Parkland

The Parkland Health & Hospital System Case Study

How we learned the hard way

what every healthcare organization should know

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Parkland

Vision and Mission

'Dedicated to the health and well-being of individuals and communities entrusted to our core'

Parkland Statement of Mission

'By our actions, we will define the standards of excellence for public academic health systems'

Parkland Statement of Vision for the Future

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Background – Since 1894

- Parkland is the sole public hospital in Dallas County and largest provider of health care to the uninsured, low-income and Medicaid-covered patients in North Texas
- North Texas' regional trauma center, regional burn center, and regional disaster recovery coordinator
- One of the busiest Emergency Departments in the country with 247,519 visits reported for FY 2019
- Primary teaching hospital of University of Texas Southwestern Medical School
  - 50% of physicians practicing in North Texas trained at Parkland – program size: 1300 medical residents and fellows in 22 specialties
- Board of Managers – 11 members, each appointed by the Dallas County Commissioners Court

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Operating Metrics

- 1.2 million patient visits/year
- 878 licensed adult inpatient beds
- 107 licensed neonatal patient beds
- $2.1 billion operating budget partially supported by $620M in ad valorem tax revenue
- Level I Trauma Center with 247K visits/year
- 12 Community Oriented Primary Care health centers with 446K visits/year
- Main campus Specialty Care Clinics: 27 medical/surgical specialties with 363K visits/year
- 10 neighborhood Women & Infants Clinics, 240K visits/year
- Dallas County Jail Health System with 120K patients/year

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History : Events Leading to SIA with CMS and CIA with OIG

March 2010:

Parkland named as a defendant in qui tam or "whistleblower" lawsuit. Complaint alleged that beginning in 2007, certain claims submitted for payment for physical medicine and rehabilitation services were improper under Medicare and Medicaid requirements

Spring 2011:

Parkland underwent a series of state and federal inspections as a result of complaints and concerns about several serious and publicized adverse patient events that occurred in 2010 and 2011

- February 2011- Patient sentinel event occurs
- Complaint survey conducted by CMS in May 2011 identified Parkland not in compliance with Medicare regulations regarding patient rights
- Notification on May 23, 2011 that "deemed status" for Medicare certification removed and Parkland would have to undergo a full CMS survey

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History : Events Leading to SIA with CMS and CIA with OIG

Summer 2011:

- July 2011 - Full survey conducted by CMS
  - Surveyors identified "immediate jeopardy" (IJ) findings related to emergency medical screening exam procedures and infection control practices, putting the hospital on an accelerated track for termination from the Medicare program
- August 9, 2011 - CMS issued termination letter ("23 day letter") ending Parkland's Medicare Provider Agreement effective September 2, 2011
- Late August 2011 – Follow-up survey conducted by CMS
  - Surveyors had continuing IJ findings related to emergency services and medical screening exam procedure
- CMS notified Parkland that it still did not demonstrate satisfactory compliance with the Conditions of Participation (CoPs)
- CMS termination date was extended to September 30, 2011

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History : Events Leading to SIA with CMS and CIA with OIG

September 2011:

Due to the implications closing the hospital would have on North Texas, CMS allowed Parkland to enter into a Systems Improvement Agreement (SIA) on September 28, 2011

- SIA was a relatively new and not often used form of CMS oversight to avoid termination.
- Termination from the Medicare program would have resulted in Parkland being unable to treat Medicare patients or be reimbursed for services performed for Medicare patients
- The financial implication could have exceeded $400 million/year in Medicare reimbursement

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History : Events Leading to SIA with CMS and CIA with OIG

Fall 2011:

Department of Justice (DOJ) intervenes and qui tam lawsuit unsealed

- From the outset, Parkland cooperated fully with DOJ, Texas Attorney General (AG) and U.S. Department of Health and Human Service Office of Inspector General (OIG)

May 2013:

Parkland entered into a Settlement Agreement with DOJ and Texas AG ($1.4 million) and to ensure it would not be excluded from participation in Federal health care programs, entered into a Corporate Integrity Agreement (CIA) with OIG

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SIA: Implementation of the SIA

- Parkland was required to engage a monitor, or team of independent experts – Independent Consultative Expert (ICE) - who had clinical and hospital operations skills, to aid Parkland in coming into compliance with all of the Medicare Conditions of Participation and the Emergency Medical Treatment and Labor Act (EMTALA).
- With CMS' approval, Alvarez and Marsal (A&M) was engaged as the Independent Consultative Expert (ICE), and began work with Parkland in November 2011.

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SIA: Independent Consultative Expert Process and Objectives

The ICE assembled a team of consultants that consisted of approximately 20 individuals with diverse experience and credentials including compliance, hospital operations, performance improvement, clinical (physician, nurses, physical therapists), finance and human resources to fulfill the ICE responsibilities:

- **Conduct a comprehensive hospital-wide analysis of Parkland's current operations to industry accepted standards of practice (a "Gap Analysis") to ensure compliance with all Medicare Conditions of Participation for Hospitals and EMTALA requirements.**
- **Conduct a comprehensive review and evaluation of Parkland's Quality Assurance and Performance Improvement (QAPI) program.**
- **Based on the findings of the Gap Analysis and the QAPI review, draft a comprehensive Corrective Action Plan (CAP) to assist Parkland with coming into compliance with all Medicare Conditions of Participation and EMTALA.**
- **Serve as a "compliance officer" to advise and report to CMS any instances of non-compliance under the SIA or non-compliance with Medicare Conditions of Participation during the term of the SIA.**

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SIA: Gap Analysis and Gap Drivers

- November 2011 – Gap Analysis conducted by the ICE measuring Parkland's compliance against Medicare Conditions of Participation (CoP) and EMTALA.
- February 2012 – "Gap Analysis" Report outlining findings (submitted to and approved by CMS)
- March 2012 – Extensive Corrective Action Plan (CAP) developed by the ICE to address identified deficiencies in the Gap Analysis (submitted to and approved by CMS)

ICE identified opportunities for improvement both within departments and across the organization:

- Inadequate nursing organization, staffing, nursing practice standards and documentation
- Serious barriers to effective patient access, flow and throughput in Emergency Services and bed management
- Ineffectiveness of Case Management, staffing, infrastructure and discharge planning
- Inadequate documentation of resident supervision
- Ineffective clinical handoffs and management of patients through the continuum of care
- Ineffective Quality Assessment and Performance Improvement (QAPI) functions
- Issues related to environmental services, infection prevention and patients' rights
- Inadequate medication management

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SIA: Gap Analysis and Gap Drivers

Some of the key drivers contributing to the lack of compliance were:

- Leadership focus on margin not patient care evidenced by a marginalized nursing organization
- Lack of acknowledgement/ownership of patient care quality and safety issues
- Departments and service lines operating in independent silos, poorly communicating or sharing "best practices" or working toward organization-wide process standardization
- Lack of transparency in reporting adverse safety events and quality issues
- Lack of timely and comprehensive` quality and safety data and metrics
- Ineffective communication up, down and across the organization
- Turnover, high vacancy rates and high use of temporary/"traveler" personnel
- Lack of supporting Human Resources systems to provide effective recruitment, retention and employee engagement, performance management, training and development
- Culture of complacency and acceptance of the "status quo"
- Limitations of an old physical plant that had not been modified for new technologies and increases in patient volumes

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SIA: Corrective Action Plan (CAP)

The CAP included changes to multiple facets of the enterprise:

- Organization structure and reporting relationships
- Leadership and personnel changes
- Clinical operations and support functions performance, productivity and effectiveness
- Policies and procedures at both the System and department levels
- Patient care and support process workflows
- Staffing models and staffing levels
- Physical plant to facilitate access, throughput and patient flow
- Enabling technologies to support revised workflows
- Improvements in internal communication
- Management to metrics

To address these action items:

- Work streams developed
- Daily updates
- Weekly work stream updates
- Weekly downloads to ICE of documented progress
- Documented evidence of all actions taken to satisfy tasks
- Monthly verbal updates by workstreams to ICE
- Monthly updates to the Board of Managers
- Monthly updates to CMS

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SIA: Monitoring Progress of CAP Initiatives

Following release of the Corrective Action Plan, the ICE developed a monitoring and reporting system to track attainment of SIA goals:

- Audits and metrics for every Action Stream – to assure the CAP was being implemented as designed to continually monitor and measure the percentage of completion of the implementation plan and outcome/effectiveness of the initiative
- Comprehensive set of operating metrics – enabled measurement of the impact and success of initiatives
- Frequent and regular audits of functions, processes and departments – to validate the intended effect of the CAP initiatives, the ICE conducted frequent audits to ensure the areas cited in the CMS survey and the ICE Gap Analysis were demonstrating improvements in the patient care and safety environment

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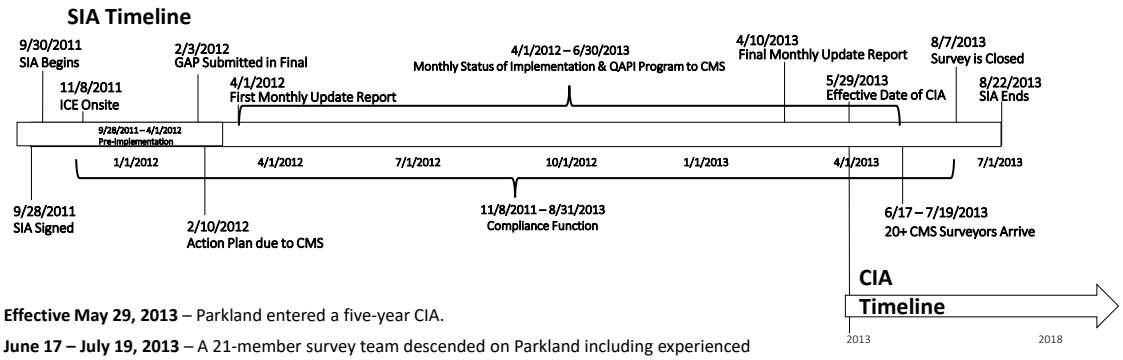
Timeline: SIA, CMS Re-Survey and "Deemed Status" Restored



Effective May 29, 2013 – Parkland entered a five-year CIA.

June 17 – July 19, 2013 – A 21-member survey team descended on Parkland including experienced surveyors from the Texas Department of State Health Services, CMS, and the federal DHHS Office of the Inspector General (OIG).

On August 7, 2013 – CMS issued a letter to Parkland having determined the Hospital was in substantial compliance, having fulfilled requirements of the Systems Improvement Agreement.

On August 22, 2013 – CMS issued a letter to Parkland restoring its "deemed status" and returning survey jurisdiction to The Joint Commission.

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Overview of OIG's Quality-of-Care CIAs

When a False Claims Act settlement resolves allegations of fraud that impact the quality of patient care, OIG may enter into a "quality-of-care" Corporate Integrity Agreement (CIA) with the settling provider.

- OIG requires that the provider retain an entity with clinical expertise to perform quality-related reviews. For example:
  - Independent quality monitor that will look at the entity's delivery of care and evaluate the provider's ability to prevent, detect, and respond to patient care problems.
  - Peer review consultant to evaluate the provider's peer review and medical credentialing systems.
  - Clinical expert to review the medical necessity and appropriateness of certain admissions and medical procedures.
- The presence of a quality-of-care CIA, alone, is not determinative of the quality of care at the provider's facility or facilities. Nor does it guarantee that the provider will provide adequate patient care going forward.
- The quality-of-care CIA does, however, require the provider to appropriately respond to the monitor and/or consultant's recommendations for improvement to quality, peer review, and/or medical credentialing systems during the term of the CIA.

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CIA: Implementation

During the course of the SIA, Parkland underwent significant change

- Transformation of culture and operations

Board and Senior Management Team viewed the CIA as Parkland's roadmap for sustainable improvements in the areas of:

- quality of care,
- patient safety, and
- regulatory compliance

Parkland had established a compliance program modeled after OIG Guidance

- CIA required Parkland to continue to maintain all elements

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CIA: Implementation

Parkland's CIA covered:

- Compliance and Ethics Program
- Quality and Patient Safety Program
- Code of Conduct and Ethics
- Core compliance, billing, reimbursement and clinical quality policies and procedures
- Specific training requirements
- Disclosure Program
- Quality of Care Dashboard to function as performance scorecard
- Rigorous reporting requirements (Reportable Events, Overpayments and Reportable Quality Events)
- Board and management level accountability

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CIA: Implementation

Parkland was required to engage a firm to serve as a Billing Independent Review Organization (Billing IRO), subject to OIG approval, to perform annual Claims Reviews.

Parkland was required to engage another firm to serve as a Quality Review Organization (QRO), chosen by OIG, to perform annual Clinical Quality Systems Reviews and other related assignments.

Parkland engaged annual external reviews of the effectiveness of its Compliance and Quality Programs. (Quality Program assessed by QRO.)

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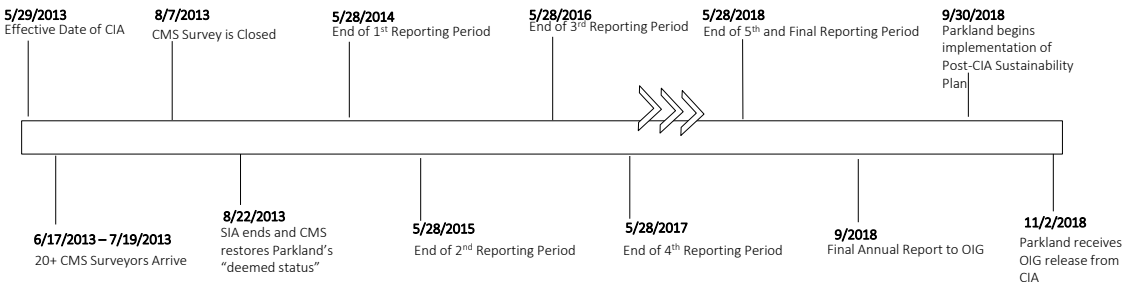
Timeline: CIA

In May 2013, Parkland entered into a Settlement Agreement with the US Department of Justice (DOJ) and the Medicaid Fraud Unit of the Texas Attorney General's office (Texas AG) to resolve a qui tam or "whistleblower" lawsuit. As part of the resolution, Parkland entered a five-year Corporate Integrity Agreement (CIA) with the Office of the Inspector General – DHHS resulting from improper billing practices



- QRO Clinical Quality Systems Review and Billing IRO Claims Review conducted each Reporting Period
- Review of Quality and Compliance Program Effectiveness each Reporting Period
- Comprehensive Implementation Report and Annual Reports following close of each Reporting Period submitted to OIG

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OIG's Approach to Monitoring the CIA

Periodic Communications with Chief Compliance Officer

Reliance on Quality Review Organization (QRO) for quality components

Required Notifications (e.g., Government Investigations)

Reportable Events (e.g., Substantial Overpayments, Ineligible Persons, violations of law)

Reportable Quality Events (e.g., deaths or injuries related to restraints/use of psychotropic medications, suicides, never events, care that fails to meet professionally recognized standards of care) submitted to the QRO

Site Visit(s)

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OIG's Approach to Monitoring the CIA

Review of Implementation Report and Annual Reports, including:

- Information related to Compliance Program and Quality Program Operations (e.g., Code of Conduct, policies and procedures, training content and reports of completion, Quality Dashboard, Disclosure Program summary, Ineligible Persons screening activities)
- Comprehensive summary of Reportable Events, Reportable Quality Events, Overpayments
- Compliance Program and Quality Program Effectiveness Review Reports
- Clinical Quality Systems Review Report from QRO and Parkland's response to QRO recommendations
- Claims Review Report (Unallowable Costs Review) from Billing Independent Review Organization (IRO) and Parkland's response to IRO recommendations
- Management Certifications and Board Resolution

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Planning for Sustainability Beyond the CIA

Consideration of current CIA requirements

Overlay the "7 Elements" of Compliance (and Quality)

Evaluate components of each element- retain, remove, or enhance components with goal of sustainability and effectiveness

For each component, assess impacted processes, committees, documents and desired outcomes

Develop action plan and communication strategy

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Element One (1 of 2): Program Oversight & Administration

Components	Post – CIA Key Consideration
• Chief Compliance & Ethics Officer (CCEO) • Compliance & Ethics Department • Chief Quality & Safety Officer (CQSO) • Quality & Safety Department	• New Compliance Program and Quality Program Policies • CCEO/CQSO reporting relationship to Board - GCEC and QBOM Charters, CCEO and CSQO job descriptions • GCEC/QBOM approval of Dept budgets; CCEO/CQSO scope of authority; role in CCEO/CQSO hiring/firing; and annual review of Dept resources and performance - GCEC and QBOM Charters
• Executive Compliance Committee (ECC) • Executive Quality & Safety Committee (EQC)	• ECC/EQC annual report to GCEC/QBOM demonstrating oversight of Programs in conformance with Charters

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Element One (2 of 2): Program Oversight & Administration

Components	Post – CIA Key Consideration
• Board Governance, Compliance & Ethics Committee (GCEC) • Board Quality of Care & Patient Safety Committee (QBOM)	• One-time post-CIA resolution (commitment to effective Programs) • No annual BOM resolution requirement – ECC, GCEC, EQC, and QBOM Charter (oversight and reporting responsibilities) • GCEC/QBOM assessment of Depts and Programs (annually, with required external reviews at minimum every three years) • Outside Expert – GCEC Charter • Ensure Board member ongoing training - GCEC Charter • QBOM meeting frequency maintained - GCEC Charter

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Element Two: Written Standards, Policies, and Procedures

Components	Post – CIA Key Consideration
• Code of Conduct & Ethics • QAPI Plan • Compliance & Quality-related policies and procedures	• Post-CIA Code and policy revisions – comprehensive review for necessary revisions • New Compliance Program and Quality Program Policies • Ongoing policy reviews and updates – updated review cycle and approval bodies

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Element Three: Training and Education

Components	Post – CIA Key Consideration
• General training • Billing & Reimbursement training • Clinical Quality training • Board Member training	• Post- CIA Compliance and Quality training plans approved by ECC/EQC – Employee requirements – Medical Staff and non-employee requirements • New/ongoing Board training – GCEC Charter • Disciplinary actions/performance evaluations for failure to complete training – Compliance Program Policy, Training and Education Policy, Progressive Discipline Policy, Quality Program Policy

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Element Four: Risk Assessment, Auditing & Monitoring

Components	Post – CIA Key Consideration
• QRO and Billing IRO • Annual and Ongoing Risk Assessments • Compliance Works Plan • Quality & Safety Workplan • QAPI Plan • Reporting to ECC/EQC and GCEC/QBOM	• Alignment with enterprise risk management (ERM)– CCO and CQSO part of ERM Core Team • Coordinate auditing/monitoring efforts across system – Compliance Auditing and Monitoring Policy • Tracking of all internal monitoring • Periodic utilization of external audits (e.g. Mock Survey, Billing/Coding audits) • GCEC and QBOM Charters require annual review of Programs (external at least every 3 years) • Ad hoc auditing/monitoring – Compliance and Quality Work Plans • Tracking/reporting of corrective actions – ECC and EQC Charters • Quarterly reporting to ECC/EQC and GCEC/QBOM – Respective Charters

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Element Five: Internal Reporting System / Disclosure Program

Components	Post – CIA Key Consideration
• Integrity Line • Disclosure Log • Safety Center/Adverse Event reporting • Notification of government investigations/legal proceedings to Compliance & Quality	• Reinforce Reporting Obligations and Non-Retaliation policies – Code of Conduct and Ethics, Reporting Obligations and Non-Retaliation Policies, Safety Event Reporting Policy, Compliance Training and Education Policy • Enhance communication of results, including corrective actions – Ongoing Compliance and Quality Program communication and training • Enhance reporting of disclosures and investigations to GCEC/QBOM – GCEC and QBOM Charters

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Element Six: Investigations & Remediation

Components	Post – CIA Key Consideration
• Compliance investigation process • Patient Safety investigation process (RCA/ACA) • Repayment of Overpayments • Reportable Events • Quality Reportable Events/Safety Event Committee • Reporting to appropriate government agencies/law enforcement when required	• Enhance reporting of investigations to GCEC/QBOM – GCEC and QBOM Charters • Preserve CIA-defined “Reportable Event” evaluation processes – GCEC Charter, QBOM Charter, Safety Event Committee Charter • Enhance communication of results, including corrective actions

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Element Seven: Enforcement & Discipline

Components	Post – CIA Key Consideration
• Disciplinary Procedure • Peer Review • Performance Review Processes • Sanctions Screening	• Communication and enforcement of disciplinary standards – Progressive Discipline Policy • Compliance and Quality performance metrics for leaders

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Guidance for Meaningful Board Oversight

The top challenges for the hospital board

- Establishing expectations for transparency, trust and non-retaliation.
- Educating board members on the challenges of large and complex healthcare delivery systems such as Parkland and on the volume and complex needs of the patient population.
- Developing standardized agendas and dashboards for compliance and quality oversight and monitoring.

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Guidance for Meaningful Board Oversight

Infrastructure and board development to meet the challenges:

- A well communicated Code of Conduct that emphasizes integrity, honesty, disclosure and non-retaliation. Creates a foundation for quality outcomes and fosters buy-in from all levels of the organization.
- Framework and appropriate governance structure to ensure the board is appropriately apprised of quality and compliance matters.
- Robust board orientation to familiarize members with the hospital and provide context and background in which they can ask relevant questions and develop informed perspective in decision-making.
- Education that not only focuses on board member roles and responsibilities but provides information and context on compliance, quality, industry challenges, best practices and benchmarking.

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Guidance for Meaningful Board Oversight

Infrastructure and board development to meet the challenges, cont'd:

- When possible to influence, select board members with clinical or compliance backgrounds.
- Develop a robust dashboard of metrics that include operational and financial data that allow board members to see early warning signs of adverse operational issues, potential compliance lapses and patient safety issues.
- Transform the board toward quality and compliance governance - hold leadership accountable by better understanding the care delivery system, the patients and their needs and the regulatory requirements and expectations.
- Establish a transparent and trusting relationship with management by setting reasonable expectations, asking meaningful questions and requiring follow up when appropriate.

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Guidance for Meaningful Board Oversight

The top areas of focus for board leadership:

- Hold leaders accountable to a compliant, quality, patient safety, just and non-retaliatory focused culture.
- Support the leadership team with adequate and appropriate resources and funding to address issues in a sustainable manner instead of addressing issues in isolation.
- Engage external subject matter experts and advisors as needed. They can provide focused expertise and industry best practices, expand management capacity and oversight identification implementation.
- Determine the right amount of information required for the board to govern versus manage.

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Guidance for Meaningful Board Oversight

The top areas of focus for board leadership, cont'd:

- Provide detailed accounts of adverse safety events. Real-life examples will resonate with board members and help them understand and correlate those events with the infrastructure needed to sustain quality outcomes. Explain the root cause of these types of events and the specific action plan that has been implemented to prevent it.
- Encourage questions and feedback –board members should be asking questions about how the organization identifies, investigates, addresses/resolves and prevents issues.

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Key Drivers to Success

The Parkland story was a success in the long run. Key drivers to success included project structure, platform for change, good leadership, accountability through metrics and implementation of sustainability measures.

Platform for Change

- "Success mattered" to everyone from the C-suite and Board to the front-line Staff. Much was at stake for the hospital, the employees, the patients and community.
- Most employees were "mission driven" and wanted to be led through change.
- Motivated by "fear" - similar to a financial crisis.

Project Structure

- Designing a project management infrastructure to "work around" dis-engaged leaders.
- Engaging a large number of middle managers and front-line staff in the detailed implementation initiatives creating ownership for transformation/change initiatives.
- Establishing realistic deadlines with accountability.

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Key Drivers to Success

The Parkland story was a success in the long run. Key drivers to success included project structure, platform for change, good leadership, accountability through metrics and implementation of sustainability measures.

Data-driven Decisions

- In order to drive change, it was critical to present leaders and employees with hard data on areas like compliance, throughput, safety events and trends, etc. in order to gain "buy-in."

Leadership

- Strong leadership and good managers make a difference -- progress was made more quickly where effective leadership was in place or could be readily put in place.
- Ability to change management personnel when necessary and manage through or around recalcitrant stakeholders.

Sustainability

- From day one, designed the implementation plan for sustainability – knowledge transfer, engagement of key stakeholders, internal process ownership, outcomes measurement, and ongoing monitoring and measurement of metrics.

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Key Drivers to Success

The Parkland story was a success in the long run. Key drivers to success included project structure, platform for change, good leadership, accountability through metrics and implementation of sustainability measures.

Transforming an Organization	• Priority focus of organization's resources driven from the top. • High levels of engagement by new leadership and the Board helped in driving the message, direction and demonstrating commitment. • Identifying "informal leaders" and untapped/unidentified talent to seed the organization with "change agents." • Managing progress to robust and meaningful metrics and holding leaders accountable for failing to meet goals on agreed upon metrics. • Developing transparency throughout the process and effective communication among internal and external stakeholders.
Cultural Change	• Driving the message of accountability – for patient care, patient safety, compliance, ownership, mission, and effective communication. • Designing infrastructure to support change – effective recruitment strategies, employee reward and retention, performance management and progressive discipline

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The Toll: Monetary and Non-Monetary Costs and Implications

Public Perception and Reputation	Regulatory	Staff and Leadership
• Headline news at the local and national level • Reports are public record • Social media • Stigma associated with organization	• Increased CMS, DSHS, Joint Commission surveys • Increased complaints to regulatory agencies • Required reporting of adverse events to CMS, DSHS, and OIG • Settlement Cost • Costs associated with engaging independent review organizations and external reviews of programs	• Exit of numerous staff • Changes in Board of Managers and Executive Leadership

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Wrapping It Up

Objectives of the release from the CIA

- Not an endorsement to revert back to “business as usual”
- Leaving a sustainably compliant and quality focused organization