

SYSTEMS IMPROVEMENT AGREEMENT

for

Pine Ridge Public Health Service Indian Hospital

This Systems Improvement Agreement (referenced herein as "SIA") is between the Centers for Medicare & Medicaid Services ("CMS") of the United States Department of Health and Human Services, and the Indian Health Service of the United States Department of Health and Human Services ("IHS") (collectively, "the Parties"), regarding the Pine Ridge Public Health Service Indian Hospital ("the Hospital"). This SIA is being executed and will be implemented to further the objectives of Titles XVIII and XIX of the Social Security Act, to facilitate the delivery of quality health care services to the community served by the Hospital, and to promote consistent compliance by the Hospital with all of the applicable Medicare Conditions of Participation (CoPs) and the requirements of the Emergency Medical Treatment and Labor Act ("EMTALA").

This SIA is in effect until midnight 365 calendar days after the signature date of the SIA, unless the Hospital voluntarily withdraws its participation in or is terminated by CMS from the Medicare Program, CMS determines that the terms of the SIA are fulfilled earlier, or the terms of the SIA are extended in accordance with the provisions contained in this SIA. All timelines referenced in this SIA will be calendar days, unless otherwise noted.

Recitals

Whereas, on a recertification survey conducted October 26 through 29, 2015, CMS Federal surveyors found the Hospital was not in compliance with three Conditions of Participation (CoPs): 42 CFR §482.12 Governing Body; 42 CFR §482.21 Quality Assurance and Performance Improvement (QAPI); and 42 CFR §482.22 Medical Staff. CMS informed the Hospital in a letter dated November 13, 2015 that the Hospital was subject to termination from the Medicare program with a projected termination date of Thursday, February 11, 2016, which was amended on November 24, 2015 to a projected termination date of January 27, 2016;

Whereas, in a letter to the Hospital dated January 29, 2016, CMS informed the Hospital that a revisit survey completed January 14, 2016 verified that the Hospital had achieved and maintained substantial compliance with the CoPs, and that the termination action which was to be effective January 27, 2016 had been rescinded;

Whereas, on an Emergency Medical Treatment and Labor Act (EMTALA) complaint survey conducted on October 26-29, 2015, CMS Federal surveyors identified EMTALA violations at the Hospital, including failure to provide medical screening exams and/or necessary stabilizing treatments within the capabilities of the hospital. CMS informed the Hospital in a letter dated November 25, 2015 that the Hospital was subject to termination from the Medicare program with a projected termination date of February 23, 2016;

Whereas, CMS notified the Hospital in a letter dated December 16, 2015 that its Plan of Correction (PoC) for deficiencies cited on the October 29, 2015 EMTALA survey was acceptable;

Whereas, on an EMTALA revisit survey on January 14, 2016, CMS Federal surveyors identified further EMTALA violations at the Hospital;

Whereas, CMS notified the Hospital in a letter to the Hospital dated February 4, 2016 that its PoC for deficiencies cited on the January 14, 2016 EMTALA revisit survey was unacceptable. In a letter to the Hospital dated February 5, 2016, CMS communicated that the subsequent PoC received on February 4, 2016 was acceptable.

Whereas, CMS communicated in a letter to the Hospital dated February 10, 2016 that it extended the projected termination date of February 23, 2016 to April 15, 2016 to allow time for a revisit survey to verify the Hospital's compliance;

Whereas, on February 25, 2016, CMS completed a third follow-up EMTALA revisit survey for the EMTALA complaint investigation originally conducted on July 16, 2015 with revisits on October 29, 2015 and January 14, 2016. Additionally, a new EMTALA complaint was investigated;

Whereas, on the February 25, 2016 survey, CMS Federal surveyors identified additional EMTALA violations, including failure to provide a medical screening examination sufficient to determine whether or not an Emergency Medical Condition existed;

Whereas, on February 10, 2016, CMS notified the Hospital that its Medicare participation would be terminated but with an extended termination date of April 15, 2016;

Whereas, on April 8, 2016, in a letter from the Associate Regional Administrator of the CMS Western Division of Survey and Certification to the Principal Deputy Director of the IHS and the Acting Administrator of the Hospital, CMS re-issued a notice of final termination from the February 25, 2016 revisit survey and agreed to further extend the termination date to May 16, 2016 in order to allow a short period of exploratory time, until April 29, 2016, to determine if IHS and CMS could formulate a structured SIA that could enable the Hospital to achieve substantial compliance with the hospital quality and safety standards for Medicare participation including EMTALA requirements;

Whereas, CMS has determined that, in view of the impact the Hospital's termination would have on the community as well as the commitment to achieve long lasting compliance as evidenced in this SIA, affording the Hospital an additional opportunity to achieve and maintain substantial compliance with all the Medicare CoPs and EMTALA is in the best interest of Medicare beneficiaries in the Pine Ridge Tribal areas and the community served by the Hospital generally;

THEREFORE, CMS agrees to further extend the termination date of May 16, 2016 through the duration of this SIA in consideration of the Parties' fulfillment of the obligations contained herein.

A. CMS Obligations

1. **Extension of Termination Date:** Within 10 calendar days of the execution of this SIA, CMS will extend the May 16, 2016 prospectively-scheduled date for termination of the Hospital's participation in the Medicare Program for the duration of this SIA. Prior to the end of the SIA, CMS will assess whether the Hospital has achieved and is currently in substantial compliance with all of the Medicare CoPs and EMTALA requirements through an onsite survey by CMS or CMS-contract agents. Upon CMS's determination that the Hospital has achieved substantial compliance with Medicare participation requirements, CMS will then rescind the scheduled termination of the Hospital's Medicare participation. If CMS determines that the Hospital fails to achieve substantial compliance by the end of this SIA or the SIA is terminated under the conditions noted throughout this SIA, the extension of termination of the Hospital's participation will end and the termination will proceed with the appropriate notice required under CMS requirements and procedures.
2. **Modifications:** CMS agrees to consider the modification of this SIA in advance of its ending date if CMS determines that modification(s) are necessary to facilitate progress towards accomplishing the purposes of this SIA.
3. **QIN/QIO Assistance:** CMS will provide technical assistance to the Hospital's management team, practitioners and staff to help them improve the quality of their health care and health care delivery systems through engagement with the QIN-QIO system. CMS and IHS will work collaboratively to develop a mutually-agreeable framework with which to address these issues so that the QIN/QIO is able to effectively provide such assistance to the Hospital.
4. **Provide an Independent Monitor for CMS:** CMS will appoint, or engage the services of, a Quality Monitor to provide on-site observation and independent evaluation of the Hospital's progress in meeting the terms of the SIA. The Monitor will work directly with the Hospital management team, the Emergency Services team, and other Hospital staff and will communicate directly with CMS and, as directed by CMS, with the other parties to this SIA.
 - a) **Monitor's Reports:** The Monitor will provide written reports on or before the last day of each month to CMS, which will include:
 - (i) Dates and times of the Monitor's visits;
 - (ii) Summary of observations made during the visits;
 - (iii) Summary of any interviews conducted during the visit and with whom;
 - (iv) Summary of any records reviewed;
 - (v) Any patient safety or quality concerns identified;
 - (vi) Any complaints received by the Monitor;
 - (vii) Assessment of adequacy of Hospital staffing;

- (viii) Information on the progress or lack thereof made on each IHS obligation under the SIA, including the Action Plans described in Section C of the SIA, and;
- (ix) Any other issues or concerns that arise during the period of the SIA.

The parties agree that CMS will provide the written Monitor's reports to IHS and that IHS will identify and share a copy of the report with the Tribe(s) it deems appropriate. Information protected from disclosure by Federal law, such as HIPAA and the Privacy Act, will be redacted from the Monitor's Reports prior to such disclosure.

- b) The Monitor(s) will also arrange and conduct at least quarterly comprehensive reviews of the Hospital's progress with respect to the terms of the SIA and will provide the results to CMS in a quarterly teleconference which, at the discretion of CMS, may include key members of the Hospital, including contracted and permanent managers and staff involved in areas being discussed on a particular call, any other consultants, IHS, and/or representatives from other components of the Department of Health and Human Services. In addition to the quarterly calls, CMS reserves the right to call other individuals within the hospital at any time to confirm appropriate implementation, involvement and knowledge of SIA activities.
- c) If CMS determines in good faith that it is not feasible to appoint or enter into a contract with a Monitor despite its best efforts, these circumstances will not be considered non-compliance with the SIA. If CMS is unable to successfully engage a Monitor, the Parties agree to meet and consider all options available to them at that time.

B. IHS Obligations

1. **Immediate- and Short-Term Oversight of the Hospital:** IHS will take an active role in effecting and supporting the management and quality improvement efforts at both the Hospital and the IHS Great Plains Area Office (GPA), strengthening the Area Office and administrative capabilities of the GPA, and will apply available IHS resources and assistance for improvement processes immediately needed by the Hospital.
2. **Identification, Notification, and Action on Safety and Quality Issues:** IHS will ensure that there is an effective system of identifying unsafe situations and other barriers to safe, high quality care, adverse events and near misses and for, immediate reporting of those issues and events to both Hospital and IHS management, analysis of the issues and events to identify systemic changes that can prevent recurrence, and timely action to implement such systemic changes. IHS will timely address any urgent quality and safety concerns brought to its attention by IHS providers or CMS.
3. **Independent Monitor for CMS:** IHS and the Hospital will fully cooperate with the Monitor specified in Section A of this SIA; will provide the Monitor with full access to staff and Hospital facilities; and will provide all requested access, information and documents, except to the extent prohibited by Federal law and regulations, including but not limited to 25 U.S.C. § 1675. If IHS determines that it must withhold information requested by the

Monitor and CMS for purposes of monitoring progress and compliance with the SIA, IHS will make every effort to identify alternative source(s) of information that may be released to CMS and the Monitor. It is within the sole discretion of CMS to determine whether the nature and extent of information released by IHS to the Monitor and CMS provides sufficient evidence of compliance with the terms of the SIA. CMS will provide IHS with written notice in such a situation and provide IHS no less than 15 business days to cure unless there is less than 15 business days until the end of this SIA, in which event CMS will in good faith attempt to notify IHS as soon as practicable of such a situation. Additionally, such attempts by IHS to cure will not automatically extend this SIA. Extensions or other modifications to the SIA are made by mutual agreement by the Parties according to the "Modification" provisions at Section C.14 below.

4. **Hospital Governing Body:** IHS will establish a Governing Body consisting of Federal employees that will be delegated authority necessary to carry out Governing Body responsibilities for the Hospital in accordance with IHS authority, relevant CMS requirements and CMS Hospital Interpretive Guidelines. IHS will establish procedures so that there is meaningful input from the Tribe(s) IHS deems appropriate. IHS will identify and clarify the roles of the positions at IHS headquarters, GPA and the Hospital who participate directly as members of the Governing Body and those responsible for supporting governance of the Hospital, and will strengthen the Hospital's governance.
 - a) **Roles:** IHS will incorporate into the Hospital's bylaws and/or other relevant documents a detailed, written description of the Governing Body's membership, structure, authority, duties, functions and processes and will ensure they are compliant and implemented in a manner consistent with the applicable CoPs. The documents will clearly specify the roles and responsibilities of IHS headquarters, the GPA, and the Hospital Governing Body members, including the expected functions and outcomes and clear lines of authority and accountability for each entity in relation to quality of care, patient safety and other Governing Body responsibilities.
 - b) **Governing Body Policies, Procedures and Plans:** IHS will ensure the development and implementation of written Hospital Governing Body policies and procedures; interim and long-term Governing Body goals and plans for accomplishing the goals, including but not limited to goals for improving quality of care and patient safety; a schedule for regular governing body meetings throughout each year and a plan for how the Governing Body will fulfill all of the Governing Body responsibilities under the relevant CoPs during and between Governing Body meetings; and a plan for Governing Body review and monitoring of indicators and actions taken to address and continuously improve quality of care and patient safety.
 - c) **Education and Support for Governing Body:** IHS will develop and implement a plan for initial and ongoing education and other support for the Hospital Governing Body and all IHS headquarters and GPA staff involved in oversight and/or support of Hospital governance to ensure they each fully understand and are able to implement their respective roles and responsibilities. The plan will be informed by the literature

and other resources regarding best practices for hospital governing bodies, with an emphasis on the responsibilities of the governing body for making health care quality and patient safety the primary goal of the entire system, active engagement of the governing body in the leadership of the Medical Staff to effectively comply with the CoP requirements, and ensuring that the Hospital achieves and sustains compliance with all of the other CoPs. The plan will include the educational approach, design, timeframe and resources to be used.

5. **Emergency Department:** IHS will implement immediate, short-term, and long-term plans to ensure competent and qualified emergency department (ED) care that is sustainable over time.

a) **IMMEDIATE TERM - ED:** IHS will work to improve ED services and capability to provide competent and safe emergency care on a sustainable basis, consistent with the following:

(i) IHS will have qualified medical professionals with expertise in hospital emergency services evaluate current barriers to safe operation and devise immediate steps that can be taken to address or mitigate patient safety issues related to at least the deficiencies identified in recent CMS EMTALA revisit surveys (e.g., conducting comprehensive and accurate medical screening exams).

(ii) IHS will devise and implement an interim plan to closely monitor and address identified barriers to conducting comprehensive and accurate ED medical screening exams and any other identified patient safety concerns on an ongoing basis, until such a time that IHS can recruit and chooses to engage an experienced, capable, external Emergency Care Medical Group contractor to operate the ED and to provide competent and qualified emergency room care.

b) **SHORT TERM - ED:** The IHS will work to obtain the services of an experienced and qualified ED medical group contractor to provide emergency care in addition to the other services described below as soon as possible. An initial solicitation (Request for Proposal, "RFP") is currently active, closing in April 2016.

(i) If an ED medical group responding to the initial Request for Proposal (RFP) is found to be acceptable by IHS, IHS will award a contract and the timeframe for the successful medical group contractor to be on-board is within 30 calendar days of the contract award, if feasible.

(ii) If there is no acceptable proposal found from the initial RFP, within 45 calendar days of the closing of the initial RFP, IHS will rework the solicitation with input from CMS to increase the likelihood that an

acceptable proposal is received, and will re-issue within 60 calendar days a second RFP that provides between 21 and 45 calendar days during which time the solicitation is open for bidding, and ensure that there is a bidder's conference or similar method for potential bidders to obtain clarifications with respect to questions they may have. If the contracting criteria are satisfied and in accordance with federal procurement law, IHS anticipates it will award a contract. The timeframe for the successful medical group contractor (Group) to be on-board is within 30 calendar days of the contract award, if feasible.

- (iii) The contract, or a subsequent contract, will ensure that the Group will institute a program of regular training for all emergency department staff, monitor care provided as per 42 C.F.R. § 482.55, and contribute to the overall IHS efforts for effective workforce development, for at least the duration of this SIA.
- (iv) The contract will ensure that the Group will develop and implement a Quality Assessment and Performance Improvement (QAPI) system that is effective for Emergency Services to monitor the quality of care provided, triage process, compliance with EMTALA, provision of safe and capable transfers of patients to other facilities, and to continuously evaluate and improve the care rendered. Over time, the contracted emergency services team will develop and help Hospital staff implement a comprehensive plan for ongoing operation to meet evidence-based standards of practice and the relevant CoPs.
- (v) If IHS determines that there are no acceptable proposals after the close of the second RFP or if IHS determines that it is not feasible to contract the operation of the ED, these circumstances shall not be considered non-compliance with the SIA, but the Parties agree to meet and consider all options available to them at that time, including the option of termination of the SIA by either party, a decision by IHS to suspend ED operations, or to explore mutual agreement on an amendment or modification to the SIA.

6. **Hospital Management:** IHS will implement long-term plans to ensure a competent and qualified Hospital leadership and management that is sustainable over time, with an understanding that the initial focus of the Hospital management team(s) must be to mitigate immediate risks and build or restore basic hospital support structures and processes before the Hospital will be in a position to become engaged with a broader array of quality improvement resources and activities.

- a) **LONG-TERM HOSPITAL MANAGEMENT:** IHS agrees to promptly explore and take all necessary steps to procure the contracts and engage the individuals needed to implement Option 1 or Option 2 further described below for managing the Hospital: a

contracted "Hospital Management Firm" or a permanent Federal Hospital management team to be supported by contracted "Hospital Coach/Consultants" for at least the duration of this SIA. IHS may also choose to implement Option 1 followed by Option 2.

Any deadlines described below may be briefly extended by CMS in its sole discretion. IHS will use best efforts to implement Option 1 or Option 2 further described below within 6 months from the date of this SIA. If IHS is unable to successfully meet the requirements of this paragraph within the anticipated timeframe, or if IHS determines in good faith that Option 1 is not feasible or if no acceptable proposals become available to IHS for either option despite its best efforts, these circumstances will not be considered non-compliance with the SIA, but the Parties agree to meet and confer in good faith to address such circumstances and consider all options available to them at that time, including the option of termination of the SIA by either party, a decision by IHS to suspend Hospital operations, or to explore mutual agreement on an amendment to the SIA.

Whichever Option is selected, IHS must facilitate and ensure adequate communication and close and effective coordination with and among Hospital management, the Hospital Governing Body, relevant IHS Headquarters and GPA staff and all other consultants and resources being made available to the Hospital.

The information for the Hospital Management Firm or Hospital Coaches/Consultants to be provided to CMS must include credentials, curriculum vitae, national certifications and other information pertinent to their qualifications.

(i) OPTION 1 – Retain Contracted Hospital Management Firm:

- (1) IHS will engage the services of an experienced and qualified hospital management firm to manage the hospital full-time on-site for at least the duration of this SIA, to include a Chief Executive Officer, Chief Operations Officer, Chief Nursing Officer, Chief Medical Officer and Director of Quality and Performance Improvement (QAPI).
- (2) The Hospital Management Firm will provide a team to manage the Hospital while working with the individuals, if any, who will serve as the permanent Hospital managers to build the structures, processes and skills the permanent Hospital management team will need to achieve successful outcomes both clinically and operationally; provide support and coaching to address identified learning needs; and make interim, ongoing and final recommendations to support effective succession planning and successful transition to sustained and sustainable successful administration of the hospital.
- (3) IHS will conduct and complete market research, within 60 days of completion of the SIA or as soon as practicable, regarding prospective hospital management firms in order to gain insights into the considerations that may affect the extent to which acceptable proposal might be submitted in response to an IHS RFP.

- (4) IHS will issue, within 60 days of completion of the market research, or as soon as practicable, an RFP that provides between 21 and 45 calendar days during which time the solicitation is open for bidding, and ensure that there is a bidder's conference or similar method for potential bidders to obtain clarifications with respect to questions they may have.
- (5) If a Hospital management firm responding to the RFP is found to be acceptable, IHS will award a contract and the timeframe for the successful contractor to be on-board is within 30 days of the contract award, if feasible.
- (6) At a minimum, the Hospital Management Firm Team members must include individuals with demonstrated expertise and experience in hospital management, leadership, governance and organizational effectiveness; evaluation, design and implementation of clinical and non-clinical hospital protocols and practices meeting evidence-based standards of practice for hospital services; and quality improvement and patient safety, with particular expertise in organizational development as it relates to safety climate and culture; application of high reliability and human factors engineering principles; and successful implementation of patient safety modalities involving team training/crew resource management and engagement of front-line staff and hospital leadership.

(ii) OPTION 2 – Hire Permanent Management Team and Retain Team of Corresponding Hospital Management Coaches/Consultants:

- (1) IHS will retain and/or hire a permanent Federal Chief Executive Officer, Chief Operations Officer, Chief Nursing Officer, Chief Medical Officer and Director of Quality and Performance Improvement (QAPI) for the Hospital.
- (2) IHS will engage the services of an experienced and qualified hospital management firm to provide a team of Coaches/Consultants to work full-time on-site with each of these managers, consisting of a Chief Executive Officer Coach/Consultant, Chief Operations Officer Coach/Consultant, Chief Nursing Officer Coach/Consultant, Chief Medical Officer Coach/Consultant and Director of Quality and Performance Improvement (QAPI) Coach/Consultant.
- (3) The permanent leadership staff will work closely with the Hospital Coaches/Consultants to build the structures, processes and skills the permanent Hospital management team will need to achieve successful outcomes both clinically and operationally; provide support and coaching to address identified learning needs; and make interim, ongoing and final recommendations to support effective succession planning and successful transition to sustained and sustainable successful administration of the hospital.
- (4) IHS will conduct and complete market research, within 60 days of this SIA or as soon as practicable, regarding prospective hospital management or consultant

firms in order to gain insights into the considerations that may affect the extent to which acceptable proposal might be submitted in response to an IHS RFP.

- (5) IHS will issue, within 60 days of completion of the market research or as soon as practicable, an RFP that provides between 21 and 45 calendar days during which time the solicitation is open for bidding, and ensure that there is a bidder's conference or similar method for potential bidders to obtain clarifications with respect to questions they may have.
- (6) If a Hospital Coach/Consultant firm responding to the RFP is found to be acceptable, IHS will award a contract and the timeframe for the successful medical group contractor to be on-board and substantially onsite is within 30 days of the contract award, if feasible.
- (7) At a minimum, the Hospital Coaches/Consultants must include individuals with demonstrated expertise and experience in hospital management, leadership, governance and organizational effectiveness; evaluation, design and implementation of clinical and non-clinical hospital protocols and practices meeting evidence-based standards of practice for hospital services; and quality improvement and patient safety, with particular expertise in organizational development as it relates to safety climate and culture; application of high reliability and human factors engineering principles; and successful implementation of patient safety modalities involving team training/crew resource management and engagement of front-line staff and hospital leadership.

7. **Human Resources Generally:** IHS, working with appropriate contractors and/or consultants, will review the Hospital's organizational structure, vacant positions, and staff proficiency and performance of the existing management structure to determine organizational needs and develop and implement a plan to address identified needs in the Action Plan described in Section C below. In the Action Plan, IHS will identify short- and long-term goals for staffing levels and coverage essential for safe care in all clinical areas; and short- and long-term plans for addressing workforce and human resources issues generally, including but not limited to:

- a) Availability of position-specific competency specifications for permanent and contracted staff;
- b) Recruitment, assessment and screening of applicants;
- c) Initial and ongoing orientation and competency assessment;
- d) Ongoing practice improvement strategies and resources;
- e) Ongoing practice evaluation for competency assessment using multiple data sources; and
- f) Evaluation and action in response to identified concerns.

8. **Hospital Policies, Procedures and Processes:** IHS will ensure that the Hospital, working with appropriate contractors and/or consultants, reviews, updates, develops and implements policies/protocols/processes and conducts ongoing compliance assessment for the same to

ensure that services are provided in accordance with the applicable Medicare Conditions of Participation and evidence-based standards of practice with respect to all aspects of clinical care and clinical support processes in all areas, including but not limited to the ordering, maintenance and repair, disinfection and sterilization, and recall processes pertaining to equipment and supplies.

9. **Quality Assessment and Performance Improvement (QAPI):** IHS, with appropriate consultant(s) and/or contractor(s), will ensure that the Hospital designs, implements and maintains effective structures, processes, culture and supports for an effective and sustainable QAPI system that complies with the Medicare CoPs at and for the Hospital. The individual(s) in the role of Director of Quality and Performance Improvement will assess and address identified needs with respect to at least the following:

- a) Identify resource needs, structures, processes, strategies and tools needed to build an effective, Hospital-wide QAPI program that reflects the complexity of the Hospital's organization and services; involves all Hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes, the prevention and reduction of medical errors, and mechanisms for achieving, monitoring and sustaining compliance with the Medicare CoPs for acute care hospitals and EMTALA requirements.
- b) An initial, particular area of emphasis for the QAPI program will be assessment of and intervention with safety culture in order to engage all staff in all departments on a Hospital-wide basis, Hospital management and Governing Body members and the GPA in building and sustaining a culture of safety and learning. The appropriate contractors and/or consultants and the Director of Quality and Performance Improvement will identify barriers to setting and achieving goals for quality and safety and staff reporting of unsafe situations and adverse events and design, implement and/or recommend strategies to address them. They will also build effective systems for multidisciplinary approaches that engage all levels of Hospital staff and leadership in proactive identification of barriers to providing safe and high quality care, triaging this information as well as information from all available sources regarding unsafe situations, near misses and adverse events, and thoroughly analyzing this information with the intent to identify system changes that can prevent recurrence in the future.

10. **Medical Staff:** IHS and/or specifically the Hospital Governing Body, depending on the allocation of responsibility under the relevant CoPs, working with appropriate contractors and/or consultants, will:

- a) Review and revise Medical Staff Bylaws to comply with the CoPs.
- b) Organize the Medical Staff to include a Medical Executive Committee that operates under the authority of the Governing Body and is organized consistent with the newly-established Medical Staff by-laws.
- c) Strengthen the process for privileging and credentialing of all medical staff including contracted physicians, locum tenens, and interim medical staff.

- d) Establish and implement a Peer Review process for all members of the medical staff, including ongoing practice improvement strategies/resources, ongoing practice evaluation for competency assessment using multiple data sources, and evaluation and action in response to identified concerns.
- e) Establish a process for the Governing Body to hold the Medical Staff accountable for the quality of care provided throughout the Hospital.

11. Nursing Services: IHS, working with appropriate contractors and/or consultants, will:

- a) Perform a comprehensive assessment of the nursing process currently in place at the Hospital. All components of the process are to be assessed and evaluated for strength, compliance, effectiveness, and associated outcomes.
- b) Complete a full assessment of the competency of all staff delivering care in the Hospital including experience, education, orientation to Hospital/unit, evaluation scores, credentialing, skill level, etc.
- c) Perform a gap analysis of findings re ideal process and current state with identification of contributing factors.
- d) Develop and implement actions to address the issues identified in the gap analysis
- e) Identify recruitment and retention strategies to address nursing vacancies throughout the Hospital and the ED and develop recommendations for broader strategies that could be implemented by IHS.
- f) Develop a plan to integrate agency and per diem staff safely into the Hospital workforce.
- g) Develop a strong clinical education program to address orientation to unit/Hospital, competencies, assessment skills, critical thinking, and documentation skills.
- h) Develop recommendations for IHS to contract with area colleges, etc. to offer skills training, etc. to improve level of nursing care provided.
- i) Collaborate with pharmacy to provide medication administration training to improve knowledge of medication, indications, precautions, preparation, administration, and documentation requirements and pharmacy support to implement proactive strategies for preventing medication adverse events.

12. Infection Control: IHS, working with appropriate contractors and/or consultants, will:

- a) Develop and implement a comprehensive Infection Control/prevention program to integrate surveillance, data collection, outcome analysis, and improvement opportunities in all aspects of the Infection Control Practitioner's duties.
- b) Include Housekeeping staff and services in IC assessment, including checks for appropriate cleaning solutions use and monitoring for appropriate uses at critical times of year, such as flu season.
- c) Develop ongoing monitors/audits to assess high risk areas such as OR, ED, ICU, etc. to proactively address infection risks.
- d) Provide the education, structures, processes and resources required to support staff in effectively implementing their role in infection prevention.

13. Patient Rights: IHS, working with appropriate contractors and/or consultants, will:

- a) Establish a process to ensure that all patients are cared for in a manner that is consistent with the protection and promotion of those rights as it relates to resolution of grievances, informed consent, ability to communicate with staff, and the provision of care within a safe environment.
- b) Develop and implement a grievance procedure that allows for timely resolution, communication to all involved parties, and tracking of grievances to establish patterns contributing to the cause of the grievance.
- c) Incorporate information gained from the grievance procedure into the QAPI program to address issues, improve patient experience and reduce risk.

14. Physical Environment: IHS, working with appropriate contractors and/or consultants, will:

- a) Evaluate the facility and ensure implementation of a comprehensive plan to address the environment of care, the reduction of hazards in all clinical locations including locations in which risk factors related to mental health conditions need to be anticipated and addressed, and Life Safety Code compliance.
- b) Develop and maintain comprehensive plans (including training and competency assessment specific to responsibilities, ensuring usable/comprehensible instructional material, schedules, etc.) for cleaning, routine maintenance, environmental rounds, etc. Departmental management is accountable to ensure that staff have the information and resources needed to carry out their duties and will hold staff accountable for assigned duties.

15. Medical Records: IHS, working with appropriate contractors and/or consultants, will:

- a) Assess and improve processes for the management of the medical record with provisions for collection, storage, completeness, and legibility of the medical record.
- b) Train staff on the proper handling of the medical record, including compliance with HIPAA Privacy and Information Security Rules and other applicable laws and regulations.
- c) Develop daily audits for review of medical record deficiencies.
- d) Collaborate with Quality, Medical staff, unit management, ancillary departments, etc. to develop mechanisms to address and correct the identified issues in usability and workflow processes that contribute to the deficiencies.

16. Assess and Address Barriers to Quality and Patient Safety: IHS will analyze GPA and IHS Headquarters policies and procedures affecting the Hospital in at least the following areas; and provide to CMS a description of identified barriers to maintaining and improving the timely delivery of safe, high quality, evidence-based patient care. IHS will develop and implement short-term and long-term action plans to mitigate or resolve the identified barriers:

- a) Development, maintenance, usability assessment, implementation and communication of clinical and operational policies and procedures.

- b) Hospital staff and contracted clinical services recruitment, hiring, initial and ongoing competency assessment, orientation and training, performance evaluation and management.
- c) Selecting, obtaining and ongoing evaluation of key clinical and clinical support items and services, including but not limited to biomedical and other types of equipment and equipment maintenance services, medications and supplies, housekeeping and ambulance services.
- d) Alignment, collaboration and coordination of health care services and resources within the IHS system and between the IHS system and non-IHS health care services and resources (e.g., emergency medical services, academic medical centers, schools of medicine, nursing and other health professions)
- e) Patient access to care not available locally.

Plans to address any barriers identified as a result of this analysis will be included in the Action Plan described in Section C.4 of this SIA.

17. Quality Management Activities at IHS Headquarters: IHS intends to establish formal quality management functions throughout all levels of its system, from its Headquarters level to the individual Service Units. The functions of these quality management activities will be to adopt measures to draw upon DHHS and external resources to build effective, evidence-based structures, processes and other supports for sustainable bi-directional communication and partnership with the GPA to assess and continuously improve health care quality and safety at the Hospital in a manner consistent with the Medicare CoPs.

18. Long-Term Workforce Development: IHS will identify needs, barriers, and potential resources and actions to design and implement an effective long term workforce development strategy, to be included in the Action Plan described in section C.4 of this SIA, including actions to strengthen:

- a) Recruitment of staff;
- b) The process for tracking vacancies, and timely and effective filling of vacancies with individuals who have skills, knowledge and ability to provide quality, safe health care;
- c) Orientation of new staff;
- d) On-going support for professional continuing education, acquisition and maintenance of critical skills, and leadership development of permanent staff;
- e) On-going coaching or consultation support for key management team positions.

C. Timeframe, Additional Deliverables and Other Requirements

1. Plan of Correction (PoC): IHS will timely submit an acceptable PoC for any survey that requires a PoC prior to and during the pendency of the SIA. For a PoC to be acceptable, it must address all of the required elements specified in Chapter 2728 of the CMS State Operations Manual. IHS must obtain approval of the PoC from CMS. Failure to submit an acceptable PoC by the due date will result in the termination of this SIA and CMS will be free to take whatever action it deems appropriate, under applicable law.

2. Independent Consultants, Reviewers and Providers:

- a) **Payment:** IHS will:
 - (i) Be financially responsible for payment for all consultants, reviewers and providers retained by IHS.
 - (ii) Provide a copy of the contracts for all approved consultants, reviewers and providers required by this SIA to CMS within 14 days after execution of the contract.
- b) **Change of Consultants, Reviewers or Providers:** If any consultant, reviewer or provider retained by IHS fails to fulfill its obligations as specified in its agreement with IHS, its agreement may be terminated and/or amended. IHS shall promptly provide CMS with written, explanatory notice and explain its options and plan for proposed alternatives/replacements.
- c) CMS may, in its sole discretion, subject to the terms regarding Advance Notification specified in paragraph C. 18 in this SIA, determine whether to terminate this SIA or amend it to incorporate the completion timeline based upon the selection of the alternative/replacement(s).
- d) **Meeting with CMS Monitor:** Prior to the start of any consultant/team, reviewer or provider required by this SIA, IHS agrees to arrange a conference call between the consultant, reviewer or provider and CMS Monitor. The purpose of the call is for CMS to orient the team to the intent and goals of the SIA and to answer any related questions.

3. **Gap and Root Cause Analyses:** IHS, working with appropriate contractors and/or consultants, will, within 90 calendar days, conduct and provide a written report to CMS of an initial gap analysis and, should it be deemed necessary, a report identifying the root causes and factors contributing to the obstacles and system failures that are preventing or inhibiting the Hospital from attaining or maintaining safe and acceptable standards of practice and compliance with all Medicare CoPs and EMTALA requirements. CMS reserves the right to request additional information or additional analyses at any time prior to the conclusion of the SIA.

In completing the gap and root cause analyses, the following steps will be taken by IHS:

- a) Gather, systematically review and organize information from the multiple sources of existing information readily available to IHS regarding at least the areas of the Hospital and issues mentioned in section B of this SIA.
- b) The review will include information on the progress of actions taken to improve quality and safety for patients at the Hospital, barriers that remain to be addressed, known quality and safety issues, performance gaps in relation to acceptable standards of clinical practice, and deficient practices with respect to compliance with the Medicare Hospital CoPs and EMTALA requirements; and the root causes and factors contributing to the obstacles and system failures that are preventing or inhibiting the Hospital from attaining or maintaining safe and

acceptable standards of practice and compliance with all Medicare CoPs and EMTALA. These information sources include, but are not limited to, internal IHS and Hospital information sources; ongoing observations and input from staff, patients and families; activities such as patient safety-focused leadership rounds at the Hospital; Congressional testimony; CMS survey reports; any applicable Government Accountability Organization (GAO) reports; and reports of studies conducted by the Office of the Inspector General.

4. **Action Plan:** IHS intends to work with the HHS Executive Council for Quality Care (ECQC), and, as applicable, appropriate contractors and/or consultants, to develop an initial Action Plan based upon the gap and root cause analyses that IHS will carry out to make the improvements needed to fulfill the terms of the SIA and enable the Hospital to achieve and sustain compliance with the Medicare CoPs and EMTALA requirements.
 - a) The initial and revised Action Plans must include (a) identification of specific actions to resolve or mitigate the root causes of and factors contributing to the identified performance gaps and deficiencies; (b) projected timeframes for completion of each action; (c) processes to evaluate the success of the actions, the specific measures to be monitored, the frequency of monitoring for each measure, and plans for revision of actions as needed. The Action Plan will include initial plans with respect to strengthening the Hospital workforce consistent with section C.3 of this SIA. The initial Action Plan will be due to CMS no later than 90 calendar days after completion of the gap and root cause analyses.
 - b) After a review and assessment of the adequacy of and progress with the initial action plan by the "Option 1" and/or "Option 2" Hospital Management contractor(s) at subsequent dates during the SIA, revised action plans will be required at subsequent dates during the SIA, to be determined by CMS. IHS will be responsible for payment of all costs for developing and implementing the Action Plan(s), including any revisions CMS may require before CMS will accept the Action Plan(s).
 - c) IHS will provide the CMS Monitor with ongoing updates and at least monthly written reports or other documents that clearly reflect the progression and status of the Action Plan, including identification of problems that may jeopardize the successful implementation of the plan and actions underway to address those problems. A written report or other documents clearly reflecting the progression and status of the Action Plan, shall be due to the Monitor by the 15th day of each month. The Monitor will summarize and/or append these reports in the Monitor's monthly and quarterly communications with CMS. At the discretion of the Monitor and/or CMS, these reports may be followed by face-to-face or telephone conferences with IHS and appropriate contractors and/or consultants.
5. **Appeals Waived:** IHS agrees to waive its right to appeal any remedies, including termination of the Hospital's right to participate in Medicare, imposed as a result of any surveys conducted during the term of this SIA or for failure to either comply with the terms

of the SIA or to achieve compliance by the end of the SIA as determined by CMS. This paragraph shall survive the termination of this SIA for any reason stated herein.

6. **CMS Authority:** Notwithstanding any provision of this SIA, or any document generated pursuant hereto, CMS and its agents retain full legal authority and responsibility to conduct unannounced surveys, investigate complaints and otherwise evaluate the Hospital's compliance with all Medicare requirements, including but not limited to the Medicare CoPs and EMTALA requirements and to this end may survey, or authorize its agents to survey the Hospital and take enforcement action including, but not limited to, termination of the Hospital's participation in the Medicare Program. Nothing in this SIA should be construed as limiting or otherwise interfering with CMS' enforcement authority including, but not limited to, CMS' authority to revoke the Hospital's Medicare certification in the event that the Hospital is not found to be in substantial compliance with Federal requirements at 42 C.F.R. Part 482, or fails to comply with any of the provisions of this SIA as determined by CMS.
7. **Non-compliance and Termination for Cause:** Any terms of the SIA not met by IHS will constitute non-compliance with the SIA and may result in CMS exercising its right to proceed with the termination of the Hospital's Medicare participation. CMS reserves the right to terminate this SIA and proceed with termination of the Hospital from Medicare participation if it is determined that IHS or the Hospital has not fully disclosed information about the Hospital and/or the personnel, activities, and outcomes as they relate to any of the items outlined in this SIA or if the Hospital has been found to be out of substantial compliance at a recertification survey, subject to the terms regarding Advance Notification and opportunity to cure, as specified in paragraph C. 18 in this SIA,. If IHS refuses to make the necessary commitments to implement the Action Plan(s) developed pursuant to this SIA without good cause, as determined by CMS, CMS will view this as a non-compliance with the SIA. This SIA does not affect any other federal oversight functions or administrative actions authorized by law.
8. **Communication with the Public:** The Parties will provide reasonable advance notice to all of the Contacts listed for each other in Paragraph C.24 of this SIA and an advance copy of any written comments they elect to share with any members of the public, including but not limited to members of the news media, regarding the SIA or the Hospital's status with respect to Medicare Certification, participation or termination.
9. **Public Disclosure:** The parties recognize that this SIA is a public document. IHS will disclose the final terms of this SIA, and any amendments to the SIA, when executed, to the Tribe(s) IHS deems appropriate. The parties will also respond in accordance with written requests for the SIA submitted under the Freedom of Information Act, 5 U.S.C. Section 552.
10. **Extensions of Time:** Any deadlines or time parameters referenced in this SIA may be extended for good cause at the sole discretion and approval of CMS. If IHS believes there is a need to extend any deadlines, it will first determine whether the CMS Monitor concurs with the need and suggested timeframe. IHS shall send written notice to CMS detailing the reasons for the requisite extension, the additional time needed, and information regarding the Monitor's concurrence or lack thereof. CMS will determine whether or not good cause exists for an extension.

11. **SIA as a Basis for Resolution and Waiver of Liability:** This SIA sets forth the full and complete basis for the resolution of this matter by the Parties.
12. **Binding Nature of SIA:** This SIA shall be final and binding upon the Parties, their successor and assigns, upon execution by the undersigned, who represent and warrant that they are authorized to enter into this SIA on behalf of the Parties hereto.
13. **Medicare Contingency:** In the event the Hospital: (1) chooses to voluntarily terminate its participation in the Medicare Program, or (2) fails to demonstrate substantial compliance with Medicare CoPs, including EMTALA requirements, and is involuntarily terminated by CMS as a Medicare provider; the Hospital will be able to seek to be reinstated as a Medicare provider after demonstrating substantial compliance with the Medicare requirements and providing reasonable assurance that the problems that gave rise to the Medicare termination will not recur. The Parties agree that after an initial survey in which the Hospital demonstrates substantial compliance, the applicable reassurance period established by CMS will not exceed 120 calendar days.
14. **Modification:** This SIA may be amended by the written agreement of both Parties.
15. **Authority to Represent:** Each person executing the SIA in a representative capacity on behalf of each party warrants that he or she is duly authorized to do so and to bind the party he or she represents to the terms and conditions of the SIA.
16. **Voluntary Agreement:** CMS and IHS warrant that this SIA is entered into voluntarily with knowledge of the events described herein and upon the advice of legal counsel.
17. **Execution in Multiple Identical Counterparts:** This SIA may be executed in multiple identical counterparts, each of which shall be considered original for all purposes.
18. **Advance Notification:** CMS will provide IHS with advance written notice and an opportunity of no less than 15 business days to cure if it determines that IHS has failed to comply with one or more terms of the SIA, unless there is less than 15 business days until the end of this SIA, in which event CMS will in good faith attempt to notify IHS as soon as practicable of such a situation. Additionally, such attempts by IHS to cure must be completed before the expiration of this SIA.
19. **Indian Self-Determination and Education Assistance Act:** The Parties acknowledge that the Hospital and all or part of its functions are subject to the Indian Self-Determination and Education Assistance Act (ISDEAA). Should the Hospital, or any portion thereof, be contracted for under the ISDEAA, performance under this SIA may become moot. In the event of a decision to pursue contracting under the ISDEAA, IHS will notify CMS and CMS will determine, within its sole discretion, whether to re-sign or renegotiate the SIA with the Tribe and IHS, to the extent IHS remains a Party to the SIA; or to terminate the SIA.
20. **Limitation with Respect to Funds:** Nothing in this SIA shall be construed to require the Parties to allocate funds or execute contracts in excess of their authority or appropriations. Amounts expended by IHS in implementing this SIA do not constitute tribal shares pursuant to section 106(a)(1) of the ISDEAA.

21. **IHS and CMS Authority:** IHS and CMS shall not be required, under the terms of this SIA or resulting from the performance of this SIA, to take any action that is not within IHS' or CMS' legal authority. The failure to take such action shall not be construed as non-compliance with this SIA.
22. **Information Sharing:** Notwithstanding any disclosure provision contained in this SIA, CMS and IHS will comply with all applicable Federal laws and regulations regarding the confidentiality of health information. Medical, health, and billing records of IHS patients are subject to some or all of the following laws: the Privacy Act, 5 U.S.C. § 552a; the Freedom of Information Act, 5 U.S.C. § 552; the Drug Abuse Prevention, Treatment, and Rehabilitation Act, 21 U.S.C. § 1101; the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act, 42 U.S.C. § 4541; the Administrative Simplification requirements of HIPAA, 45 C.F.R. Parts 160 and 164; Confidentiality of Medical Quality Assurance Records, 25 U.S.C. § 1675; the Patient Safety and Quality Improvement Act of 2005; and Federal regulations promulgated to implement those Acts. CMS acknowledges that records and testimony protected by 25 U.S.C. § 1675 in CMS possession may not be disclosed or used in any judicial or administrative proceeding against IHS or the Hospital, except as provided for in 25 U.S.C. § 1675(d).
23. **Complete Agreement:** This SIA contains a complete description of the bargain of and between the Parties. All material representations, understandings, and promises of the Parties are contained in this SIA.
24. **Contacts for Reporting Requirements:** For the purposes of this SIA, all information, documents, reports and notices specified in this SIA shall be forwarded to the following representatives:

Contact Information for Pine Ridge IHS Hospital:

Chief Executive Officer
Highway 18 East, Pine Ridge, South Dakota, 57770

Contact Information for the GPA:

Area Director, IHS Great Plains Area Office
115 4th Street, Room 309, Aberdeen, South Dakota, 57401

Contact Information for IHS Headquarters:

Athena S. Elliott, Executive Advisor to the IHS Director
IHS Headquarters, Office of the Director, Mail Stop 08E53
5600 Fishers Lane, Rockville, MD 20857
athena.elliott@ihs.gov
301.443.1083

Contact Information for CMS Regional Office:

Steven D. Chickering, Associate Regional Administrator
Western Division of Survey and Certification, CMS
90 – 7th Street, Suite 5-300 San Francisco, CA 94103-6706
Steven.Chickering@cms.hhs.gov
415.744.3682

Contact Information for CMS Central Office:

Marie Vasbinder, JD, MBA, RN, CHC, NEA-BC
Director for the Division of Acute Care Services
Survey & Certification Group, CMS
7500 Security Blvd Baltimore, MD 21244
410.786.8665
Marie.Vasbinder1@cms.hhs.gov

Contact Information for CMS Consortium for Quality Improvement and Survey and Certification Operations (CQISCO):

David Wright, Associate Consortium Administrator
CQISCO-Dallas
1301 Young Street, Suite 714, Dallas, TX 75202
214.767.6426
David.Wright@cms.hhs.gov

SIGNED THIS DAY BELOW:

FOR IHS:

Printed Name: **Mary L. Smith, Principal Deputy Director**

By: /Mary L. Smith/ Date: APR 30 2016
Mary L. Smith, Principal Deputy Director
IHS Headquarters, Office of the Director, Mail Stop 08E53
5600 Fishers Lane, Rockville, MD 20857

FOR CMS:

Printed Name: **Steven D. Chickering, Associate Regional Administrator**

By: /Steven D. Chickering/ Date: 04-30-2016
Steven D. Chickering, Associate Regional Administrator
Western Division of Survey and Certification, CMS
90 – 7th Street, Suite 5-300 San Francisco, CA 94103-6706