

Methodist Health Services Corporation & UnityPoint Health Methodist Proctor Laboratory ADMINISTRATION	Page # 1 of 2	Section: UPPIA LA Regulatory & Administrative	Policy #: 02.002 Formerly: B 02	
	Approved by: see signature block at end of document		Date 5/19/16	
	Revised: 5/19/16 9/2/15, 7/11/11, 6/22/10, 2/12/08, 4/19/06, 8/18/04, 1/3/03, 6/19/00, 1/8/96			
	Reviewed: 8/2/13			
	Policy/Revision Submitted by:		Richard Borge/POC Coordinator	
	CAP Standard: NA			
POLICY GUIDELINE ON:				
Compliance of CAP terms of accreditation including notification				

I. POLICY:

According to CLIA regulations the lab complies with terms of accreditation and CAP & HHS, will be notified of changes in laboratory directorship or testing complexity and complaints.

II. PURPOSE:

Laboratory making any changes must notify the Health Care Finance Administration and the College of American Pathologists within certain time frames as established in the CLIA rules and regulations.

III. POLICY SCOPE:

This policy applies to all Laboratory Staff and physicians at Methodist & Proctor Campuses.

IV. GENERAL INFORMATION:

- A. The Department of Pathology and Laboratory Medicine must notify HHS in writing when changes are made to directorship or to testing complexity.
 - 1. This is a requirement under the Clinical Laboratory Improvement Act of 1988, Subpart D, Section 493.63.
- B. The laboratory must agree with the CAP terms of accreditation not involving notification.

V. PROCEDURE:

Laboratories issued a certificate of accreditation must:

- 1. Notify HHS and the CAP and the approved accreditation program within 30 days of any changes in
 - a. ownership
 - b. name
 - c. location, or
 - d. Director. Newly assigned Medical Director will have 6 months from start date to review and sign off on various policies.
- 2. Notify the CAP no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

3. Notify the CAP no later than 6 months after any additions, deletions, or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.
4. Notify the CAP immediately if there is an investigation of the laboratory by a government entity, or if there is an adverse media attention related to the laboratory's performance, or discovery of actions that violate regulations by an employee.
5. All changes will be forwarded to the Lab Operations Assistant, who also coordinates Laboratory User's Manual changes.
 - The Director or designee will notify HCFA in writing of the changes.
 - A copy will be kept on file.
6. HCFA requires notification no later than 6 months after any deletions or changes in test methodologies, subspecialties including testing complexity.
 - Address to notify of changes:
Illinois Department of Public Health
Division of Health Care Facilities Programs
525 W. Jefferson Street
Springfield, IL 62761
Phone # (217) 782-7412
7. Methodist Medical Center Laboratory CLIA ID Number is 14D0431854.
8. Methodist Medical Center Point of Care CLIA ID Number is 14D1077897.
9. Proctor Hospital Laboratory CLIA ID Number is 14D0044346
10. Lab agrees to provide an inspection team every 2 year period.
11. The laboratory will provide annual proficiency testing results upon request of any person.

V. MAINTENANCE AND STORAGE:

- A. All policies and procedures are reviewed every two years by Laboratory Administration and or the Medical Director of the Laboratory or designee.
- B. The Laboratory Administration and Medical Director review policies and procedures when there are changes in practice standards, or requirements.
- C. All policies and procedures are reviewed every two years by staff or at the time new or revised ones are put in effect.
- D. All policies are retained 8 years after being discontinued or revised.
- E. All procedures are retained 2 years after being discontinued or revised.

REVISION HISTORY (began using 2011)			
Rev	Description of Change	Author	Effective Date
1	Updated maintenance, every 2 years per CAP regulations. Added revision history chart	R. Borge	7/11/11
2	Added policy scope, changed to reflect name change of organization. Formatting changes.	T. Lanan	8/2/13
3	Added proctor CLIA, and inspection team every 2 year, proficiency testing proof upon requesting	R. Borge	9/2/15
4	Added terms of new medical director to review and sign on off on all procedures in designated sections.	R. Borge	5/18/16

Reviewed by

Designee	Date	Laboratory Director	Date
		<i>Richard J. Borge</i>	9/2/15
		<i>Richard J. Borge</i>	5/18/16