

Electronic Health Records (EHRs) are real-time, patient-centered records that make information available to those who are involved in the care of a patient and to the patients themselves. The Health Insurance Portability and Accountability Act (HIPAA) Omnibus Rule and the Health Information Technology for Economic and Clinical Health (HITECH) Act are driving the establishment of EHRs and patient portals, which are secure online websites that provide patients access to personal health records.

The establishment of EHRs and patient portals would provide direct access of laboratory test results to patients. In New York State, laboratory test results cannot be reported directly to the patient unless authorization is first provided by the physician or authorized person. The regulation describing this requirement is found in 10 NYCRR § 58-1.8 ([http://www.health.ny.gov/regulations/nycrr/title\\_10](http://www.health.ny.gov/regulations/nycrr/title_10)) which states the following:

**58-1.8 Results of tests to be reported only to physicians or other authorized persons.** No person shall report the result of any test, examination or analysis of a specimen submitted for evidence of human disease or medical condition except to a physician, his agent, or other person authorized by law to employ the results thereof in the conduct of his practice or in the fulfillment of his official duties. Reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person, except that information concerning blood type and Rh type factor may be provided in writing to the individual whose blood was testing without the consent of the individual's physician.

As facilities establish and activate EHRs and patient portals, this regulatory requirement needs to be considered before lab results are made available to patients through patient portals. Below are frequently asked questions (FAQs) that will provide guidance on how to maintain compliance with 10 NYCRR § 58-1.8 while also meeting Federal goals for access to medical records by patients.

**FAQ1:** Is there a Federal regulation that allows patients direct access to laboratory test results?

**ANS1:** The Department of Health and Human Services proposed a rule in 2011 that would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon a patient's request, the laboratory may provide access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient (<http://www.gpo.gov/fdsys/pkg/FR-2011-09-14/html/2011-23525.htm>). At this time, the rule is not final, and the status of this proposed rule is unknown. If this rule were to become final, New York State would follow this federal rule and allow patients direct access to their laboratory test results.

**FAQ 2:** Why can't a laboratory that tests samples originating from New York State release laboratory results directly to a patient?

**ANS2:** Current New York State Regulation 10 NYCRR § 58-1.8

([http://www.health.ny.gov/regulations/nycrr/title\\_10](http://www.health.ny.gov/regulations/nycrr/title_10)) states that reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person.

**FAQ3:** Can a laboratory release test results into an EHR for access by the patient through the patient portal?

**ANS3:** Since the patient would have direct access to the lab results, the laboratory would need to obtain written consent from the physician or other authorized person before the patient could access the laboratory test results via the patient portal.

**FAQ4:** 10 NYCRR § 58-1.8 states that reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person. Who can be considered to be an authorized person?

**ANS3:** Authorized person refers to persons who have been authorized to order tests and receive directly the results of certain laboratory tests for specimens accepted from New York State. A complete list of authorized person can be found at the following link:

<http://www.wadsworth.org/labcert/regaffairs/clinical/personsauthorizedtoordertests.pdf>

**FAQ5:** How do we obtain written consent from the physician or other authorized person to allow a patient access to their lab results?

**ANS5:** The physician or other authorized person could provide consent when the lab tests are ordered. In this circumstance, consent can be given on the test requisition whether it is an electronic or paper based ordering system. Alternatively, the physician or other authorized person can give a onetime “blanket” approval to the laboratory that would allow the lab to release the lab results directly (and/or automatically) from the EHR to personal health records for all their patients. Email correspondence from the physician or authorized person would fulfill the requirement of obtaining written authorization.

**FAQ6:** Would consent from the physician or authorized person to release laboratory results still be required if there is a documented provider/patient encounter?

**ANS6:** Yes.

**FAQ7:** Whom do I contact if I have further questions?

**ANS7:** For further clarification on this guidance, please contact Division of Laboratory Quality Certification at [dlcqinfo@health.state.ny.us](mailto:dlcqinfo@health.state.ny.us)