Clinical Research Billing Compliance Risks and Challenges

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Learning Objectives

Upon completion of this presentation, you will be able to:

- Analyze basic billing rules
- Create an "audit ready" environment
- Review process (case study)

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Common Areas of Risk

- Clinical trial billing compliance not see as a priority
- Lack of business & financial management
- Lack of organizational structure, leadership, roles and responsibilities
- Lack of Policies & Procedures
- Disconnect between facility and physician practices

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Common Areas of Risk

- Subject enrollment and identification
- Unbalanced study portfolio
- Strong review of study feasibility & start-up
- Integrating information technology (IT) – Epic, Velos implementation, e-Regulatory
- Payer management denials, appeals & authorization
- Lack of staff training and quality assurance and monitoring
- Lack of communication, collaboration and transparency

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What Does It Take to Get Clinical Trial Billing Compliance Right?

- A broad understanding of many fragmented, disconnected processes and systems
- An appreciation of many events that take place before and after submitting a claim

- Four main reasons for incorrect billing:
  - Technological error
  - Human error
  - Lack of training
  - Awareness of the coverage analysis process

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Clinical Trial Billing & Coverage Risks

- Billing for services paid for or invoiceable to the sponsor
- Billing for services promised free in the informed consent form
- Not Identifying subjects enrolled in the study and reviewing claims
- Billing without codes and modifiers or billing Medicare Advantage Plans incorrectly for drug clinical trials

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What Is Clinical Research Billing?

CRB is the accurate completion of the research revenue cycle, sponsor invoicing and payment process, study funds allocation and account reconciliation.

- Correct planning for and communications around protocol visit charges, costs, and reimbursement (authorizations, registration, visit/service tracking)
- Identification of subjects and their protocol-related service charges in the billing system(s)
- Prompt direction of protocol visit charges and other study costs to the correct payor in accordance with the study contract, and the relevant payor coverage, coding, and billing rules
- Collection and proper allocation of payments to the facility, provider, Investigator

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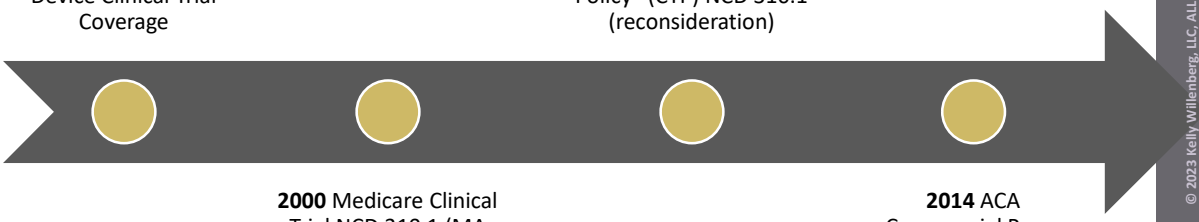
Clinical Trial Coverage & Billing Compliance Primary Rules*



State Laws – Clinical trial coverage laws or cooperative agreements
Medicaid – Coverage depends on state Medicaid programs
Medicare – Claims processing rules
False Claims Act - Protects federal taxpayers from overpayment for services provided
****Other laws, regulations, rules also are relevant but are largely captured by 310.1 and claims requirements***

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Foundation of Clinical Trial Coverage

- **Medicare** – "Clinical Trial Policy" National Coverage Determination 310.1
  - Medicare may cover the routine costs of qualifying clinical trials, if the routine costs are:
    - NOT paid for by the sponsor
    - NOT promised free in the informed consent form
    - Covered by Medicare
  - Routine costs:
    - Conventional care
    - Detection, prevention, & treatment of complications
    - Administration of investigational item
  - All other Medicare rules apply!

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Example of a Coverage Analysis

Protocol related tests and procedures	Range of CPT/ HCPCS Codes	Pre-Procedure	Procedure	Post Procedure	1 Month	Unscheduled Repeat Angio/Revascularization	
Test and Services							
Physical Exam (E&M)	99201-99205; 99211-99215; 99218-99226; G0463	Q1		Q1	Q1	M	IDE Guidelines allow for the coverage of routine cost of conventional care. E&M visit at workup appears reasonable and necessary, prior to angioplasty procedure to establish patient's health/condition. The ACC/AHA guidelines recommend periodic follow-up after surgery for claudication. Follow-up consists of "periodic clinical evaluations" that should note any return or progression of symptoms of claudication Circulation. 2006;113(11):e463. If repeat Angio or revascularization is necessary, it is assumed it would be clinically indicated. Medical records must document medical necessity.
Duplex Ultrasound	93925-93926			S			DUS may be captured anytime 0-6 weeks post procedure. Per Exhibit B of the Executed CTA, sponsor to pay
Resting ABI	93922-93923	Q1		Q1	Q1	M	IDE Guidelines allow for the coverage of routine cost of conventional care. ABI at workup appears reasonable and necessary prior to angioplasty procedure for measurement of the severity of disease. The ACC/AHA guidelines recommend periodic follow-up after surgery for claudication. Follow-up consists of periodic clinical evaluations that should include measurement of the ankle-brachial pressure index (ABI). Circulation. 2006;113(11):e463. If repeat Angio or revascularization is necessary, it is assumed it would be clinically indicated. Medical records to document medical necessity.
Balloon Angioplasty	37220-37235; 75962, C1725, C1769, 75964, 36247, 35470, 35476; 36248,		Q1			M	Repeat angioplasty or bypass surgery can be used to treat in-stent restenosis and is recommend by the ACC per Circulation.2002; 105: 2586-2587 . MAC approval required for the study including the angioplasty. Prior authorization would be required for non-Medicare patients. Medical records must document medical necessity.

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Clinical Trial Billing Compliance Work Flow

- Feasibility Analysis
- Coverage Analysis & Billing Plan
- Budgeting, Pricing & Contracting
- IRB Approval
- Document Sync
- Identification of Study, Subjects and Visits
- Authorization & Documentation for Medical Necessity
- Charge Capture
- Charge Segregation
- Claims Submission
- Denials Management
- Amendments

Compliant Billing

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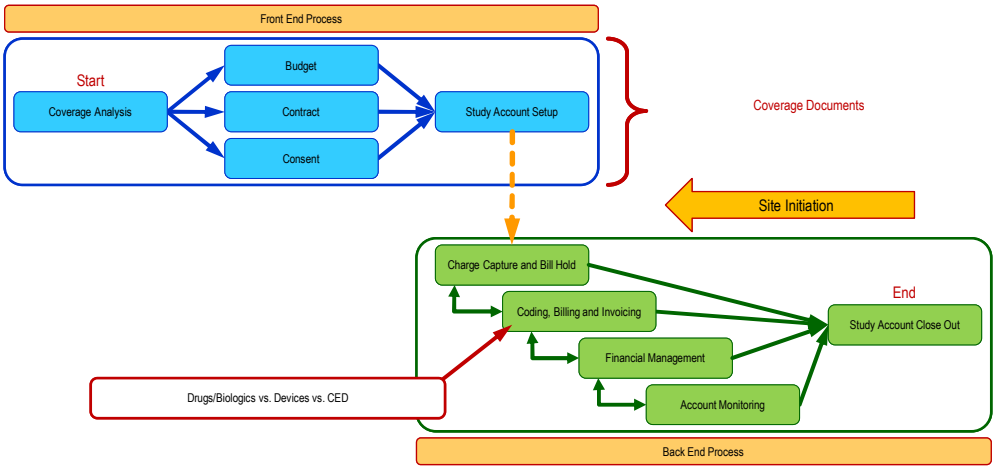
Clinical Trial Revenue Continuum



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Billing Compliance Basics

RECOGNIZE NON-COMPLIANT BILLING

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How Do You Become Non-Compliant?

- Failing to comply with laws, regulations, protocols, informed consent documents
  - Intentional or unintentional
  - Serious and “continuing” non-compliance is reportable to federal funding agencies and the FDA for studies subject to their oversight
- How does it happen?
  - Lack of attention
  - Lack of understanding
  - Decentralization
  - Failure to coordinate, collaborate, and communicate

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Consequences of Non-Compliant Billing

- Staff time lost on correcting billing errors
- Lost revenue
- Residual balances
- Fines and penalties
- Potential loss of federal grant funding
- Potential loss of participation in Medicare/Medicaid
- Enforcement actions and fines
- Corporate Integrity Agreements
- Loss of community trust and reputation

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A Successful Research Billing Compliance Program Has 9 Necessary Needs

1. Administrative buy-in (“C-suite” support)
2. Research oversite committee
3. A solid organizational structure with clearly defined roles and responsibilities
4. Policies and procedures
5. Transparent research discounting process for both government and non-government
6. Coverage analysis process that is thorough
7. Strong budgets that cover true costs
8. Ability to flag research patient bills in a queue
9. Gap analysis; self monitoring

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DEVELOP A COMPLIANT BILLING PROCESS

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Remember the Three C's of Research Billing Compliance

1. Collaboration
2. Challenges
3. Compromise

- Once you have all of the information, you must communicate and coordinate the study information to all stakeholders

The 3 Cs of Research Billing Compliance: Collaboration, Challenges, and Compromise, Meade, Willenberg, Journal of Healthcare Compliance, vol. 12, 2010

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Clinical Trial Billing Process

CA Review "Front End" Cycle

- Protocol feasibility review
- Determine Clinical Trial qualifying status
- Perform and validate Coverage Analysis
- Draft budget, contract and consent review
- NCD and LCD review
- National Guidelines for disease review
- Compare draft budget with CA
- Provide consent language based on CA

Document Review "Middle" Cycle

- Coverage Analysis guides other documents especially the consent language in the expected costs section
- Budget negotiation detailed to coverage analysis level
- Contract language consistent with budget and consent
- Document language consistency confirmed prior final IRB approval
- Document review ends with final IRB approval and study start up

Patient On Study Review "Back End" Cycle

- Patient signs consent understanding financial implications
- Patient flagged in billing systems immediately after consent signed
- Study specific visit identified
- Charges reviewed against CA and medical documentation
- Claim to correct payer
- Coding rules applied
- NCT# applied
- Medicare Advantage review for drug trials

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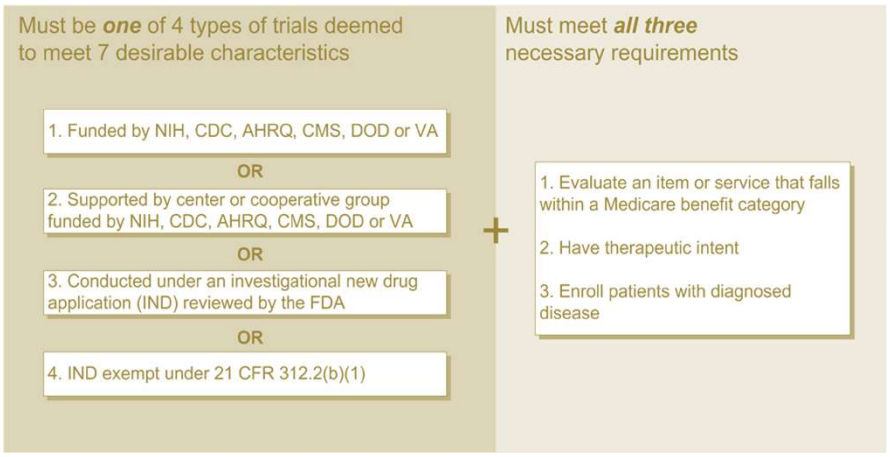
Determining a Qualifying Clinical Trial

Summary Chart



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Investigational Devices: Coverage Principles Summary

Category A	Category B	CEDs
• Trials involve immediately life-threatening condition (if trial was initiated before January 1, 2010)	• All CMS approved trials	• All CMS approved registries and trials
• Device NEVER covered	• Device covered if not provided free by sponsor or promised free • Reimbursement may not exceed amount for comparable marketed device	• Device covered if not provided free by sponsor or promised free • Reimbursement may not exceed amount for comparable marketed device
• Routine care services covered	• Routine care services covered	• Routine care services covered
• Medicare contractor approval required	• Medicare contractor approval required	• Medicare contractor approval required

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Auditing Clinical Trial Billing

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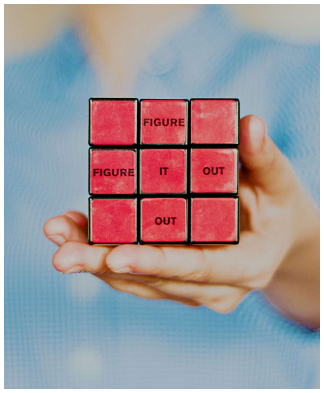
Types of Clinical Trial Billing Audits

- Process / Internal Control
- Study Level
  - Document Concordance
  - Coverage Analysis Validation
  - Invoicing
- Subject Level with Error Reporting
  - Claims
  - Denials
  - Invoicing



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Error Rate Calculations - Examples

Payment Error Rate

- Total dollars paid in error / total dollars paid
  - EX: $195,000 / $500,000 = 39% payment error rate

Claim Error Rate

- Total # of claims billed to the incorrect payer / Total # of claims reviewed
  - EX: 90 / 500 = 18% claim error rate

Line Item Error Rate

- Total # of line items billed to incorrect payer / Total # of line items reviewed
  - EX: 975 / 5000 = 20% line item error rate

Coding Error Rate

- Total # of claims billed to correct payer, incorrect coding / Total # of claims reviewed. Coding errors count as 1 error per claim.
  - EX: 200 / 500 = 40% coding error rate

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CMS Error Rate Data – A/B MACs

Improper Payment Rate Scores/Rankings:

- 1 0.0% - 3.9% (Oh Yeah!)
- 2 4.0% - 7.9% (Getting Better)
- 3 8.0% - 11.9% (Tighten Up)
- 4 12.0% - 15.9% (Processes?)
- 5 16.0% and above (Uh-OH!)

Focused monitoring and corrective action help organizations get to an acceptable ranking

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What is Double Billing?

- Sponsor agreed to pay for physician visits/history & physical/E&M
- Physician practice is outside of the institution and bills separately for professional services
- Patient has E&M visits at the physicians office post admission for implantation of a category B approved device
- Professional and technical billing do not sync

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Common Audit Findings

- Non-employed physician group not notified of clinical trial / subject
- Under budgeting of clinical trial procedures
- Lack of fund accounting
- Excessive residual balances and no residual funds policy with no resolution
- Claims submission errors
- Billing of professional (pro) and technical (tech) charges not coordinated.
- “Off the books” research activities or charges not posted in billing systems
- Patient reimbursements held or not paid

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Federal Sentencing Guidelines OIG Compliance Program Guidance

- The organization exercises due diligence to prevent and detect inappropriate conduct by the Medicare and Medicaid provider; the organization promotes an organizational culture that encourages ethical conduct and is committed to compliance with the law; and he compliance program is reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting improper conduct.
- Failure to prevent or detect specific offenses does not necessarily mean that the program is not generally effective in preventing and detecting such conduct.
- Federal Sentencing Guidelines amendment effective 11/1/2010 Section 8B2.1(a)

(including compliance program guidance for hospitals, small physician practices, and PHS research awards)

https://oig.hhs.gov/compliance/compliance-guidance/index.asp

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False Claims Act

- Prohibits filing or causing the filing of false claims, or creating a false record to get a claim paid
- The core of a false claims case is that the government was cheated in one form or another - the "false claim"
  - Knowingly presenting the government with a false claim for payment or approval
  - Knowingly making a false statement to get a fraudulent claim paid by the government
  - Conspiring to defraud the government by getting a false or fraudulent claim paid
  - Knowingly making a false record or statement to conceal, avoid, or decrease an obligation to pay the government
  - Causing a false claim to be submitted

The FCA intent standard is "knowing," which includes "should have known" (reckless disregard). Basically, if there is a rule out there on the subject and the provider has violated it (no matter how buried/accessible it is), the government takes the position that the intent element has been met.

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False Claims Act and Penalty Examples

- A crime to knowingly make a false record or file a false claim
- Violations can result in significant fines and penalties
- Financial penalties to the person or organization includes recovery of three times the amount of the false claim(s), plus an additional penalty of $5,500.00 to $11,000.00 per claim (*chart shows adjustment for inflation)

Item/Service	Claim Amount	Triple Damages	Subtotal	Penalty*	Potential Total
Lab test	$ 200	$ 600	$ 800	$ 11,803	$ 12,603
CT scan	$ 4,000	$ 12,000	$ 16,000	$ 11,803	$ 27,803
Hospital admission	$ 125,000	$ 375,000	$ 500,000	$ 11,803	$ 511,803

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Summary/Close

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Thank you!

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St. Jude Children's Research Hospital

Research Billing Compliance

Case Study

Isaiah Costner, CCRP
Director - Research Finance
Clinical Trials Finance Office

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Context

- Clinical Trials Finance Office
  - Centralized finance office for clinical trials funded by:
    - St Jude
    - Industry
    - Foundations
    - Cooperative groups
- St Jude Children's Research Hospital
  - Not-for-profit ($1.4B annual budget)
  - 5000 employees (+1400 FY22-27)
  - Primarily research (8,600/yr)
  - 1024 open studies (as of 10/16/23)
  - Primarily outpatient (77 beds)

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CTFO Vision Statement

The Clinical Trial Finance Office (CTFO) is dedicated to advancing quality clinical trial research in accordance with St. Jude's exceptional clinical care and unique world-wide service mission. The ***CTFO supports investigators and research staff in clinical trial financial management and billing practices by establishing uniform requirements for clinical trial budgets and billing of clinical services for research participants*****.** It seeks to ensure that St. Jude adheres to laws, regulations, and requirements governing research funding and billing practices. Its mission is to facilitate clinical research by providing outstanding services, promoting innovative solutions, and fostering collaboration and continuous quality improvement.

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History

- Office was started in 2016
- Gap analysis (2015)
  - Billing compliance was de-centralized
  - Dictated by clinical staff
  - Audited by small office utilizing basic billing plans
- Determined we needed a central office for research finance
- Developed a standardized (yet SJ appropriate) centralized office
- Cerner EHR and separate billing system (GE/IDX/Athena)
  - Developed a process that leveraged billing interface
- Went live with Epic (EHR) in Oct 2022
  - Combined medical record with billing module
  - Pre-determined research review functionality

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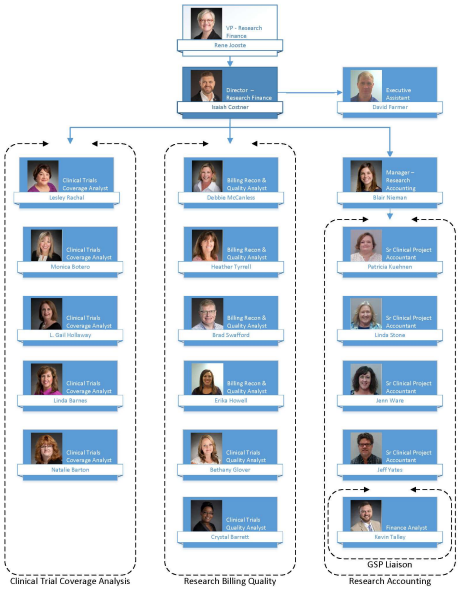
Who



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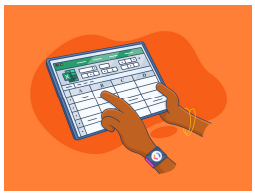
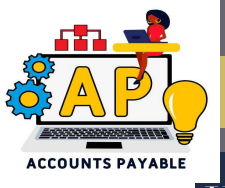
Who

- Three functional teams within the CTFO
  - Coverage Analysis Team
    - Clinical trial budgeting (ensure adequate funding)
    - Contract review
    - Coverage analysis creation (NCD 310.1)
  - Quality Analyst Team
    - Research billing compliance – 100% charge review
- Clinical Trial Accounting Team
  - Clinical trial account set-up and maintenance
  - Sponsor invoicing & payment application
  - Collaborative site payments





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How

- Collaborate with several internal partners at St Jude
  - Study teams & investigators
  - Clinical Trials Operations & Administration
  - Contracting & Legal
  - Epic orders groups
  - Revenue Cycle & Revenue Integrity
  - Compliance & Audit
  - Finance & research leadership
- External partners
  - Pharma companies (sponsors)
  - Foundations/co-op groups (sponsors)
  - Collaborative sites (SJ-initiated studies)

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How

- Systems
  - OnCore – Clinical Trial Management System (Aug 31, 2021)
    - Study info, calendar, budget, coverage analysis, billing grids, subject visits, invoicing, site payments
  - Epic – Medical Record System & Billing System (Oct 2022)
    - Orders linked to research studies, charge review, OnCore interface
  - MARS – Grants Management System (April 2021)
    - MARS is the single point of entry for study accounts in Workday
  - Workday – Accounting System (July 1, 2023)
    - Study setup (from MARS), staffing allocations, invoicing, site payments

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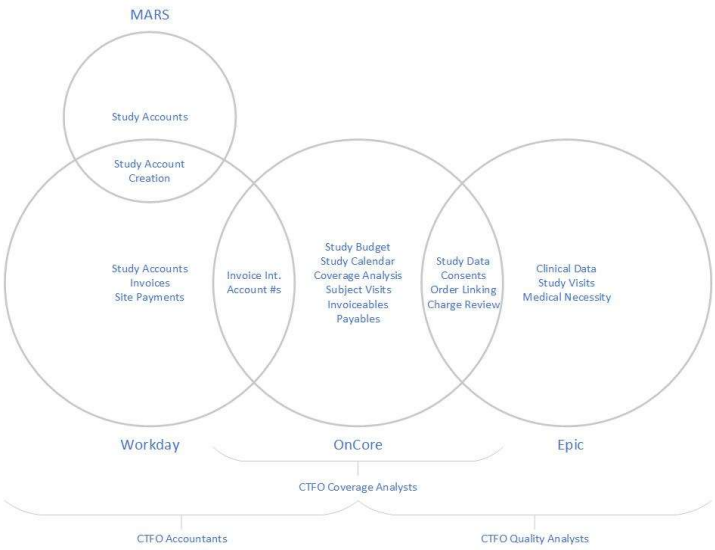
How



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Process – Coverage Analysis

- Studies enter Coverage Analysis (CA) process in a few ways
  - IRB Submission
  - Contracts Office Communication
  - PI & Study Team Communication
- Any sponsor agreements are reviewed for budget & terms/conditions
  - Contract review takes many paths (contracts <-> legal, legal <-> CTFO, contracts <-> CTFO, etc)
  - CTFO determines if agreements provide adequate funding, may negotiate directly with sponsors
- Calendar builders are working parallel to coverage analysts (OnCore)
- Once a budget is started and calendar is built, coverage analysis is completed
  - Qualifying studies – CA team uses NCD 310.1, relevant compendia, and peer reviewed literature
  - CA consists of each evaluation/procedure, a billing designation & justification(s)
  - Budgets contain invoicing designations and triggers for items paid for by sponsor

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Study Calendar Engagement

- Study calendars are in OnCore (CTMS)
- When patients are seen for study visits, study staff mark visits complete in OnCore
  - In addition to clinical documentation in Epic (EHR)
- This engagement is important for billing review, as the CTMS should be the primary source of truth for study activities
  - CTMS calendar is used by the charge review team to validate study activities and timepoints

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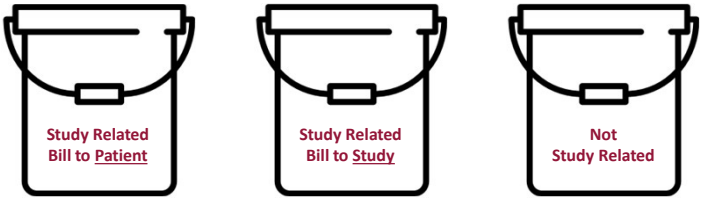
Process – 100% Charge Review

- Patients on trial are enrolled in OnCore (CTMS), interfaced to Epic (EHR)
  - Registration on trial generally opens study-specific ordering in Epic
- Basic Epic functionality
  - One tier vs two tier research review
  - Charge review qualification (list of specific criteria, set by institution)
- Epic orders must be "linked" to studies (automatically or manually)
- Epic charges may land in one of three buckets



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Process – 100% Charge Review

- Epic research flagging relies on ordering tool and human intervention
  - Beacon orders (cyclical, ie-oncology)
    - Orders automatically linked
    - Generally, individual events/charges can be pre-set with billing designations
  - Smart Sets (bundling of ad hoc orders)
    - Orders automatically linked
    - Routed to study-determined charge bucket, but not at the event level
  - Ad hoc
    - Must be manually linked to a study
    - Study specific charge routing determines bucket
- All charges for consented patients end up on a charge review report, pre-flagged based on ordering tool or manual flag
  - We review 100% of all charges
  - Special reports/process for non-consented patients (utilizing a 5-day bill hold)

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Process – 100% Charge Review

- Research Biller Report (Epic language)
  - All qualified charges, by patient, along with each study to which the patient is consented
    - Charges initially appear within the default bucket, determined by ordering tool, routing rules, and manual flagging
    - Charges are held in this report indefinitely, until reviewed
  - Charge review team (CTFO Quality Analysts) systematically reviews charges per patient, per study
  - Charge bucket is validated for each charge
    - Information is compiled from initial bucketing, Epic medical records, and OnCore activities
  - Any charges incorrectly bucketed are moved via “research correct”
  - When charges are bucketed correctly for a patient/study, account is marked as reviewed
    - This allows the revenue cycle to continue

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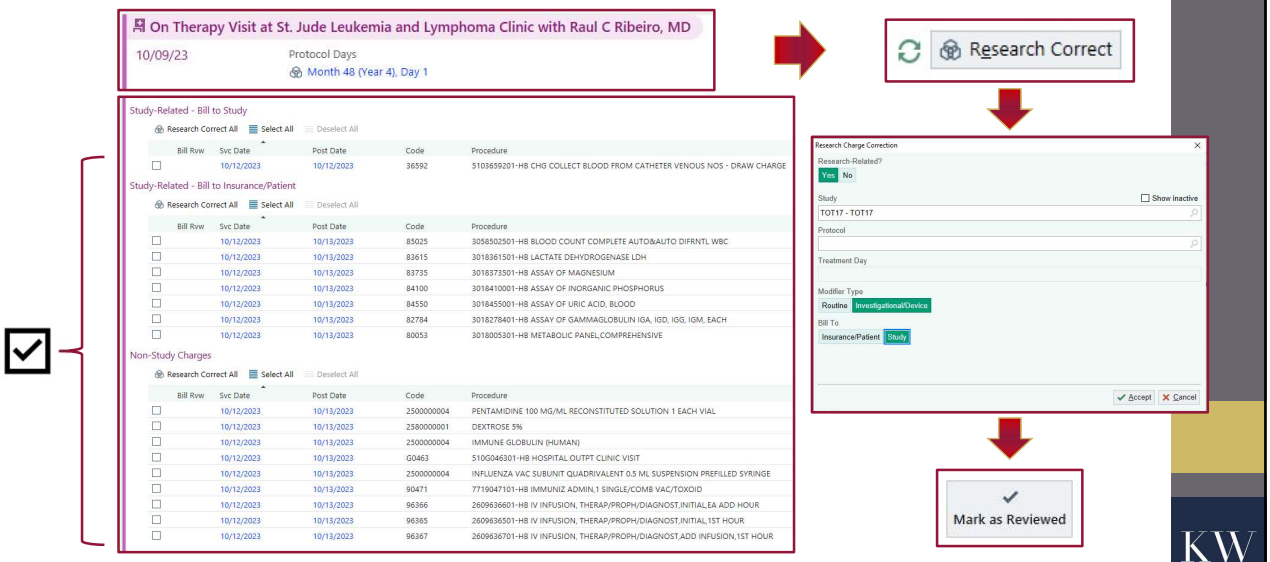
Process – 100% Charge Review



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Process – Invoicing

- Invoicing is done almost entirely out of OnCore (CTMS)
  - Auto-paid items (from CRFs in sponsor systems)
    - Invoice generated in OnCore after payment received, reconciled to study calendar
  - Pass-through items (from OnCore calendar)
    - Invoice generated in OnCore prior to payment, sent to sponsor
    - Reconciled when payment is received
  - All invoices generated in OnCore are interfaced to Workday
    - Allows for recording all accounting in hospital accounting system
    - Invoice details and reporting maintained in OnCore – Workday is summary level

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Governance

- Biennial internal audits
  - Reviews current SOPs and processes to ensure proper controls
  - Suggest process improvements, additional layers of control
- Biennial external audits
  - Voluntary audits of coverage analyses to ensure accuracy and best practices
  - Suggest enhancements to processes

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Why

RUSH UNIVERSITY MEDICAL CENTER Rush University Medical Center agreed to a $1 million settlement after self-disclosure of improperly billing Medicare for physician and hospital services and as routine costs in cancer care.	USC Norris Comprehensive Cancer Center Tenet USC Norris Cancer Hospital settled for $1.9 million after self-disclosure of overbilling with oncology trials.
UAB The University of Alabama at Birmingham accepted a $3.39 million settlement for falsely billing Medicare for researcher time spent on patient care when no patients had been seen.	EMORY UNIVERSITY Emory University agreed to a $1.5 million settlement for falsely billing Medicare and Medicaid for clinical trial services that were not permitted by the Medicare and Medicaid rules in a whistleblower case.

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