

# Laboratory Stewardship: How to get started

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



# 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 <sup>a</sup>  , Sandy Richman MBA <sup>b</sup>, Andrew Fletcher MD, MBA <sup>a, b</sup>, Jane Dickerson PhD <sup>c, d</sup>, Brian R. Jackson MD, MS <sup>a, b</sup>

# 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

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Stewardship Committee Charter

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CMS Utilization Review

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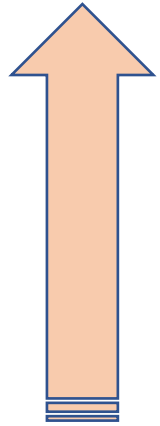
Office of Inspector General - Compliance

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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>

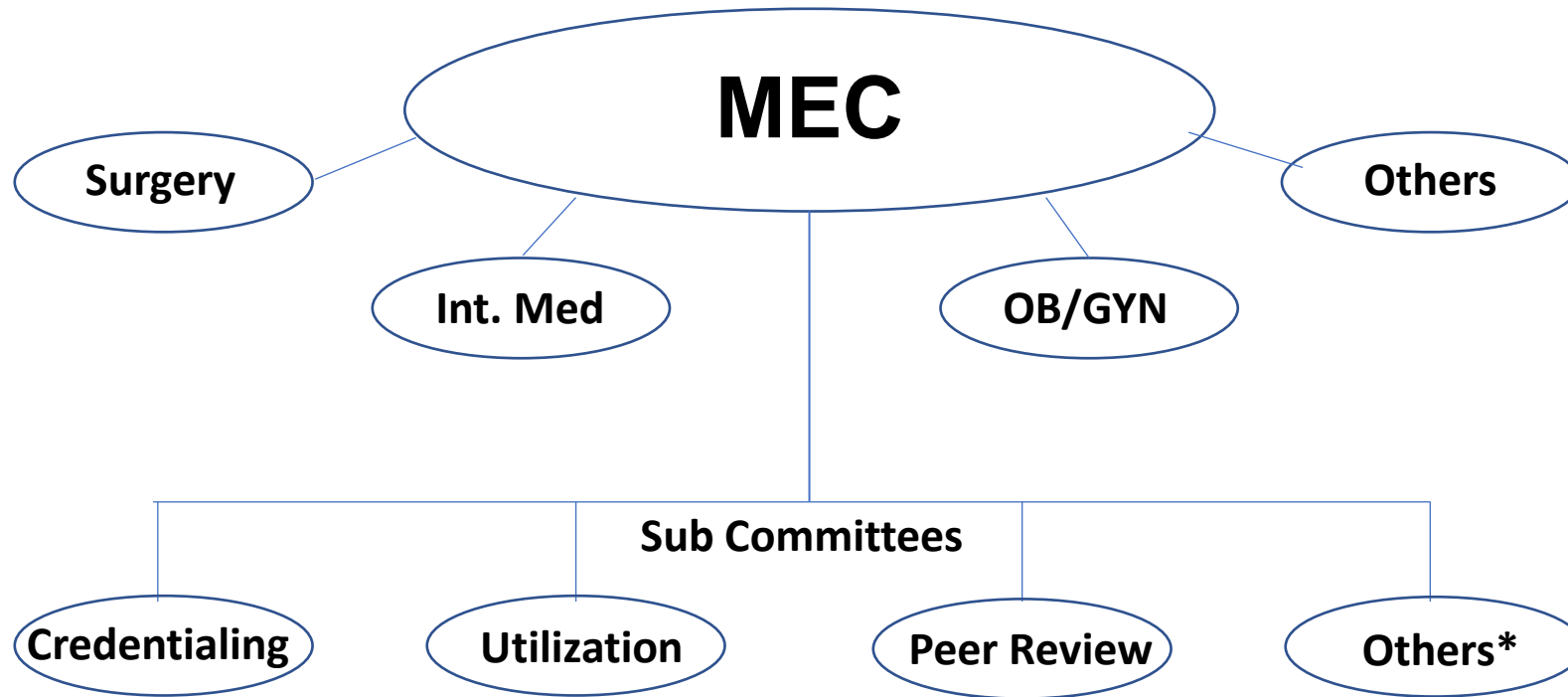


**BYLAWS OF THE  
MEDICAL STAFF**

**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

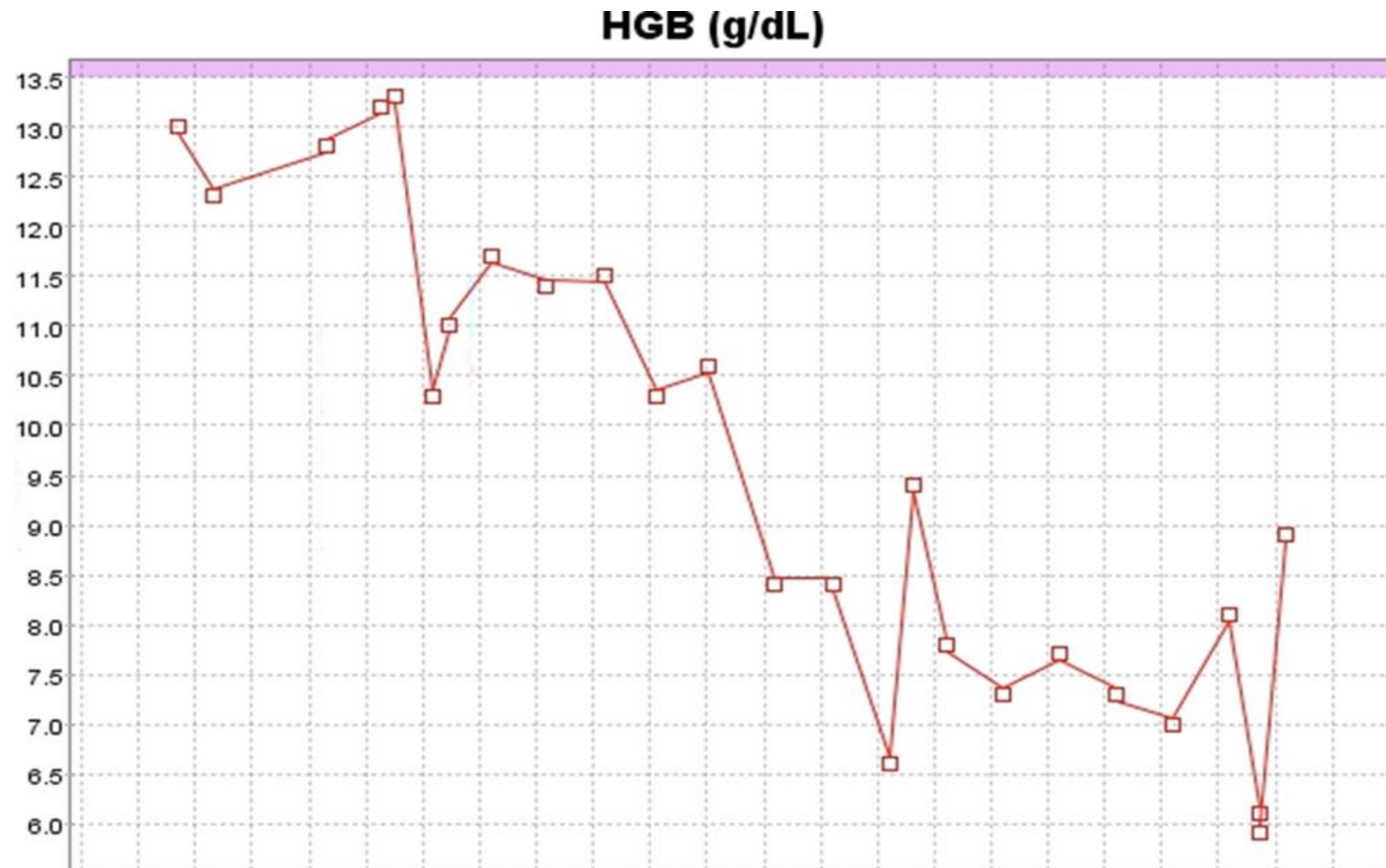
**\$106**

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Free Phenytoin at  
Primary Lab Vendor

**\$13**

# Example



# Example

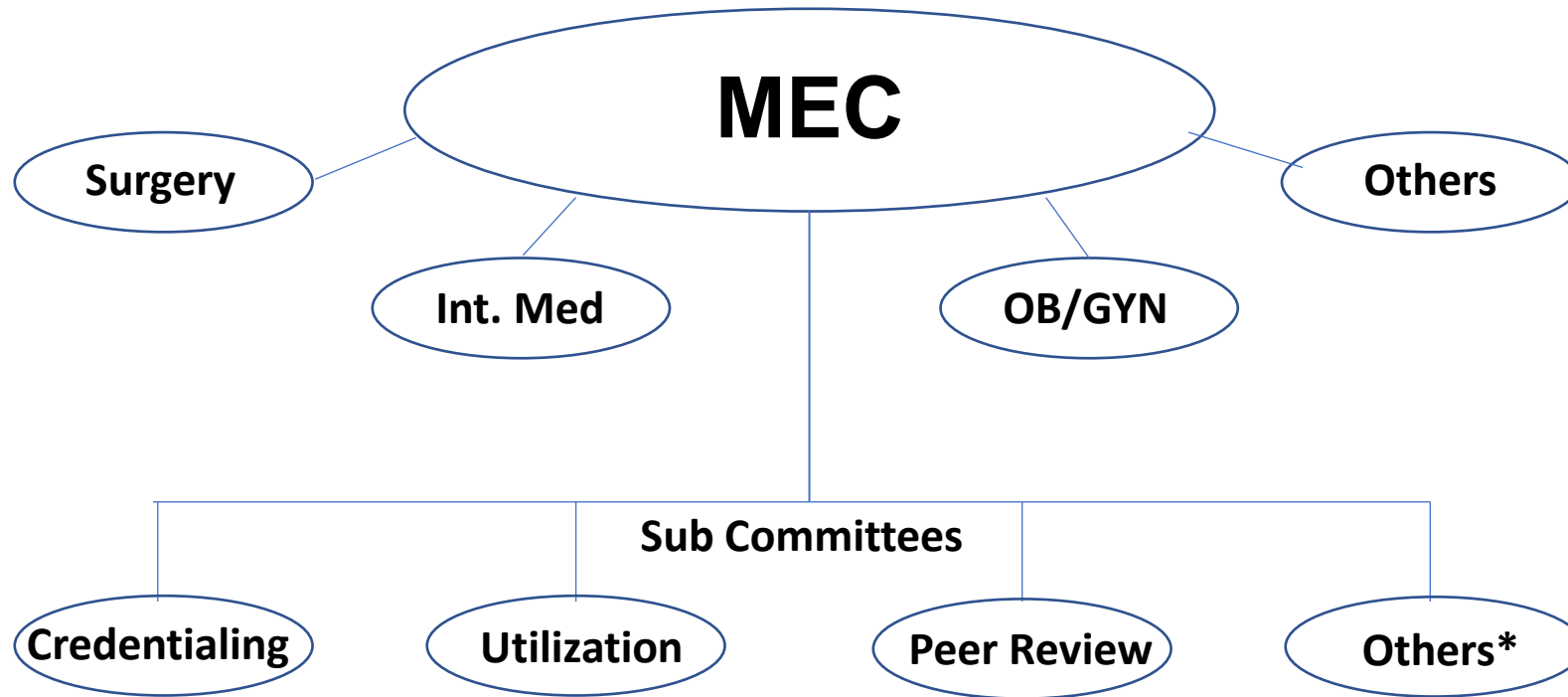
<u>Total:</u>	LAV	GRN	BLU	PIK	GRAY	SYR	XBC	SST	DGR	RED			
136	31	52	11	5	7	8	10	7	2	3			
	5	5	4.5	7	5	5	10	7	5	7			Tube Capacity in mL

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

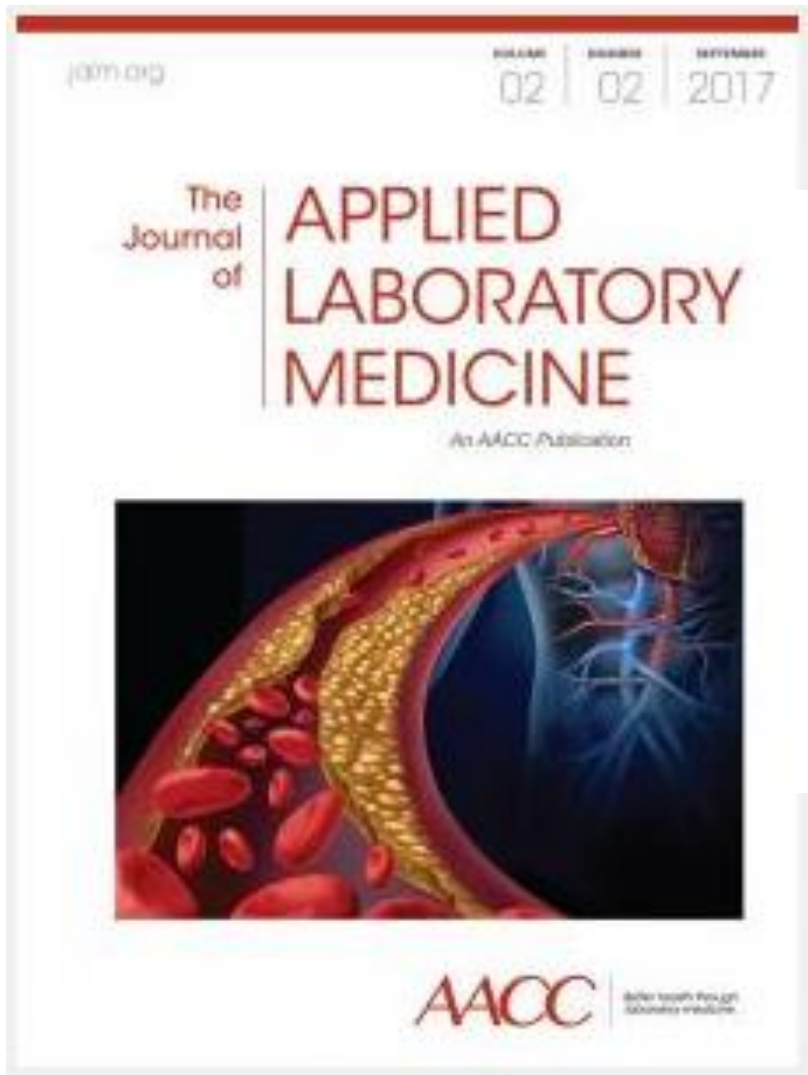
**3 units of blood Transfused during stay for Hgb <8 g/dl**



# Medical Executive Committee







## SPECIAL REPORT



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

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

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



# Agenda

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Stewardship Committee Charter

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CMS Utilization Review

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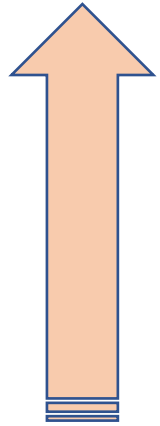
Office of Inspector General - Compliance

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College of American Pathology - QMS

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**Slow**





# Code of Federal Regulations

A point in time eCFR system



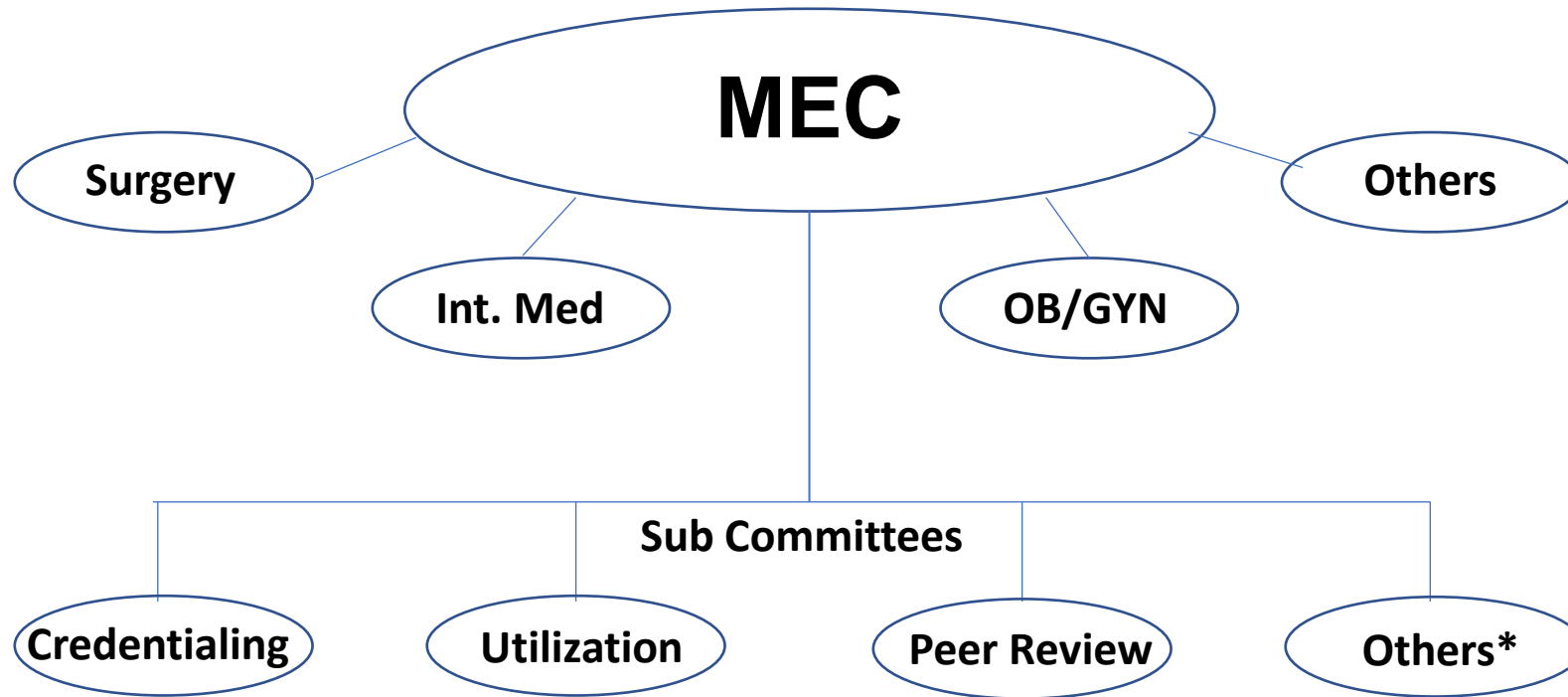
## § 482.30 Condition of participation: Utilization review

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>



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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**



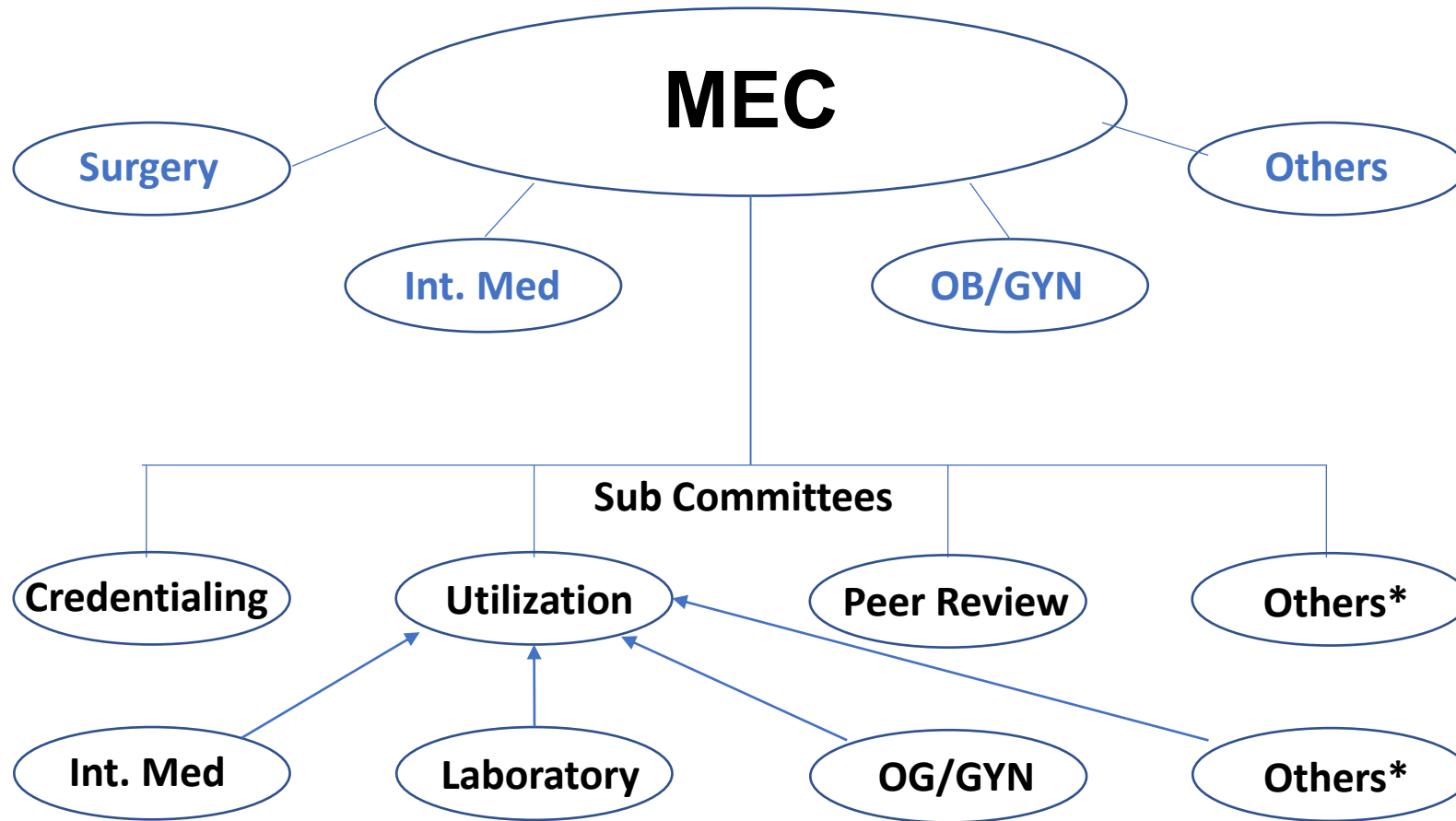
# Utilization Review

Each department shall:

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



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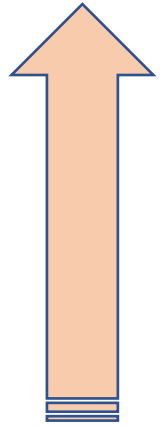
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# False Claims Act of 1863



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>



OFFICE OF INSPECTOR GENERAL:

# Laboratory Stewardship is Mandatory

Andrew Fletcher MD, MBA, CHCQM, CPE

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



# FEDERAL REGISTER

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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/cpglab.pdf>





## FEDERAL REGISTER

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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>







## FEDERAL REGISTER

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Vol. 63 Monday  
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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



## FEDERAL REGISTER

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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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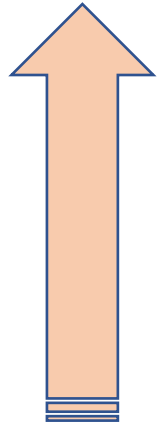
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# Laboratory General Checklist



COLLEGE of AMERICAN  
PATHOLOGISTS

CAP Accreditation Program



**\*\*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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