F I S C A L I M P A C T R E P O R T

SPONSOR Sandoval **ORIGINAL DATE** 01/29/08 **LAST UPDATED** **HB** 389

SHORT TITLE Hospital Clinical Lab Hospital Testing Project **SB**

ANALYST Geisler

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY08	**FY09**		
	$500,000	Non-Recurring	General

(Parenthesis ( ) Indicate Expenditure Decreases)

Relates to: SB 408

SOURCES OF INFORMATION
LFC Files

Responses Received From
Department of Health (DOH)
Health Policy Commission (HPC)

SUMMARY

Synopsis of Bill

House Bill 389 would appropriate $500,000 from the general fund to the Department of Health (DOH) to fund a pilot project that is intended to reduce utilization of laboratory testing within hospital settings in New Mexico. DOH would develop standards for the pilot project and may contract with a clinical laboratory for this pilot project. DOH will also be required to seek federal matching funds for this pilot project. Any unexpended funds at the end of fiscal year 2010 would revert to the general fund.

FISCAL IMPLICATIONS

The appropriation contained in HB 389 was not included in the FY09 DOH budget request. The request in the bill to "seek federal matching funds" for the pilot project could lead to questions about the adequacy of the appropriation in the bill if the federal match is not received.

SIGNIFICANT ISSUES

DOH notes that unnecessary laboratory testing is seen in many parts of the health care system with great variation in laboratory test ordering patterns between providers of similar patients. Unnecessary laboratory tests increase the cost of health care, may cause discomfort for the patient and do not improve health care. This issue has been studied in several hospital settings and potential means of reducing unnecessary laboratory testing have been identified. Strategies found to decrease unnecessary testing include: not allowing standing orders for patients admitted with some medical conditions; monitoring patterns of lab testing and providing feedback to providers; and using technology such as electronic medical records and test ordering that can help to guide clinical decision-making and that allow providers to see what tests have already been completed.

Currently, the regulatory oversight of clinical laboratory hospitals is under the Centers for Medicare and Medicaid Services (CMS) through the implementation of the Clinical Laboratory Improvement Act, (CLIA), section 5(a) Part F of Title III of the Public Health Service (PHS) Act (42 U.S.C. 262-3). While there are no state regulations for laboratories or laboratory personnel, the Department, through the CLIA program, assists clinical laboratory in hospitals in setting minimum standards for all laboratories to follow and to determine if laboratories are achieving those standards through certification and survey.

HPC notes that since the late 1990s, much of the laboratory testing within the three larger hospitals systems in New Mexico (Presbyterian, University of New Mexico Hospital and St. Vincent's Hospital) has been done outside of a hospital. The creation of TriCore Reference Lab as a consolidated regional laboratory, moved most of the laboratory testing within the hospital setting for these three organizations to a central location outside of the hospital. The volume of lab testing that remained within the hospital setting has been greatly reduced over the last decade for the three large New Mexico hospital organizations. What remained within the hospital settings were specimen collection locations and "stat" labs for tests of an emergent basis that had to have a very rapid (within minutes) turnaround.

DUPLICATION

HB 389 relates to SB 408, which appropriates $100 thousand for the same purpose.

OTHER SUBSTANTIVE ISSUES

<u>HPC provided background on clinical testing</u>:

According to the American College of Chest Physicians' published article, Laboratory-Clinical Interface: Point-of-Care Testing, point-of-care (POC) testing refers to the performance of diagnostic testing at or near the site of patient care rather than in the traditional central laboratory. Sites for POC testing include areas of the hospital that provide care to patients in the most urgent need of rapid diagnosis and therapy. These sites include the emergency department, the operating room, critical care units, and certain outpatient areas.

Historically, diagnostic technology has influenced where testing is performed. Large and complex laboratory analyzers have allowed testing to be batched efficiently and economically in centralized locations. With the evolution of the central laboratory, methods of quality control

matured significantly and produced accurate and precise results. Current technologic advancement is characterized by microchemistry (biosensors and whole-blood analysis), micro-computerization, miniaturization, and noninvasive testing procedures.

The Centers for Disease Control and Prevention's report, Good Laboratory Practices for Waived Testing Sites, discusses the Clinical Laboratory Improvement Amendments relating to testing. The following information pertains to waived testing:

Clinical Laboratory Improvement Amendments (CLIA) Requirements for Waived Testing

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under CLIA. The CLIA program is administered by Centers for Medicare and Medicaid Services and is implemented through three federal agencies—the Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, and the Food and Drug Administration. When CLIA was implemented in 1992, CLIA Committee was chartered to provide scientific and technical advice and guidance to the U.S. Department of Health and Human Services about laboratory standards and their impact on medical and laboratory practice.

By law, CLIA regulations are based on a complexity model, with more complicated testing subject to more stringent requirements. The three categories of testing for CLIA purposes are waived, moderate complexity (including the provider performed microscopy procedures [PPMP] subcategory), and high complexity. Facilities performing only waived tests have no routine oversight and no personnel requirements and are only required to obtain a Certificate of Waiver, pay biennial certificate fees, and follow manufacturers' test instructions. Tests can be waived under CLIA if they are determined to be simple tests with an insignificant risk of an erroneous result. Approximately 1,600 test systems representing at least 76 analytes are waived under CLIA.

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