

## SYSTEMS IMPROVEMENT AGREEMENT

This Systems Improvement Agreement (“SIA” or “the Agreement”) between the Centers for Medicare & Medicaid Services (“CMS”), a division of the United States Department of Health and Human Services (“DHHS”), and Dallas County Hospital District d/b/a Parkland Health & Hospital System (“PHHS”)(collectively, “the parties”) 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 hospital services to the community served by PHHS, and to promote consistent compliance by PHHS with all the Medicare Conditions of Participation for Hospitals at 42 C.F.R. §§482.11 - 482.57 and all the requirements of the Emergency Medical Treatment and Labor Act (EMTALA) at 42 C.F.R. §489.20 and §489.24. This agreement is in effect for the time period beginning September 30, 2011 through April 30, 2013, unless voluntary withdrawal or termination of the Medicare Provider Agreement occurs, or the terms of the Agreement are fulfilled earlier, in accordance with the provisions contained in this Agreement. All timeline referenced in this agreement will be calendar days.

### Recitals

**Whereas**, on May 12, 2011, a CMS Complaint Survey of PHHS found non-compliance with one of the Medicare Conditions of Participation (“CoPs”) for Hospitals (42 C.F.R. § 482.13 Patient Rights), which included significant deficiencies that affect or had the potential for affecting the health and safety of patients.

**Whereas**, on May 23, 2011, CMS issued a Letter to PHHS removing the deemed status of the hospital and notifying the hospital the state survey agency would soon complete a full survey of the hospital.

**Whereas**, on July 21, 2011, the first CMS Follow-up survey of PHHS found non-compliance with five of the Medicare Conditions of Participation (“CoPs”) for Hospitals (42 C.F.R. §§ 482.11, 482.12, 482.23, 482.42 and §489.20) and EMTALA requirements which included deficiencies that represented immediate jeopardy to patient health and safety.

**Whereas**, on August 9, 2011, CMS issued a Termination Letter to PHHS terminating the Medicare Provider Agreement effective September 2, 2011.

**Whereas**, on August 31, 2011, a Follow-up Survey of PHHS, found continued non-compliance at condition level with five of the Medicare Conditions of Participation for Hospitals (42 CFR §§ 482.11, 482.12, 482.23, 482.24, and 482.55) and EMTALA requirements which included deficiencies that represented immediate jeopardy to patient health and safety.

**Whereas**, on September 1, 2011, CMS issued a letter to PHHS extending the termination date to September 30, 2011.

***Whereas, on September 9, 2011, CMS issued a Termination Letter to PHHS terminating the hospital's Medicare Provider Agreement, effective September 30, 2011. This letter transmitted the August 31, 2011 survey findings.***

***Whereas, on August 31, 2011, a substantial allegation survey conducted concurrently with the Follow-up Survey of PHHS and completed on September 9, 2011 found non-compliance at condition level with two of the Medicare Conditions of Participation for Hospitals (42 CFR §§ 482.43, 482.54).***

***Whereas, on September 21, 2011, CMS issued a letter to PHHS transmitting the September 9, 2011 substantial allegation survey findings.***

***Whereas, CMS has determined that, in view of the impact PHHS' termination would have on the community, affording the hospital an additional opportunity to achieve and maintain substantial compliance with all the Medicare Conditions of Participation and EMTALA is in the best interest of the Medicare program in particular and the community served by PHHS generally.***

**THEREFORE, in the interest of avoiding termination of PHHS' Medicare Provider Agreement on September 30, 2011 and in bringing PHHS into full compliance in a timely manner with all regulatory Conditions of Participation for hospitals at 42 C.F.R. §§482.11 - 482.57 and EMTALA, the Parties agree as follows:**

CMS agrees to stay the scheduled termination action during the pendency of this Agreement by written notice to be executed and delivered to PHHS within 24 hours of execution of the Agreement.

In consideration for CMS' stay of the scheduled termination action, PHHS agrees to do the following at its own expense:

- 1. Obtain Independent Consultative Review:*** PHHS will obtain an independent expert onsite review that will provide the following: a comprehensive hospital-wide analysis of its current operations compared to industry accepted standards of practice to ensure compliance with all the Medicare Conditions of Participation for acute hospital provider and EMTALA requirements related to the timely provision of care and services; recommendations for hospital-wide changes and improvement to ensure compliance with all the Medicare Conditions of Participation for acute care hospitals and EMTALA; assistance in implementing and evaluating such changes and improvement; and implementation of an effective and ongoing hospital-wide Quality Assessment and Performance Improvement program to ensure continued compliance. Further, PHHS will provide CMS with written information that identifies and details the composition of a proposed group of independent experts with expertise in the design, implementation, management and evaluation of hospital services, including, but not limited to, the following:

leadership and management supervision and accountability; quality and appropriateness of services, including emergency services, provided to patients in accordance with the Medicare Conditions of Participation for acute care hospitals and EMTALA; infection prevention practices; protection and promotion of patient's rights; discharge planning; outpatient services, qualified and supportive staffing resources; staff training and education; and quality assessment and performance improvement, as discussed in Section 2 below. The information will include the curriculum vitae and other information pertinent to the qualifications and credentials of each expert proposed for retention. PHHS will not retain the services of any of the proposed experts until CMS concurs. At a minimum, the team of experts will have expertise and national certifications, as appropriate, related to their respective field and area of expertise. Unless otherwise approved in writing by CMS, no one who currently is, or in the past 12 months has been, an employee of, or affiliated with, PHHS or Dallas County or has any other conflict of interest (as defined in Attachment A hereto), may be included in the group of independent experts. Further, the experts may be obtained from a variety of sources rather than one consulting group.

- a. The independent consultative experts will identify, in writing, areas of improvements in PHHS' performance and conduct a root cause analysis (See Attachment A for definition of term). The report should provide details of identified obstacles and system failures that are preventing or inhibiting PHHS from attaining or maintaining safe and acceptable standards of practice to ensure compliance with all the Medicare Conditions of Participation at 42 C.F.R. §§ 482.11 - 482.57 and with EMTALA. The analysis must include, but is not limited to, review of the following: leadership/management accountability and supervision; quality and appropriateness of services, including emergency services and outpatient services, provided to patients in accordance with the Medicare Conditions of Participation for acute care hospitals and EMTALA; infection prevention practices; discharge planning process; qualified and supportive staffing resources; staff training and education; and quality assessment and performance improvement as discussed in Section 2 below. The written report will be submitted to CMS for review prior to issuance to PHHS, and will be accompanied by an oral briefing, at the discretion of CMS, on the report's findings. This report will be due to CMS no later than 60 days after CMS has approved the proposed independent consultative experts. CMS may require the independent consultative experts to revise the report, at PHHS' expense, before CMS will accept the report. If CMS accepts the report, the independent consultative experts will issue the accepted report to PHHS no later than 5 days after the date CMS accepts it. No later than 5 days after receipt of the report PHHS must notify CMS in writing that it has received the report.

b. The independent consultative experts will develop a detailed written plan identifying specific actions to be taken, including milestones, which will lead to substantial compliance with all the Medicare Conditions of Participation for acute care hospitals and EMTALA. The action plan will be due to CMS no later than 30 days after CMS has accepted the analysis report. CMS may require the independent consultative experts to revise the action plan, at PHHS' expense, before CMS will accept the action plan. If CMS accepts the action plan, the independent consultative experts will issue the accepted action plan to PHHS no later than 5 days after the date CMS accepts it.

1. No later than 15 days after receipt of the action plan, PHHS must notify CMS in writing that it has received the action plan and is committed to implementing the action plan. If PHHS refuses to make these commitments to implement the action plan(s) developed by experts without good cause, as determined by CMS, CMS will view this as a breach of the SIA.

c. Beginning 30 days after the month in which CMS has accepted the implementation plan, the independent consultative experts will submit monthly reports and updates to CMS through April 30, 2013, on the progression and status of the implementation plan, including identification of problems that may jeopardize the successful implementation of the plan and actions underway to address those problems. Updates shall be due by the 10<sup>th</sup> day of each month. The reports and updates will then be forwarded to PHHS no sooner than five days after submission to CMS. At the discretion of CMS, these reports may be followed by face-to-face or telephone conference discussions between the independent consultative experts and CMS as needed, and at the expense of PHHS.

2. ***Acquire Expertise in the development and implementation of an effective Quality Assessment and Performance Improvement (QAPI) program:*** PHHS will engage the services of individual(s) with national expertise and credentials in the development and implementation of effective Quality Assessment and Performance Improvement (QAPI) programs to work with PHHS to design and implement a comprehensive, hospital-wide, and effective QAPI program no later than 60-days after the date that CMS approved the proposed consultative experts. No one who currently is, or in the past 12 months has been, an employee of, or affiliated with, PHHS or Dallas County or has any other conflict of interest (as defined in Attachment A hereto), may be considered for this position. At a minimum, the expert(s) would conduct the following activities:

a. Conduct an analysis of the hospital's current QAPI Program in terms of its ability to meet the requirements of 42 C.F.R. § 482.21 for an effective,

ongoing, hospital-wide, data-driven QAPI program that is used to develop and implement performance improvement activities and projects that improve the timeliness and quality of care and the safety of patients at PHHS. The analysis will include, but not be limited to, evaluation of the adequacy of the QAPI program's resources, the qualifications of the QAPI staff, and the level of engagement of PHHS's governing body, administrative officials, and medical staff in the QAPI program. The QAPI program expert's analysis is to be included in the report referenced in Section 1a above.

- b. Provide recommendations and a detailed implementation plan, including milestones to close any gaps identified in the analysis. The QAPI program expert's plan is to be included in the plan referenced in Section 1b above.
- c. Develop a monthly report and update, consistent with the requirements of Section 1. c., above.

3. ***On-Site Expert:*** In addition to engaging independent consultative experts, PHHS will engage the services of an independent, full-time, on-site Compliance Officer. The Compliance Officer will provide oversight and coordination of PHHS's compliance efforts in accordance with the reports and plans as required pursuant to this Agreement and provide ongoing feedback to the parties about PHHS's improvements and compliance with all the Medicare Conditions of Participation for acute care hospitals and EMTALA. The Compliance Officer will work directly with the Chief Executive Officer, the Chief Medical Officer, and PHHS' Corporate Compliance Officer to coordinate the QAPI program with accountability for specific goals and objectives. The Compliance Officer must have knowledge of clinical policies and procedures and the ability to choose among a number of alternatives in overseeing and monitoring the development and implementation of the QAPI program.

- a. PHHS will engage the Compliance Officer for the duration of this Agreement.
- b. As part of the oversight, as the independent compliance expert, the Compliance Officer will conduct quarterly comprehensive reviews of the QAPI program activities and status of the hospital's compliance with the Conditions of Participation and EMTALA, and will provide the results to PHHS and CMS.

4. ***Selection of Consultants:*** Within 45 days after the effective date of this Agreement, PHHS shall provide CMS with information that identifies and provides the

qualifications (i.e. curriculum vitae) about one or more proposed Independent Consultative Experts, QAPI Expert Consultant, and On-Site Compliance Officer.

For all approvals of individuals or companies required under this Agreement by CMS, PHHS shall submit the names and qualifications of the designated individuals or companies via electronic mail or overnight mail. Within 10 days after receiving the information about the proposed consultants, CMS will approve one or more of the professionals proposed to serve in each capacity. CMS shall not unreasonably withhold approval

5. **Surveys:** CMS will authorize a Medicare certification survey of all the Medicare Conditions of Participation for acute care hospitals and EMTALA no sooner than 180 days and no later than 365 days from the date that CMS accepts the consultative experts' written implementation plan as provided in 1.b.
6. The parties further understand and agree:
  - a. Notwithstanding any provision of this Agreement, or any document generated pursuant hereto, CMS and its agents retain full legal authority and responsibility to investigate credible complaints and otherwise evaluate compliance with Medicare participation requirements, and to this end, may survey, or authorize its agents to survey, PHHS and take enforcement action including, but not limited to, termination of PHHS's Medicare provider agreement, in accordance with the procedures set forth at 42 C.F.R. § 489.53 and more fully at State Operations Manual sections 3010 and 3012. CMS will, however, provide PHHS with the opportunity to provide information about any deficiencies identified during the survey and to meet with CMS to discuss the findings/deficiencies. CMS may, at their discretion, provide the Independent Consultant Experts with information acquired during the course of this Agreement that may be relevant to the development or implementation of their action plan.
  - b. In the event that the survey referenced in Section 5 herein demonstrates that PHHS is substantially in compliance with all Medicare Conditions of Participation and EMTALA, CMS will promptly rescind the pending termination. PHHS will be released from the survey jurisdiction of the Texas State Agency and CMS will restore the deemed status of PHHS.
  - c. In the event that the survey referenced in Section 5 herein demonstrates that PHHS is found with Condition-level non-compliance in one or more of the Medicare Conditions of Participation for acute care hospitals or any

requirements of EMTALA at 42 C.F.R. §489.24, CMS will promptly notify PHHS of these findings and set a date for termination of the hospital's Medicare provider agreement, consistent with the notice requirements at 42 C.F.R. § 489.53(d) and more fully at State Operations Manual sections 3010 and 3012. CMS agrees that this termination decision will be based solely on the findings from the Medicare certification survey referenced in Section 5.

- 7.** PHHS shall remain solely responsible for achieving and maintaining substantial compliance with all applicable Medicare requirements and may not transfer this responsibility to any third party.
- 8.** CMS is not responsible for providing either PHHS, or its outside expert consultants, with technical advice in meeting its obligations under the existing Medicare provider agreement.
- 9.** All reference to number of days herein refers to "calendar days" rather than "business days." Any deadlines or time parameters referenced in this Agreement may be extended for good cause at the sole discretion and approval of CMS. In the event of the need to extend any deadlines, PHHS shall send written notice to CMS detailing the reasons for the requisite extension and indicating the additional time needed to meet the referenced deadline or time parameters.
- 10.** PHHS waives all rights to administratively or judicially challenge in any forum and for any purpose the legal or factual validity of the findings set forth in the Statements of Deficiencies (Form CMS 2567) from the surveys described in the Recitals. Further, PHHS shall neither file nor submit any action or suit against the United States, DHHS, CMS (including its officers, employees, and agents), Texas Department of State Health Services ("DSHS"), or any other component of the Federal Government in any administrative or judicial forum with respect to any matter related to the Medicare surveys described in the Recitals. This paragraph shall survive the termination of this Agreement for any reason stated here.
- 11.** This Agreement sets forth the full and complete basis for the resolution of this matter by the parties. Each party shall be responsible for its own costs including attorney fees associated with this Agreement.
- 12.** This Agreement will be executed with duplicate originals signed by both parties.

- 13.** All reports and notices referenced in this Agreement are to be submitted to the parties as follows:

For CMS:

Ginger Odle, Manager  
Non-Long Term Care Certification & Enforcement Branch  
Division of Survey & Certification  
Centers for Medicare & Medicaid Services  
1301 Young Street, Room 832  
Dallas, TX 75202  
[Ginger.Odle@cms.hhs.gov](mailto:Ginger.Odle@cms.hhs.gov)

For PHHS:

Ron Anderson, M.D., Chief Executive Officer  
Parkland Health and Hospital System  
5201 Harry Hines Blvd  
Dallas, TX 75235  
[Ron.Anderson@phhs.org](mailto:Ron.Anderson@phhs.org)

With a copy to:

Paul S. Leslie  
Executive Vice President & General Counsel  
Parkland Health and Hospital System  
5201 Harry Hines Blvd  
Dallas, TX 75235  
[Paul.Leslie@phhs.org](mailto:Paul.Leslie@phhs.org)


- 14.** If PHHS wishes to dispute any action taken by or on behalf of CMS under this Agreement, excluding possible termination at the end of the Agreement based on continued non-compliance with one or more Medicare Conditions of Participation or EMTALA, it may submit a written statement with supporting evidence to CMS within ten (10) days of receiving written notice of such action. CMS will review such submission and promptly issue a written final determination.
- 15.** The terms of this Agreement shall be binding on the parties hereto, including their successors, transferees, administrators, heirs, executors, designees, assigns, agents and contractors.
- 16.** Each person executing the Agreement in a representative capacity on behalf of either 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 Agreement.

17. This Agreement may be amended by the written agreement of both parties. Any terms of the Agreement not met by the provider will constitute a breach of the Agreement, and may result in CMS exercising its right to proceed with the termination of the Medicare provider agreement.

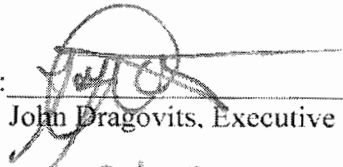
18. The Parties hereby agree that all documents, information and data produced or prepared in accordance with this Agreement are subject to applicable federal and state law privacy protections including, but not limited to, 5 U.S.C. § 552(b), 45 C.F.R. §§ 5.61–5.69, and Texas statutes protecting the privilege and/or privacy of medical records, quality assurance, patient safety, peer review, and performance improvement activities.

THE FOREGOING PROVISIONS ARE HEREBY AGREED TO ON THE DATE(S)  
INSCRIBED BELOW

**For Dallas County Hospital District**

By:   
Ron Anderson, M.D., President & CEO

Date: 9/27/11

By:   
John Dragovits, Executive Vice President & CFO

Date: 9/27/2011

**For the Centers for Medicare & Medicaid Services**

By:   
Gerardo Ortiz, Acting Associate Regional Administrator  
Division of Survey & Certification  
CMS Dallas

Date: 9/28/11

## **Attachment A:**

### **Definitions:**

**Conflict of Interest:** A situation in which a person has a financial, private, or personal interest that may adversely affect or influence or appear to adversely affect or influence the professional and objective exercise of his or her duties and obligations as set forth in this Systems Improvement Agreement by and between CMS and PHHS.

**Root Cause Analysis:** An analysis that includes problem identification and definition; investigation for gathering information; identifying root causes; implementing solutions; and monitoring these solutions to ensure they continue to prevent the original problem identified.

### **Minimum Scope of Gap Analysis and Written Action Plan:**

At a minimum, the following areas must be addressed by the independent consultative experts:

The analysis report must include the following:

1. comprehensive analysis of the hospital's current operations compared to industry accepted standards of practice that ensure PHHS's compliance with all the Medicare Conditions of Participation for acute care hospitals and EMTALA related to the provision of patient care and services, including, but not limited to, leadership/management accountability mechanisms, quality and appropriateness of services, including emergency services and outpatient services, provided to patients, infection prevention practices, discharge planning process, patient's rights protection, qualified and supportive staffing resources, staff training and education, and, per D below, Quality Assessment and Performance Improvement (QAPI);
2. root cause analysis of process and system failures; and
3. recommendations for changes and improvement to ensure full compliance with all the Medicare Conditions of Participation for acute care hospitals and EMTALA.

B. The action plan must include the following:

1. identification of actions to correct identified deficiencies in each service/functional area; and
2. identification of detailed milestones, including completion dates, related to each deficiency.

- C. The independent consultants must provide :
1. Monthly written update to CMS regarding:
    - a. progression and status of implementation plan
    - b. problems that may jeopardize successful implementation of plan; and
    - c. actions taken to address identified problems.
  2. Face-to-face or telephone conference to discuss monthly updates as needed.
- D. The analysis and action plans must also contain a section that specifically addresses the hospital's QAPI program, including:
1. Assessment of the Hospital's current QAPI program, including, but not limited to:
    - a. Effectiveness of the program in achieving increased patient safety and improved quality of care;
    - b. Whether it is ongoing and has adequate resources;
    - c. Whether the hospital's leadership (including its Board of Managers) is appropriately engaged in the program;
    - d. Whether it is hospital-wide;
    - e. Whether it is data-driven, including the process for determining the selection of tracking measures that comply with the requirements of 42 C.F.R. §482.21, definitions of adverse events and methods to identify them;
    - f. Adequacy of data collection and analysis; and
    - g. Process to develop, implement and evaluate performance improvement activities and projects.
  2. Recommendations and action plans to address identified weaknesses in the QAPI program, including detailed milestones and timelines for completion.