Clinical Laboratory Health Screening Tests: A Regulatory Case Study

LYNN GORDON

INTRODUCTION

Typically, any diagnostic procedure involving clinical laboratory testing must be ordered by a licensed physician. Health screening tests, however, often are administered without a physician order. For example, a hospital or other health-care entity will promote health screenings for the general public through an annual health fair, with individuals agreeing to simple health checks independent of their physicians (e.g., blood testing with blood pressure, cholesterol, and blood glucose tests). As these tests are offered more frequently, or even on a routine basis, institutions need to be aware of the relevant federal and state laws governing their administration.

This article will present a case study on federal and state laws applicable to health screening tests in the state of Illinois. Although such tests may face similar regulations in other states, clinical laboratories and other health-care entities involved in health screening activities should be aware of and comply with applicable state laws in tandem with the relevant federal rules and regulations.

FEDERAL LAW

Any testing, including health screenings, that must be accomplished through a clinical laboratory must comply with the federal Clinical Laboratories Improvement Act (CLIA) (42 USC § 263). Congress passed CLIA in 1988, establishing quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of test location. Failure to comply with CLIA and its regulations could result in significant penalties, including suspension, limitation, or revocation of CLIA certification, cancellation of Medicare approval, sanctions, and/or civil money penalties.

CLIA regulations vary based on the complexity of the test method at issue (42 CFR § 493), and any health screening activity should begin with an assessment of the category of tests to be offered. Under federal regulations, the more complicated the test, the more stringent the testing requirements. The three categories of tests established by federal regulations include waived complexity, moderate complexity, and high complexity.

Waived complexity are tests considered lower complexity ("waived tests") and include those tests identified as such by the Health Care Financing Administration (e.g., tests for blood glucose levels, pregnancy, cholesterol levels, anemia, and streptococcal infection [see www.hcfa.gov/medicaid/clia/waivebl.pdf for the most recent list of waived tests]). These frequently are offered as health screening tests to the general public, with private individuals directly requesting such tests and receiving results without a physician order. Unless further restricted under state law, such limited health screening activity is permissible under CLIA without specific health-care provider involvement.

With respect to who may order moderate and high complexity tests and receive corresponding reports, CLIA is more stringent. CLIA requires that these tests be ordered by and reported to "authorized persons," as defined by applicable state law. States generally define an "authorized person" to be, for example, a licensed physician, dentist, or podiatrist. The laws of some states are more definitive than others as to who qualifies as an "authorized person." To determine appropriate test requisition authority, state law must be consulted in tandem with federal law when engaging in moderate and high complexity testing.

Furthermore, CLIA’s test requisition standard for moderate and high complexity tests includes additional requirements beyond specifying the appropriate authority for ordering tests and receiving corresponding reports. The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently requests written authorization for testing within 30 days. The laboratory must maintain the written authorization or documentation of efforts made to obtain a written authorization. Records of test requisitions or test authorizations must be retained for a minimum of 2 years. The patient’s chart or medical record, if used as the test requisition, must be retained for a minimum of 2 years and must be available to the laboratory at the time of testing and available to the

Elizabeth Lynn Gordon, J.D., is a health-care attorney with the law firm of Ungaretti & Harris in Chicago, Illinois.

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Department of Health and Human Services on request. The laboratory must ensure that the requisition or test authorization includes:

- the patient’s name or other unique identifier
- the name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values
- the test(s) to be performed
- the date of specimen collection
- for Pap smears, the patient’s last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment, or biopsy
- any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results (42 CFR 493.1105).

These parameters, including requisition authority, typically are not incorporated into the protocols for health screenings offered to the general public. Accordingly, clinical laboratories and other health-care entities involved in such health screening activities must limit testing to waived tests to remain CLIA-compliant. Moreover, health-care entities should be aware that CLIA defers to individual states for any additional regulations on such testing.

STATE LAW

As CLIA anticipates, many states have specific requirements as to who is able to order and receive reports on clinical laboratory testing. Illinois providers, for example, must comply with the Illinois Clinical Laboratory and Blood Bank Act (the “act”) (210 ILCS 25/1 et seq and Title 77 Ill. Admin. Code 1/450 et seq). The act’s provisions serve to limit even further the waived tests otherwise allowed by CLIA to be ordered by/reported to private individuals.

Under the act, as a general rule, clinical laboratories are restricted to examining specimens only at the request of a licensed physician, licensed dentist, licensed podiatrist, licensed physician assistant (in accordance with the Physician Assistant Practice Act of 1987), or therapeutic optometrist for diagnostic or therapeutic purposes related to the use of diagnostic topical or therapeutic ocular pharmaceutical agents (as defined by the Illinois Optometric Practice Act of 1987), authorized law enforcement agency, or, in the case of blood alcohol, at the request of the individual for whom the test is to be performed (in accordance with the Illinois Vehicle Code) (collectively referred to herein as “authorized persons”). If the request to the laboratory is oral, the authorized person must submit a written request to the laboratory within 48 hours. Tests then are reported directly to the authorized person making the request. It is unlawful for any person to accept specimens for tests from and make reports to persons other than those authorized to submit specimens and receive reports. The Illinois Department of Public Health (IDPH) may assess penalties or fines for such conduct.

Certain health screening tests are not as highly regulated. These are tests that are performed for the purpose of assessing a phase of the general state of health of human subjects. Specifically, the following tests are defined as “Health Screenings” under Illinois law and are exempt from the requirement that only authorized persons may submit specimens for testing and receive reports, allowing private individuals to request limited testing by and reporting from a laboratory:

- blood total cholesterol testing by finger stick method
- blood glucose testing by finger stick method.

Although such tests may be requested by and reported to private individuals, pursuant to the act, all health screenings must be conducted under a protocol approved by a physician licensed to practice medicine in all its branches (the “physician protocol”) that outlines, for example, the following:

- disclosure of the purpose and limitations of the screening tests to test subjects
- proper collection of samples and administration of tests including staffing
- staff training and equipment monitoring
- adequate procedures for protecting the confidentiality of test subjects and test results
- appropriate referrals for medical attention.

Illinois regulations provide further specific direction for these physician protocols. Any institution wanting to provide health screenings should develop and implement a protocol as described in Table 1. Moreover, Illinois regulations on health screenings provide that:

- Such activities may be conducted only by unlicensed laboratories on a not-for-profit or free-of-charge basis. Licensed laboratories may conduct such activities on either a not-for-profit or a for-profit basis.

- Any entity that conducts more than one health screening event per calendar year must file the above-referenced physician protocol with IDPH. A health screening event is defined as any day, or continuous series of days not exceeding 5, on which health screening activities are conducted in the same location other than the principal location of the laboratory, such as a health fair.

- Health screening tests should not be used as diagnostic tests (i.e., an atypical result should lead to a referral for medical attention and diagnostic work, rather than reported with potential diagnoses).
Table 1
Illinois state required protocol for conducting health screening

I. Any entity which performs health screening shall establish a protocol for health screening activities which is approved by a physician licensed to practice medicine in all its branches.

II. The protocol for conducting the health screening shall:
   A. Indicate the tests to be conducted.
   B. Indicate the way in which results shall be reported to the test subject including any available oral counseling and health professional referral program.
   C. Indicate how confidentiality will be maintained with provisions which allow testing personnel, test subject, and test subject's representative access to the test results.
   D. Include a written quality control program to ensure accurate and precise test values as set by the physician signing the protocol and a description of the steps to be taken if the control values fall outside acceptance limits as set by the physician in the written quality control program.
   E. Include the step by step instructions for:
      1. specimen collection, handling, transport, storage and disposal
      2. patient preparation
      3. type and volume of specimen needed and the established rejection criteria
      4. proper specimen identification
      5. proper reagent use, such as labeling, proper lot number usage, expiration dates, and storage requirements
      6. instrument operation and calibration in accordance with the manufacturer's instructions.
   F. Include a detailed procedure for all quantitative methods, to be performed at least once each 24 hours, to determine method linearity over the reportable range of values for each analyzer and instrument.
   G. Include directions for the use of one reference material and one calibrator or two reference materials with different concentrations once each 24 hour period in which the analyzer is used.
   H. Include a description of the training required of all staff conducting specific health screening tests.
   I. Include a copy of educational materials for each individual screening test given to each test subject.
   J. Be available to all health screening personnel at the test site.
   K. Be sent to the Department at least 30 days prior to the initial testing date if more than one health screening event is conducted by that entity in a calendar year. Such protocols will be effective for 1 year. An existing protocol may be renewed by submitting a letter from the physician who signed the protocol specifying that no changes have been made in the protocol and that protocol will be used for health screenings throughout the next year. This letter must be submitted within 30 days prior to the expiration of the existing protocol.
   L. Be signed, dated, and approved by a physician licensed to practice medicine in all its branches no earlier than 3 months prior to submission date.
   M. Include, for not-for-profit or free-of-charge operations, a statement from the physician who signs the protocol that the education and experience of the staff members are adequate to ensure proper specimen collection, specimen handling, instrument operation quality assurance, record keeping, reporting of results, and proper sanitary conditions to protect the test subjects and the environment.
   N. Include a copy of the document to be given to each test subject which discloses the purpose and limitations of each individual screening test to be conducted.
   O. State whether the testing to be conducted will be done on a not-for-profit or free-of-charge basis or for-profit basis. If the testing is conducted to a not-for-profit basis, then the calculations used to determine the actual cost of the test material and equipment must be included.
   P. Include copies of any forms used in the course of conducting health screening activities.
   Q. Indicate how documentation and quality control items are traceable to each individual analysis and instruments used in the health screening process and how records shall be maintained.
   R. Indicate how records of test subject results and documentation of quality control items shall be maintained for 2 years.
   S. Document the basis for any fee charged to the recipient indicating whether testing is being done on a not-for-profit basis.


Per CLIA and Illinois law, Illinois health-care entities can perform limited health screening tests (finger stick blood total cholesterol and finger stick blood glucose) for private individuals requesting such tests for themselves, pursuant to an appropriate physician protocol (following the requirements set forth in the table and assuming that such tests are included in CLIA's list of waived tests). If the entity provides such tests at a location other than where it has an established laboratory, and such testing would occur on more than one occasion per year (i.e., more than a 1 to 5 day event in a single location), the entity must file its physician protocol with IDPH to remain legally compliant.

**CONCLUSION**

Although Illinois law requires a fairly conservative protocol for health screening activities, many states have
similar requirements. In determining the appropriate parameters for the increasing practice of conducting health screenings for the general public, all entities (e.g., hospitals, physician practices, and clinical laboratories) need to be aware of applicable state and federal rules and regulations. Finally, understanding the interplay of state and federal law in this area will allow entities to devise health screening protocols that are both CLIA and state compliant.  

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