



Laboratory Stewardship: How to get started

Andrew Fletcher, MD, MBA, CPE,
CHCQM, FCAP

April 23, 2024

Learning Objectives

- Describe how to create a stewardship committee using a committee charter
- Explain how to integrate stewardship interventions into an existing Utilization Review committee structure
- Discuss the role of stewardship interventions in an existing Compliance program structure
- Summarize how College of American Pathology accreditation standards support laboratory stewardship





A Century of Hospital Laboratory Stewardship

By **Andrew Fletcher** - February 14, 2022



<https://criticalvalues.org/news/item/2022/02/14/a-century-of-hospital-laboratory-stewardship>






Academic Pathology

Volume 9, Issue 1, 2022, 100039



Regular Article

Current state of laboratory test utilization practices in the clinical laboratory ☆

Grace M. Kroner PhD ^a  , Sandy Richman MBA ^b, Andrew Fletcher MD, MBA ^{a, b}, Jane Dickerson PhD ^{c, d}, Brian R. Jackson MD, MS ^{a, b}

43%

Respondents had Stewardship activities

<https://www.sciencedirect.com/science/article/pii/S2374289522000288>



How to Get Started?

- No Laboratory Stewardship Committee
- Not much Administrative Support
- No Physician Champion
- Others don't understand why it's important



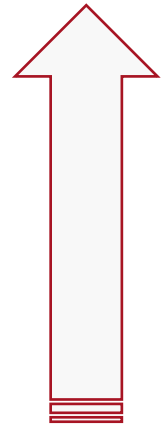
Agenda

- Stewardship Committee Charter
- CMS Utilization Review
- Office of Inspector General - Compliance
- College of American Pathology - QMS



Options for Lab Stewardship

Hard



Easy

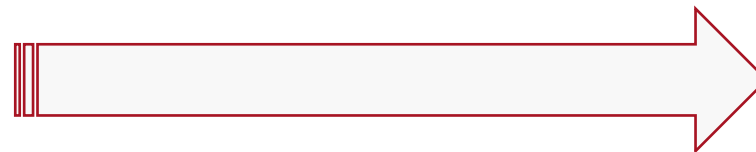
Stewardship Committee

Utilization Review

Compliance

College of American Pathology

Fast



Slow





Code of Federal Regulations

A point in time eCFR system



§ 482.22 Condition of participation: Medical staff.

The [hospital](#) must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to [patients](#) by the [hospital](#).

<https://www.law.cornell.edu/cfr/text/42/482.22>



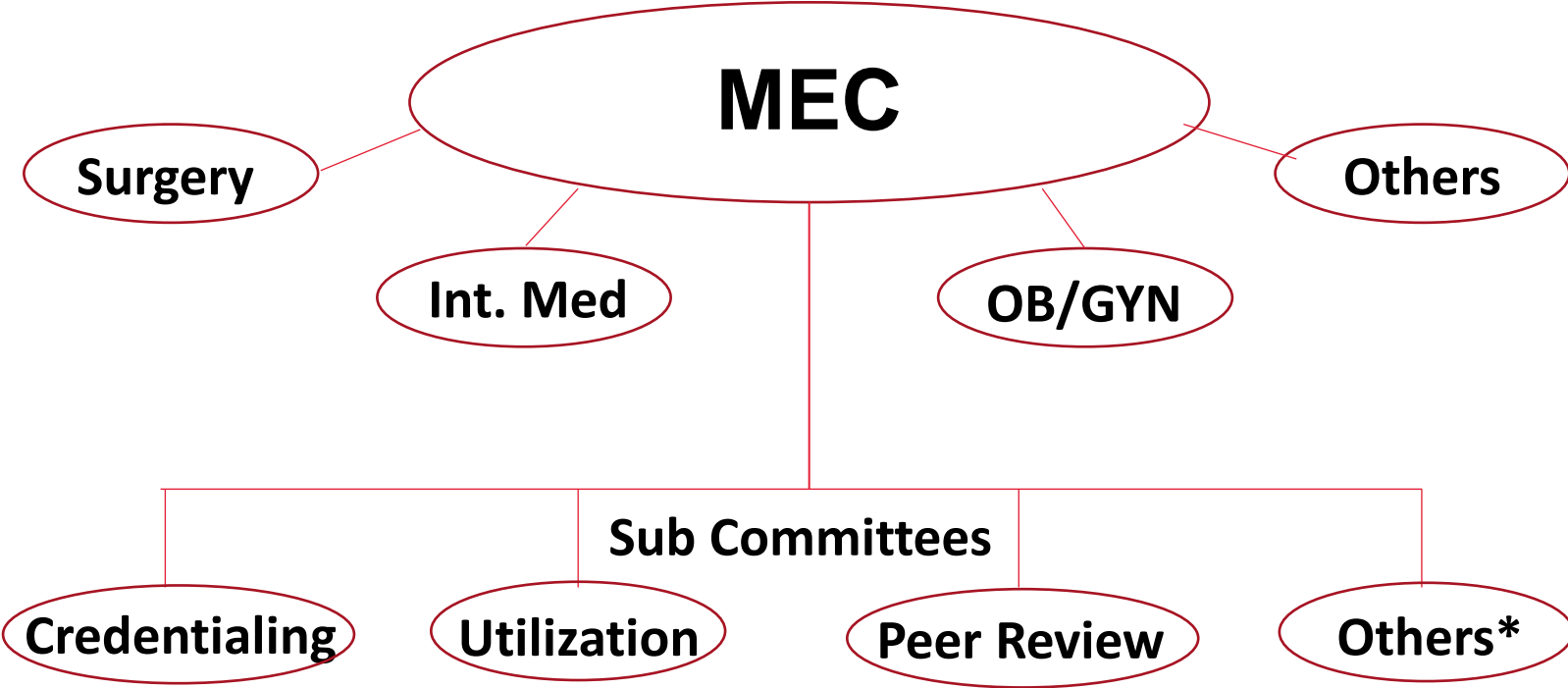
**BYLAWS OF THE
MEDICAL STAFF**

**UNIVERSITY OF XYZ
HOSPITALS AND CLINICS**

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Medical Executive Committee



Committee Charter Definition

A committee charter is a **document that outlines the specific purpose, authority, and procedures of a particular committee.**

- Purpose
- Roles/Responsibilities
- Goals/Objectives
- Scope
- Membership
- Member Roles/Responsibilities
- Meeting Schedule
- Reporting Relationships
- Decision Making



Medical Center Laboratory Diagnostics Committee Charter

Purpose:

The purpose of the Medical Center Laboratory Diagnostics Committee is to ensure optimal patient care by efficient clinical and anatomical laboratory diagnostic utilization via overview by a multi-disciplinary committee comprised of board-certified physicians. The Committee accomplishes this by assessing the clinical utility of the increasing number of laboratory tests.

Authority and Accountability:

Membership: The members of this sub-committee are members credentialed and privileged representing the follow disciplines

- a. Internal Medicine
- b. Oncology/Hematology
- c. Infectious Disease
- d. Pathology
- e. Pediatrics
- f. Chief Medical Officer
- g. Ad Hoc Specialists

The Department of Pathology's Chairperson will serve as Chairman. The Director of Laboratory Services will serve as Secretary.

Composition: The core committee will consist of members from the following departments

- a. Internal Medicine
- b. Oncology/Hematology
- c. Infectious Disease
- d. Pathology
- e. Pediatrics

Mandatory Membership: The Department of Pathology's Chairperson will serve as Chairman.

Committee Name: Laboratory Stewardship Steering Committee

Document Owner: Your Name

Scope:

Systemwide: Hospital X, Hospital Y, Hospital Z

Purpose:

The Laboratory Stewardship Committee is a multidisciplinary group charged with making decisions that promote and ensure appropriate diagnostic & therapeutic laboratory testing that are both clinically effective and cost-effective.

Key Outcomes/Objectives:

- The committee will be responsible for the development and surveillance of all laboratory test utilization policies and practices within all M Systemwide hospitals and all network of care locations to promote optimum clinical test utility and minimize inappropriate use.
- The committee will review, approve and when necessary, develop evidence-based protocols and practice standards concerning the clinically effective and cost-effective use of laboratory tests in conjunction with relevant hospitalists, clinicians, and sub-specialists.
- The committee will inform the educational material needed to guide medical providers to select the most appropriate laboratory testing options.
- The committee will monitor utilization against baseline indicators and industry benchmarks resulting in efficiencies and financial savings to the health system.

Meeting Schedule/Frequency:

The committee will meet monthly.

Communication/Document Storage Location:

- Committee actions will be communicated to appropriate staff members.
- Committee members will bring information and policy decisions to their respective department meetings for dissemination.
- An agenda and supplementary materials (i.e., minutes from prior meetings, documents supporting agenda items) will be prepared by the secretary and submitted to committee members in sufficient time to allow for review prior to the meeting.
- Final minutes from the meetings will be maintained by the secretary (Laboratory Director) as permanent electronic records of the organization.
- Minutes from the committee will be submitted to the Executive Leadership Team- Clinical Affairs Committee.

Membership:

- Chair- Physician
- Co-Chair- Laboratory Medical Director
- Chief Analytics and Care Innovation Officer
- Laboratory Director (Clinical, Specialty, AP)
- VP Laboratory Operations
- Chief Medical Officer or VPMA
- VP Quality Officer
- EPIC EMR Analyst
- Laboratory Information Systems
- Pathology Informatics
- Hospital Operations Executive
- Director of Pharmacy



How many reference laboratories do you use?

1. **Not using primary vendor?**
2. **Why are tests sometimes not consolidated?**
 - » Physician request
 - » Patient request
 - » Insurance requirement
 - » Easier process for lab staff

**Free Phenytoin at
Lab X**

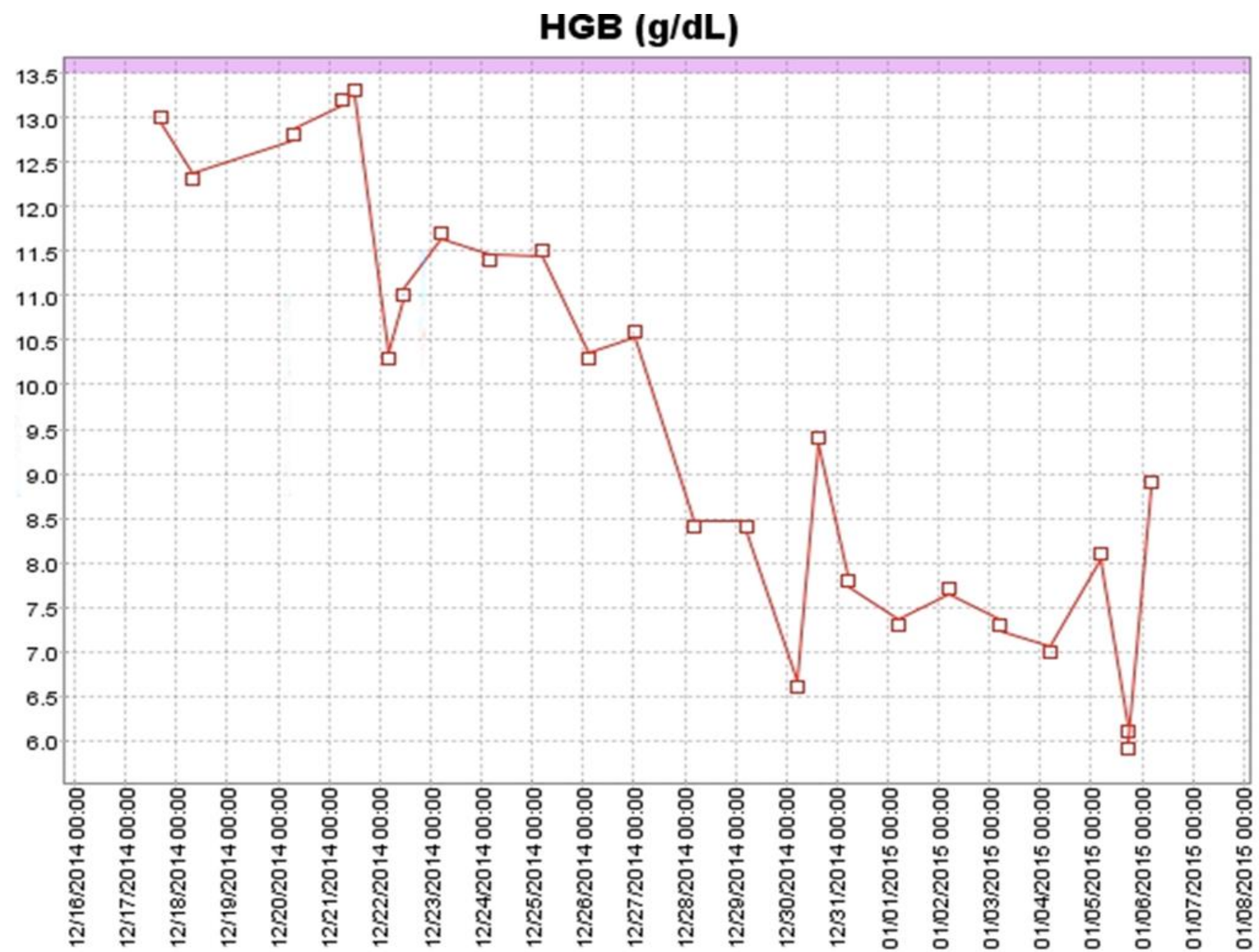
\$106

**Free Phenytoin at
Primary Lab Vendor**

\$13



Example



Example

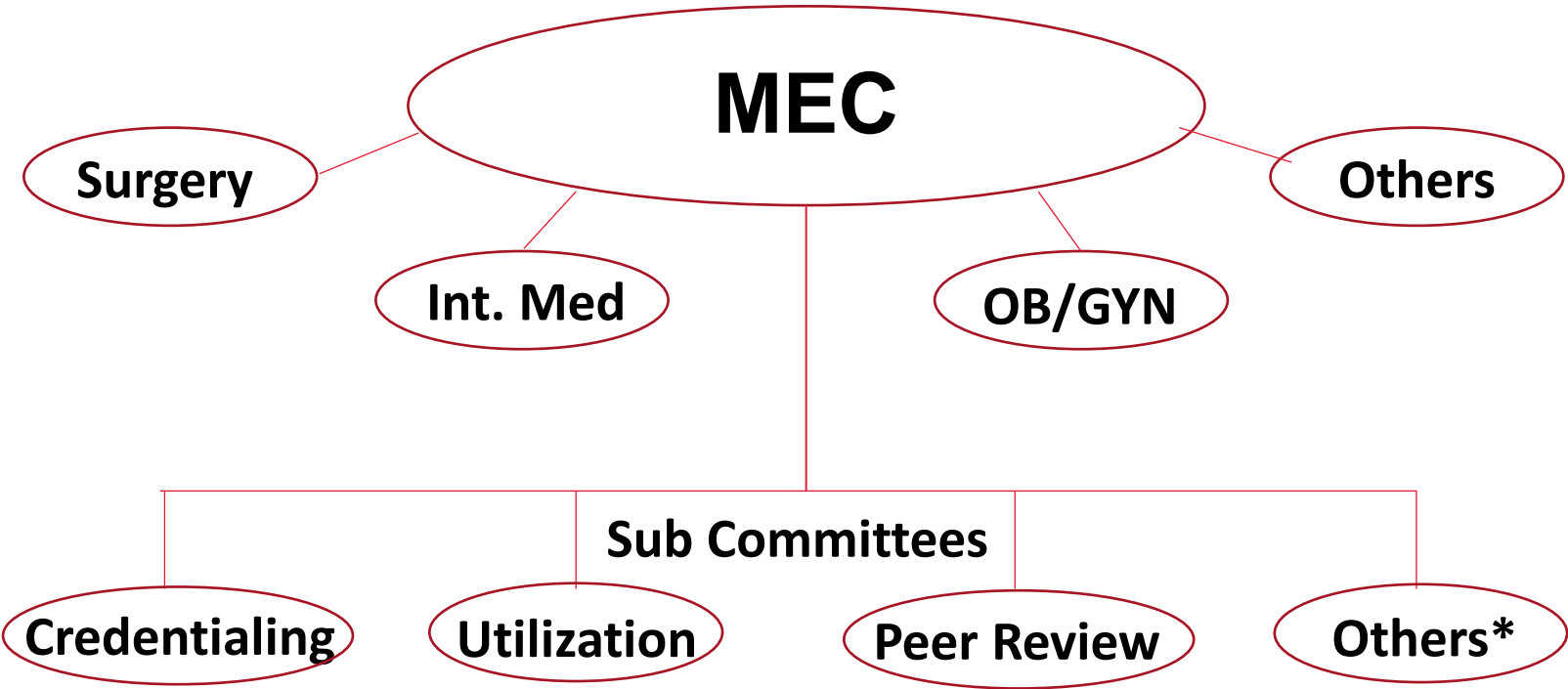
Total:	LAV	GRN	BLU	PiNK	GRAY	SYR	XBC	SST	DGR	RED			
136	31	52	11	5	7	8	10	7	2	3			
	5	5	4.5	7	5	5	10	7	5	7		Tube Capacity in mL	

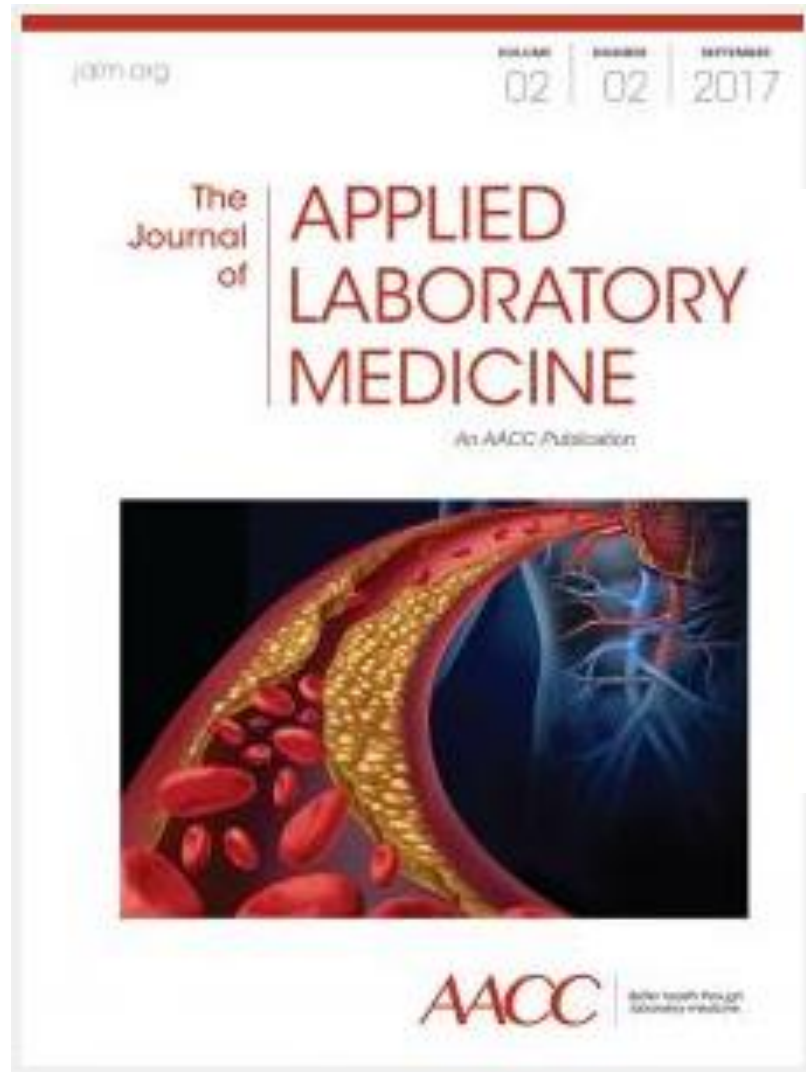
80 separate collection episodes*
136 tubes of blood
754.5cc blood

3 units of blood Transfused during stay for Hgb <8 g/dl



Medical Executive Committee





SPECIAL REPORT



Transforming Laboratory Utilization Review into Laboratory Stewardship: Guidelines by the PLUGS National Committee for Laboratory Stewardship

Jane A. Dickerson,^{1,2*} Andrew H. Fletcher,³ Gary Procop,⁴ David F. Keren,⁵ Ila R. Singh,⁶ Joaquin J. Garcia,⁷ Robert B. Carpenter,³ Joe Miles,³ Brian Jackson,³ and Michael L. Astion^{1,2}

<https://pubmed.ncbi.nlm.nih.gov/32630981/>



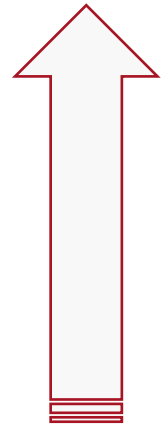
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Options for Lab Stewardship

Hard



Easy

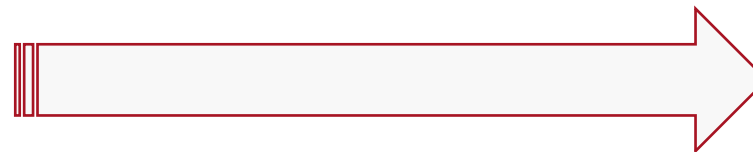
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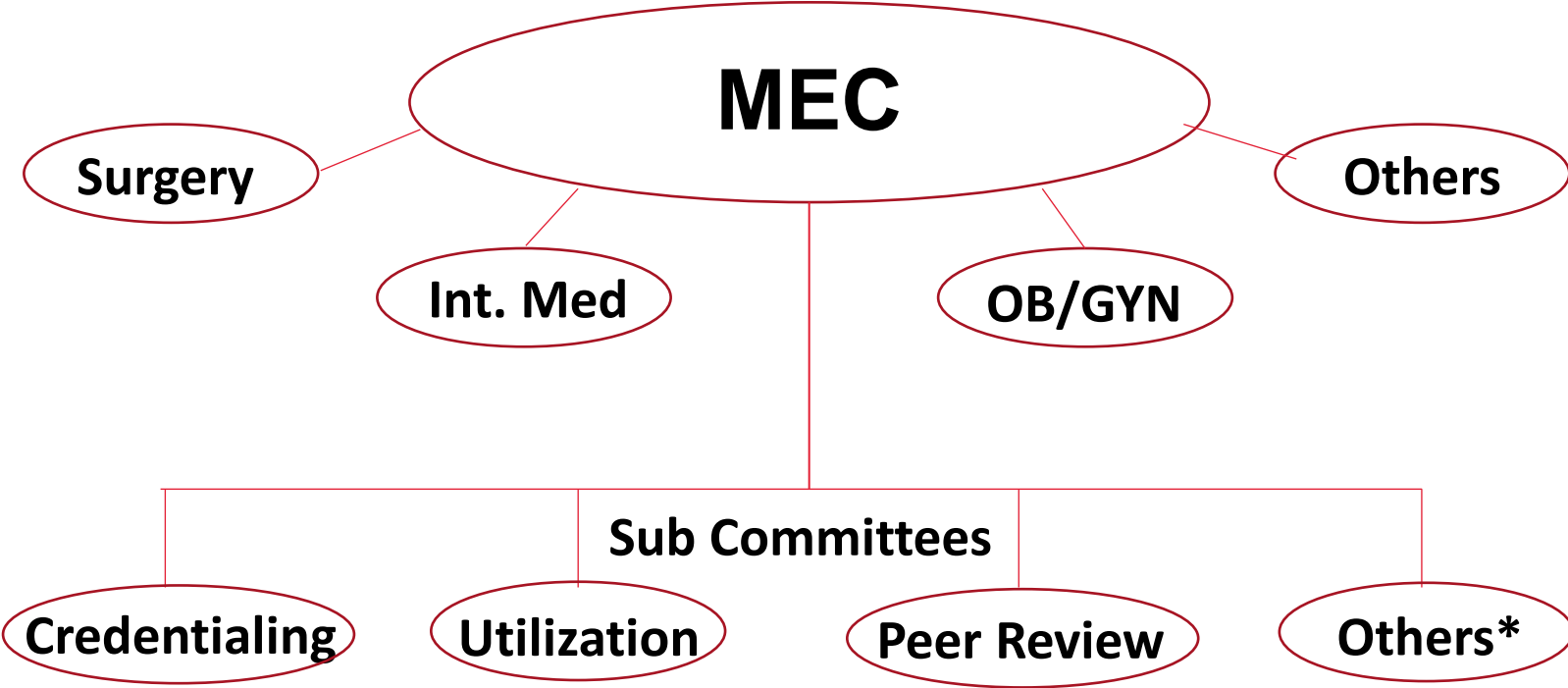
§ 482.30 Condition of participation: Utilization review

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

<https://www.law.cornell.edu/cfr/text/42/482.22>



Medical Executive Committee



**BYLAWS OF THE
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**UNIVERSITY OF XYZ
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Approved by the Medical Staff November 27, 2019
Approved by the Hospital Board on December 5, 2019

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Utilization Review Committee

- Provide oversight and direction to assure quality patient care is maintained
- Provide patient focused care where there is demonstrated best practice and most efficient processes
- Measure quality and report process of care; patient satisfaction results, indicator metrics in relation to clinical care and cost



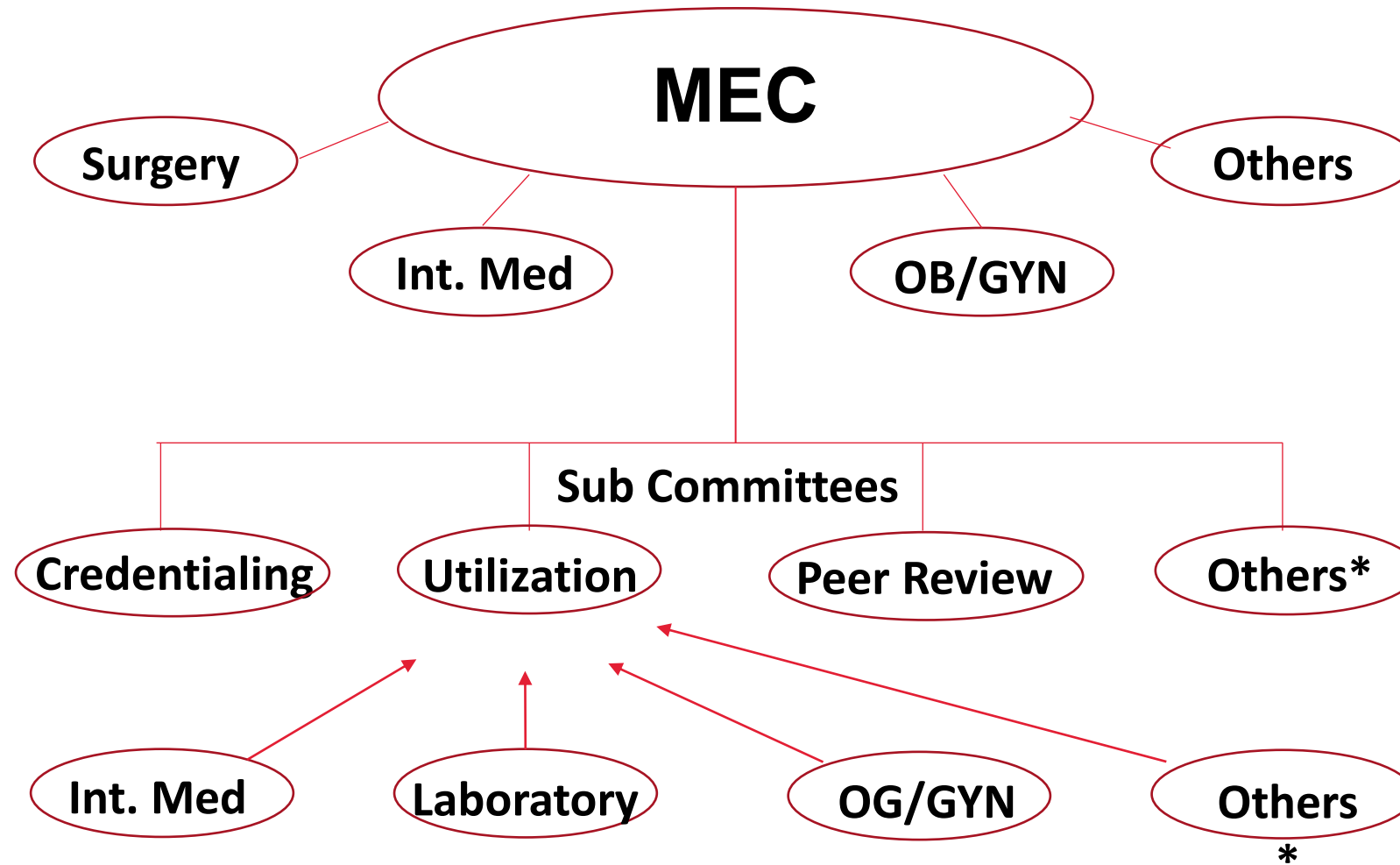
Utilization Review

Each department shall:

a. Review quality improvement, utilization and risk management pertinent to the department, and make recommendations or take action as appropriate



Medical Executive Committee



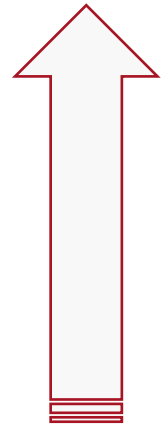
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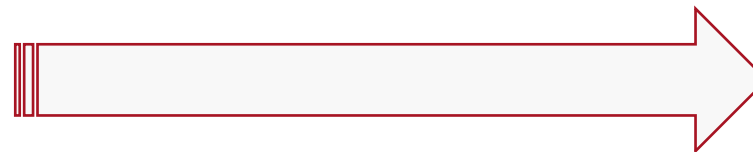
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Slow



False Claims Act of 1863



Prohibited fraudulently
obtaining money from
the government

Focused on military
contractors

<https://www.justice.gov/civil/false-claims-act>





U.S. Department of Health and Human Services
Office of Inspector General

False Claims Act
Anti-Kickback
Self-Referral
Exclusion

Civil Fines
Criminal Penalties

<https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/#:~:text=It%20is%20illegal%20to%20submit,plus%20%2411%2C000%20per%20claim%20filed>

<https://www.nexsenpruet.com/publication-federal-enforcement-actions-against-clinical-laboratories>

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OFFICE OF INSPECTOR GENERAL:
**Laboratory Stewardship
is Mandatory**
Andrew Fletcher MD, MBA,

<https://criticalvalues.org/news/item/2023/01/05/office-of-inspector-general-laboratory-stewardship-is-mandatory>





FEDERAL REGISTER

Vol. 63 Monday

No. 163 August 24, 1998

Pages 61217-61440

OFFICE OF THE FEDERAL REGISTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Compliance Program Guidance for Clinical Laboratories

**AGENCY: Office of Inspector General
(OIG), HHS.**

<https://oig.hhs.gov/documents/compliance-guidance/806/cpqlab.pdf>





FEDERAL REGISTER

Vol. 63 Monday

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Pages 61217–61440

OFFICE OF THE FEDERAL REGISTER

Written Policy
Compliance Officer and Committee
Training
Communication
Enforce Standards
Internal Monitoring and Auditing
Response and Corrective Action

<https://oig.hhs.gov/documents/compliance-guidance/806/cpglab.pdf>





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OFFICE OF THE FEDERAL REGISTER

Written Policy

Page 45080

e. Test utilization monitoring

– Laboratories can and should determine whether physicians are ordering medically unnecessary tests

- Laboratories have duty to notify the physician and modify the ordering of unnecessary tests





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OFFICE OF THE FEDERAL REGISTER

Written Policy

Page 45080

e. Test utilization monitoring

- Have an outside consultant to analyze patterns of utilization
- Greater than 10% growth in top 30 high volume tests
- Increase in utilization caused by physician ignorance or misunderstanding not acceptable





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OFFICE OF THE FEDERAL REGISTER

Written Policy

Page 45081

4. Reliance on Standing Orders

- Have led too often to abusive practices
- Compliance program requires the lab to periodically monitor standing orders
- Fixed term of validity and must be renewed at their expiration



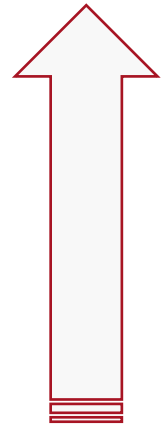
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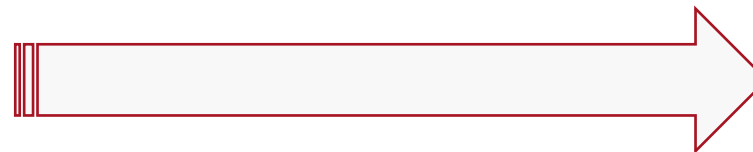
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Fast



Slow



Laboratory General Checklist

CAP Accreditation Program



COLLEGE of AMERICAN
PATHOLOGISTS

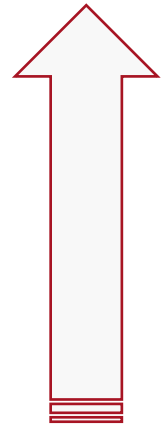
****REVISED** 09/22/2021**
GEN.20316 QMS Indicators of Quality

- *Laboratory Test Utilization: Percent of tests (or a test) that appear to be redundant, excessive or noncontributory to good patient care.*



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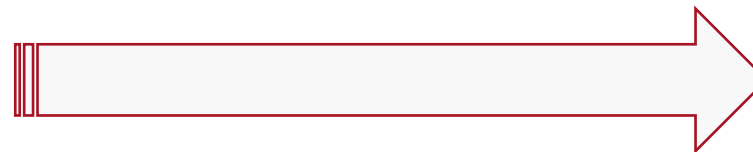
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Thank you

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