California Trauma Regulations (Title 22) versus
ACS RESOURCES FOR OPTIMAL CARE OF THE INJURED PATIENT 2014 (Orange Book)

(Level IV Trauma Centers only)

Key: Bold/Underlined are Type I Level IV ACS criteria

Requirement	TITLE 22	ACS ORANGE BOOK®
Requirements of a Level IV Trauma Center	*Section 100264*: • Designated by the Local EMS Agency as a Level IV trauma center • Have equipment and resources necessary for initial stabilization • Have personnel knowledgeable in the treatment of adult and pediatric trauma *Section 100264 (c)* "A service which can provide for the implementation of the requirements specified in this section and provide for coordination with the Local EMS Agency (LEMSA)" *(Intent system in place)* *H&S Code Division 2.5 (1798.101 statute)* (2) A local EMS agency which utilizes in its EMS system any facility which does not have a special permit to receive patients requiring emergency medical care pursuant to paragraph (1) shall submit to the authority, as part of the plan required by 1797.254 (annual submission of EMS Plan), protocols approved by the medical director of the local EMS agency to ensure that the use of that facility is in the best interests of patient care. The protocols addressing patient safety and the use of the non-permit facility shall take into account, but not be limited to, the following:	ACS CD 5-1 **TYPE I**: **A decision by a hospital to become a trauma center requires the commitment of the institutional governing body and the medical staff. Documentation of administrative commitment is required from the governing body and the medical staff.** ACS CD 1-1 TYPE II: *Chapter 1*:The individual trauma centers and their health care providers are essential system resources that must be active and engaged participants ACS CD 1-1 TYPE II: *Chapter 13*: The best possible care for patients must be achieved with a cooperative and inclusive program that clearly defines the role of each facility within the system ACS CD 1-2 TYPE II: They must function in a way that pushes trauma center based standardization, integration and PIPS out to the region while engaging in inclusive trauma system planning and development ACS CD 1-3 TYPE II: Meaningful involvement in state and regional trauma system planning, development and operation is essential for all designated trauma centers and participating acute care facilities within a region

	(A) The medical staff, and the availability of the staff at various times to care for patients requiring emergency medical services. (B) The ability of staff to care for the degree and severity of patient injuries. (C) The equipment and services available at the facility necessary to care for patients requiring emergency medical services and the severity of their injuries. (D) The availability of more comprehensive emergency medical services and the distance and travel time necessary to make the alternative emergency medical services available. (E) The time of day and any limitations which may apply for a non-permit facility to treat patients requiring emergency medical services. (3) Any change in the status of a non-permit facility, authorized pursuant to this subdivision to care for patients requiring emergency medical services, with respect to protocols and the facility's ability to care for the patients shall be reported by the facility to the local EMS agency. *Section 100264 (d)* The capability of providing prompt assessment, resuscitation and stabilization to trauma patients *Section 100264 (e)* The ability to provide treatment or arrange transportation to higher level trauma center as appropriate *Section 100264 (f)* An emergency department, division, service or section staffed so that trauma patients are assured of immediate and appropriate initial care *Section 100264 (g)* A multidisciplinary trauma team responsible for the initial resuscitation and management of the trauma patient	**ACS CD 2-1 TYPE I: Must have an integrated, concurrent performance improvement and patient safety (PIPS) program to ensure optimal care and continuous improvement in care** ACS CD 2-3 TYPE II: Must be able to provide necessary human and physical resources (physical plant and equipment) to properly administer acute care consistent with level of verification **ACS CD 2-8 TYPE I: The physician or mid-level provider will be in the ED on patient arrival, with adequate notification from the field. Maximum acceptable response time is 30 minutes for the highest level activation (tracked from patient's arrival). PIPS program must demonstrate compliance at least 80% of the time** ACS CD 2-13 TYPE II: Well-defined transfer plans are essential. Treatment and transfer guidelines reflecting Level IV capabilities must be developed & regularly reviewed with input from higher level trauma centers in the region ACS CD 2-14 TYPE II: Must have 24 hour emergency coverage by a physician or midlevel provider ACS CD 2-15 TYPE II: The ED must be continuously available for resuscitation with coverage by a Registered Nurse and physician or mid-level provider (and, it must have a physician director. ACS CD 2-16 TYPE II: (Level IV) Providers must maintain current ATLS certification as part of their competencies in trauma ***NOTE: Per 8/18/16 ACS Clarification Document: "Refer to CD 7-14 & CD 7-15" :*** ACS CD 7-14 TYPE II: All board certified emergency physicians or those eligible for certification by an appropriate emergency medicine board according to current requirements must have successfully completed the ATLS course at least once. ACS CD 7-15 TYPE II: Physicians who are certified by boards other than emergency medicine who treat trauma patients in the

	Section 100264 (j) Have written transfer agreements with Levels I, II, & III trauma centers, Level I or II pediatric trauma centers or other specialty centers for the immediate transfer of patients for whom the most appropriate medical care requires additional resources	emergency department are required to have current ATLS status. ACS CD 2-17 TYPE II: A trauma medical director (and trauma program manager) knowledgeable and involved in trauma care must work together with guidance from the trauma peer review committee to identify events, develop corrective action plans and ensure methods of monitoring, reevaluation and benchmarking. The Level IV TMD may be an ED physician *(Also listed under TMD, but is a requirement of the Level IV center)* ACS CD 2-18 TYPE II: Must have a multi-disciplinary trauma peer review committee that meets regularly, required attendance of medical staff active in trauma resuscitation, to review systemic and care provider issues, as well as propose improvements to the care of the injured ACS CD 2-19 TYPE II: Must have a PIPS program with audit filters to review and improve pediatric and adult patient care ACS CD 2-20 TYPE II: Must actively participate in regional and statewide trauma system meetings and committees that provide oversight ACS CD 2-21 TYPE II: Must be the local trauma authority and assume the responsibility for providing training for prehospital and hospital-based providers ACS CD 2-22 TYPE II: The facility must participate in regional disaster management plans and exercises

Trauma Medical Director	*(Section 100264)* A trauma program medical director is a qualified specialist whose responsibilities include, but are not limited to factors that affect all aspects of trauma care, including pediatric trauma care. *(Section 100242)*: ▪ Physician licensed in CA ▪ Board certified in a specialty by the American Board of Medical Specialties *(Section 100264 (a) (1-6)* ▪ Factors that affect all aspects of adult and pediatric trauma care ▪ Recommend trauma team physician privileges ▪ Work with nursing administration to support the nursing needs of trauma patients ▪ Develop treatment protocols ▪ Have authority and accountability for the quality improvement process ▪ Correct deficiencies in trauma care, or excluding from trauma all those trauma team members who no longer meet the standards of the quality improvement program ▪ Assisting in the coordination of the Budgetary process for the trauma program	(CD 2-17 TYPE II) A trauma medical director (and trauma program manager) knowledgeable and involved in trauma care must work together with guidance from the trauma peer review committee to identify events, develop corrective action plans and ensure methods of monitoring, reevaluation and benchmarking. The Level IV TMD may be an ED physician Annual review, by the TMD, for: Appropriate orientation, credentialing processes and skill maintenance for advanced practitioners (CD 11-87 TYPE II) *(Under "Collaborative Clinical Services", ch 11)*
Trauma Program Nurse Coordinator / Manager	*Section 100264 (b) (1-3):* Registered Nurse with evidence of education preparation and clinical experience in the care of the adult and pediatric trauma patient, administrative responsibilities. The following responsibilities include, but are not limited to: ▪ Organize services and systems necessary for multidisciplinary approach to the care of	(CD 2-17 TYPE II): A trauma program manager (and trauma medical director) knowledgeable and involved in trauma care must work together with guidance from the trauma peer review committee to identify events, develop corrective action plans and ensure methods of monitoring, reevaluation and benchmarking

	adult/pediatric trauma patients ▪ Coordinate day-to-day clinical process and performance improvement of nursing and ancillary personnel ▪ Collaborate with Trauma Program Medical Director to carry out educational, clinical, research, administrative and outreach activities of trauma program	
Helicopter Landing Site	*Section 100254 (c)* A local EMS agency may require trauma centers to have helicopter landing sites. If helicopter landing sites are required, then they shall be approved by the Division of Aeronautics, Department of Transportation	**NOTE:** No actual ACS CD associated with this section. However, the following information is felt to be important (Orange Book, pg 26, "Air Transportation"): ▪ Patient population defined: injured patients transported from the scene or from the transferring facility to a trauma center ▪ Criteria and procedures for requesting air medical transport should be developed and monitored as part of the trauma PIPS process ▪ A structured air medical safety program should be in place to guide prehospital personnel in establishing ▪ A safe landing site ▪ Proper loading procedures ▪ Communications with pilots and medical personnel ▪ Safe procedures in proximity to an operating helicopter ▪ Medical flight crew should have a structured air medical educational curriculum and an ongoing performance improvement program that is integrated with the **trauma system** performance improvement program.
Trauma Team Activation	*Section 100264 (d, f, g)* (d) Capability of providing prompt (defined in 100241) assessment, resuscitation and stabilization to trauma patients. (e) An emergency department, division, service or section staffed so that trauma patients are assured of immediate and appropriate initial care. (f) A trauma team, which will be a multidisciplinary team responsible for the initial resuscitation and management of the trauma patient.	**ACS CD 2-8 TYPE I: The PHYSICIAN OR MID-LEVEL PROVIDER will be in the ED on patient arrival, with adequate notification from the field. Maximum acceptable response time is 30 minutes for the highest level activation (tracked from patient's arrival). PIPS program must demonstrate compliance at least 80% of the time** (ACS CD 5-13 TYPE II) - The criteria for a graded activation must be clearly defined by the trauma center, with the highest level of activation including the six required criteria listed in Table 2

		▪ Confirmed blood pressure less than 90 mm Hg at any time in adults and age-specific hypotension in children; ▪ Gunshot wounds to the neck, chest, or abdomen or extremities proximal to the elbow/knee; ▪ Glasgow Coma Scale less than 9 with mechanism attributed to trauma; ▪ Transfer patients from other hospitals receiving blood to maintain vital signs; ▪ Intubated patients transferred from the scene, -OR – ▪ Patients who have respiratory compromise or are in need of an emergent airway ○ Includes intubated patients who are transferred from another facility with ongoing respiratory compromise (does not include patients intubated at another facility who are now stable from a respiratory standpoint) ▪ Emergency physician's discretion (ACS CD-5-15 TYPE II) – ▪ Maximum acceptable response time is 30 minutes for highest level activation, tracked from patient arrival. ▪ "In Level IV trauma centers THE TEAM must be fully assembled within 30 minutes". (ACS CD-5-16 TYPE II) – Other potential criteria for trauma team activation that have been determined by the trauma program to be included in the various levels of trauma activation must be evaluated on an ongoing basis in the PIPS process to determine their positive predictive value in identifying patients who require the resources of the full trauma team
Radiology Services	*(Section 100264 h (1))* Radiological Services: *The radiological service shall have a radiological technician promptly available*	**(ACS CD 11-29 TYPE I): Conventional radiography must be available 24 hours per day**

Laboratory Services	*(Section 100264 h. (2))* Clinical Laboratory Services: ▪ Comprehensive blood bank or access to a community central blood bank ▪ Clinical laboratory services immediately available	**(CD 11-80 TYPE I): Laboratory services must be available 24 hours per day for the standard analyses of blood, urine and other body fluids, including micro-sampling when appropriate** **(CD 11-81 TYPE I): The blood bank must be capable of blood typing and cross-matching** **(CD 11-84 TYPE I): Must have a massive transfusion protocol developed collaboratively between the trauma service and the blood bank**
Transfer	*Section 100264 (e)* Ability to provide treatment or arrange transportation to higher level trauma center as appropriate *Section 100264 (i)* Written transfer agreements with Level I, II, III trauma centers, Level I or II pediatric trauma centers or other specialty care centers, for the immediate transfer of those patients for whom the most appropriate medical care requires additional resources *Section 10026 (a)* *(a)* Patients may be transferred between and from trauma centers providing that: (1) Any transfer shall be, as determined by the trauma center surgeon of record, medically prudent; and (2) In accordance with Local EMS Agency inter-facility transfer policies	(ACS CD 2-13 TYPE II)-*Chapter 2* (Description of Trauma Centers…..) Collaborative treatment and transfer guidelines reflecting the Level IV facilities' capabilities must be developed and regularly reviewed with input from higher level trauma centers in the region (ACS CD 2-13 TYPE II)-*Chapter 2* - Well-defined transfer plans are essential (ACS CD 2-13 TYPE II)-*Chapter 13* (Rural Trauma Care) Transfer guidelines and agreements between facilities are crucial and must be developed after evaluating the capabilities of the rural hospitals and medical transport agencies (ACS CD 4-1 TYPE II)-Direct physician to physician contact is essential (ACS CD 4-3 TYPE II)-Perform a PIPS review of all transfers (ACS CD 14-1 TYPE II) – Trauma centers that refer burn patients to a designated burn center must have in place written transfer agreements with the referral burn center NOTE: No actual ACS CD associated with this section. However, the following information is felt to be important (Orange Book, pg 26, "Air Transportation": ▪ Patient population: injured patients transported from the

		scene or from the transferring facility to a trauma center ▪ Criteria and procedures for requesting air medical transport should be developed and monitored as part of the trauma PIPS process ▪ A structured air medical safety program should be in place to guide prehospital personnel in establishing 1. A safe landing site 2. Proper loading procedures 3. Communications with pilots and medical personnel 4. Safe procedures in proximity to an operating helicopter • Medical flight crew should have a structured air medical educational curriculum and an ongoing performance improvement program that is integrated with the **trauma system** performance improvement program.
Trauma Registry	*(Section 100257 (a))* The local EMS agency shall develop and implement a standardized data collection instrument and implement a data management system for trauma care. *(Section 100257 (a) (1))* System shall include both prehospital and hospital data collection, as determined by the Local EMS Agency *(Section 100257 (a) (2))* Trauma data shall be integrated into the LEMSA and EMSA data management systems *(Section 100257 (a) (3))* All hospitals that receive trauma patients shall participate in the Local EMS Agency data collection effort in accordance with Local EMS Policies and Procedures	(ACS CD 15-1 TYPE II): Chapter 15 Trauma Registry): Data must be collected and analyzed by every trauma center (ACS CD 15-1 TYPE II): Chapter 13 (Rural Trauma Care): The foundation for evaluation of a trauma system is the establishment and maintenance of a trauma registry. (ACS CD 15-3 TYPE II) The trauma registry is essential to the performance improvement and patient safety (PIPS) program and must be used to support the PIPS process (ACS CD 15-4 TYPE II) These findings must be used to identify injury prevention priorities that are appropriate for local implementation (ACS CD 15-6 TYPE II) Trauma registry should be concurrent. At a minimum, 80% of cases must be entered within 60 days of discharge (ACS CD 15-8 TYPE II) Must ensure that the appropriate measures are in place to meet the confidentiality requirements of the data

	(Section 100257 (c)) The hospital data shall include at least the following, when applicable: ▪ Time of arrival and treatment in: o ED or trauma receiving area o OR ▪ Dates for: o Initial admission o Intensive Care o Discharge ▪ Discharge data including: o Total hospital charges o Destination o Discharge diagnosis o Total hospital charges o Destination o Discharge diagnosis	(ACS CD 15-10 TYPE II) Strategies for monitoring data validity are essential
Quality Improvement Process	*Section 100265* Shall have a process to include structure, process, and outcome evaluations which focus on improvement efforts to identify root causes of problems, intervene to efforts to identify root causes of problems, intervene to reduce or eliminate these causes, and take steps to correct the process, which shall include: ▪ detailed audit of all trauma related deaths ▪ major complications ▪ transfers (a) A multi-disciplinary trauma peer review committee that includes all members of the trauma team (b) participate in the trauma system data management system (c) Participation in the Local EMS Agency trauma evaluation committee	**(ACS CD 2-1 TYPE I) - Must have an integrated, concurrent Performance Improvement and Patient Safety (PIPS) Program to ensure optimal care and continuous improvement in care** **(ACS CD 5-1 TYPE I) - Because the PIPS program crosses many specialty lines, it must be empowered to address events that involve multiple disciplines and be endorsed by the hospital governing body as part of its commitment to optimal care of injured patients** **(ACS CD 5-1 TYPE I) – The TMD and the TPM must have the authority and be empowered by the hospital governing body to lead the program** (ACS CD 5-1 TYPE II) – The trauma center must demonstrate that all trauma patients can be identified for review (ACS CD 16-10 TYPE II) – Sufficient mechanisms must be available to identify events for review by the trauma PIPS program

	(d) Written system in place for patients who have specific legal needs (please refer to Title 22, Section 100265 (e) Will follow confidentiality requirements	(ACS CD 16-11 TYPE II) – Once an event id identified, the trauma PIPS program must be able to verify and validate that event (ACS CD 15-3 TYPE II) - The PIPS program must be supported by a registry and a reliable method of concurrent data collection that consistently obtains information necessary to identify opportunities for improvement (ACS CD-5-15 TYPE II) – All trauma team activations must be categorized by the level of response and quantified by number & percentage, as shown in Table 2 (ACS CD 4-3 TYPE II)- A very important aspect of inter-hospital transfer is an effective PIPS program that includes evaluating transport activities; a PIPS review of all transfers will be done. (ACS CD 16-8 TYPE II) - Transfers to a higher level of care within the institution (ACS CD 16-5 TYPE II) - All process and outcome measures must be documented within the PIPS program's written plan and reviewed / updated at least annually (ACS CD 15-1 TYPE II) - PIPS program must be supported by a reliable method of data collection that consistently obtains the information necessary to identify opportunities for improvement (ACS CD 2-17 TYPE II) - The process of event identification and levels of review must result in the development of corrective action plans and methods of monitoring, re-evaluation, benchmarking and documentation (ACS CD 2-18 TYPE II) - Peer review must occur at regular intervals to ensure that the volume of cases is reviewed in a timely fashion (ACS CD 11-60 TYPE II) –The PIPS program must document that timely and appropriate ICU care and coverage are being provided

Prevention	Not included in Title 22 for Level IV trauma centers	(ACS CD 18-1 TYPE II) Must have an organized and effective approach to injury prevention and must prioritize those efforts based on local trauma registry and epidemiology data (ACS CD 18-2 TYPE II) Must have someone in a leadership position who has injury prevention as part of his/her job description (ACS CD 18-3 TYPE II) Universal screening for alcohol use must be performed for all injured patients and must be documented. (All patients who meet ACS registry inclusion criteria with a hospital stay > 24 hours)
Education	Specific reference in Title 22 not found	(ACS Chapter 17: TYPE II) The successful completion of the **ATLS course, at least once, is required for all** general surgeons (CD 6-9), **emergency medicine physicians (CD 7-14)** and mid-level providers (CD 11-86). Advance Practice Providers (APP) who are responsible for evaluation of trauma patients in the ED, who meet activation criteria, must be current in ATLS. This would include ED and trauma APPs. Level IV physicians working in the ED must be current in ATLS (CD 2-16) ***Note: Per Clarification Document dated 8/18/16:*** ACS CD 7-14 TYPE II: All board certified emergency physicians or those eligible for certification by an appropriate emergency medicine board according to current requirements must have successfully completed the ATLS course at least once. ACS CD 7-15 TYPE II: Physicians who are certified by boards other than emergency medicine who treat trauma patients in the emergency department are required to have current ATLS status.
Continuing Education	*Section 100264 k (1-5)* Continuing Education in trauma care shall be provided for: (1) staff physicians (2) staff nurses (3) staff allied health personnel (4) EMS personnel	ACS CD 2-21 TYPE II: Must be the local trauma authority and assume the responsibility for providing training for prehospital and hospital-based providers (ACS CD 3-1 TYPE II) Must participate in the training of prehospital personnel, the development and improvement of prehospital care protocols and the performance improvement / patient safety programs

	(5) other community physicians and health care personnel	
Outreach Program	*Section 100264 (j) (1)* *Capability to provide both telephone and on-site consultations with physicians in the community and outlying areas; and* *Section 100264 (j) (2)* *Trauma prevention for the general public*	(ACS CD 17-1 TYPE II) Must engage in public and professional education
Disaster Planning	Not included in Title 22 for Level IV trauma centers	(ACS CD 20-1 TYPE II) Must meet the disaster requirements of the Joint Commission. Equivalent program may be acceptable if it follows Joint Commission structure. (ACS CD 20-3 TYPE II) Hospital drills that test the individual hospital's disaster plan must be conducted at least twice a year, including actual plan activations that can substitute for drills (ACS CD 20-4 TYPE II) Must have a hospital disaster plan descried in the hospital's policy and procedure manual or equivalent
Prehospital Care	Not included in Title 22 for Level IV trauma centers	(ACS CD 3-2 TYPE II) The protocols that guide prehospital trauma care must be established by the trauma health care team, including surgeons, emergency physicians, medical directors for EMS agencies and basic / advanced prehospital personnel (ACS CD 3-7 TYPE II) When a trauma center is required to go on bypass or to divert, the center must have a system to notify dispatch and EMS agencies) The center must do the following: ▪ Prearrange alternative destinations with transfer agreements in place ▪ Notify other centers of divert or advisory status ▪ Maintain a divert log ▪ Subject all diverts and advisories to performance improvement procedures

Trauma System Evaluation	*Section 100258 (a)* The local EMS agency shall be responsible for the development and ongoing evaluation of the trauma system. *Section 100258 (b)* The local EMS agency shall be responsible for the development of a process to receive information from EMS providers, participating hospitals and the local medical community on the evaluation of the trauma system, including but not limited to: (1) Trauma plan (2) Triage criteria (3) Activation of trauma team (4) Notification of specialists *Section 100258 (c)* The Local EMS Agency shall be responsible for periodic performance evaluation of the trauma system, which shall be conducted at least every two (2) years. Results to be made available to system participants. *Section 100258 (d)* The Local EMS Agency shall be responsible for ensuring that trauma centers and other hospitals that treat trauma patients participate in the quality improvement process.	(Trauma center verification is the process by which the ACS confirms that the hospital is performing as a trauma center and meets the criteria contained in the Resources for Optimal Care of the Injured Patient, and is required every three years to maintain verification) **** **Currently not in effect for LEVEL IV trauma facilities**
Solid Organ Procurement Activities	Not included in Title 22 for Level IV trauma centers	(ACS CD 21-3 TYPE II) – It is essential that each trauma center have written protocols defining the clinical criteria and confirmatory tests for the diagnosis of brain death