



# OLR RESEARCH REPORT

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## **DIRECT PATIENT ACCESS TO LAB TEST RESULTS**

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This report provides information on the direct reporting of clinical laboratory test results to patients in Connecticut and other states.

### **SUMMARY**

Patients' direct access to lab test results is governed by two federal laws: (1) the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which regulates all clinical lab testing performed on humans and (2) the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which exempts CLIA labs from providing lab test results directly to patients unless states allow it. Under CLIA, a lab can disclose patient test results only to (1) a referring lab, (2) an individual responsible for using the test results in the treatment context, or (3) an "authorized person." States can define an "authorized person" as either a health care provider, patient, or both.

According to the U.S. Department of Health and Human Services (HHS), 23 states have no laws addressing the issue. Only seven states and the District of Columbia allow such direct reporting and thirteen states prohibit it. Connecticut is one of seven states that allow it only with a health care provider's approval.

In 2011, the federal Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), and the HHS Office for Civil Rights (OCR) jointly [proposed a rule](#) requiring clinical

laboratories covered under CLIA and HIPAA to directly report test results to patients upon request (most labs must comply with both laws). The proposed rule would preempt states' direct patient access laws and regulations that restrict patients' direct access to lab results and establish a national standard for such access. The proposed rule has not been finalized and it is unclear when or if it will be.

### STATES DIRECT PATIENT ACCESS LAWS

According to HHS, seven states and the District of Columbia allow the direct reporting of lab test results to patients; 13 states prohibit such direct reporting; seven states, including Connecticut, allow it only with a health care provider's approval; and 23 states have no laws addressing the issue. Table 1 lists the states by category.

**Table 1: State Laws Regarding Direct Reporting of Lab Test Results to Patients**

States That Allow Direct Patient Reporting Without Provider Approval	States That Prohibit Direct Patient Reporting	States That Allow Direct Patient Reporting Only With Provider Approval	States With No Laws on the Issue
Delaware	Arkansas	California	Alabama
Maryland	Georgia	Connecticut	Alaska
New Hampshire	Hawaii	Florida	Arizona
New Jersey	Illinois	Massachusetts	Colorado
Nevada	Kansas	Michigan	Idaho
Oregon	Maine	New York	Indiana
West Virginia	Missouri	Virginia	Iowa
	Pennsylvania		Kentucky
	Rhode Island		Louisiana
	Tennessee		Minnesota
	Washington		Mississippi
	Wisconsin		Montana
	Wyoming		Nebraska
			New Mexico
			North Carolina
			North Dakota
			Ohio
			Oklahoma
			South Carolina
			South Dakota
			Texas
			Utah
			Vermont

Source: Centers for Medicare and Medicaid Services, Proposed Rule: CLIA Program and HIPAA Privacy Rule; Patient's Access to Test Reports. September 14, 2011.

## **CONNECTICUT'S DIRECT PATIENT ACCESS LAW**

Connecticut law generally does not allow the direct reporting of clinical laboratory test results to patients. But, Department of Public Health regulations allow them to be reported directly to patients upon the written request of a provider statutorily authorized to order the testing (Conn. Agencies Reg., [§ 19a-36-D32](#)). If a provider asks the patient to undergo repeated testing at regular intervals over a specified time period, the law permits the provider to issue a single authorization allowing the lab to give all these test results directly to the patient. The testing must be to determine a diagnosis, prognosis, or recommended treatment course ([CGS § 20-7c\(c\)](#)).

Generally, this prohibition is designed to protect the patient by insuring proper explanation and interpretation of laboratory findings, and avoiding possible harmful misinterpretations.

## **PROPOSED FEDERAL RULE**

In 2011, the CMS, CDC, and OCR jointly proposed a [rule](#) that (1) expressly allows CLIA labs to provide patients direct access to their lab test results and (2) requires labs covered under HIPAA to provide test results directly to patients (most labs must comply with both CLIA and HIPAA). Under the HIPAA Privacy Rule, labs would have to provide these test results to the patient in the form or format requested, (i.e., paper or electronic) if it is readily producible in that manner. If the rule is finalized, it will override state laws and regulations that prohibit such action. Specifically, it would directly affect clinical labs in the 36 states that currently prohibit or do not have laws regarding direct access reporting. It also would preempt laws in states like Connecticut that allow direct reporting only with provider approval.

The proposed rule was prompted by the HHS Health Information Technology Policy Committee's review of the issue, which concluded that current CLIA and HIPAA regulations prevent patients from taking a more active role in their personal health care decisions. Opponents of the proposed rule express concerns about providing sensitive and complicated medical information directly to patients without the benefit of a healthcare provider's interpretation and guidance. Suggested changes to the rule include, (1) limiting the types of tests patients can directly access, (2) requiring provider notification before labs release test results to patients, and (3) implementing a waiting period before labs release test results to allow providers to review and discuss them with patients.

## **RESOURCES**

CMS, CDC, and OCR Proposed Rule: CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Results, <https://www.federalregister.gov/articles/2011/09/14/2011-23525/clin-program-and-hipaa-privacy-rule-patients-access-to-test-reports#h-8>, website last visited on February 14, 2013.

CMS Fact Sheet: HHS Proposes Broad Patient Rights Access to Clinical Laboratory Test Result Reports, <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4079&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>, website last visited on February 14, 2013.

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