



Billing Compliance Fundamentals for Successful Clinical Trial Operations

Kathleen Hurtado, RPh, Consultant, Kelly Willenberg & Associates, Houston, TX, USA
Chris Longspagh, PharmD, Consultant, Kelly Willenberg & Associates, Seattle, WA, USA

Billing Compliance Fundamentals for Successful Clinical Trial Operations

- Learning Objectives:
 - Overview of billing compliance in clinical trials
 - Discuss the CMS Clinical Trial Policy (NCD 310.1) and Investigational Device regulations
 - Identify key risk areas
 - Tools and best practices for implementing a clinical trial billing compliance program to enhance clinical trial operations



Disclaimer

- No legal advice is provided during this session.
- This is a training seminar for your use at your Institution within parameters of state and federal laws and your Institutional requirements.
- Please seek legal representation to have your questions clarified or discussed.



Research Billing Compliance Definition

- Awareness and accuracy from the intake of a study, regardless of study sponsor, throughout the revenue cycle, including human subject protection, reimbursement by payer, sponsor invoicing (if applicable), payment process, claims adjudication, study funds allocation and account reconciliation.



What is compliance?

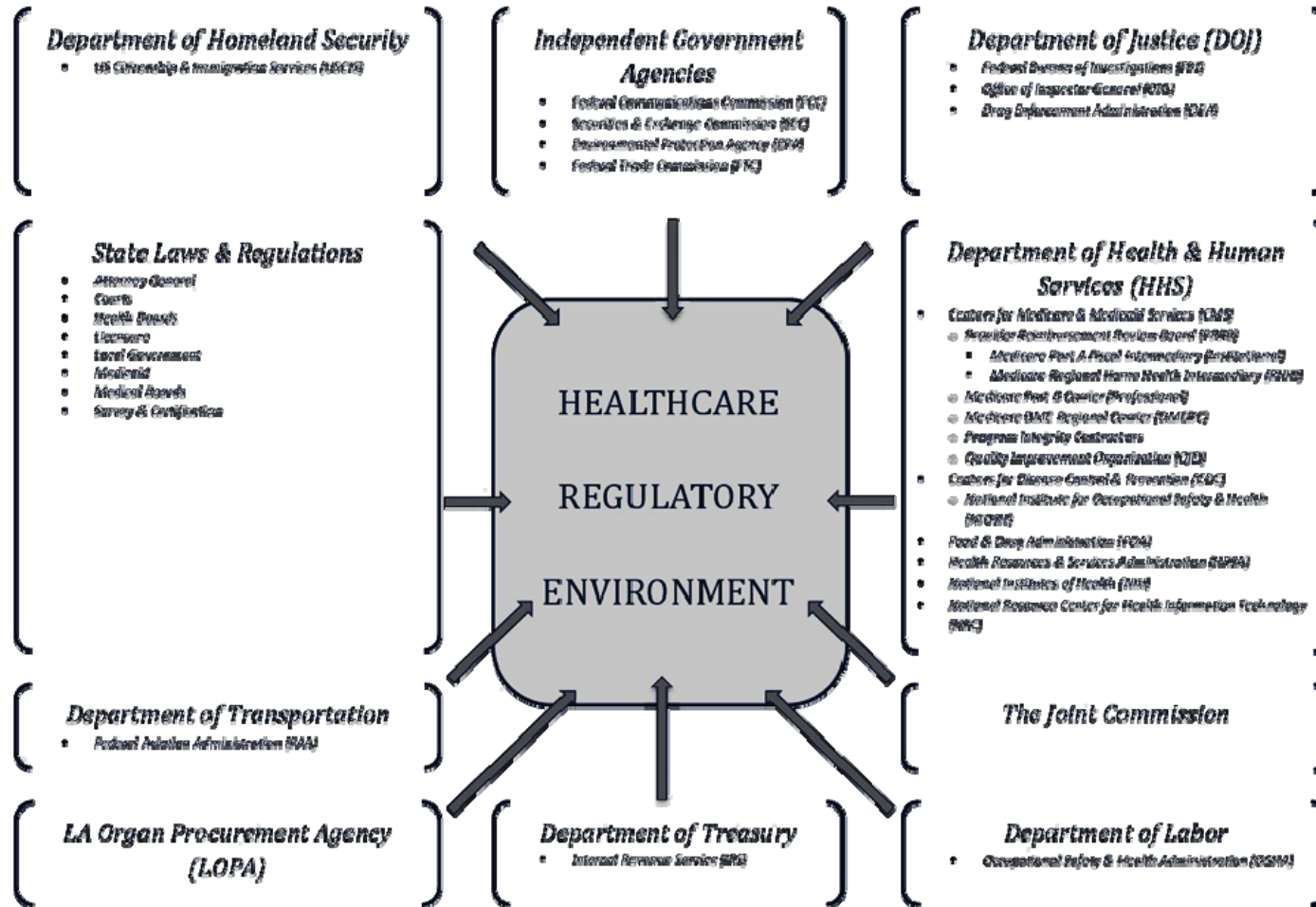
Recognize Importance of Compliance

- Carrying out your daily work guided by both:
 - The laws, regulations and policies which govern you, and
 - Appropriate ethical standards
- Preserve institutional integrity and investigator/research program reputation

**COMPLIANCE MEANS
DOING THE RIGHT THING ALL THE TIME**



Oversight of the Health Care Industry



How do you become non-compliant?

- By failing to comply with laws, regulations, protocols, informed consent documents
 - May be intentional or unintentional
 - Serious and “continuing” non-compliance is reportable to federal funding agencies and FDA for studies subject to their oversight
- How does it happen?
 - Not paying attention
 - Lack of understanding of the rules
 - Decentralization
 - Failure to coordinate, collaborate, and communicate



Clinical Research Financial Compliance Risks

1

FCA Violations

2

Double Dipping

Payments from sponsors and from 3rd party payers for same item/service

3

Inducement

Investigator incentives may entice stacking of patients in studies

4

Kickback

Residual research account balances



Non Compliance

Clinical Trial Billing Errors

- Billing for services not rendered
- Billing for services that are already paid by the sponsor, promised to be paid or promised free in the informed consent
- Billing for services that are for research-purposes only or are part of a non-qualifying clinical trial (without policy)
- Billing Medicare for device trials without Centers for Medicare and Medicare Services (CMS) approval
- Bill Medicare Advantage Plans (Part C) when claims should be directed to the Medicare Administrative Contractor



Non Compliance

Clinical Trial Billing Errors

- Frequency of Services Required by Protocol
 - Examine items and services that are “confirmatory” as these may not be reimbursable
 - Imaging done to confirm tumor progression or response outside of recommendations in guidelines.
 - Identify items and services unnecessarily repeated to fit the protocol’s screening or other windows
 - If a patient has had a procedure that is “just outside” the protocol window, talk to the Sponsor about using it instead of taking a billing risk of doing another test just for the protocol, or be sure that the Sponsor (or Grant) pays for that extra procedure necessary for screening.



Non Compliance

Clinical Trial Billing Errors

- Billing for items or services not supported by required documentation
 - A proper, signed order
 - Adequate documentation of medical necessity for the item or service
 - Documentation of study participation, as required
- Billing without proper codes, modifiers or NCT #



Non Compliance

Waiving Patient Co-payments

- Government Payers
- The OIG has long taken the position that routine waiver of patient responsible amounts can constitute a type of healthcare fraud (OIG Special Fraud Alert, 1994).
- The OIG takes the position that waiver of co-payment is misstating the actual charge.
 - If a doctor states that his charge for a visit is \$100, but routinely waives the 20 percent copayment, the OIG feels the actual charge is \$80.
 - Medicare should be paying 80 percent of \$80 (or \$64), rather than 80 percent of \$100 (or \$80).
 - As a result, the Medicare program is paying \$16 more than it should for this item.



Non Compliance

Waiving Patient Co-payments

- Two federal statutes prohibiting waivers of co-payments
- Beneficiary Inducement Statute 42 U.S.C. 1320a-7a
 - Prohibits the offer or payment of "remuneration" to a beneficiary by any person/entity if the person/entity knows (or should know) that the remuneration is likely to influence the beneficiary to obtain items or services from a particular supplier.
 - "Remuneration" specifically includes waivers or reductions of copayment amounts, except when....
- Medicare Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b)
 - Prohibits, among other things, the offer or payment of remuneration to induce a person to purchase a Medicare or Medicaid-covered item or service.
 - The anti-kickback statute does not include a definition of "remuneration." It is generally accepted that the term includes transferring "anything of value."



Non Compliance

Waiving Patient Co-payments

- Private Payers
- Insurance network contracts have long contained a provision that the physician will seek to collect the patient-responsible portion.
- Insurance auditors have begun to request evidence of attempts to collect coinsurance.
- Manuals state that the physician must actually collect this payment.
- If the physician cannot provide proof, the insurance company may demand repayment of benefits or terminate the contract.



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



False Claims Act

- Intent must be proven (knowing or willful)
- Criminal and civil penalties exists
- Fitting into a safe harbor is not required to comply but is highly advisable
- Most safe harbors require:
 - a written agreement and
 - payments that are within Fair Market Value



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

Example:

Item/Service	Claim Amount	Triple Damages	Subtotal	Penalty	Potential Total
Lab test	\$ 200	\$ 600	\$ 800	\$ 11,000	\$ 11,800
CT scan	\$ 1,000	\$ 3,000	\$ 4,000	\$ 11,000	\$ 15,000
Hospital admission	\$ 20,000	\$ 60,000	\$ 80,000	\$ 11,000	\$ 91,000



Federal Anti-kickback Statute

- Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal Health Care program business
- Intent must be proven (knowing or willful)
- Criminal and civil penalties exists
- Fitting into a safe harbor is not required to comply but is highly advisable
- Most safe harbors require a written agreement and payments that are within FMV



AKS And Clinical Trial Billing

- Problematic Compensation Arrangements
 - Excess compensation (over fair market value) so that residual balances can be retained
- Recruitment Bonuses/Finders Fees
- Arrangements in clinical trials to pay subjects for their time, travel, meals for attending their protocol visits where one or more of the hospital and professional charges from that visit will be billed to insurance/Medicare, presents a strong appearance of intent to induce the patient to receive those services at the clinical trial site, implicating the AKS.
- Provision of equipment to carry out the study (e.g., EKG machines, laptops, etc.) that are not returned at the end of the study. Can't keep as part of compensation or as a gift



Consequences of Non-compliant Billing

- Staff time lost on correcting billing errors
- Lost revenue both on payer side and in research
- 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





A TOUR THROUGH CLINICAL TRIAL BILLING RULES



Clinical Trial Billing Rules

- Drug Studies
 - Clinical Trial Policy (CTP):
 - A National Coverage Determination (NCD 310.1) delineating routine costs in a qualifying clinical trial
- Device Trial Studies:
 - Device Regulations found in Medicare Benefit Policy Manual, Ch. 14
 - Stipulates coverage based on FDA category determination (Category A and B)
 - Requires Medicare approval in all cases
- Coverage with Evidence Based Development
- Everything else
 - Is there something investigational or experimental?
 - If yes, then see above.
 - If no, then defer to MAC for approval or defend as “reasonable and necessary”



Why Medicare?

- Medicare's Clinical Trial Policy (CTP) is generally used in Coverage Analyses across the country because:
 - It is often the largest single payor
 - Many plans have adopted CTP principles
 - Some state Medicaid rules follow the CTP
 - Nearly impossible to do a CA based on all payors
- Medicare has a Big Stick!
 - If you file a False Claim or violate Stark Laws/AKS, you can be barred from participating in Medicare (often the largest payer)



The Legal Structure of Medicare

- To understand Medicare research billing rules, it is important to step back and understand the legal structure of Medicare
- Statutory basis for Medicare coverage follows this principle:
 - Medicare covers items and services that are “reasonable and necessary to diagnose or treat illness or injury”
 - Known as the “Reasonable & Necessary Rule”



Medicare Reimbursement

- Coverage rules are based on arguments of whether an item or service is “reasonable and necessary” for the majority of patients
- Note: MEDICARE IS NOT FDA!
 - Just because it is approved by FDA does not mean it is covered and reimbursed
- The question for any drug, device or service is whether it is “reasonable and necessary to diagnose or treat illness or injury”
 - There is very little deference to the physician



Medicare Reimbursement

- Medicare Administrative Contractors
 - Multi-state, regional contractors responsible for administering both Medicare Part A and Medicare Part B claims
 - Medical review and coverage adjudication
 - Allowed to issue coverage rules if CMS is silent or a CMS rule needs clarification
 - The law allows MACs from different parts of the country to disagree with each other

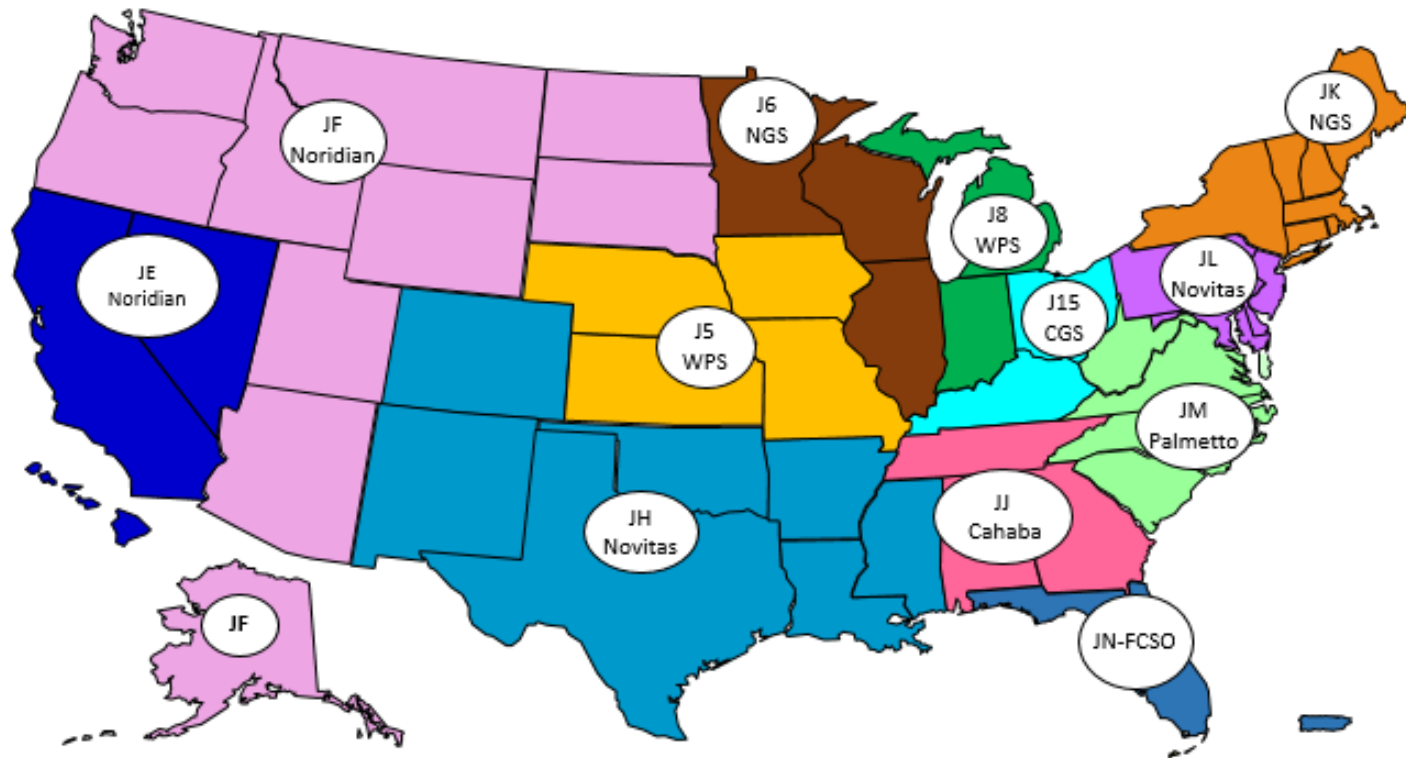


Hierarchy of Medicare Coverage Rules

- Statutes
- National – CMS
 - National Coverage Determinations (NCD)
 - Manuals (e.g., Benefit Policy Manual)
- Local - Local Medicare Contractor
 - Local Coverage Determinations (LCD)
 - Medical Director “articles”
- “Reasonable & Necessary Rule”
 - Document medical necessity when no coverage rule



A/B MAC Jurisdiction Map (12/2015)



<https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors>



Three Myths Regarding Clinical Trial Billing

- The Medicare program's CTP simply divides services between "Standard of Care" and "Research."
- All services not reimbursed by NCTN studies are automatically billable (therefore reimbursable)
- If NIH does not fund a service through a grant, then that means it is billable to insurance.



“Standard Of Care”

- SOC is not a Medicare or other Payor Concept
- Under CMS NCD 310.1, Medicare covers the ROUTINE COST of a qualifying clinical trial; one type of routine cost is CONVENTIONAL CARE
- The Medicare terms “routine costs” and “conventional care” come close to what the research community means by “standard of care” but it is **not** a one-for-one interchangeable concept



A Warning From HHS-OIG

- “Physician practices should remember that ‘necessary’ does not always constitute ‘covered’....”
 - OIG Compliance Program Guidance for Individual and Small Group Physician Practices (October 5, 2000)



Clinical Trial Billing Rules

- Medicare clinical trial billing rules are not found in one place
 - Statutes
 - Regulations
 - CMS National Coverage Determinations
 - CMS Manuals
 - Local Coverage Determinations



NCD 310.1

- Medicare covers the **routine costs of qualifying clinical trials**, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.
- All other Medicare rules apply

Determining A Qualifying Clinical Trial

Qualifying Clinical Trial Analysis			
Requirement	Yes	No	Comment
<p>Does the investigational item or service fall into a Medicare benefit category?</p> <p>Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).</p>			1 of 72 categories (NCD 310.1)
Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with Institutional policy?			Objectives / Endpoints / Statistical Section
Does the study enroll patients with diagnosed diseases?			Inclusion / Exclusion
<p>Is the study a deemed trial?</p> <p>(Study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or supported by cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or Provided under BLA / BB IND / IND # or IND Exempt as verified by the FDA or IRB)</p>			IND/ IND Exempt, etc.
<p>Is the study a qualifying clinical trial?</p> <p>(All questions must be answered "Yes" to qualify)</p>			Yes / No



Device Types



- Investigational Device Exemption
- 510K Devices
- Pre Market Approval
- Post Approval Extension Study
- Humanitarian Device Exemption
- IRB Approved Devices



Device Trial Qualifying Documentation

INVESTIGATIONAL DEVICE ANALYSIS				
Question	Yes	No	N/A	Comment
Does the study have an IDE from the FDA?				
Is the Device assigned Category A status?				
Is the Device assigned Category B status?				
Is it listed as an Approved IDE Study per CMS? (http://www.cms.gov/Medicare/Coverage/IDE/)				
What is the IDE number?				
If the trial does not have an IDE, has the device been approved/cleared by the FDA?				
If the trial does not have an IDE, is the trial involving FDA approved device approved during the PMA process or a 510K cleared device? If yes, What is the PMA/ 510K number?				
If the device is being used off-label?				
If off-label is the device IDE exempt and verified by the FDA or IRB?				
Does the trial qualify for coverage?				





ROUTINE COSTS

As Defined by CMS

“ROUTINE COSTS”

Under the CTP

- “Items or services that are typically provided absent a clinical trial (e.g., conventional care);”
- “Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and”
- “Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.”

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Costs That Cannot Be Billed

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring quarterly scans); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.



Summary Of Costs Defined As Routine

- Short-version approach to “routine costs” used in Medicare Coverage Analysis (MCA):
 1. Conventional care
 2. Administration of investigational item
 3. Detection or prevention of complications
- If study documents are not clear: will each subject enrolled in the study need the item or service for the patient’s clinical management?



Conventional Care

- MCA should identify objective clinical guidelines to support the designation of “conventional care”
 - Professional association guidelines
 - Peer-reviewed literature
 - Significant textbooks
 - Disease associations
 - NIH recommendations
 - Guidelines.gov
- Ask the PI for guidelines!



Conventional Care

- Questions for conventional care if no guidelines identified:
 - QUESTION 1: Would physician perform this service at the required frequency for a patient not in the study?
 - QUESTION 2: Is physician able to document the medical necessity of the item or service in the medical record for every subject?
 - QUESTION 3: Will physician use the test for the direct clinical management of every patient enrolled in the research study?

- IF ANY ANSWER IS NO, probably not conventional care⁴²



Administration Of Investigational Item

- What is required to administer the investigational item?
 - Surgery?
 - Infusion?
- Note: must be something that would be covered outside of study if similar therapy or procedure occurs.



Detecting or Preventing Complications

- MCAs identify nexus between the purpose of the item or service and a known potential side effect of the investigational item or service
 - What are the potential side effects of the drug?
 - What are the potential complications of use of the device?



Detecting or Preventing Complications

- Places in which MCAs identify potential side effects
 - Protocol
 - Investigational drug or device brochure
 - Informed Consent
 - Product Label
 - Drug information resources
- Documenting Reasoning – Example:
 - This test is performed to detect kidney dysfunction. The study drug is known to have renal toxicity (Protocol, p. 50)

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Routine Cost Examples

- IV drug administration
- ECHO to monitor cardiotoxicity
- CMP to monitor kidney toxicity
- Cardiac Catheterization for investigational stent placement
- Hydration prior to chemotherapy
- CT Scan every 8 weeks to monitor disease progression in metastatic Lung Cancer





Mitigating Non-compliance

How do you reduce the risk?

Benefits of a Research Billing Compliance Program

- Mitigate risk
- More efficient management of funds
- Worry free audits
- Maintaining a research program's reputation
- Sponsor and subject trust
- Human subject protection



The Village

- Principal Investigator
- Clinical Research Coordinator
- IRB process
- Budget negotiators
- Clinical Trial Agreement negotiators
- Project Accounting/Grant administration
- Health Information Management/IT
- Registration/Scheduling/Authorizations/Denials
- Medical center billing and coding
- Physician professional fee billing and coding
- Offsite facilities providing Clinical Trial services
- Managed care contract negotiatorsand others!



Must Haves for a Solid Billing Compliance Infrastructure

- Aligned, clear and functional reporting relationships and structure
- Identified roles and responsibilities
 - Research business operations
 - Clinical research coordinators
- Training and verification of clinical research competency
- Tracked metrics and training to gaps



Infrastructure Models

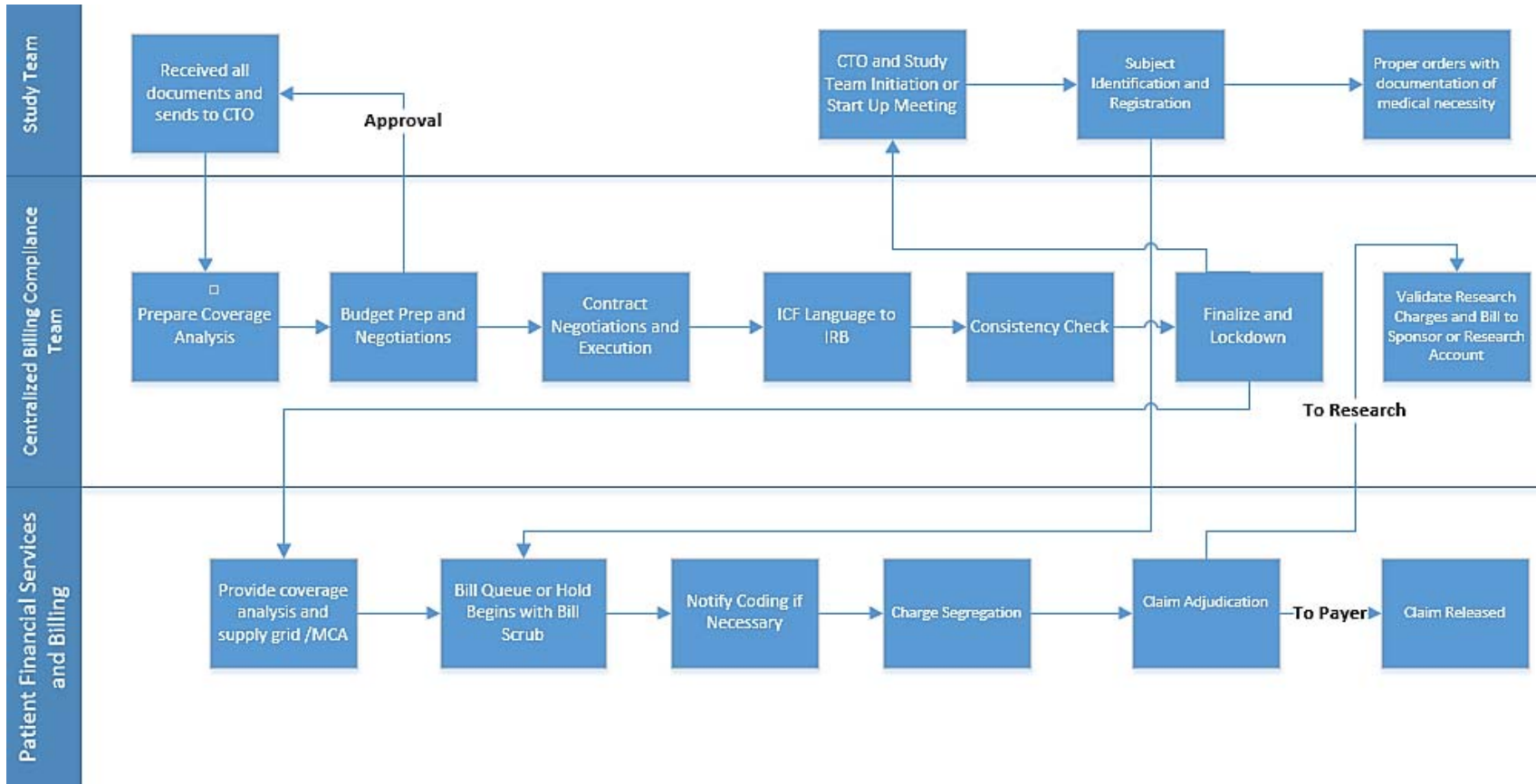
Centralized vs Decentralized

Clinical trial operations require regulatory, statistical and financial activities

DE-CENTRALIZED	SEMI-CENTRALIZED	CENTRALIZED
Duplication of effort	Less duplication of effort	Even less duplication of effort
Resource and labor intensive	Less resource and labor intensive	Shared resources, labor optimization and coverage support
PIs and study teams must be heavily involved and coordinators often have roles beyond study coordination	Study teams still drive process which relies heavily on good communication	Develops internal expertise
Institutional policies and procedures may not fit exactly	Specific policies and procedures developed with tools	Policies, procedures and tools centrally developed
No consistency or standardization	Some consistency and standardization	Consistency and transparency
Ad-hoc training	Training and monitoring occurs with some consistency	Minimizes education efforts
Disjointed and no accountability	Disjointed and no accountability	Accountability
Self-monitoring	Self-monitoring	Centralized monitoring



Clinical Trial Billing Process



Clinical Trial Billing Process

Coverage Analysis Review “Front End” Cycle

- Review protocol for feasibility
- Do a Qualifying Clinical Trial status
- Perform Coverage Analysis with validation
- Review draft budget, contract and consent
- National Guidelines for disease
- NCD’s and LCD’s review
- Review draft budget against CA
- Provide consent language based on CA

Document Review “Middle” Cycle

- Ensure Coverage Analysis guides other documents especially the consent language in the expected costs section
- Budget negotiation detailed to coverage analysis level
- Contract language matches financial piece and consent
- Consistency checklist confirming all pieces match in language prior final IRB approval
- Document review ends with final IRB approval and study start up

Patient On Study Review “Back End”

- Patient signs consent understanding financial implications
- Patient Flagged in billing systems
- Identification of Study Specific Visit
- Charge review against Coverage Analysis and medical documentation
- Coding rules applied
- NCT# applied
- Medicare Advantage review for drug clinical trials



Primary Goals For Clinical Trial Billing

- Clinical research studies must meet federal billing compliance requirements:
 - No double billing
 - Documentation supporting coding – no more and no less
 - Research modifiers, diagnosis codes, condition codes and clinical trial number when study is qualifying
 - Transparent and consistent documentation for compliance assurance



Must Have Policies

- Overarching Clinical Trial Billing Compliance Policy
- Contracting and Budgeting
 - Research Pricing Policy
 - Charge Backs
 - Residual Funds
- Bill Hold and Claims Adjudication Policy
- CTMS





COVERAGE ANALYSIS

The Roadmap to Clinical Trial
Billing Compliance

What is a Coverage Analysis (CA)?

- Systematic review of research-related documents to determine the Medicare billing status of both the study itself and the items and services provided to the research subjects that are outlined in the research documents over the course of the study
- Review based on thorough research, supported by industry guidelines which meet the “generally accepted in the medical community” standard and are compliant with government regulations
- Provides subjects with an accurate accounting of their financial liability before they enroll
- Provides an accurate assessment of the true costs of the clinical trial with potential increased revenue
- Protects your institution from violations of the False Claims Act and other regulations by showing due diligence



The Coverage Analysis: Critical Information Tool

- The Coverage Analysis:
 - Carries the information necessary to review & segregate charges correctly
 - Serves as the translation tool between the research study and the billing process
 - Must be based on billing rules, not clinical intent
 - Provides roadmap for use of modifiers and NCT # to be placed on the government claims
 - Identifies costs for Clinical Study services and procedures are apportioned between research costs and routine care to ensure proper billing of such costs to either the Clinical Study Sponsor or a Third Party Payor



The Coverage Analysis: Critical Information Tool

- Billing rules are about who pays for what
- Health plans (private or public) do not defer to the physician; coverage is based on rules that sometimes have nothing to do with clinical goals
- Medicare Administrative Contractors (MACs) expect providers to have processes for compliant clinical research billing



Using the MCA for Budget and Contract Development

- The MCA is a key tool in budget development
- What is billable to Medicare
- What is for research only
- Format MCA and budget to easily integrate
- Negotiate stronger budgets
- Eliminate conditional payment clauses



Justification for Striking Conditional Payment Clauses

- Clinical Trials Medical Policy Article:

“Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial should likewise not be billed to Medicare. Items and services provided regularly free of charge to any segment of the study's enrollees are not included as routine costs and are not dependent on payer type. **For example, because Medicare may pay for certain costs in the study, but other payers will not and the study sponsor provides those items or services for free to those study participants, then Medicare likewise must not be billed for those items and services.** Medicare's potential willingness to pay for an item or service does not determine whether that item or service is covered. Medicare must be on a level playing field with all payer types regarding billing for the routine costs in clinical trials. “

- Exception: Patients who are indigent and for whom the hospital routinely offers care without payment.



Common Problems in CTAs

- Language is ambiguous nobody understands what something means and how it could be interpreted
 - “The payments in Exhibit A cover all research related protocol services.”
- Lines appear to contradict each other
- Language is not clear as written nor is it as the parties intended because the person negotiating it does not understand what it means



Common Problems in Budgets

- Patient Care Costs (Clinical Services) must be priced at Fair Market Value
- Do not go below the Medicare fee schedule
- There is some argument that Medicare rate is FMV
- Check best payer rate
- Defend your FMV calculations
 - Tax Implications

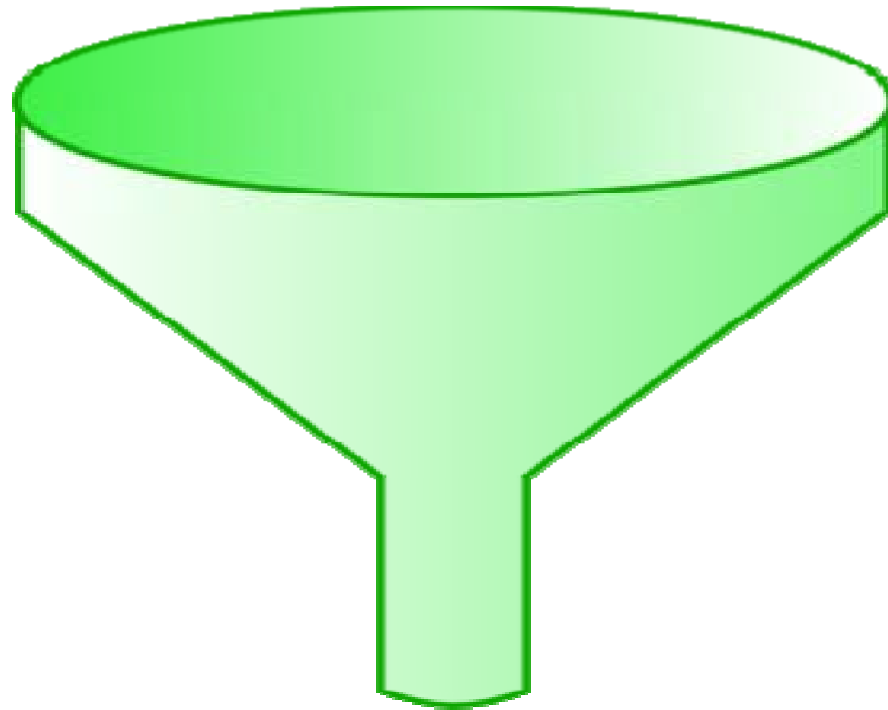


Sample Checklist

IRB #: 12-00000 PI Name: MD Study Name: XYZ Study Consistency Checklist Date:				
Issue	Agreement / Budget Date	ICF Version /Date:	Protocol	Reviewer
A. Confidentiality Describe how data or information will be shared between INSTITUTION, or sites and the research sponsor.	N/A	YES	YES	XXX
B. Benefits of Taking Part in the Study Describe benefits of participating for the subject and/or others in the context of therapeutic intent.				XXX
C. Research vs. Conventional Care The procedures that will be performed during the course of the trial that are considered to be part of the subjects' conventional care and that would be performed anyway notwithstanding the research study are differentiated from the procedures that will be performed during the course of the study that are for research purposes only.	N/A	YES	N/A	XXX
D. Additional Costs Subjects will be required to bear additional costs beyond those associated with their conventional care as a result of participating in the study.	N/A	N/A	N/A	XXX
E. Subject Compensation Subjects will be compensated for agreeing to participate in the trial.	N/A	N/A	N/A	XXX
F. Research Related Injury Identify the individual or entity responsible for the costs of any research-related injuries to subjects.	N/A	N/A	N/A	XXX
G. Future Use Of Data Are subjects asked or expected to donate data, materials, samples etc. to databases or tissue repositories and if the sponsor receive any future rights to the data or materials collected in the course of the study?	N/A	YES	YES	XXX
H. Study is registered at clinicaltrials.gov and statement is in the ICF (Input Registration Number)				XXX
I. Medicare Advantage statement included in the ICF				XXX



Bill Hold And Review



General Bill Hold Process

- Clinical Trial identified in system
- Patient linked to study
- Capture patient charges
 - Facility and Professional
- Review patient charges
 - Using the final MCA to determine responsible payer
- If billed to Medicare or insurance, identify the appropriate research codes to be applied to claim
- Release charges from hold



Key Determinations During Bill Hold

- Study Level
 - Is the study a qualifying clinical trial per the Coverage Analysis
 - If it is not, do you have a policy to bill only the conventional care
- Patient Level
 - Is this a Medicare/Medicaid/Tricare recipient
 - Is this a Medicare Advantage recipient
 - Is this patient privately insured
 - Is this patient indigent according to hospital policy
- Encounter Level
 - Is this encounter research-related
- Charge Level
 - Is the codeable item related to the study
 - Is this codeable item a routine cost billed to Medicare/Insurance per CA and does it require any modifiers
 - Is this codeable item being paid by the sponsor per the CA
 - Is this a non-codeable item that is to be billed to the sponsor per the CA



The Three C's...

Of Research Billing Compliance:

- ***Collaboration, Communication and Cooperation***
- Communication and coordination of the study information
 - Process improvement Task Force
 - Regular Meetings
 - Get PI and Study Team involvement
- Collaboration and cooperation among stakeholders
 - You will not be successful otherwise
 - Buy in from senior leadership

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



Questions?

- Kathleen Hurtado, RPh, Consultant
Kelly Willenberg & Associates, USA
 - Email: Kathleen@KellyWillenberg.com

- Chris Longspaugh, PharmD, Consultant
Kelly Willenberg & Associates, USA
 - Email: Chris@KellyWillenberg.com

