Coverage Analysis at UTHealth

Clinical Research Finance and Administration

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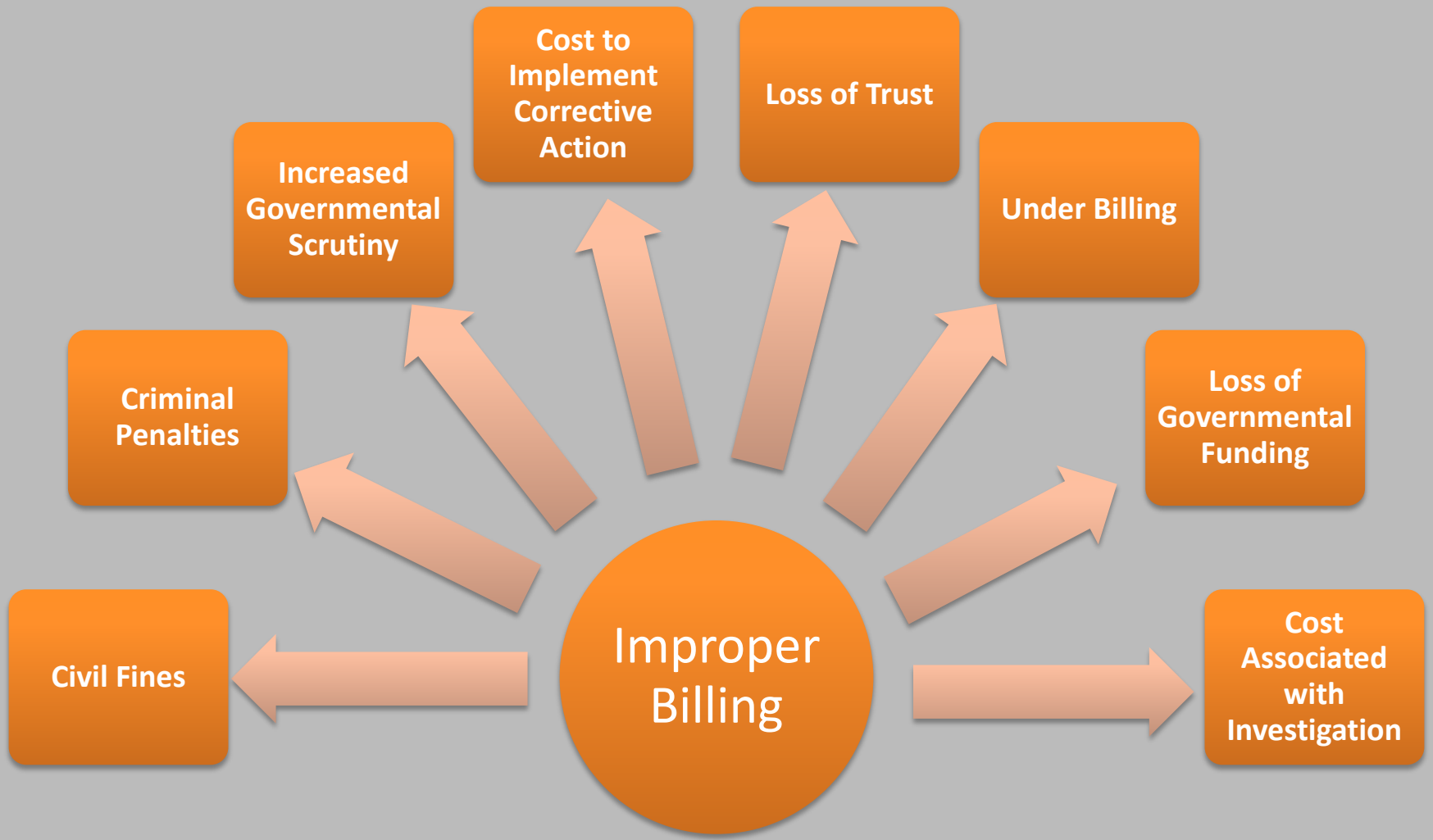
What is a Coverage Analysis?

An itemized breakdown of each procedure in a Clinical Trial which identifies the appropriate payer of the procedure.

Why are CA's Necessary?

- Multiple Payers for Clinical Research
- Federal Regulations
- Streamline scheduling and billing


Improper Billing
Cost to Implement Corrective Action
Loss of Trust
Increased Governmental Scrutiny
Under Billing
Criminal Penalties
Loss of Governmental Funding
Civil Fines
Cost Associated with Investigation

Consequences: Settlements/Fines

- **Rush University Settlement**
  - $1Million
  - Improperly billed Medicare attributed to “the absence of synchronization of the Medicare rules, the compensation arrangements with the sponsor, & the financial discussion in the Informed Consent”
- **University of Alabama at Birmingham**
  - $3.39Million
  - Falsely billed Medicare for researcher’s time spent on patient care when no patients had been seen
  - Falsely billed Medicare for clinical research trials that were also billed to the sponsor of the research grant
- **Emory University**
  - $1.5Million
  - Falsely billing Medicare & Medicaid
  - Sponsor agreed to pay for services which were not invoiced by Emory

Who are the payers?

- Patient out of pock expense
- Patient's Insurance
- Government – Centers for Medicare and Medicaid (CMS)
- UTHealth
- Sponsor

Who pays for what?

- Routine Costs (Standard of Care)
  - Patient
  - Patient Insurance
  - CMS
- Research Costs
  - Sponsor
  - UTHealth

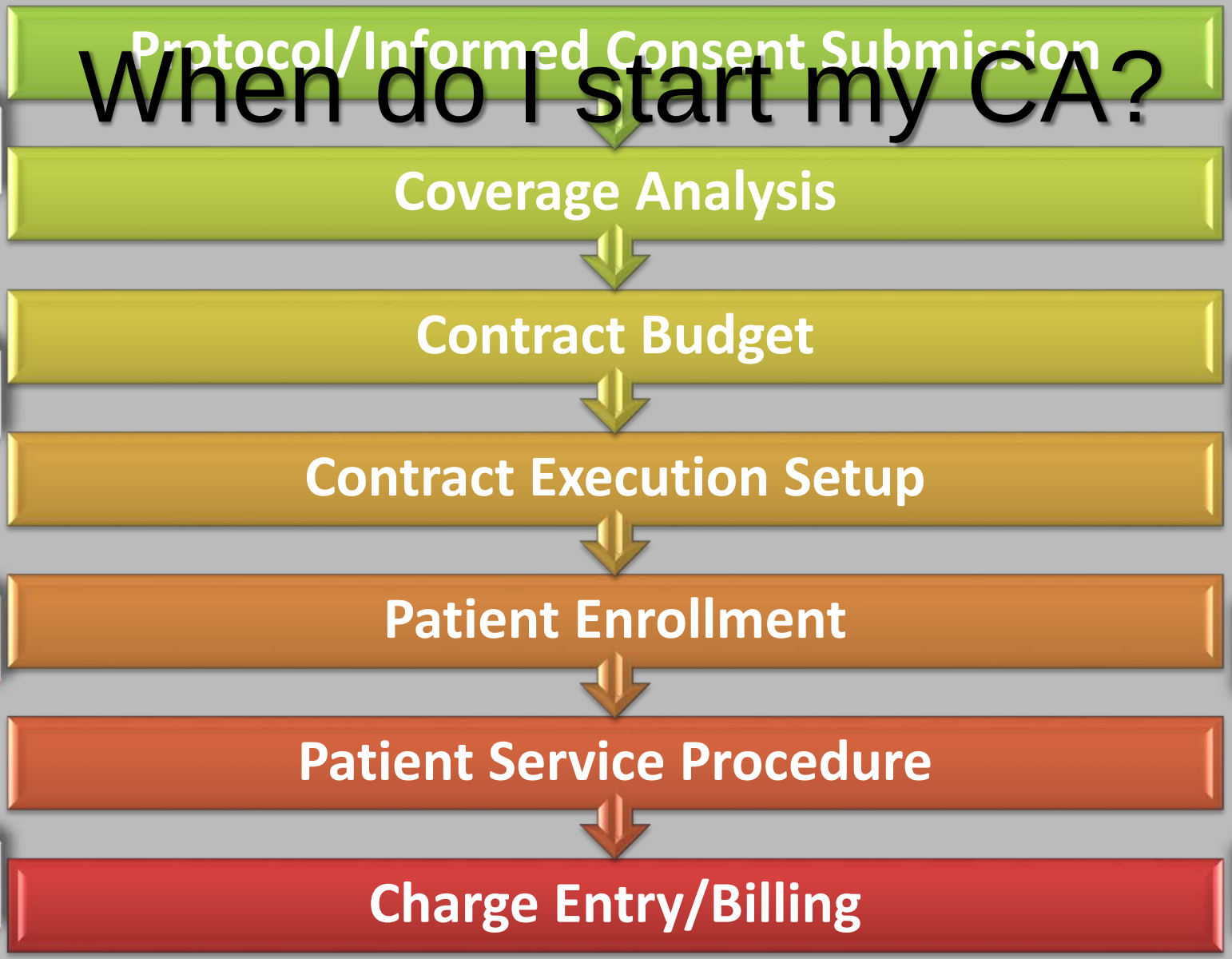
What is a Routine Cost?

- Provided when the patient is not on a clinical trial
- Required for the provision of the investigational item or service (Example- administration of the study drug)
- Items clinically indicated for the monitoring of the effects of the investigational item or service
- Needed for reasonable and necessary care arising from the provisions of an investigational item or service in particular, for the diagnosis or treatment of complications

What is not Routine Cost?

- The investigational item/service unless it is already covered outside of the clinical trial (Example- comparison trials)
- Provided solely for research purposes
- Provided solely to determine eligibility
- Provided/Paid by the Sponsor
- No cost items listed in the informed consent
- Items excluded from typical coverage

When do I start my CA?



What is the CA Routing Process?

CRF

Billing Risk Assessment by CRF using the protocol Submitted to iRIS

CRF

CRF enters the initial data into the CA tool. All study visits, services, and procedures will be listed out in Costs/CA tab

CRF sends to dept. and notifies them to complete CA, Costs, Effort, qualifying questions, and billing certification.

Dept.

Department completes coverage, budget, qualifying questions, and submits it for review

Both

CRF reviews and works with department to finalize CA approval

CRF

CRF emails contract specialist, PI, dept contact, CPHS, with approval notice

How do I Perform a CA?

- Determine if it is a Qualifying Clinical Trial
- Review Documents
- Review Documents
- Meet with the PI, Research Nurses, Billing/Coding Specialists, CRF Team
- Complete the Cost Coverage Analysis
- Review Documents

What is a Qualifying Clinical Trial?

3 Requirements:

- Evaluate an item or service that falls within a Medicare benefit
- The trial has therapeutic intent
- Must enroll patients with disease diagnosis

What are Deemed Studies?

- Trials funded by federal sponsors or supported by their centers or cooperative groups (NIH,DOD,etc)
- Trials conducted under an investigational new drug application (IND)
- Drug Trials that are exempt from having an IND by the FDA

What About Devices?

- CMS requires advance designation for billing of routine costs to device trials.
- Submission includes the protocol, FDA approval of IDE, IRB approval letter and NCT#
- Memorial Hermann will require the CMS packet to be submitted along with the CA

What Documents Should I Review?

- Protocol
- Informed Consent
- Contract
- Previous Internal Budgets
- Investigator Brochure
- Sponsor Reimbursement Guide
- Clinic SOPs
- Internal Pricing

What happens when I meet with the PI and Admin?

- Which procedures are SOC/RES
- What does it costs to perform the procedure
- How much time/effort each takes
- Put it in writing

Procedure	Location	CPT Code	Visit 1	Visit 2	Visit 3	Justification
CMP	UTP Clinic	80053	SOC			UTHSC Dept. of Surgery Trauma and Surgical Trauma ICU Resident Handbook
X-Ray Imaging	UTP Clinic	71010-26	SOC			Guidelines for the Acute Medical Management of Severe Traumatic Brain Injury, July 2003 (4)3, p 1-76
MRI (Brain)	MHHS	70543	SOC	$80	$80	
MRI (read fee)	UTP Clinic	70543	SOC	$9	$9	
Pregnancy Test, Urine	UTP Clinic	81025	$10	$10	$10	

Reach Out For Help

One on One Trainings Available

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