

APPENDIX 16



Clinical Laboratory Assessment & Improvement Strategy

Final Report April 7, 2008

Scope of Responsibility

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- The information, opinions and recommendations contained in this report have significance only within the context of the entire report. No parts of this report may be used or relied upon outside that context.

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Section I – Introduction

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Engagement Objectives

- NCI was asked to evaluate California Department of Corrections and Rehabilitation (CDCR) laboratory facilities and services with the following objectives:
 - Conduct an operational and risk assessment of the existing laboratory network in which facilities will be evaluated individually in terms of their overall operational infrastructure, and collectively as a network;
 - Render recommendations on the strategic restructuring of the laboratory program in accordance with the mission of the CDCR (and the CDCR's planned enhancements in healthcare, including an overhaul of information systems); and
 - Create a plan with clear priorities and accountabilities for implementing the project's recommended improvement interventions and for monitoring progress going forward.

Scope of Work

- Specifically NCI agreed to:
 - Conduct an operational and risk assessment of the current state of the laboratory network.
 - Evaluate the feasibility of in-house and/or contracted (purchased) laboratory services.
 - Conduct an assessment of the existing Point of Care Testing (POCT) program (including STAT services available).
 - Evaluate the feasibility of centralized or regionalized laboratory services.
 - Evaluate existing and needed information systems.
 - Assist in creating a vision for a future, optimized operating model.
 - Determine the type and level of POCT and STAT services necessary to support the clinical needs of patients and physicians.
 - Determine the best strategic contracting/partnership relative to commercial laboratories.
 - Determine if centralization of laboratory services best fits CDCR's ideal model.

Outcomes

Milestone I

- Establish CPR Executive Steering Committee to participate in engagement oversight.
- Develop detailed time table for project completion and key deliverables.
- Begin CDCR facility on-site visits and interviews.

Milestone II

- Convene second meeting with Executive Steering Committee.
- Complete site visits and stakeholder interviews.
- Present preliminary assessment findings with focus on areas of priority.

Milestone III

- Convene third meeting with Executive Steering Committee.
- Present draft of initial models.
- Complete data collection efforts and data evaluation.

Milestone IV

- Convene final meeting with Executive Steering Committee.
- Present final laboratory operational models, including logistics and cost.

Navigant Consulting Inc. Team

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CPR Steering Committee

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- Justin V. Graham, MD., M.S., Chief Medical Information Officer
- Nadim Khoury, M.D.
- Terry Hill, M.D., Chief Medical Officer
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- Stan Ketchum, PMP, Project Manager
- Richard Kirkland, Director, Plata Support Division
- Glen Moy, Director of Health Information Integration
- Yulanda Mynhier, Assistant Deputy Director
- William Wilson, Central Regional Administrator

Meetings and Interviews

- To develop a robust understanding of the issues, NCI met with CPR representatives, Correctional Facility health care providers and administrators, Laboratory Vendors and Reference Laboratory Service Providers, as well as Sacramento Administrative stakeholders. (Exhibit I)
- NCI used a multidisciplinary Steering Committee to review the deficiencies and recommendations for development of strategic models, comprehensiveness, and ability to execute. NCI and the CPR Steering Committee met four separate times.
- NCI interviewed Correctional Facility representatives from other states including Texas, New York, Nevada, and Florida to identify best laboratory practices of laboratory service models in the prison environment (Exhibit IV)

Executive Summary – Immediate Recommendations

- The existing clinical laboratory services fail to provide the necessary service requirements to guarantee safe and adequate quality healthcare to inmates at the CDCR facilities.
 - 48% of the CDCR facilities are concerned with STAT turn around time; 94% perform Point of Care Testing without the proper medical oversight; and 21% reported multiple incidents of questionable quality of test results. (Exhibit XVI)
- CDCR will be required to implement immediate improvements to minimize risk, and concurrently begin planning a long-term corrective action plan to overhaul existing laboratory systems and create a safe and sustainable future operational model.
- *In light of the findings presented in this report;*
 - CDCR will need to establish adequate governance and oversight of laboratory services.
 - CDCR will need to strategically cease laboratory testing at facilities without licensed Acute Hospital Beds, as deemed prudent based on Key Improvement Plan Activities).
 - CDCR will implement adequate POCT at all facilities.
 - CDCR will resolve the reference laboratory vendor relationship, cost, quality, and STAT service.
 - CDCR will initiate a formal deployment of additional 'Key Improvement Activities' contained in this report.
 - CDRC will begin planning a long-term laboratory operational model based on improvements and various models identified in this report.

Executive Summary – Issues

- Physician performance is severely hindered by the inability of laboratories to provide basic laboratory information, which is required for adequate patient management. This in turn is leading to waste, unnecessary testing, and treatment delays.
- The overall laboratory services enterprise operates in a vacuum without the required level of leadership and management; it lacks accountability and oversight.
- The overall laboratory enterprise is in need of radical change and a comprehensive overhaul is due - several laboratories operating *within* CDCR facilities will need to be closed, while adequate provisions will need to be implemented to support access to STAT laboratory services.
- The infrastructure of laboratories operating within CDCR facilities is sub-standard and unsustainable in its current state.
- The reference laboratory services purchased from commercial providers is driven by 'low cost' with little emphasis given to aligning quality and service.
- The relationship with commercial laboratories lacks any level of accountability, which is resulting in substandard services and broken contractual obligations. (Exhibit VI)
- The Medical Directorship required to comply with State and Federal Regulations is sorely missing.

Executive Summary – Issues

- Two facilities operating in-house laboratories have discontinued testing since December 2007 (CMF* and CCI) due in part to infrastructure, inadequate medical directorship, and regulatory concerns; other facilities may soon follow suit unless preventive steps and/or corrective action are taken.
- The training of personnel, competency validation, and required quality control monitoring are inadequate and in some cases non-existent.
- The operational workflow for blood collection, testing and reporting of laboratory results is inefficient and plagued with burdensome paper work.
 - Test results are frequently not available in the chart for physicians to manage their patients and render the necessary care; unnecessary test re-orders are common.
- Laboratories lack the necessary centralized management structure; as well as appropriate policies and procedures, test menus and priorities, information systems, and proper supervision of processes and personnel.
- The organizational structure is cumbersome and personnel classification is ineffective to attract the required level of personnel. Recruitment and retention of qualified laboratory personnel is hindered by poor working conditions, remote facility locations, and low pay.

** At the end of February 2008, CMF passed a regulatory inspection conducted by the State's Field Services inspectors, following CMF's diligent corrective action implementation.*

Executive Summary – Issues

- The rate of pay for Clinical Laboratory Scientists is 27% under the market rate and 50% of phlebotomists are registry personnel.
- Laboratory facilities and infrastructure are inadequate and outdated in almost every aspect and cannot support in-house laboratory operation improvements, unless the status quo is desired; their chances of modernization to create an optimal and sustainable environment are slim.
- The laboratory enterprise lacks the necessary Laboratory Information System (LIS) to provide universal access to laboratory orders and test results. The limited stand-alone LIS capabilities that exist at six laboratory facilities are inadequate to achieve the required improvements.
- Laboratories have incorporated sub-standard, yet necessary, manual specimen collection schedules and patient logs, handwritten test requisitions, and manual entry of test results, among other processes.
- Test results from commercial laboratories are, at times, of questionable accuracy, delays in turnaround time are not uncommon, and access to timely STAT testing support is consistently unacceptable. (Exhibit VII)
- Reference laboratory billing is outside standard laboratory market billing practices. (Exhibit VIII)
- The current procurement of laboratory supplies, driven by Sacramento, is cumbersome, ineffective, and frequently wasteful.

Executive Summary – Corrective Action

- The laboratory enterprise requires a well thought-out improvement plan that will first include a 'Key Improvement Phase' to create the basic and fundamental infrastructure that will precede future strategy.
- The future state of clinical laboratory services for CDCR will include quality and safety guarantees through the creation of an 'Integrated Laboratory System' constituting key attributes, such as:
 - External (independent) oversight of the clinical laboratory enterprise.
 - Internal, multidisciplinary, centralized governance; medical directorship, and laboratory management.
 - A comprehensive, enterprise-wide, quality management program encompassing all areas and aspects of laboratory services, operations, and infrastructure.
 - Appropriate space and state-of-the-art equipment.
 - Robust, enterprise-wide laboratory information systems.
- The overall laboratory improvement plan will be aligned with CDCR-wide health care improvements.
 - Key improvements, deployed concurrently, will occur over a period of 3 - 18 months with the bulk of the benefits realized by month 12; a full improvement strategy, including a new strategic model, may take up to 48 months.

Executive Summary – Cost

- NCI estimates the current laboratory services cost CDCR approximately \$30M/Yr. Costs will increase to approximately \$35M/Yr over the next five years.
- Long-term improvements are estimated to require between \$2.4M - \$6.7M in one-time capital expenses depending on the future operating model.
- Operational costs of improved laboratory services will range from \$33M/Yr - \$37M/Yr over the next five years depending on the strategy.
- NCI evaluated various future laboratory operational models presented in this report. The ideal long-term model is for CDCR to “establish a single off-site core laboratory supported by advanced POCT and robust local STAT services with contracted local hospitals and a reference laboratory partner.” This model guarantees high-quality and yields five-year cumulative savings of approximately \$5M.
- In NCI's experience this model has the potential to additionally reduce operating costs by 10-15% over five years.
- ***In summary, it is NCI's opinion that maintaining the status quo in laboratory operations is unsafe and prone to trigger adverse patient outcomes. In addition, current laboratory operations are unsustainable and unfit to support the health care improvement mission of CDCR. Radical changes and improvements must be made.***