

Procedure for Releasing Results Directly to Patient

I. Patient Access:

- A. The U. S. Department of Health and Human Services (DHHS) published a final rule (February 2014) amending the Clinical Laboratory Improvement Amendments of 1998 (CLIA) regulations and the Health Insurance Portability and Accountability Act (HIPAA) regulations to allow individuals and their personal representatives to access protected health information (PHI) directly from clinical laboratories.
- B. The laboratory must be able to fulfill the request directly (i.e., it cannot refer the patient to another entity), within 30 calendar days.
- C. Results will be released directly to the patient or their legal representative when requested, according to the following procedure.

II. Procedure:

- A. The request must be made in writing.
- B. The laboratory will send the patient (by mail, email or fax):
 - 1. Access to Records Request form (DCH-1226)
 - 2. Cover letter with instructions
 - 3. MDCH Notice of Privacy Practices
- C. If a patient arrives in person to request a copy, the laboratory will also make a photocopy of the patient's valid identification which must include their signature and photo.
- D. The completed form and patient identification are returned to the MDCH Privacy Office for verification of identity. If the patient returns the form to the BOL, BOL will forward to the Privacy Office.
- E. The Privacy Office will approve or deny the request. The Privacy Office will contact the patient directly when the request is denied.
- F. Approved requests will be forwarded to the BOL DASH Unit. The DASH unit will generate reports through StarLIMS or LifeCycle, either in electronic or paper format, as indicated on the request form DCH-1226, page 1.
- G. Laboratory reports are routed to the Privacy Office for transmittal to the patient or their authorized representative.
 - 1. If no laboratory records are found, the Privacy Office will inform the patient.
 - 2. If the report will take more than 30 days to complete, the Privacy Office will inform the patient.

- H. The report is provided to the patient or their authorized representative without additional comment. No laboratory employee shall advise the patient or their representative on the interpretation, meaning, or use of the results in their laboratory report.
- I. Requests from another health care provider not involved in the care of the patient are referred to the original submitter for a copy of the test results.
- J. The laboratory is not required to provide to the patient or their authorized representative a copy of results if the testing was performed by another laboratory. For example, if a specimen was referred to and testing was performed at the Centers for Disease Control (CDC), the patient should request their results directly from the CDC.

III. Notifications

- A. Any known disclosure of patient information whether accidental or intentional, such as a report sent to the wrong address or incorrect submitter, must be documented and reported to the MDCH Privacy Office as described in DASH procedure DA.03.
- B. Any employee could potentially be notified of a disclosure (e.g., by a phone call from the incorrect submitter). To facilitate reporting of the disclosure, any employee who receives such notification should obtain and document:
 - 1. The agency that received the information incorrectly
 - 2. The name and phone number of the caller (in case more information is needed for the disclosure report)
 - 3. By what manner the recipient will destroy the report (e.g., shred on site or return to MDCH laboratory).

Providing Patient Access to Lab Report

