ACS NSQIP®

HOSPITAL PARTICIPATION AGREEMENT
INCLUDING BUSINESS ASSOCIATE AND DATA USE AGREEMENTS

NAME OF HOSPITAL: Natividad Medical Center, County of Monterey

HOSPITAL FEIN/TAX ID: 94-6000524

HOSPITAL ADDRESS: 1441 Constitution Blvd.

                                   Salinas, Ca. 93906

This **Hospital Participation Agreement Including Business Associate and Data Use Agreements** ("Agreement") is effective as of the date signed by both parties ("Effective Date") between Natividad Medical Center ("NMC"), a general acute care teaching hospital wholly owned and operated by the County of Monterey, which is a political subdivision of the State of California ("Hospital") and the American College of Surgeons ("ACS") and shall continue through the end of the "Participation Period" as defined in Section 1 below.

WHEREAS, Hospital desires to participate in the ACS National Surgical Quality Improvement Program ("ACS NSQIP") and ACS desires to receive data from Hospital for inclusion in the ACS NSQIP.

1.   Participation Period. The "Participation Period" is defined as the period beginning on the first day of the month that Hospital's first Surgical Clinical Reviewer ("SCR") participates in the training session and will continue for the length of time described on Exhibit A, attached to and made a part of this Agreement. ACS will send Hospital a letter confirming the commencement of the Participation Period and its end date after the SCR has registered and been confirmed for the SCR training session.

2.   Options. The ACS NSQIP has established participation levels (the "Option(s)"), each of which has associated data contribution requirements and fees. Hospital has chosen, and ACS has confirmed, the Option indicated on Exhibit A ("Hospital's Option"). Hospital will continue participation in the chosen Option through the Participation Period unless ACS and Hospital mutually agree in writing to change the Hospital's Option and amend this Agreement accordingly. ACS will consider the timing of data reporting cycles to determine when participating hospitals will have an opportunity to select a different Option.

3.   Contribution of Data. Hospital agrees to contribute certain data (the "ACS NSQIP Data") to a proprietary database established by the ACS (the "ACS NSQIP Database"). Hospital must submit its ACS NSQIP Data in accordance with the data reliability standards established by ACS NSQIP. Hospital agrees to contribute a set number of cases based on the minimum data contribution requirements for Hospital's Option as established by ACS NSQIP and generally described on Exhibit B. Hospital will submit data in the format as required by ACS NSQIP via the official ACS NSQIP web-based data collection system ("Workstation") with standardized fields as developed by ACS and/or ACS authorized vendor(s). Hospital agrees to use an ACS authorized vendor and ACS will not be required to accept data from any other vendor. Hospital shall retain ownership of the data it submits to the ACS NSQIP and, subject to the terms and conditions set forth herein, hereby grants to ACS a non-exclusive, perpetual, irrevocable license to utilize the ACS NSQIP Data contributed to the ACS NSQIP and to share it with other participants for purposes of quality improvement/benchmarking in the area of health care, or for related Research purposes in the area of health care (as further described in Section 13.b.iv. below).

4.   Fees. Hospital agrees to pay to ACS an annual fee for participation in the ACS NSQIP for the Participation Period described on Exhibit A. Hospital shall pay additional fees as described in Section 10, Data Collectors, and Section 12, Audits, as applicable.

5.   Payment. Hospital will pay the annual fee for participation for each year of the Participation Period, in advance. ACS will provide Hospital with an invoice for the first year of the Participation Period upon receipt of a fully executed Agreement. Thereafter, ACS will provide an invoice thirty (30) days prior to the anniversary date of the Participation Period. Payment is due in accordance with the County of Monterey Agreement for Services ("County Agreement").

6.   Services Provided to Hospital. ACS will provide to Hospital the services described on Exhibit C.

7.   Hospital Requirements. Hospital will continuously comply with the participation requirements described on Exhibit D and subject to change from time to time.

8.   Access to and Use of Data. Hospital will have continuous access to Hospital's own ACS NSQIP Data. Hospital will also have continuous access to cumulative non-risk-adjusted ACS NSQIP Data of all contributors, in a manner that does not identify or permit identification of the contributors, and presented for the purpose of comparison to national averages and peer groups. Notwithstanding the ownership rights of contributing hospitals to the data submitted to the ACS NSQIP, ACS owns all right, title, and interest in the ACS NSQIP Database and the aggregated data contained therein. ACS hereby grants to Hospital a limited, non-exclusive, revocable license to utilize these non-risk-adjusted ACS NSQIP Data for appropriate internal purposes only. ACS NSQIP will provide reports to Hospital from time to time, which will contain risk-adjusted ACS NSQIP Data. ACS hereby grants Hospital a non-exclusive license to use the risk-adjusted data for appropriate internal and external purposes.

9.   Confidentiality of Hospital's Identity. ACS will not release Hospital's ACS NSQIP Data in any format or circumstance that identifies Hospital or its medical or professional staff or employees as the contributor of its specific data, except to the Hospital, as required by legal process, or as specifically authorized by Hospital. If any legal demand for Hospital's ACS NSQIP Data is made upon ACS, ACS will promptly notify Hospital so that Hospital may, at its option, challenge the validity of the legal process. The provisions of this section shall survive any termination or expiration of this Agreement.

10.   Data Collectors. Hospital agrees to dedicate the required number of data collectors as determined by Hospital's surgical volume. Replacement and backup SCRs and additional staff may attend the SCR training for a fee of $2,500 per individual trained.

11.   Access to Workstation. Hospital acknowledges and agrees that it is responsible for controlling access to Hospital's own data and Hospital's Workstation at all times. Hospital will provide ACS NSQIP with a current and up to date list of authorized Hospital users with a need to access the Workstation. Hospital agrees to promptly notify ACS NSQIP of any changes to its list of authorized users, including additions and deletions to the list of authorized users.

12.   Audits. In order to monitor the quality of the data entered into the ACS NSQIP system, Hospital agrees that ACS or its agents may from time to time conduct on-site and/or remote audits of Hospital's data and collection procedures. ACS will provide at least ten (10) business days notice of an on-site audit. To the extent medical records are needed to conduct the audit, ACS will request and Hospital will provide only the minimum necessary portions of the record needed for the audit. Additional audits may be required by ACS NSQIP or requested by Hospital for an additional fee of $3,500 per audit.

13.   Business Associate and Data Use Provisions. ACS NSQIP requires Hospital to Disclose to ACS and for ACS to Use and Disclose patient Protected Health Information ("PHI"), including Electronic Protected Health Information ("EPHI"), as those terms are defined in the Health Insurance Portability and Accountability Act of 1996, including the Administrative Simplification provisions, the Secretary of Health and Human Services regulation modifications for 45 CFR Parts 160 and 164, the HIPAA Privacy Rule ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH") and the State of California Confidentiality of Medical Information Act ("CMIA"), California Civil Code Section 56 et seq., Senate Bill 541, enacted September 30, 2008, and Assembly Bill 211, enacted September 30, 2008 and the regulations issued thereunder (collectively, the "HIPAA and CMIA regulations"). The parties acknowledge that California law may include provisions more stringent and more protective of the confidentiality of health information than the provisions of HIPAA. These Uses and Disclosures are for purposes of conducting data analyses that relate to Hospital's Health Care Operations, including but not limited to Data Aggregation and quality assessment. The ACS NSQIP also may from time to time require the Disclosure of PHI in the form of a Limited Data Set for ACS to provide services to Hospital related to its Health Care Operations and for Research purposes. The HIPAA and CMIA Regulations require Hospital and ACS to enter into a Business Associate Agreement and a Data Use Agreement to protect PHI and EPHI and Limited Data Sets. The parties agree that the provisions of this Section 13 constitute the equivalent of a Business Associate Agreement and a Data Use Agreement.

a.   Definitions. Capitalized terms used but not otherwise defined in this Agreement will have the meaning ascribed to them in the HIPAA Regulations. PHI and EPHI will have the meaning ascribed to them in the HIPAA and CMIA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Hospital to ACS or an agent or subcontractor of ACS, or created by ACS or its agent or subcontractor on behalf of Hospital. Unless otherwise specified, PHI will include EPHI for purposes of this Agreement. Limited Data Set will have the meaning ascribed to "Limited Data Set" in the Privacy Rule, but for the purposes of this Agreement will refer solely to Limited Data Sets transmitted from or on behalf of Hospital to ACS or an agent or subcontractor of ACS, or created by ACS or its agent or subcontractor on behalf of Hospital. The parties agree that ACS is a Business Associate and Hospital is a Covered Entity under the terms of the HIPAA Regulations. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of HIPAA, as amended, the HIPAA Privacy Rule shall control. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of CMIA, California law shall control. Where provisions of this Agreement are different than those mandated in HIPAA and CMIA, but nonetheless are permitted by HIPAA and CMIA, the provisions of this Agreement shall control.

b.   Specific Permitted Uses and Disclosures. Except as otherwise specified in this Agreement, ACS may Use or Disclose PHI on behalf of, or in order to provide services to, Hospital to the extent such Use or Disclosure is reasonably necessary to facilitate Hospital's participation in the ACS NSQIP, provided that such Use or Disclosure of PHI would not violate the HIPAA and CMIA Regulations if done by Hospital. Without limiting the generality of the foregoing, Hospital further agrees that ACS may Use and Disclose the PHI received for the following specific purposes:

i.   To analyze, aggregate, produce and publish data on clinical patterns of diagnosis, treatment and outcomes of patients to assist with Health Care Operations;

ii.   To produce reports of aggregated, de-identified data and data not identifiable by contributing hospital that describe the diagnosis, treatment and outcomes of patients to assist with Health Care Operations;

iii. To evaluate hospital performance, develop effective interventions to improve outcomes at the national and local level, and provide feedback in the form of an individual facility's ACS NSQIP Data benchmarked against regional and national ACS NSQIP Data to assist with Health Care Operations; and

iv. To create, Use and share Limited Data Sets with ACS NSQIP participants and with other researchers for Research in the area of health care, subject to the provisions of Subsection 13.c.vii. and 13.e. below.

v. For data aggregation services, if to be provided by ACS for the Health Care Operations of Hospital. For purposes of this Agreement, data aggregation services means the combining of PHI by Business Associate with the PHI received by ACS in its capacity as a Business Associate of another Covered Entity, to permit data analyses that relate to the Health Care Operations of the respective Covered Entities.

c. General Uses and Disclosures.

i. Except as otherwise limited in this Agreement, ACS may Use PHI for the proper management and administration of ACS or to carry out the legal responsibilities of ACS.

ii. Except as otherwise limited in this Agreement, ACS may Disclose PHI for the proper management and administration of ACS, provided that Disclosures are Required By Law, or ACS otherwise obtains reasonable assurances from the person to whom the PHI is disclosed that the person will (a) protect the confidentiality and security of the PHI, (b) Use or further Disclose it only as Required By Law or for the purpose for which it was disclosed to the person, and (c) notify ACS of any instances of which the person is aware that the confidentiality or security of the PHI has been breached.

iii. Nothing in this Agreement will be interpreted to prevent ACS from Disclosing PHI in accordance with the HIPAA Regulations, 45 CFR 164.502(j)(1), and CMIA concerning Disclosures in the public interest, or other permissible Uses or Disclosures by a Business Associate as set forth in the HIPAA and CMIA Regulations.

iv. Except as otherwise limited in this Agreement, ACS may Use and Disclose PHI to provide Data Aggregation services to Hospital as permitted by 45 CFR 164.504(e)(2)(i)(B).

v. ACS may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b) and CMIA, including without limitation any documentation requirements. ACS may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is otherwise consistent with this Agreement.

vi. ACS may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2) and CMIA.

vii. ACS may, consistent with this Agreement, Use or Disclose PHI that consists solely of Limited Data Sets to a third party for Research, Public Health, or Health Care Operations purposes in accordance with the provisions of the HIPAA and CMIA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to facilitate Hospital's participation in the ACS NSQIP or for ACS's research purposes; (ii) is otherwise consistent with this Agreement; and (iii) would not violate the HIPAA and CMIA Regulations if done by Hospital. Consistent with the HIPAA and CMIA Regulations and HHS' December 3, 2002 Guidance Document, the term Health Care Operations includes Data Aggregation.

d. Obligations of ACS as Business Associate.

i. ACS agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law.

ii. ACS agrees to use appropriate safeguards to prevent Use or Disclosure of PHI by ACS or its agents or subcontractors other than as provided for by this Agreement, including Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the EPHI that ACS creates, receives, maintains or transmits on behalf of Hospital. Without limiting the foregoing, ACS and/or its subcontractors will, at its own expense, provide the equipment and software services necessary to reasonably protect and safeguard the PHI consistent with industry standards of similarly situated business associates.

iii. ACS agrees to promptly report to Hospital any Use or Disclosure of PHI not authorized by this Agreement of which it becomes aware and any Security Incident of which it becomes aware within 5 days.

iv. ACS agrees to ensure that any agent, including a subcontractor, to whom it provides or who accesses Hospital's PHI or EPHI will agree to comply with the same restrictions and conditions that apply to ACS through this Agreement, including the implementation of reasonable and appropriate safeguards to protect EPHI and the provisions of Section 13.e. below.

v. ACS agrees to make its internal practices, books and records relating to the Use and Disclosure of PHI and EPHI received from, or created or received by ACS on behalf of Hospital and ACS's Administrative, Physical and Technical Safeguards for EPHI, available to the Secretary of the U.S. Department of Health and Human Services ("Secretary"), during reasonable business hours, for purposes of the Secretary determining Hospital's compliance with the HIPAA Regulations.

vi. If PHI provided to ACS constitutes a Designated Record Set, ACS agrees to provide Hospital with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Hospital's request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 and CMIA concerning access of Individuals to Protected Health Information. In the event an Individual contacts ACS or its agent or subcontractor directly about gaining access to his or her PHI, ACS will not provide such access but rather will promptly forward such request to Hospital.

vii. If PHI provided to ACS, or to which ACS otherwise has access, constitutes a Designated Record Set, ACS agrees to make timely amendment(s) to such PHI as Hospital may reasonably direct or agree to pursuant to 45 CFR 164.526 and CMIA. In the event an Individual contacts ACS or its agent or subcontractor directly about making amendments to his or her PHI, ACS will not make such amendments, but rather will promptly forward such request to Hospital.

viii. ACS agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Hospital to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528 and CMIA. In addition, ACS agrees to provide promptly to Hospital or an Individual, upon Hospital's reasonable request, information collected in accordance with this subsection in order to permit Hospital to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528 and CMIA. Notwithstanding the foregoing, this subsection will not apply with respect to Disclosures made to carry out Hospital's Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528 as set forth in the HIPAA and CMIA Regulations.

ix. ACS agrees to mitigate, to the extent practicable, any harmful effect that is known to ACS of an improper Use or Disclosure of PHI or EPHI by ACS,

x. In the event of an unauthorized Use or Disclosure that constitutes a Breach of Unsecured PHI (as defined by the HITECH Act), ACS will notify Hospital without unreasonable delay but in no event later than five (5) calendar days following the Discovery of such Breach. Such notice shall include, to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by ACS to have been, accessed, acquired, used, or disclosed during the Breach, and such other available information as is required to be included in the notification to the individual under 45 CFR 164.404(c).

e. <u>Data Use Agreement Obligations</u>. With respect to the Limited Data Sets that ACS may create, Use and Disclose for Research purposes pursuant to Section 13.b.iv herein, ACS agrees that it:

i. will Use the Limited Data Set only for such Research purposes and will Disclose the Limited Data Set only to participants in ACS NSQIP and other researchers for Research in the area of health care in accordance with the provisions of 45 CFR 164.512(i) and CMIA;

ii. will not Use or further Disclose the Limited Data Set in a manner that would violate the HIPAA and CMIA Regulations if done by Hospital;

iii. will not Use or Disclose the Limited Data Set other than as permitted by this Agreement or as otherwise Required By Law;

iv. will use reasonable and appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement, including Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic Limited Data Set that it creates, receives, maintains, or transmits on behalf of Hospital as required by 45 CFR 164.314 and CMIA;

v. will promptly report to Hospital any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware and any Security Incident involving the Limited Data Set of which it becomes aware within five (5) calendar days of discovering such improper access, use or disclosure. In addition, ACS agrees to mitigate, to the extent practicable, any harmful effect that is known to ACS of a use, disclosure, or access of Protected Health Information by ACS in violation of the requirements of this agreement;

vi. will ensure that any ACS NSQIP participants or other researchers, and any agents or subcontractors to whom it provides the Limited Data Set, contractually agree to the same restrictions and conditions that apply to ACS with respect to such information; and

vii. will not use the Limited Data Set to identify or contact the individuals who are the subject of the information. Nothing in this subsection will be interpreted to limit ACS's ability to provide its Data Aggregation and analysis services as otherwise provided by this Agreement.

f. <u>General Obligations of Hospital</u>.

i. Hospital represents and warrants that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and CMIA and any other applicable provisions of the HIPAA Regulations. Hospital will provide ACS with a copy of its Notice of Privacy Practices upon request.

ii. Hospital shall notify ACS of any limitation(s) in Hospital's Notice of Privacy Practices, to the extent that such limitation may affect ACS's Use or Disclosure of PHI.

iii. To Hospital's knowledge, as of the Effective Date, all Disclosures of PHI made to ACS are permissible Disclosures under the HIPAA and CMIA Regulations, and no individual has restricted Disclosure so as to make the

Disclosure to ACS impermissible. Hospital will notify ACS of any restriction on the Use or Disclosure of PHI that Hospital has agreed to in accordance with the HIPAA Regulations, 45 CFR 164.522, and CMIA if such restriction affects ACS's Use or Disclosure of PHI.

iv. Hospital will not ask ACS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA and CMIA Regulations if undertaken by Hospital; provided that Hospital may, as otherwise permitted under this Agreement, request that ACS Use or Disclose PHI for the purposes of Data Aggregation or the proper management and administrative activities of ACS or to carry out the legal responsibilities of ACS, as provided for in 45 CFR 164.504(e)(4) and CMIA.

14.   Hospital's Confidential Business Information. In addition to the patient confidentiality protections above, ACS will take reasonable steps to protect the confidentiality of all other non-patient information concerning Hospital that it receives or generates in connection with this Agreement and that Hospital designates as confidential. ACS will use such information solely to carry out this Agreement and will not disclose such information without Hospital's prior written approval or as Required By Law. The provisions of this section shall survive any termination or expiration of this Agreement.

15.   Use of Name. Neither ACS nor Hospital shall use the name or logo of the other party or of any of its affiliates, or any variation or acronym thereof, without the prior written consent of the other party, except that ACS may include the name of Hospital in lists of participants in the ACS NSQIP, and Hospital may state that Hospital participates in the ACS NSQIP.

16.   Termination.

(a)   ACS reserves the right to terminate this Agreement upon thirty (30) days prior written notice to Hospital, if Hospital materially fails to fulfill the terms of the Agreement or materially violates its conditions, in which case ACS will not refund fees previously paid by Hospital. Hospital may terminate this Agreement at any time, provided that Hospital will be obligated to pay (to the extent Hospital has not already paid) the fees calculated as follows: (i) all fees applicable for the then-current Participation Period if the Participation Period is one (1) year; or (ii) if the Participation Period is three (3) years, all fees applicable for the then-current one (1) year period calculated without application of any multi-year discount, plus the amount of the multi-year discount for prior years during the then-current three-year term.

(b)   If ACS is in material breach of this Agreement and fails to correct or cure such breach within thirty (30) days following written notice from Hospital, then Hospital may terminate this Agreement. ACS may also terminate this Agreement prior to the end of a Participation Period if ACS suspends data collection. In either case ACS will refund to Hospital the pro rata portion of fees paid by Hospital for the unfulfilled portion of the year for which the annual fee was paid.

17.   Effect of Termination on ACS Obligation to Destroy or Protect Data. Except as provided below, upon termination of this Agreement, for any reason, ACS will, at Hospital's direction, return or destroy all PHI received from Hospital, or created or received by ACS on behalf of Hospital, and ACS will retain no copies of the PHI. Data contained in a Limited Data Set shall not be subject to the obligations of this section provided that the Data Use provisions pertaining to such Limited Data Set that are set forth above will survive any termination or expiration of the Agreement. In the event that ACS reasonably determines that returning or destroying the PHI is infeasible due to inclusion of the PHI in ACS's database or for other legitimate reason, ACS will give Hospital a statement of reasons why the return or destruction of the PHI is infeasible. As the sole consequence of such determination, ACS will extend the protections of this Agreement to such PHI and limit further its Use and Disclosure to those purposes that make the return or destruction infeasible, for so long as ACS maintains such PHI. The obligations of this section will survive any termination or expiration of this Agreement.

18.   Effect of Termination on Provision of Data to ACS. The parties acknowledge and agree that the provision of any PHI to ACS in accordance with this Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the parties agree that Hospital will refrain from submitting PHI to ACS, and ACS will refrain from accepting PHI from Hospital.

19.   Force Majeure. Neither party shall be liable for failure to meet any requirements of this Agreement, and this Agreement may not be terminated for such cause, if such failure is due to electrical outage, strike, natural disaster or other event beyond the control of the party, which makes performance impossible or impractical.

20.   No Warranty; Limitation of Liability; Indemnification.

a.   Disclaimer of Warranty. To the maximum extent permitted by applicable law, ACS NSQIP and the services provided by ACS hereunder ("ACS NSQIP Materials") are provided "as is" with all faults, and ACS disclaims any and all express or implied representations and warranties with respect to the ACS NSQIP Materials, including any express or implied warranty of merchantability, fitness for a particular purpose, accuracy, non-infringement, or that the ACS NSQIP materials will operate error free, uninterrupted or be free of viruses. The entire risk as to the selection, satisfaction quality and performance and use of ACS NSQIP materials shall be with hospital.

b.   Limitation of Liability. To the maximum extent permitted by applicable law, in no event shall ACS be liable for any indirect, special, incidental, consequential, punitive, or exemplary damages (including damages related to delays, loss of data, interruption of service or loss of use, business, revenue, or profits) in connection with this agreement, use or inability to use the ACS NSQIP Materials, under any legal theory, even if ACS has been advised of the possibility of such damages. In no event shall ACS be liable for any third party claim. Liability for damages shall be limited and/or excluded as provided in this agreement, even if any exclusive remedy provided for in this agreement fails of its essential purpose.

c.   Indemnification. Each party (the "Indemnifying Party") agrees to indemnify, defend and hold harmless the other party (the "Indemnified Party"), its directors, officers, employees and agents from any and all liabilities, claims, damages, loss and costs (including reasonable attorney's fees) to the extent arising from the negligent acts or omissions or willful misconduct of the Indemnifying Party related to Section 13 of this Agreement and/or a violation of HIPAA related to this Agreement. Notwithstanding anything herein to the contrary, neither party shall be liable for indirect, special, or consequential damages.

21.   Miscellaneous.

    a.   Regulatory References. A reference in this Agreement to a section in the HIPAA and CMIA Regulations means the section as in effect or as amended and for which compliance is required.

    b.   Amendment. Any amendment to this Agreement must be in writing and signed by each of the parties. The parties agree to amend this Agreement from time to time as necessary for the parties to comply with the requirements of federal and applicable state law and regulations including the HIPAA and CMIA Regulations and the HITECH Act of 2009. Either party may request that the other party amend this Agreement in order to comply with applicable state and federal law and regulations. If after a reasonable period of good faith negotiation, an amendment of this Agreement is not achieved to the satisfaction of both parties, then either party may terminate this Agreement without penalty. In the event the parties engage in negotiations undertaken in accordance with this subsection, the parties may suspend during such period of negotiation any provision of this Agreement requiring or obligating either party to Use or Disclose

PHI in a manner that either party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA and CMIA Regulations.

c.   Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Hospital and ACS to comply with HIPAA and CMIA and applicable state and federal laws and regulations.

d.   Assignment. Except as otherwise provided herein, neither party may without the written consent of the other assign, delegate or otherwise transfer this Agreement or any of its rights or obligations under this Agreement.

e.   Severability. If any part of this Agreement is determined to be invalid, illegal or unenforceable by any Act of Congress, state legislature, or by any regulation issued by the United States or a State, or declared null and void by any court with valid jurisdiction, then the parties will modify such part, if possible, to conform to the law, and the remaining parts will be fully effective and operative insofar as reasonably possible.

f.   Entire Agreement. This Agreement and the County Agreement constitute the entire understanding and agreement between the parties concerning the subject matter of this Agreement, and supersedes all prior negotiations, agreements and understandings between the parties, whether oral or in writing, concerning its subject matter.

g.   Jurisdiction. Intentionally omitted.

h.   Third Party Beneficiaries. ACS and Hospital agree that individuals whose PHI is Used or Disclosed to ACS or its agents or subcontractors under this Agreement are not third-party beneficiaries of this Agreement.

i.   Waiver. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

j.   Relationship of the Parties. The parties are independent contractors of each other. Nothing in this Agreement shall be construed to create an employer/employee, joint venture, or other similar relationship between the parties. Neither party shall have the right to exercise control or direction over the business of the other party.

k.   Authority. The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the party he or she represents, and that this Agreement will be binding on such party, and its officers, directors, agents, and employees.

l.   Insurance. ACS Agrees to maintain insurance that ACS determines in its sole discretion is reasonable.

m.   Notices. Any notices required pursuant to this Agreement shall be in writing and sent by US Mail, personal delivery, next-day express mail, or by facsimile addressed as identified below:

American College of Surgeons   Hospital:
Attn: Gay Vincent
633 North Saint Clair Street
Chicago, Il 60611
Fax: 312-202-5025

Gay L. Vincent, CPA MBA
Chief Financial Officer

Print Name and Title of person on behalf of the
American College of Surgeons

Gay Vincent   3/12/13

Signature of person on behalf of the   Date
American College of Surgeons

Harvey Weis   CEO   12/10/12
Print Name and Title of person accepting on
behalf of Hospital

[signature]   12/10/12

Signature of person accepting on behalf of   Date
Hospital

ACS NSQIP

EXHIBIT A
SERVICE LEVEL OPTIONS

NAME OF HOSPITAL: Natividad Medical Center

HOSPITAL ADDRESS: 1441 Constitution Blvd

Salinas, CA 93906

SELECTION OF TERM FOR PARTICIPATION PERIOD:

The "Participation Period" is defined as the period beginning on the first day of the month that Hospital's first Surgical Clinical Reviewer ("SCR") participates in the training session and will continue for the length of time described on Exhibit A, attached to and made a part of this Agreement. ACS will send Hospital a letter confirming the commencement of the Participation Period and its end date after the SCR has registered and been confirmed for the SCR training session.

Select the term for the Participation Period:

☑   Twelve (12) consecutive months

☐   Thirty-six (36) consecutive months

SELECTION OF HOSPITAL OPTION:

The ACS NSQIP has established participation levels (the "Option(s)"), each of which has associated data contribution requirements and fees. Hospital has chosen, and ACS has confirmed, the Option indicated on Exhibit A ("Hospital's Option"). Hospital will continue participation in the chosen Option through the Participation Period unless ACS and Hospital mutually agree in writing to change the Hospital's Option and amend this Agreement accordingly. ACS will consider the timing of data reporting cycles to determine when participating hospitals will have an opportunity to select a different Option.

Select one of the following as Hospital's Option:

✓   **ACS NSQIP Essentials**

✓   **General & Vascular Surgery**

☐   **Multispecialty** (Must also complete and attach the Multispecialty Case Volume and SCR Worksheet)

☐   **ACS NSQIP Small & Rural**

☐   **Rural** (Hospital zip code falls under Rural Urban Commuter Area (RUCA) data codes 7.0 through 10.6.)

☐   **Small** (Hospital performs fewer than 1680 +/- 5% cases per year.)

☐   **ACS NSQIP Procedure Targeted**

        ☐   **General & Vascular Surgery**

        ☐   **Multispecialty**

☐   **ACS NSQIP Measures**

☐   **ACS NSQIP Pediatric**

SELECTION OF ANNUAL FEE:

The Hospital agrees to pay to ACS an annual fee for participation in the ACS NSQIP for the Participation Period. Detailed below is a current Pricing Guide to the ACS NSQIP Options. The annual fee that applies to the ACS NSQIP Option of choice will be fixed for the term of the Participation Period as selected above. Additional fees may apply as described in Section 10, Data Collectors, and Section 12, Audits.

Select the Annual Fee that applies to the ACS NSQIP Option of choice:

✓   **$27,000 ACS NSQIP Essentials**

☐   **$10,000 ACS NSQIP Small & Rural**

☐   **$29,000 ACS NSQIP Procedure Targeted**

☐   **$15,000 ACS NSQIP Measures**

☐   **$29,000 ACS NSQIP Pediatric**

SELECTION OF ANNUAL DISCOUNTS:

ACS will determine on an annual basis if Hospital qualifies to receive a discount(s) based on certain criteria. Small and Rural Option and Measures Option participants are not eligible for any discounts.

Select the 3 Year Contract Discount if a 3-year term for the Participation Period has been selected above:

☐   **($1,500) 3 Year Contract Discount**
    •   Hospital will receive an annual discount of $1,500, i.e. discounted each year if a 3-year term Participation Period selected above.

Hospitals are eligible for either a System Discount or a Collaborative Discount, but not both. Small and Rural Option and Measures Option hospitals that are part of a system may be counted toward the system volume threshold requirements so that larger hospitals in the system may qualify for a System Discount.

Name of Hospital: <u>Natividad Medical Center</u>

Select either System Discount or Collaborative Discount:

☐   **($3,500) System Discount**

Name of System: _____

System Discount:
- Must meet the ACS definition of a "System." A "System" is defined as two or more hospitals that are owned, leased, or contract managed by a central organization.
- 5 or more hospitals from a system must enroll in ACS NSQIP in order for any one of them to receive a system discount or 100% of the hospital system, if less than 5 hospitals in a system. Discount is $3,500 per hospital per year.
- For any hospital that participates in the ACS NSQIP prior to their system meeting the system discount requirements, that hospital will be entitled to the discount at the time of their next contract (or if on a three year contract, at the time of their next annual invoice) once their system meets the threshold requirements.
- Hospitals in a system may participate in different options.

☐   **($3,500) Collaborative Discount**

Name of Collaborative _____

Collaborative Discount:
- Hospital must be part of an ACS NSQIP recognized collaborative. The definition of an ACS NSQIP "recognized collaborative" includes the following:
    - ➤   Must have a formal data sharing agreement signed between the participating hospitals and the ACS NSQIP
    - ➤   Must hold quarterly meetings and produce meeting minutes
    - ➤   Focused on surgical quality improvement activities
- Hospitals in a collaborative may participate in different options.

☐   **($2,000) Pediatric Discount**

Name of Adult Affiliate _____

Pediatric Discount:
- Available only to Pediatric hospitals.
- Pediatric hospitals are eligible for an annual discount if their adult affiliate hospital also participates in ACS NSQIP Classic, Essentials, Small and Rural, Procedure Targeted, or Measures.

Name of Hospital: <u>Natividad Medical Center</u>

EXHIBIT B
ACS NSQIP Options

	Classic	Essentials	Small & Rural	Procedure Targeted	Pediatric	Minimum
	Any hospital	Any hospital	Small and rural hospitals (Small defined as performing fewer than 1680 +/- 5% cases per year. Rural defined as RUCA data codes 7.0 through 10.6.)	Any hospital	Freestanding General Acute Care Children's Hospital Children's Hospital within Larger Hospital Specialty Children's Hospital General Acute Care Hospital with Pediatric Wing	Any hospital
	Hospitals wanting additional data for research purposes	Hospitals wanting to collect only the essential elements for QI Purposes	Small and rural hospitals	Larger hospitals; Those w/ CPT codes available within the hospital	Hospitals with a Pediatric population	Hospitals with limited resources and need to focus on QI efforts
	Approximately 69 "Clinical" Variables	Approximately 46 "Clinical" Variables (Subset of Classic)	Approximately 46 "Clinical" Variables (Same as Essentials)	"Core" set of approximately 46 "Clinical" Variables + Procedure specific variables ("Core" set is the same as Essentials)	Approximately 94 "Clinical" Variables	Approximately 25 "Clinical" Variables
	General/Vascular Multispecialty	General/Vascular Multispecialty	Multispecialty	General/Vascular Multispecialty	Multispecialty	Multispecialty
	General/Vascular = 1680 cases per year (or all cases if less than 1680) Multispecialty = 20% total case volume by specialty (minimum 1680 cases or all cases if less than 1680)	General/Vascular = 1680 cases per year (or all cases if less than 1680) Multispecialty = 20% total case volume by specialty (minimum 1680 cases or all cases if less than 1680)	Maximum =1680 cases per year	Minimum =1680 cases per year (Exact volume dependent on the # of targeted procedures selected and hospital volume for each of these procedures)	Maximum = 1400 cases per year	Maximum = 840 cases per year
	General/Vascular = 40 cases per 8 day cycle Multispecialty = May be more than 40 cases per 8 day cycle -dependent on volume	General/Vascular = 40 cases per 8 day cycle Multispecialty = May be more than 40 cases per 8 day cycle - dependent on volume	All cases (100% capture)	15 "Core Cases" per 8 day cycle (use NSQIP standard sampling methodology to select cases) 25 "Procedure Targeted" Cases per 8 day cycle (or more if additional FTEs available)	Multispecialty = 35 cases per 8 day cycle	Multispecialty = 20 cases per 8 day cycle
	1 FTE Minimum May be more for Multispecialty- use formula: # cases required/1680 = # FTE required	1 FTE Minimum May be more for Multispecialty- use formula: # cases required/1680 = # FTE required	¼ FTE for up to 400 cases ½ FTE for up to 800 cases ¾ FTE for up to 1200 cases 1 FTE for up to 1680 cases	1 FTE Minimum May be more if hospital chooses to collect more than 1,050 "Targeted" procedures per year	1 FTE Minimum	½ FTE Minimum

Effective as of May 2012

EXHIBIT C
SERVICES PROVIDED TO HOSPITAL

A. SCR Training, Education & Support

The ACS NSQIP will provide training, education, and support to the Surgical Clinical Reviewers (SCRs):

- **Initial Training Sessions for new SCRs**
- **SCR Conference Calls**
- **Clinical Support and Communications**

In addition, the ACS NSQIP will provide:

- SCR Job Description and Hiring Qualifications Document

B. Monitoring of Data Accrual Rates and Data Sampling Methodologies

The ACS NSQIP will monitor accrual rates and data sampling methodologies and make recommendations for Hospitals that are not meeting the Program requirements. These Hospitals will then be contacted directly to discern the reason for any discrepancies and to discuss a plan of action for correcting them.

C. Clinical Performance Improvement Reports

The ACS NSQIP has developed a set of reports for use by the Hospitals in support of their Clinical Performance Improvement efforts. These reports will allow Hospitals to view their surgical data in summary and detail and to benchmark their results against other participation hospitals. These reports include:

- **Non-Risk Adjusted Online Reports & Benchmarking Tools**

- **Risk Adjusted Semiannual Reports**

D. IT and Customer Service Support

The ACS NSQIP will supply customer service and technical support to Hospitals including the set up of new Hospitals; phone and email support; quality assurance and monitoring of software performance; occasional and reasonable ad-hoc report generation for Hospitals; help desk support for SCRs; software set-up and support for workstation software; and software and application maintenance and enhancement.

E. Software

The ACS NSQIP Workstation and XML Uploader (a data automation schema) are available to Hospitals to increase productivity of data collection.

EXHIBIT D
HOSPITAL PARTICIPATION REQUIREMENTS

Requirements for a Hospital's participation in the ACS NSQIP:

A. ACS NSQIP Program Administration and Oversight at the Hospital:

- Commitment from the Hospital's Chief of Surgery or delegated surgeon to serve as Surgeon Champion (SC) and to oversee ACS NSQIP implementation and administration at the Hospital.

- Participation of the SC on program conference calls.

- Funding for the SC or his/her designee to attend a national ACS NSQIP meeting once per year.

B. Data Collection by a Trained Surgical Clinical Reviewer (SCR):

- Hospital agrees to hire a qualified, dedicated SCR to collect and submit data to the ACS NSQIP.

- This SCR will be dedicated to the ACS NSQIP and will be provided with necessary access to medical records and patient information (paper or electronic) for collection of ACS NSQIP data elements.

- The SCR must successfully complete the ACS NSQIP training program, any required or associated exams, and participate in on-going training, conferences, and conference calls.

- Hospital agrees to provide funding for the SCR to attend a national ACS NSQIP meeting once per year.

- In the event that the SCR is on extended leave or has chosen to leave the position during the program year, Hospital is expected to identify a back-up SCR ready to participate in training to assume the role of data collector.

C. Payment of Annual Fee:

- An annual fee paid to the American College of Surgeons will cover the cost of participating in ACS NSQIP:

  o ACS NSQIP website
  o Web-based Workstation
  o XML Uploader
  o Data verification and encryption
  o Data analysis
  o Report production
  o Inter-rater reliability determination and audits
  o Training and support for one SCR
  o On-line Benchmarking
  o Semiannual Report