Title: Clinical Laboratory Compliance Plan Type: Department Specific Policy/Procedure	Clinical Laboratory	Page 1 of 9
	Application or Laboratory Section: Laboratory Wide	Date of Issue: February 2019
	Contact Person: Laboratory Leadership	Supersedes: November 2016
Recommended By: Amanda Martin, MHA, BSMT(ASCP) Administrative Director General Supervisor	Approved By: Irene Castaneda-Sanchez Medical Director Department of Pathology and Laboratory Medicine Yvette Dzurik, M.D. Medical Director Hematology/Oncology Infusion Center	

INTRODUCTION

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) has recommended that clinical laboratories voluntarily develop and implement compliance plans. A compliance plan is a comprehensive strategy to ensure an organization consistently complies with applicable laws relating to its business activities. It is a process that assists an organization, such as a hospital laboratory, to improve the two major goals of meeting the needs of patients, physicians, and other health care providers and operating a business efficiently under various laws and regulations. This compliance plan when properly followed will help prevent, detect, and eliminate the possibility of fraud and abuse occurring at this institution. It is also intended to promote an organizational culture that encourages ethical conduct and compliance with the law.

The Laboratory Compliance Plan directly follows the Cook Children's system Corporate Compliance Program (CC 210), and defines laboratory procedures and policies at a more detailed level.

SCOPE

All laboratory personnel to include all locations.

COMPLIANCE PLAN ELEMENTS

The Laboratory Compliance Plan follows the Corporate Compliance guidelines. The plan further defines the elements of compliance, evaluation of business practices, and process for effective reporting and investigation through the following:

1. HIPAA Compliance
2. Employee Code of Conduct
3. Staff Education
4. Communication
5. Outpatient Laboratory Accounts
6. Medical necessity
7. Ordering of laboratory tests
8. Standing orders/ Order Expiration
9. Auditing and monitoring, test utilization
10. Record Retention
11. Coding
12. Pricing
13. Marketing
14. Billing
15. Investigation and follow up
16. Disciplinary and corrective action
17. Corporate Compliance Program

PROCEDURES AND POLICIES

1. **HIPAA Compliance**

All laboratory employees must adhere to the Health Information Portability and Accountability Act (HIPAA) which provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to privacy while it permits the disclosure of personal health information needed for patient care and other important purposes. All training received by laboratory staff is set forth to maintain compliance with federal regulations. This is to ensure that every staff member understands the regulations set forth in HIPAA and is able to implement these standards in a compliant manner that protects the patient and the laboratory.

Security Delegates, identified by the IS Security team and Laboratory Leadership, perform compliance audits, are a resource for IS Security information, and complete other tasks necessary to maintain departmental IS compliance.

2. Code of Conduct

All laboratory employees must follow the standards of conduct delineated in the "Cook Children's Health Care System Employee Code of Conduct" policy

The laboratory and all laboratory employees **will not**:

a. Use diagnostic information provided by the physician from earlier dates of service (other than standing orders).
b. Use "cheat sheets" that provide diagnostic information that has triggered reimbursement in the past.
c. Use computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the physician
d. Make up diagnostic information for claims submission purposes.
e. Record diagnostic information unless obtained from the physician/physician's office ordering the test.

In addition to the above policies and procedures, laboratory employees **will refrain from the following behavior or actions**:

a. Interpreting physician's orders. Example - deciding to order a "comprehensive metabolic profile" when the physician's order states "chemistry profile". (Clarification must be made by the ordering provider or designated nurse.)
b. Utilizing the patient's previous diagnosis for the current episode of lab testing. Example - a patient is being registered for laboratory testing; no diagnosis description or code is on the requisition, so the employee registering the patient utilizes the diagnosis from a previous admission. (The physician/physician's office must be contacted, and a current diagnosis obtained).
c. Ordering or performing laboratory tests on physicians, physician's family members or other clients without billing said physician, family member or client. (Do not do this for free or as professional courtesy).
d. Failure to cancel all tests which were ordered but not performed, due to QNS samples, laboratory errors, instrument errors, specimen problems, and/or other reasons; or sending a message to the personnel responsible for charging and crediting laboratory tests. Example - a technologist performs a Lytes II profile; the sample was QNS for the sodium and potassium, and the technologist resulted the sodium and potassium as QNS, but failed to cancel or credit the tests. (The sodium and potassium should have been canceled, or a message sent to the Lab Administrative Director or Laboratory Office Coordinator for proper crediting).

3. Staff Education

All laboratory employees will be subject to the education and training protocols set forth by the Corporate Compliance Program Education (CC 225)

All laboratory employees will be trained in the compliance plan initially as part of their Medical Center orientation and then annually as part of the ULearn PACE requirements. Each employee is required to read and acknowledge the Laboratory Compliance Plan during new employee department orientation and annually as part of policy and procedure acknowledgement.

4. Communication and the Compliance Hotline

An open line of communication between all employees and a member of the Medical Center Compliance team is available. Interpretation of CMS (Centers for Medicare and Medicaid) guidelines are often gray, so all employees are encouraged not to guess, but to ask if there is confusion or a question. Access to the compliance officer and their staff is defined in the system policy CC 160 Reporting Suspected Misconduct, Fraud, or Abuse (Whistleblower) and through communication with the Medical Center Compliance Committee.

Any suspected misconduct, fraud, or abuse occurring within the laboratory should be reported immediately to Laboratory Administration or the compliance officer; Anonymous methods of communication is described in policy CC160.

5. **Outpatient Laboratory Accounts**

Patient Registration will create an outpatient laboratory account in the hospital's information system. No laboratory outpatient accounts will be created without a completed requisition, as described in segment 8, “Ordering Laboratory Tests".
For insurance preferred laboratory testing, a “one click” registration account with a specialty billing flag designation for clients will be created with a completed requisition.

If a patient presents without a completed requisition, no accounts will be created, nor the lab tests performed unless the information can be obtained to complete the requisition.

6. **Medical Necessity**

The medical necessity requirement stems from 42 U.S.C. - 1395 y(a)(1)9)(A) which prohibits Medicare and Medicaid from reimbursing for items or services which are not "reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Laboratories do not and cannot treat patients or make medical necessity determinations. Physicians must be able to order any test(s), including screening tests that they believe are appropriate for the treatment of their patients. However, Medicare, Medicaid, or other federally funded health programs will only pay for laboratory tests which meet their definition of "medical necessity", and may deny payment for a test that the physician believes is appropriate, such as a screening test, but which does not meet the federal programs definition of medical necessity.

"Not medically necessary" means that the Medicare/Medicaid contractor, either through interpretation of national policies or through reference to local medical review policies, has determined that under specific patient circumstances, the services are not reasonable or appropriate.

The laboratory will help ensure the medical necessity of the tests it performs by:

a. Encouraging all physicians to order only laboratory tests that are medically necessary and to order tests singly.
b. Eliminating all "screening" panels and all automated chemistry panels with more than 12 individual tests.
c. Requiring the ordering physicians to provide a diagnosis or written narrative as to "why" the laboratory test was ordered, to include diagnosis, signs, symptoms, conditions, etc, with each outpatient laboratory test ordered. Similarly, information adequate to indicate the necessity of each test should be present within the medical record for inpatient laboratory tests.
d. Designing the laboratory outpatient requisition to encourage tests to be ordered singly and that are medically necessary.
e. Following the current CPT-AMA test panels and organ and disease related panels as closely as possible
f. Creating disease or organ specific profiles at the request of physicians, as long as the panels are consistent with the laboratory guidelines of medical necessity.

The laboratory will submit custom panels to the medical staff for review of the medical necessity.

7. **Ordering of Laboratory Tests**

All requests for laboratory tests performed on outpatients must include a diagnosis or a written narrative as to "why" the laboratory test was ordered, to include diagnosis, signs, symptoms, conditions, etc. All testing requests (inpatient and outpatient) must be signed by the ordering physician or qualified individual. The laboratory will not perform laboratory testing if this information is not included.

Note: Clinical Laboratory Outpatient Requisitions can be provided to any non-Cook Children's physician referring outpatients to Cook Children's Medical Center laboratory. All Cook Children's Physician Network (CCPN) should provide electronic orders in the hospital information system.

All phoned requests must be documented by obtaining a facsimile or electronic version of the written request within a reasonable time frame. All diagnosis/medically necessary data on inpatient laboratory requests will be captured by the hospital information system, and not be reviewed by the laboratory.

Point of care testing will automatically generate an order in the LIS once results have been "accepted" or downloaded from performing instrumentation. The auto-order must be traceable to a documented physician's or qualified ordering individual in a paper or electronic form.

Use of Custom Panels
The laboratory has a limited number of custom panels. Each component is billed individually, as appropriate. CCMC custom panels are listed with components provided through this link.

- **Infectious disease panel**
- **ICU Panel I**
- **ICU Panel II**
- **ICU Lytes**.
- **Pulmonary Panel**
- **Neurology Panel**
- **Hematology/Oncology Panel**
- **Lipid Panel**
- **Hypoglycemic & Infant Hypoglycemia Panel**
- **Iron Profile**

These panels are reviewed and approved by the Medical staff.

Use of Reflex Testing
The laboratory has a limited number of automatic reflex test for inhouse testing. Each reflex test is generated based on results obtained by the originally requested/ordered tests. These tests are reviewed and approved by the medical staff as a necessity for providing appropriate care to patients. The reflex tests are considered standard of care. The authorized reflex tests may be reviewed on Appendix A.

8. **Standing Orders/ Order Expirations**

It is laboratory policy to discourage the utilization of standing orders. It is the laboratory's expectation that standing orders will be reviewed regularly, and that medical necessity will determine the use of standing orders. It is expected that standing orders for inpatient laboratory testing will be reviewed at least every 24 hours. For pending orders without specimen collections, cancellation practices may be utilized to ensure necessity requirements are being reviewed and met. A cancellation guideline will be followed for ordered tests with no specimens received in the laboratory. (Cultures and referral labs will be cancelled after 7 days with no specimen receipt, all other labs will have a 3 day cancellation guide for specimens not received.)

All outpatient laboratory orders will be established with a 13-month expiration date. Orders falling outside of this time frame will be required to be re-ordered.

9. **Auditing and monitoring**

Monitoring CPT and other Billing Codes

Laboratory Administration will follow MC 221 Charge Description Master (CDM) for activities associated with billing practices. Laboratory CPT codes will be reviewed annually, with the review documentation and records retained according to the laboratory record review policy.

The laboratory will not bill for any laboratory test for which there is not an official CPT or HCPCS code that accurately describes the service(s) that was ordered and performed. The laboratory will not bill Medicaid and Medicare programs, or any other parties, for both calculations (e.g., A/G ratios, calculated LDL's, T7's) and the tests that are performed to derive such calculations.

All referred laboratory tests will have their CPT codes reviewed annually. Reference laboratories must be contacted and requested to notify this laboratory upon any and all method and CPT code changes.

Laboratory Administration will submit for approval all additions or changes to CPT codes in use.

Regular review by the Medical Director and/or delegated individual will be documented.

Performance and Accountability

All laboratory employee PACE Reviews (performance assessment and customer service evaluations) will include the employees performance, adherence and promotion of the compliance plan.

Corporate Auditing and Monitoring

All other audits are defined by the CC 220 Corporate Compliance Program Audit

10. **Record Retention**

All compliance related data, communication, and policies will be retained for the appropriate time frame as defined in CC 827 Records Management CC 827; CC 827 Retention Attachment and the laboratory specific policy "Clinical Laboratory Document Control Program".

Compliance related data, communication, and policies are defined as:

a. Physician orders,
b. Physician acknowledgment forms,
c. Procedures and policies,
d. CPT and billing code reviews and changes,
e. Correspondence with the OIG, billing companies, and Carriers.

11. **Coding**

Health Information Management (HIM) will perform all ICD-10-CM coding on all patients' laboratory tests performed and presented for billing. Diagnostic information will be maintained as part of the permanent medical record.

12. **Pricing**

All pricing will be performed and evaluated under the direction of the Finance department Cost analysis will be performed with submission to Finance, Compliance, and Accounting for approvals. Rates are determined by established calculations through accounting. All pricing is reviewed to ensure federally funded programs (i.e. Medicaid/Medicare/etc.) are submitted appropriate charges as the lowest prices offered. .

13. **Marketing**

The laboratory is not actively involved in the marketing of its services. The Strategic Marketing Department is responsible for the development and implementation of the strategic planning process which includes marketing, advertising, and promotional of clinical services offered at the medical center. Administration and Board of Trustees approve these strategic initiatives. The Strategic Marketing Department has the responsibility of following all guidelines and practices set forth by the Cook Children's Healthcare Corporate Compliance Plan.

14. **Billing**

The Central Billing Office (CBO) performs the billing for all laboratory tests ordered and performed by this laboratory. The laboratory will help ensure correct billing by monitoring and maintaining correct CPT codes, performing proper credits for tests not performed and by working with the CBO when asked. The laboratory will utilize the Laboratory Information System to check for and eliminate duplicate procedures and charges, as well as, reviewing for accurate charge association with various tests.

15. **Investigation of Non-Compliance and Follow Up**

The procedures to be used by the laboratory personnel to respond to reports by employees or others, that a laboratory department, procedure, or individual employee is engaged in activity which may be contrary to applicable Medicare, Medicaid, IRS, or other laws and regulations is defined in CC 160 Reporting Suspected Misconduct, Fraud, or Abuse (Whistleblower)

16. **Disciplinary and Corrective Action**

Any employee or other individual who fails to comply with the Laboratory Compliance Plan; will be subject to HR 400 Conduct and Corrective Action.

The laboratory will follow the CC 160 Reporting Suspected Misconduct, Fraud, or Abuse (Whistleblower) and CC 480 Sanctioned Individuals

17. **Corporate Compliance Plan**

It is the responsibility of each laboratory employee to read, understand and comply with this policy and the Corporate Compliance Program.

Appendix A

Cook Children's Medical Center "In House" Reflex Tests

Antinuclear Antibody Test (ANA) with Reflex Titer and Pattern

Antibody Screen with Reflex to Antibody Identification

Body Fluid Cell Count with Reflex Differential

Bone Marrow Differential with Reflex Cytology Stains

Complete Blood Count (CBC) with Reflex Differential

Cryptococcal Antigen with Reflex Titer & Fungal Culture, if negative (Blood, CSF)

CSF Cell Count with Reflex Differential

Enteric Panel with reflex Shigella or Salmonella Culture

Fecal Fat (negative) with Reflex to Free Fatty Acid

HSV (positive) with Typing Reflex (Care Team Only)

Peripheral Blood Smear with Pathologist Review meeting Hematology criteria

Rapid Streptococcus A with Reflex Culture

Reticulocyte (automated) with Reflex Manual Reticulocyte

Urinalysis with Reflex Microscopic

White Blood Cell Count with Reflex Differential