control plan and triage protocols;

J. Burns in children when the current hospital lacks the qualified personnel or equipment for the care of children with burns; and

K. A burn injury in patients who will require special social, emotional, or long-term rehabilitative support including cases involving suspected child abuse or substance abuse.

30.08.12 Perinatal/Neonatal Center Standards

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "E" means the standard is essential.

(2) "O" means the standard is optional.

(3) "NA" means the standard does not apply.

.02 Types of Perinatal Centers.

A. "III" is a Level III perinatal center.

B. "III+" is a Level III+ perinatal center.

C. "IV" is a Level IV perinatal center.

	III	III+	IV
.03 Organization.			
A. A hospital's board of directors, administration, and medical and nursing staffs shall demonstrate commitment to the hospital's specific level of perinatal center designation and to the care of perinatal patients by:			
(1) A board of director's resolution stating that the hospital agrees to meet the perinatal standards for the hospital's specific level of designation;	E	E	E
(2) Participation in the Statewide perinatal system, as defined in this chapter, including submission of patient care data to the Institute and the Department of Health and Mental Hygiene for system and quality management;	E	E	E
(3) Assuring that all perinatal patients will receive medical care commensurate with the level of the hospital's designation; and	E	E	E
(4) Bylaws, contracts, and budgets specific to the perinatal program, indicating the hospital's commitment to the financial, human, and physical resources necessary to support the hospital's specific level of perinatal center designation.	E	E	E
B. A hospital shall be licensed by the Department of Health and Mental Hygiene as an acute care hospital.	E	E	E
C. A hospital shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations.	E	E	E
D. A hospital shall have:			
(1) A certificate of need for its neonatal intensive care unit, issued by the Health Resources Planning Commission; or	E	E	E
(2) An exemption from the requirement for a certificate of need granted by the Health Resources Planning Commission.			
E. A hospital shall maintain current equipment and technology to support optimal perinatal care for the level of the hospital's perinatal center designation.	E	E	E
F. If maternal and neonatal air transports are accepted, a hospital shall have a heliport or helipad positioned at the closest, safe location to the hospital or access to a helicopter landing site near the hospital.	E	E	NA
G. A hospital shall have a heliport or helipad positioned at the closest, safe location to the hospital or access to a helicopter landing site near the hospital.	NA	NA	E
.04 Obstetrical Unit Capabilities.			
A hospital shall:			
A. Demonstrate its capability of providing complicated and uncomplicated obstetrical care through written standards or protocols for:			
(1) Unexpected obstetrical care problems;	E	E	E
(2) Performing a cesarean delivery within 15 minutes;	E	E	E
(3) Fetal monitoring, including internal scalp electrode monitoring; and	E	E	E
(4) Either:			
(a) Selection of only those high-risk obstetrical patients that it can manage, or	E	E	NA
(b) Management of all high-risk obstetrical patients;	O	O	E
B. Demonstrate its capability to provide critical care services appropriate for obstetrical patients;	O	O	E
C. Have a written plan for initiating maternal transports to the appropriate higher level of care;	E	E	NA
D. Have a written protocol for the acceptance of maternal transports from other institutions; and	E	E	E
E. Have approval for an accredited maternal-fetal medicine fellowship program.	O	O	E
.05 Nursery Unit Capabilities.			
A hospital shall:			
A. Demonstrate its capability to provide complicated and uncomplicated neonatal care through written standards, guidelines, or protocols for:			
(1) Resuscitation and stabilization of unexpected neonatal problems; and	E	E	E
(2) Either:			

	III	III+	IV
(a) Selection of only those high-risk neonatal patients that it can manage, or	E	E	NA
(b) Management of all neonatal patients, including those requiring pediatric cardiothoracic surgery and surgery for complex congenital defects, except extracorporeal membrane oxygenation;	O	O	E
B. Have geographic proximity to a Level IV perinatal center so that patients requiring Level IV services may be transported in less than 30 minutes by non-emergency transport;	O	E	NA
C. Provide a full range of genetic diagnostic services for family, fetus, and infant; and	O	O	E
D. Have approval for an accredited neonatology fellowship program.	O	O	E
.06 Obstetrical Personnel.			
A. A hospital shall have a:	E	E	E
Physician board certified in maternal fetal medicine on staff who shall be responsible for obstetrical services; and	E	E	E
B. Board-eligible or board-certified obstetrician present in-house 24 hours a day.			
.07 Neonatal Personnel.			
A hospital shall have:	E	E	E
A. A physician board certified in neonatology on staff who shall be responsible for nursery services;	E	E	E
B. A pediatrician, pediatric resident, or neonatal nurse practitioner present in-house 24 hours a day and assigned to the delivery area or the nursery, or both, but not shared with other units in the hospital;	E	E	E
C. A board-certified neonatologist present within 30 minutes, if needed;	E	E	NA
D. Written pediatric surgery and pediatric cardiology consultation and transfer agreements in place; and	O	O	E
E. Pediatric medical and surgical subspecialists on staff and present within 30 minutes, if needed, including:			
(1) Cardiology,			
(2) Neurology,			
(3) Hematology,			
(4) Genetics,			
(5) Cardiothoracic surgery, and			
(6) Neurosurgery.			
.08 Other Personnel.			
A hospital shall have:	E	E	E
A. A board-certified anesthesiologist skilled in obstetrical anesthesia present in-house 24 hours a day;	E	E	NA
B. If the hospital performs neonatal surgery, a board-certified anesthesiologist skilled in neonatal anesthesia present during surgery;	O	O	E
C. A board-certified anesthesiologist skilled in neonatal anesthesia present in-house 24 hours a day;	O	O	E
D. A radiologist on staff capable of providing invasive radiology services;	O	O	E
E. An obstetric and pediatric sonologist on staff;	E	E	E
F. A perinatal social worker on staff;	E	E	E
G. A registered dietitian with knowledge of parenteral and enteral management of high-risk obstetrical and neonatal patients;	E	E	E
H. A respiratory therapist skilled in neonatal ventilator management present in-house 24 hours a day;	E	E	E
I. An American College of Medical Genetics eligible or certified genetics counselor available;	E	E	E
J. A pediatric neurodevelopmental follow-up program or written referral arrangement for neurodevelopmental follow-up;	E	E	E
K. Registered nurses with advanced degrees and experience in high-risk obstetric and neonatal nursing; and	E	E	E
L. A written plan for assuring nurse-to-patient ratios as follows:			
(1) One nurse for each patient, for all obstetric patients:			
(a) Receiving antepartum testing,			
(b) In the second stage of labor,			

	III	III+	IV
(c) With any medical or obstetrical complications,			
(d) During initiation of epidural anesthesia, or			
(e) During cesarean delivery;			
(2) One nurse for every two patients, for all obstetric patients:			
(a) Receiving labor augmentation or oxytocin induction, or			
(b) Who are postoperative recovery patients;			
(3) One nurse for each neonatal patient requiring multisystem support; and			
(4) More than one nurse for each neonatal patient requiring complex critical care.			
.09 Laboratory.			
A hospital shall have:			
A. A laboratory capable of reporting:	E	E	E
(1) Hematocrit, serum glucose, and blood gas within 15 minutes,			
(2) Fetal scalp pH within 5 minutes,			
(3) CBC, platelets, micro blood chemistries, blood type and match, Coombs, and bacterial smear results and coagulation studies within 1 hour,			
(4) Amniotic fluid tests, lecithin-sphyngomyelin ratio, or phosphatidylglycerol within 6 hours,			
(5) Serum magnesium and urine electrolytes within 6 hours,			
(6) Hepatitis B surface antigen within 12 hours, and			
(7) Bacterial culture and sensitivity within 48 hours;			
B. Blood bank technicians present in-house 24 hours a day; and	E	E	E
C. Molecular, cytogenetic, and biochemical genetic laboratory capabilities readily available.	O	O	E
.10 Radiology/Ultrasound.			
A hospital shall have:			
A. Portable ultrasound equipment present in the delivery area;	E	E	E
B. Portable X-rays available to the nursery 24 hours a day;	E	E	E
C. Portable head ultrasound available to the nursery;	E	E	E
D. Physician interpretation of X-rays and sonograms available 24 hours a day;	E	E	E
E. Computed tomography or magnetic resonance imaging available in-house;	E	E	E
F. Neonatal echocardiography available in-house;	E	E	E
G. A neonatal cardiac catheterization laboratory and appropriate staff; and	O	O	E
H. Equipment for performing invasive radiology services.	O	O	E
.11 Equipment.			
The hospital shall have:			
A. A NICU bed setup and equipment available at all times for an emergency admission;	E	E	E
B. A micro pH meter immediately available to the delivery area;	E	E	E
C. Fetal diagnostic testing and monitoring equipment for non-stress and stress testing, amniocentesis, and ultrasound examinations;	E	E	E
D. Intravasular blood pressure monitors for neonates;	E	E	E
E. Laser coagulation capability;	E	E	E
F. A full range of invasive maternal monitoring available to the delivery area, including equipment for central venous pressure and arterial monitoring; and	E	E	E
G. High frequency oscillatory ventilation capability.	O	O	E
.12 Medications.			
A hospital shall have:	E	E	E
A. All neonatal resuscitation medications present in the nursery and in the delivery area;			
B. Surfactant and prostaglandin E1 immediately available to the nursery;			
C. All emergency resuscitation medications present in the delivery area; and			
D. The following medications in the delivery area or immediately available to the delivery area:			
(1) Oxytocin,			

	III	III+	IV
(2) Methergine, and			
(3) Prostin/15M.			
.13 Continuing Education Programs.	E	E	E
A hospital shall:			
A. Provide periodic continuing education programs for physicians, nurses, and allied health personnel on staff concerning the treatment and care of obstetrical patients; and			
B. Participate in perinatal case review and provide continuing education programs for referral hospitals.			
.14 Prevention/Public Education.	E	E	E
A hospital shall collaborate with the Department of Health and Mental Hygiene in:			
A. Developing and providing infant mortality prevention and public education programs; and			
B. Monitoring and evaluating the effectiveness of infant mortality prevention and public education programs.			
.15 Quality Management.	E	E	E
A hospital shall:			
A. Have a multidisciplinary continuous quality improvement program for improving maternal and neonatal outcomes;			
B. Conduct perinatal case reviews which include an audit of:			
(1) All maternal, fetal, and neonatal deaths,			
(2) All very low birth weight births, and			
(3) All maternal and neonatal transports;			
C. At an appropriate multidisciplinary forum, periodically review the performance of the perinatal program, including:			
(1) Trends,			
(2) All deaths,			
(3) All transfers,			
(4) Problem identification and solution,			
(5) Issues identified from the quality management process, and			
(6) Other perinatal system issues; and			
D. Provide documentation of quality management efforts including:			
(1) Problem identification,			
(2) Analysis,			
(3) Action plan,			
(4) Implementation, and			
(5) Reevaluation.			
.16 Policies, Protocols, Guidelines, and Agreements.			
A hospital shall have:			
A. Written policies and protocols for the care of:	E	E	E
(1) Only those obstetrical patients at 26 or more weeks of gestation, or	NA	E	E
(2) All obstetrical patients regardless of gestation;	E	E	E
B. Written policies and protocols for the care of:			
(1) Only those neonatal patients of 800 or more grams birth weight, or	NA	E	E
(2) All neonatal patients regardless of birth weight;	E	E	E
C. Maternal and neonatal resuscitation protocols;	E	E	E
D. Written guidelines for the return transport of stabilized maternal and neonatal patients to the referring hospital or a hospital closer to the patient's home; and	E	E	E
E. Either:			
(1) A licensed neonatal transport service that may not refuse to transport a patient to that hospital based on race, color, religion, sex, national origin, ancestry, or the inability to pay, or			
(2) A written agreement with a licensed neonatal transport service that includes a policy stating that the service may not refuse to transport a patient to that hospital based on race, color, religion, sex, national origin, ancestry, or the inability to pay.			

30.08.13 Disciplinary Action for Violation of Subtitle

.01 Grounds for Disciplinary Action.

The Institute may take disciplinary action against a designated trauma or specialty center if the trauma or specialty center:

A. Is out of compliance with the requirements of this subtitle, and has been unable or has refused to comply as required by the Institute;

B. Fails to comply with, or otherwise violates the provisions of, State or federal law;

C. Fails to provide data to the Institute, as required by COMAR 30.08.03.01;

D. Makes a false statement or omits a material fact in:

(1) Its application for designation,

(2) A record required by this subtitle, or

(3) A matter under investigation;

E. Prevents, interferes with, or attempts to impede in any way, the work of a representative of the Institute in the lawful enforcement of this subtitle or any other applicable State law;

F. Uses false, fraudulent, or misleading advertising, or makes any public claims regarding the center's ability to care for nontrauma or nonspecialty care patients based on its trauma or specialty center designation status; or

G. Fails to cooperate in providing documentation and interviews with appropriate staff for the Institute's investigation of complaints.

.02 Preliminary and Further Investigations.

A. Receipt of Information.

(1) The Institute shall initiate a preliminary investigation if it receives information that might form the basis for action against a trauma or specialty center.

(2) A person may file a signed, written complaint with the Office of Hospital Programs regarding an alleged violation of this subtitle.

(3) The Institute may begin an investigation without a signed written complaint if it determines that sufficient cause exists.

B. The Institute may initiate a further investigation if it needs additional information to determine whether disciplinary action is warranted.

C. Not later than 10 business days after the Institute decides to begin an investigation, the Institute shall give written notice of the investigation to the trauma or specialty center being investigated, unless extenuating circumstances exist that would reasonably preclude notification.

D. At the conclusion of the Institute's investigation, the Institute shall report its findings, in writing, to the chief executive officer of the trauma or specialty center, including requirements for corrective action, if the Institute determines that corrective action is appropriate.

.03 Confidentiality of Records of Investigation.

A. The Institute shall take reasonable precautions to ensure that an investigation is conducted in a confidential manner.

B. The Institute shall maintain a record for each designated trauma and specialty center in Maryland.

C. If the Institute begins an investigation, it shall create a confidential record containing the investigatory material, which:

(1) Is exempt from disclosure under Health Occupations Article, Title 14, Subtitle 5, Annotated Code of Maryland, and State Government Article, Title 10, Subtitle 6, Part III, Annotated Code of Maryland; and

(2) Shall be placed in the designated trauma or specialty center's official record.

D. A request for records maintained by the Institute shall be processed under Health Occupations Article, Title 14, Subtitle 5, Annotated Code of Maryland, and State Government Article, Title 10, Subtitle 6, Part III, Annotated Code of Maryland.

.04 Finding of Violation.

If the Institute finds that a trauma or specialty center has violated this subtitle, the Institute may:

A. Require a trauma or specialty center to submit a plan of corrective action;

B. Place a designated trauma or specialty center on probation;

C. Lower a trauma center's level of designation;

D. Suspend a trauma or specialty center's designation; or

E. Revoke a trauma or specialty center's designation.

.05 Plan of Corrective Action.

A. If the Institute requires a trauma or specialty center to submit a plan of corrective action, the notice required by Regulation .02D of this chapter shall include a deadline for submission of the plan of corrective action by the trauma or specialty center.

B. The plan shall include:

(1) Steps that the trauma or specialty center intends to take to correct deficiencies; and

(2) The projected date of completion.

C. Not later than 15 business days after it receives the plan, the Institute shall:

(1) Decide whether to approve the plan; and

(2) Provide written notice of its decision to the trauma or specialty center.

D. If the Institute disapproves the plan, not later than 15 business days from the date of disapproval, the trauma or specialty center may request an informal meeting in accordance with Regulation .06D of this chapter.

E. If the Institute approves the plan of correction, the trauma or specialty center shall:

(1) Begin implementation of the plan immediately upon receiving notice of approval; and

(2) Notify the Institute upon completion of the plan.

F. Review of Compliance with Plan.

(1) The Institute may conduct an on-site review to determine whether the trauma or specialty center has complied with the plan of correction.

(2) If the Institute determines that the trauma or specialty center has satisfactorily complied with the plan, the trauma or specialty center shall retain its designation status.

(3) If the Institute determines that the trauma or specialty center has not satisfactorily complied with the plan, the Institute may take further disciplinary action against the trauma or specialty center under Regulation .06 of this chapter.

.06 Procedures for Disciplinary Actions.

A. The Institute shall initiate an action to place a trauma or specialty center on probation or to lower, suspend, or revoke a trauma or specialty center's designation if the Institute:

(1) Determines that the violation warrants probation, lowered level of designation, suspension, or revocation; or

(2) Has required a plan of corrective action, and the:

(a) Trauma or specialty center fails to submit a plan within the time set by the Institute, or

(b) Institute determines that the trauma or specialty center has not satisfactorily complied with the plan.

B. Notice of Action.

(1) The Institute shall notify a trauma or specialty center of the disciplinary action by issuing a written notice of suspension, revocation, lowered level of designation, or probation to the chief executive officer of the hospital.

(2) The notice of suspension, revocation, lowered level of designation, or probation shall conform to State Government Article, §10-207, Annotated Code of Maryland.

(3) The Institute shall notify the EMS Board of the action taken.

C. Except in the case of an emergency suspension or revocation under §F of this regulation, the suspension, revocation, lowered level of designation, or probation is stayed pending the final agency decision.

D. Informal Meeting.

(1) Not later than 15 business days from the date a trauma or specialty center receives a notice of suspension, revocation, lowered level of designation, or probation, the trauma or specialty center may request, in writing, an informal meeting with the Institute to discuss the Institute's action.

(2) The meeting shall be held not later than 10 business days from the date the Institute receives the request.

(3) If the trauma or specialty center does not timely request an informal meeting, the Institute's notice of suspension, revocation, lowered level of designation, or probation is the final agency decision.

E. Request for Hearing.

(1) This section does not apply to an emergency revocation or suspension hearing under §F of this regulation.

(2) If the trauma or specialty center is not satisfied with the result of the informal meeting, not later than 15 business days from the date of the meeting, it may request a hearing by sending a written request for a hearing by certified mail, return receipt requested, addressed to the MIEMSS Office of Hospital Programs in Baltimore, Maryland.

(3) Not later than 5 business days from the date of receipt of a timely request for a hearing, the Institute shall forward the request to OAH.

(4) From the date OAH receives the hearing request, OAH shall schedule a hearing as soon as practicable for all parties and OAH, but not later than:

(a) 60 calendar days for temporary suspensions or revocations; or

(b) 90 calendar days for all other hearings.

(5) The hearing is conducted in accordance with the procedures set forth in §G of this regulation.

(6) If the trauma or specialty center does not request a hearing in a timely manner, the Institute's notice of suspension, revocation, lowered level of designation, or probation is the final agency decision.

F. Emergency Revocation or Suspension.

(1) If the Institute determines that grounds exist that require immediate suspension or revocation of designation for the public's protection, the Institute may issue a notice of immediate suspension or revocation of designation to the chief executive officer of the trauma or specialty center.

(2) The suspension or revocation of designation is effective immediately upon service of the notice of immediate suspension or revocation of designation.

(3) Request for Hearing.

(a) Not later than 15 business days after service of the notice of immediate suspension or revocation of designation, the trauma or specialty center may request a hearing by sending a written request for a hearing by certified mail, return receipt requested, addressed to the MIEMSS Office of Hospital Programs in Baltimore, Maryland.

(b) Requesting a hearing does not negate, or act as a stay of, the suspension or revocation.

(c) If the trauma or specialty center does not request a hearing in a timely manner, the Institute's notice of immediate suspension or revocation of designation is the final agency decision.

(4) Upon receipt of a hearing request, the Institute shall send a written request to OAH to schedule a hearing.

(5) OAH shall conduct the hearing within 10 business days of the date it receives the hearing request, except that the time period may be extended by:

(a) OAH for good cause; or

(b) Agreement of the trauma or specialty center and the Institute.

(6) Except as modified in this section, the hearing shall be conducted in accordance with the procedures set forth in §G of this regulation.

(7) Not later than 10 business days after the close of the hearing record, OAH shall issue a proposed decision that includes proposed findings of fact and conclusions of law and a proposed order, except that the time period may be extended by:

(a) OAH for good cause; or

(b) Agreement of the trauma or specialty center and the Institute.

(8) Appeal to the EMS Board.

(a) Filing of Exceptions.

(i) Not later than 5 business days from the date it receives the proposed decision, a party aggrieved by the proposed decision may appeal by filing written exceptions with the Executive Director, for consideration by the EMS Board.

(ii) The exceptions shall state with specificity the reasons why the proposed decision should be overturned.

(iii) A party filing exceptions may request an oral agreement and shall submit the request with the exceptions.

(iv) A party filing exceptions shall mail a copy of its exceptions to the opposing party by first class mail, postage prepaid.

(v) If exceptions are not filed within the specified time period, the OAH proposed decision is the final agency decision.

(b) Response to Exceptions.

(i) Not later than 5 business days after the opposing party receives a copy of the exceptions, the opposing party may file a response with the EMS Board.

(ii) A party filing a response may request an oral argument and shall submit the request with the response.

(iii) A party filing a response shall mail a copy of its response to the party filing exceptions by first class mail, postage prepaid.

(c) Decision of EMS Board.

(i) Not later than 30 calendar days after the filing of the exceptions or the response, whichever is later, the EMS Board shall issue a written decision granting or denying the exceptions.

(ii) The EMS Board may, in its discretion, rule on the exceptions with or without oral argument.

(d) If the EMS Board denies the exceptions, the proposed decision, as affirmed by the EMS Board, is the final agency decision.

(e) If the EMS Board grants the exceptions, in whole or in part, the EMS Board shall modify the proposed decision accordingly and the modified decision is the final agency decision.

(f) The EMS Board shall issue its final decision in accordance with State Government Article, §§10-220 and 10-221, Annotated Code of Maryland.

(9) A party aggrieved by a final agency decision may seek judicial review in accordance with State Government Article, §10-222, Annotated Code of Maryland, and the Maryland Rules of Civil Procedure.

G. Hearing Procedures.

(1) A hearing shall be conducted in accordance with the procedures and regulations of OAH set forth in COMAR 28.02.01, except as modified by this regulation.

(2) Confidential Materials Not Discoverable.

(a) In addition to the restrictions on discovery of documents under COMAR 28.02.01.10, a party is not entitled to discovery of any confidential:

(i) Record;

(ii) File;

(iii) Memorandum;

(iv) Correspondence;

(v) Document;

(vi) Object; or

(vii) Other tangible thing.

(b) For purposes of this regulation, all records, files, memoranda, correspondence, documents, objects, other tangible things, notes, minutes of conferences, and any other communications of members of an on-site review team are confidential.

(c) This subsection does not restrict the rights of:

(i) The Institute to obtain any information to which it is entitled under this subtitle; and

(ii) A hospital to information originating from the hospital's files.

(3) In a proceeding before an administrative law judge or a court:

(a) The Institute may disclose information or present evidence that contains or might reveal confidential information if the information is relevant to the case; and

(b) If there is an objection, before the information is disclosed, the administrative law judge or court that is conducting the proceeding shall determine whether the information is confidential and, if it is, enter an order that it determines is appropriate to protect the confidentiality of the information.

(4) The Institute has the burden of proving, by a preponderance of the evidence, the grounds for suspension, revocation, lowered level of designation, or probation.

(5) Except for an emergency suspension or revocation under §F of this regulation, not later than 60 business days after the close of the hearing, OAH shall issue a proposed decision that shall include proposed findings of fact and conclusions of law and a proposed order.

H. Appeal to the EMS Board.

(1) This section does not apply to an emergency revocation or suspension under §F of this regulation.

(2) Filing of Exceptions.

(a) Not later than 15 business days from the date it receives the proposed decision, a party aggrieved by the proposed decision may appeal by filing written exceptions with the Executive Director, for consideration by the EMS Board.

(b) The exceptions shall state with specificity the reasons why the proposed decision should be overturned.

(c) A party filing exceptions may request an oral argument and shall submit the request with the exceptions.

(d) A party filing exceptions shall mail a copy of its exceptions to the opposing party by first class mail, postage prepaid.

(e) If exceptions are not filed within the specified time period, the proposed decision is the final agency decision.

(f) Response to Exceptions.

(i) Not later than 15 business days from the date of the filing of the exceptions with the EMS Board, the opposing party may file a response with the EMS Board.

(ii) A party filing a response may request an oral argument and shall submit the request with the response.

(iii) A party filing a response shall mail a copy of its response to the party filing exceptions by first class mail, postage prepaid.

(3) Decision of EMS Board.

(a) The EMS Board may, in its discretion, rule on the exceptions with or without oral argument.

(b) If the EMS Board denies the exceptions, in whole or in part, the proposed decision is the final agency decision.

(c) If the EMS Board grants the exceptions, the EMS Board shall modify the proposed decision accordingly and the modified decision is the final agency decision.

(d) The EMS Board shall issue its final decision in accordance with State Government Article, §§10-220 and 10-221, Annotated Code of Maryland.

I. A party aggrieved by a final agency decision of the EMS Board may seek judicial review in accordance with State Government Article, §10-222, Annotated Code of Maryland, and the Maryland Rules of Civil Procedure.

ROBERT R. BASS, M.D.
Executive Director
MIEMSS
