

DESIGNATION AGREEMENT
FOR TRAUMA CENTER SERVICES BETWEEN
MONTEREY COUNTY EMERGENCY MEDICAL SERVICES AGENCY AND
NATIVIDAD

This Designation Agreement is established pursuant to the California Health and Safety Code Division 2.5, Chapter 6, Article 2.5, Regional Trauma Systems, and the California Code of Regulations (CCR), Title 22, Division 9, Chapter 7, Trauma Care Systems. Natividad, referenced as "Trauma Center" , and Monterey County Emergency Medical Services Agency, referenced as the local "EMS Agency", enter into this Agreement with reference to the following:

A. TERM OF Designation Agreement :

This Designation Agreement shall be effective upon execution and continue through June 30, 2026 unless earlier terminated or otherwise extended pursuant to this Designation Agreement.

B. DEFINITIONS:

American College of Surgeons (ACS) Verification Review and Consultation (VRC)

Program: A program designed to assist hospitals in the evaluation and improvement of trauma care and provide objective, external review of institutional capability and performance.

Contract Administrators: The Designation Agreement Administrators shall be the Monterey County EMS Agency Director or his / her designee and the Natividad Chief Executive Officer or his / her designee.

Monterey County Emergency Medical Services Agency ("EMS Agency"): The Health Department's EMS Bureau, which is the local EMS Agency for Monterey County, as

designated by the Monterey County Board of Supervisors, pursuant to California Health and Safety Code, Section 1797.200.

Santa Clara County Trauma Care System Quality Improvement Executive Committee:

The Santa Clara County Emergency Medical Services Agency's committee that performs peer review trauma audits and performance reviews on trauma, trauma center and trauma systems, as required by regulations and Santa Clara County EMS Agency Policies and Procedures.

Trauma Center or Designated Trauma Center: A licensed general acute care hospital, accredited by The Joint Commission (TJC), which has been designated as a Level I, II, III, or IV trauma center and/or Level I or II pediatric trauma center by the EMS Agency in accordance with the aforementioned statutes and regulations.

Trauma Center Medical and Physician Services: Services which are customary, appropriate, and necessary during the full period of acute in-hospital care and for medically necessary outpatient care with access to appropriate follow-up visits up to 60 days after discharge. These services include medical diagnosis, treatment and care to be provided to each Critical Trauma Patient (CTP), which includes, but is not limited to, personnel, equipment, and facilities as described in the Monterey County Trauma System Plan.

Trauma Center Standards: The obligations of the Trauma Center as defined by the provisions of California Code of Regulations, Title 22, Division 9, Chapter 7, §100236 – 100266 applicable to trauma centers, and EMS Agency Policies and Procedures, the Trauma Plan, and the EMS Plan. The Policies and Procedures, Trauma Plan and the

EMS Plan shall be provided to Natividad or may be accessed on the EMS Agency's website at www.MoCOEMS.org

Major Trauma Patient: A patient who meets criteria for transport to a designated Trauma Center in the Field Triage Decision Algorithm (Monterey County EMS System Policy #4040)

Trauma Patient: A patient who meets criteria for inclusion in the Monterey County EMS Agency's Field Triage Decision Algorithm, contained in the Field Triage Criteria policy.

C. RESPONSIBILITIES OF THE EMS AGENCY:

1. To develop, implement, monitor and evaluate on an ongoing basis the county-wide trauma care system pursuant to applicable statutes, regulations, and EMS Agency Policies and Procedures.
2. To define Natividad's catchment area.
3. To develop, implement, and monitor trauma care system policies and guidelines.
4. To develop, implement, and monitor compliance of prehospital procedures including injury severity assessments and the determination of patient destinations.
5. To develop, with input from Natividad, a process to monitor, evaluate and report on the necessity, quality and level of trauma care services.
6. To perform periodic announced site visits, to monitor contract performance and compliance or other specific requirements as determined by the Monterey County EMS Agency. Site visits shall not unnecessarily interrupt Natividad's personnel.

7. To develop trauma system policies and procedures ("Policies and Procedures") which address at a minimum all policy areas set forth in California Code of Regulations, Title 22, Division 9, Chapter 7 § 100255.
8. To assure the Trauma Center's compliance with all EMS Agency Policies and Procedures, the Trauma Plan, and all state and federal regulations and statutes.
9. To maintain a Trauma Registry for the purposes of data collection, compliance, monitoring and evaluation of the trauma care system (CCR, Title 22, Chapter 7, section 100257).
10. To meet all other requirements applicable to a local EMS Agency as set forth in California Code of Regulations, Title 22, Division 9, Chapter 7, § 100236-100266.
11. The EMS Agency makes no guarantees and cannot assure any number of trauma patients delivered to Natividad during the term of this MOU.

D. RESPONSIBILITIES OF NATIVIDAD:

1. NMC shall provide Trauma Center Medical and Physician services to any adult Major Trauma Patient that comes to Natividad's emergency department, throughout the full period of emergency department and inpatient hospital care, regardless of any patient's ability to pay physician fees and/or hospital costs, unless the Major Trauma Patient is transferred in compliance with federal and state law and EMS Policies and Procedures.. To assure continuity of care, Natividad shall also provide all medically necessary outpatient visit(s), related to the trauma incident, as determined by Natividad's physicians providing treatment to the major trauma patient or arrange such visit(s) as may be required by a

patient's health plan or other applicable third-party payor; provided, however, that the Monterey County EMS Agency may, in its sole and absolute discretion and on a case by case basis, waive Natividad's obligation to provide such outpatient visit(s) or arrange such visit(s). Nothing in this Agreement shall require Natividad to provide outpatient visits to a Major Trauma Patient for more than sixty (60) days following the Major Trauma Patient's discharge. For the purposes of this agreement, the phrase "comes to the emergency department" shall have the same meaning as set forth in the Emergency Medical Treatment and Active Labor Act (42 U.S.C.§1395dd) and the regulations promulgated thereunder (EMTALA).

2. Natividad shall comply with applicable federal, state, county and local statutes, rules and regulations, ordinances, EMS Agency Policies and Procedures current and hereinafter enacted, including facility and professional licensing and/or certification laws and regulations, policies and procedures; and maintain in effect any and all licenses, permits, notices and certificates as are required. This shall include but not be limited to California Health and Safety Code, Chapter 6, Article 2.5 (commencing with Section 1798.160 et seq) and the regulations promulgated as California Code of Regulations, Title 22, Division 9, Chapter 7 and the California Evidence Code, Section 1157.7.
3. To meet the Monterey County EMS Agency Trauma Center Standards, incorporated herein by this reference. The current and future versions shall be found in the Policies and Procedures section of the EMS website www.mocoems.org.

Policy 5060 Trauma Center Standards shall be accessed at

<http://www.co.monterey.ca.us/home/showdocument?id=63243>

4. To provide the necessary medical staffing with reputable medical skills in providing trauma center services. Natividad will continuously monitor, maintain and upgrade where necessary the care, skill and diligence provided to trauma patients, so that each trauma patient receives care meeting or exceeding the Monterey County Trauma Center Standards. Documentation of the process for monitoring and upgrading competencies will be maintained by Natividad.
5. To appoint specified individuals to assume responsibility for their component of Natividad's operation, as identified in the Monterey County EMS Agency Trauma Center Standards.
6. Trauma Registry/Data Management System: Natividad agrees to use a standardized data collection instrument for trauma care, which includes the collection of both pre-hospital and hospital patient care data utilizing specified format rules. Trauma data shall be integrated into the Monterey County EMS Agency and State EMS Authority data management systems. Data collection shall include, but not be limited to, data elements required by the National Trauma Data Bank.
7. To have a Trauma Performance Improvement Plan available for the Monterey County EMS Agency's review upon request.
8. To assure the Trauma Director, Trauma Program Manager, and other specified individuals as identified, participate as members of the Trauma Executive Committee, and other related committees as may be required by the EMS Agency.

9. To permit announced site surveys of its facilities by the Monterey County EMS Agency representatives and allow reasonable access to any and all documentation on any trauma patient or on the trauma system as a whole for the purposes of monitoring contract compliance, quality of care and adherence to performance standards.
10. To maintain documentation of public education and injury prevention outreach activities, consistent with trauma system goals, and to submit an annual summary of completed activities to the Monterey County EMS Agency for review.
11. Natividad agrees to cooperate with the Monterey County EMS Agency in investigating complaints and concerns regarding patient care issues.
12. Natividad agrees to maintain ACS Level II Trauma Center Verification throughout the term of this agreement. ACS Site Verification will be coordinated with the Monterey County EMS Agency. This in no way precludes Natividad from pursuing ACS Level I Trauma Center designation.
13. Natividad shall meet and abide all EMS Agency Policies and Procedures, and protocols as have been or may be established by the EMS Agency, provided that such Policies and Procedures and protocols are made available to Natividad.
14. Natividad shall notify the EMS Agency in writing in advance of planned changes in any of the capabilities or resources, including personnel, described in its Proposal or in its ability to meet trauma center standards.
15. Natividad shall notify the EMS Agency in writing in advance of policy changes impacting EMS field operations.

16. Natividad shall notify the EMS Agency Duty Officer immediately of any disruption in Natividad's provision of trauma center services.
17. Natividad shall notify the EMS AGENCY, in writing, within twenty-four (24) hours of becoming aware of any failure to meet compliance with Trauma Center Standards and shall take corrective action within a reasonable period of time to correct said failure.
18. Natividad shall have and maintain a fulltime trauma medical director with substantial previous experience at a level I or II trauma center.
19. Natividad shall ensure that trauma services and care delivered are evaluated by Natividad's internal performance improvement and patient safety (PIPS) program and as necessary, through the EMS AGENCY's quality improvement (QI) program in order to improve and maintain effective clinical performance and adherence to standards.
20. Natividad shall ensure that all surgeons on the trauma call panel are board certified or board eligible by American Board of Surgery. Natividad shall ensure surgical residents working in the trauma program are properly supervised by an attending trauma surgeon.
21. Trauma Surgeon staffing will be in accordance with Title 22 and ACS requirements for Level II trauma centers.
22. Natividad shall manage its operating suites in accordance with Title 22 and ACS requirements for Level II trauma centers.
23. Natividad shall have an operating suite team available in accordance with Title 22 and ACS requirements for Level II trauma centers.

24. Natividad shall ensure that all specialty services inclusive of Neurosurgery and Interventional Radiology comply with Title 22 and ACS requirements for level II trauma centers.

25. Natividad shall meet and adhere to all requirements as a base hospital.

E. AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA (ACS-COT)
VERIFICATION

1. Natividad may appeal findings of the ACS-COT verification report pursuant to the provisions established by the ACS-COT. Natividad shall simultaneously inform EMS Agency of all objections, appeals, clarifications sought by Natividad from the ACS-COT.

2. Natividad shall inform ACS-COT to directly provide EMS Agency with copies of all documents given to Natividad. These reports contain performance improvement and will be kept confidential.

3. If Natividad fails to pass the ACS-COT verification site visit, following provisions shall apply:

A. Natividad shall comply with any plan of correction, including any timeframes therein, required by the EMS Agency to address any failure of Natividad to meet ACS-COT standards. Any such plan of correction may be imposed and amended in collaboration with and approval of the EMS Agency.

B. Notwithstanding the termination provisions in Section ‘L’ and ‘M’ of this Agreement, if the EMS Agency determines in its sole and absolute discretion that Natividad is not complying with the terms of a corrective action plan required by the EMS Agency, such failure to comply shall constitute Cause

for EMS Agency's termination of Natividad's designation as a trauma center without any further opportunity for Natividad to cure the default or provide evidence that Cause for termination does not exist. Following determination of Natividad's failure to comply with a required corrective action plan, EMS Agency may exercise this right to terminate the trauma center designation immediately upon written notice or upon as many days written notice as shall be specified by EMS Agency.

- C. During any period of time in which Natividad fails to be verified as a trauma center by the ACS-COT, the EMS Agency may undertake a review of the Natividad's trauma center, including but not limited to its clinical data and patient files, to verify the quality of care provided (hereinafter "Quality Assurance Review"). The Quality Assurance Review shall be conducted in any manner deemed appropriate by the EMS Agency, in its sole and absolute discretion. Natividad shall promptly and fully respond to any requests made by the EMS Agency for a Quality Assurance Review, including but not limited to trauma patient charts and information concerning Natividad's progress toward meeting Trauma Quality improvement Program benchmarks. Notwithstanding the termination provisions in Sections "L" and "M" of the Agreement, if there are issues identified with the quality of care provided by Natividad's Trauma Center at any time when the trauma center fails to be verified by the ACS-COT, the EMS Agency may terminate this Agreement upon written notice to Natividad.

D. All subsequent ACS-COT verification visits shall be arranged and facilitated by Natividad. The EMS Agency shall participate in the site visit/verification process.

F. IMPLEMENTATION OF FEE SCHEDULE FOR DESIGNATION OF TRAUMA CENTERS:

1. Pursuant to California Health and Safety Code Section 1798.164 and California Code of Regulations, Title 22 Section 100255, the Monterey County EMS Agency reserves the right to implement fees to any applicant seeking initial or continuing designation as a trauma facility, in an amount sufficient to cover the costs directly related to the designation of trauma facilities pursuant to California Health and Safety Code Section 1798.165 and to the development of the plans pursuant to California Health and Safety Code Sections 1797.257 and 1797.258. The EMS Agency also reserves the right to implement fees in an amount sufficient to cover the costs directly related to ongoing trauma system planning, quality improvement and oversight activities.
2. The methodology for the development of a fee schedule will follow established County policy. Trauma Centers will be given six months written notice by the Monterey County EMS Agency of any requirement to pay newly established or increased fees.
3. In the event that the Monterey County EMS Agency charges fees to Natividad pursuant to this Paragraph F, a report will be provided to Natividad annually containing sufficient detail to apprise Natividad of the specific application of fees

collected, to assure that fees collected were expended in compliance with California Health and Safety Code Section 1798.164(a).

4. If Natividad fails to pass the initial or any subsequent ACS-COT verification site visit, Natividad shall reimburse EMS Agency for all costs of any third party engaged by the EMS Agency to conduct, or assist in the conducting, of a Quality Assurance Review.

G. CONFIDENTIALITY:

The Monterey County EMS Agency and Natividad agree to maintain the confidentiality of all information and records obtained in the course of providing services to patients under this MOU in accordance with applicable federal and state statutes and regulations and EMS Agency Policies and Procedures relating to confidentiality.

H. MAINTENANCE OF RECORDS:

All administrative records under this MOU shall be maintained by Natividad for a minimum of five (5) years after the termination date of the MOU for inspection by the Monterey County EMS Agency.

I. DATA SUBMISSION:

Natividad shall submit data quarterly on a schedule synchronized with data submission to the EMS Agency to comply with applicable laws, regulations and this Designation Agreement. The reporting format will be in accordance with EMS Agency Policies and Procedures, related to submission of data, including encryption of data.

J. EVALUATION STUDIES AND PUBLICATIONS:

Natividad will participate as requested by the Monterey County EMS Agency in reasonable research and/or evaluation studies reviewed and approved by the University of

California San Francisco's (UCSF) Institutional Review Board (IRB). Natividad agrees to meet with other designated trauma center personnel to establish guidelines concerning the publication and use of data relating to trauma care.

K. TERMINATION FOR CONVENIENCE

Either party may terminate this Agreement upon one-hundred and eighty (180) days written notice to the other party.

L. TERMINATION FOR CAUSE

The EMS Agency may terminate this Agreement upon written notice to Natividad, subject to Natividad's opportunity to cure as set forth below, upon the occurrence of any one or more of the following events:

- A. Any material breach of this Agreement by Natividad;
- B. Any violation by Natividad of any applicable laws, regulations, local ordinances, or EMS policies and procedures;
- C. Any failure by Natividad to provide timely surgical and non-surgical physician coverage for trauma cases;
- D. Submission by Natividad to the EMS Agency reports or information that Natividad knows or should know are incorrect in any material respect;
- E. Any failure by Natividad to comply with trauma center standards;
- F. Loss or suspension of licensure as an acute care hospital, loss or suspension of any existing or future special permits issued by state or federal agencies necessary for the provision of the services provided by Natividad under the terms of this Agreement, or loss or suspension of accreditation by the Joint Commission or an equivalent accreditation body;

- G. Any failure to comply with a plan of correction imposed by the EMS Agency;
- H. Any failure to remedy any recurring equipment malfunction, shortages of physicians, nurses and or other staff, staff response delays, or facility problems of Natividad, which causes or contributes to Natividad 's diversion of ambulances transporting trauma patients intended for Natividad; and
- I. Repeated failure to submit specified reports, trauma registry data, or other information required under this Agreement.

M. OPPORTUNITY TO CURE

Prior to the exercise of the EMS Agency's right to terminate for cause, the EMS Agency shall give Natividad written notice of the violation(s) thirty (30) days prior to the termination date (hereinafter "Correction Period") specifying in reasonable detail the grounds for termination and all deficiencies requiring correction. If Natividad has not substantially remedied each deficiency prior to the end of the Correction Period to the satisfaction of the EMS Agency, or submitted a plan of correction to EMS Agency within the Correction Period that is accepted by EMS Agency, then after the Correction Period EMS Agency may terminate this Agreement upon written notice to Natividad, specifying the effective date of termination. The EMS Agency may shorten the Correction Period to immediate suspension if the EMS Agency determines that Natividad's action or inaction has seriously threatened, or will seriously threaten, public health and safety.

N. LAME DUCK OPERATIONS

In the event of a change in providers of trauma center services leading to the termination of this Agreement, and at the sole direction of the EMS Agency, Natividad will continue to operate as a trauma center at the level that is provided for in this Agreement, including

during any appeal or legal challenge and the reasonable start-up period for the new trauma center.

O. WAIVERS, AMENDMENTS AND OTHER AGREEMENTS:

This Trauma Center Designation Agreement and its references express the full understanding of the parties concerning the matters covered herein and supersede and replace all other prior Trauma Center Agreements with their references. Any waivers, additions or alterations to this Agreement shall be made in the form of written amendments. This Agreement does not affect any concurrent Agreement between Natividad and the Monterey County EMS Agency.

P. Natividad and the Monterey County EMS Agency are subject to all relevant requirements contained in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-91, enacted August 21, 1996, and the laws and regulation promulgated subsequent hereto, as well as all relevant requirements contained in California Civil Code Sections 56 – 56.37 (The Confidentiality of Medical Information Act), enacted 1988, for purposes of services rendered pursuant to this Agreement. Both parties agree to cooperate in accordance with the terms and intent of this Agreement for implementation of relevant law(s) and/or regulation(s) promulgated under this Law. Both parties further agree that it shall be in compliance with the requirements of HIPAA, and the laws and regulations promulgated subsequent hereto.

Q. NON-DISCRIMINATION

Natividad shall comply with all applicable federal, state, and local laws and regulations including County equal opportunity requirements. Such laws include but are not limited to the following: Title VII of the Civil Rights Act of 1964 as amended; Americans with

Disabilities Act of 1990; The Rehabilitation Act of 1973 (Sections 503 and 504); California Fair Employment and Housing Act (Government Code sections 12900 et seq.); California Labor Code sections 1101 and 1102. Natividad will not discriminate against any Natividad, employee, or applicant for employment because of age, race, color, national origin, ancestry, religion, sex, gender, gender expression, gender identity, genetic information, sexual orientation, mental disability, physical disability, medical condition, political beliefs, organizational affiliations, or marital status in the recruitment, selection for training including apprenticeship, hiring, employment, utilization, promotion, layoff, rates of pay or other forms of compensation. Nor will Natividad discriminate in the provision of services provided under this Agreement because of age, race, color, national origin, ancestry, religion, sex, gender, gender expression, gender identity, genetic information, sexual orientation, mental disability, physical disability, medical condition, political beliefs, organizational affiliations, or marital status.

T. NOTICE:

Any notice or notices required or permitted to be given pursuant to this MOU may be personally served on the other party by the party giving such notice, or may be served by certified mail, postage prepaid, return receipt requested, to the following representatives:

NMC:
Natividad Medical Center
1441 Constitution Boulevard
Salinas, CA 93906
Attn: Natividad Administration

EMS Agency
Monterey County Emergency Medical Services Agency
1441 Schilling Place
Salinas, CA 93901
Attn: Monterey County EMS Agency Director

Signature: _____

Date: _____

Signature: _____

Date: _____