



CLINICAL TRIALS BILLING COMPLIANCE OVERVIEW: AUDITING & MONITORING TACTICS

February 28, 2020

REGULATORY COMPLIANCE OVERVIEW

AGENDA

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Clinical Trial Billing Case Study



THE REGULATORY COMPLIANCE CHALLENGE

Almost every aspect of clinical research is governed by regulations.

Clinical research is overseen by multiple governmental agencies (e.g., HHS, FDA, NIH, OMB).

FDA and HHS human subject protection regulations are not harmonized.

Complex requirements related to Medicare coverage and clinical trial billing.

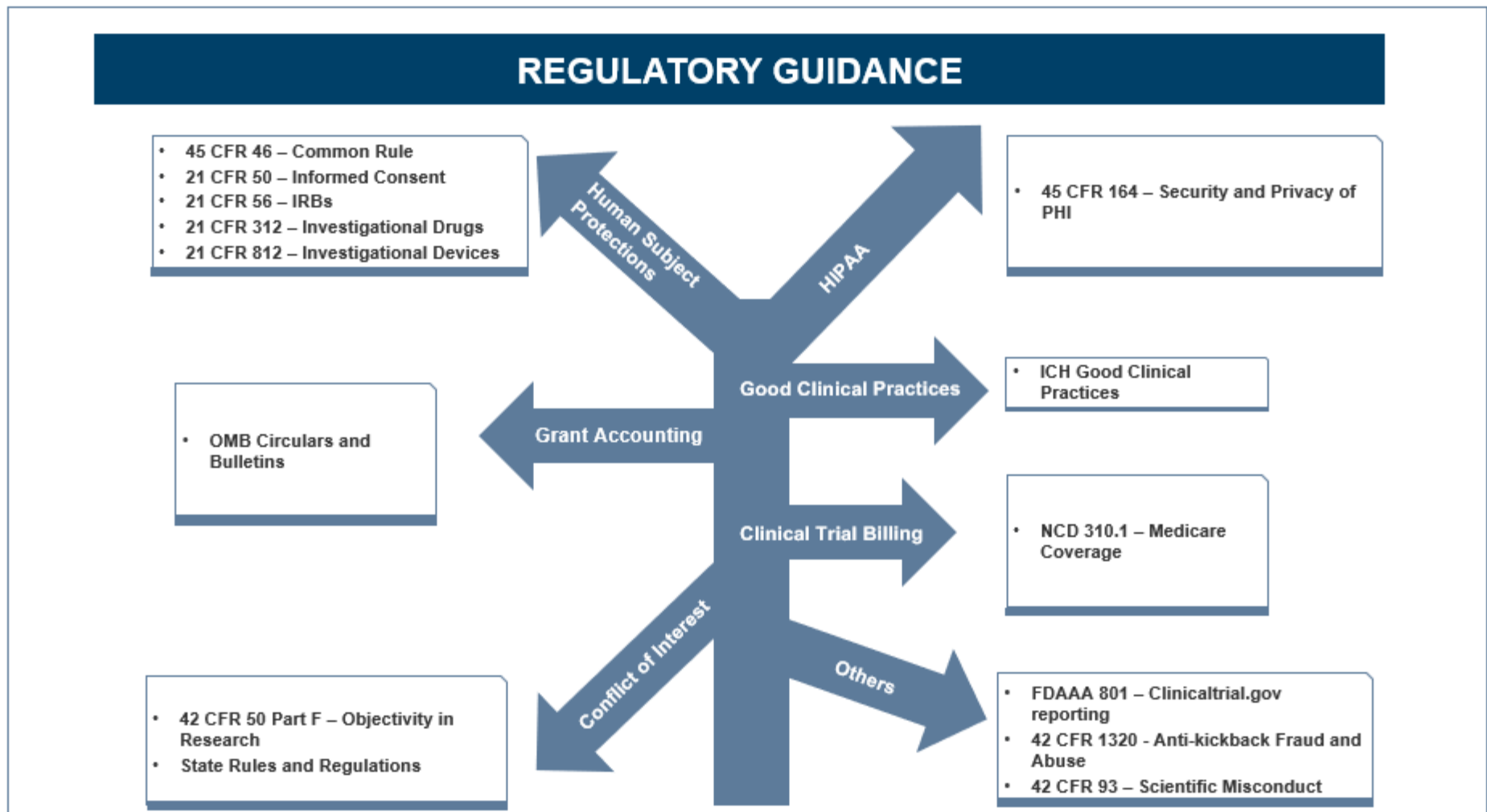
FDA has stepped up its enforcement efforts for clinical research non-compliance.

Blurry lines between intentional and unintentional fraud/misconduct.

Research non-compliance can lead to settlement costs and/or damages arising from False Claim Act actions.



THE REGULATORY COMPLIANCE CHALLENGE



THE REGULATORY COMPLIANCE CHALLENGE



Informed Consent of Human Subjects 21 CFR 50

- No investigator may involve a human being as a subject in research unless the investigator obtained informed consent
- Exceptions from informed consent for (some) emergency research; however, consent should be obtained at the earliest feasible opportunity
- All Informed Consent Forms must contain certain elements



IRB composition, operation and responsibilities 21 CFR 56

- At least five members, with varying backgrounds to promote complete and adequate reviews of research
- IRB shall review and have authority to approve, require modifications, or disapprove all research activities
- IRB may use expedited review procedures for certain kinds of research involving minimal risk to the patient, and for minor changes in approved research
- In order to approve research, the IRB should ensure that certain requirements are met
- If apparent noncompliance with the IRB regulations is observed by an FDA investigator, and the organization fails to implement the corrective action plan, the IRB may be disqualified

THE REGULATORY COMPLIANCE CHALLENGE



Promoting Objectivity in Research 42 CFR 50 and 21 CFR 54

- **HHS** - Disclosable financial interest and arrangement:
 - Significant Financial Interest (SFI) consists of one or more of the following interests of the PI/Co-I (including spouses and dependent children).
 - Public traded entity - any significant remuneration or equity interest (e.g., ownership, stock options, etc.) from the entity in the twelve months preceding the disclosure, and when the value, when aggregated, exceeds \$5,000.
 - Non-publicly traded entity – any remuneration from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000.
 - Any reimbursed or sponsored travel
 - Proprietary interest in the tested product, including, a patent, trademark, copyright, or licensing agreement
- **FDA** - An applicant is required to submit to the FDA a list of all investigators involved with the clinical trial and identify/disclosure any significant financial interests:
 - No significant financial interests or arrangement exist: FDA form 3454 “Certification: Financial Interests and Arrangement of Clinical Investigators”
 - A significant financial interest exists: FDA form 3455 “Disclosure: Financial interests and arrangement of clinical investigators”

THE REGULATORY COMPLIANCE CHALLENGE



Protections of Human Subject Research 45 CFR 46

- Also known as the “Common Rule”, is a rule regarding biomedical and behavioral research involving human subject research participants in the United States, and consists of five subparts:
 1. Subpart A: Protection of human subject research participants
 2. Subpart B: Additional protections for pregnant women, human fetuses, and neonates
 3. Subpart C: Additional protections pertaining to research involving prisoners
 4. Subpart D: Additional protections for research involving children
 5. Subpart E: Registration of IRBs



Clinical Research Billing Policy NCD 310.1

- Medicare covers the routine costs of Qualifying Clinical Trials (QCT), as well as a reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials.
- Any clinical trial receiving Medicare coverage of Routine Costs must meet three mandatory requirements and seven desirable characteristics. The following four types of studies are deemed to have met the desirable characteristics and they are automatically qualified to receive Medicare coverage.
- Routine costs of clinical trials include all items and services that are generally available to Medicare beneficiaries, except for some categories.

CLINICAL RESEARCH BILLING RISKS



Non-compliant billing can result in penalties and violations, including violations under the False Claims Act (FCA). The key areas of FCA risk include:

- Billing a government payer and/or beneficiary for services which have been paid for by the sponsor (double-billing)
- Billing a government payer and/or beneficiary for services which are promised free in the informed consent
- Billing a government payer for services which are performed for research-purposes and do not qualify for coverage
- Billing a government payer for routine-care services associated with a study that does not qualify for coverage



FALSE CLAIMS ACT



- Federal FCA establishes liability for anyone who submits a false claim for payment to the government
- Federal penalties for violating the FCA are severe and include fines of \$11,463 and \$22,927 per claim
- Specific intent not required
- Possible exclusion from federal health care programs
- Obligation to respond promptly when there is a reason to suspect potential overpayment
- Typically occurs in research by double billing or improper or unnecessary billing



RESEARCH-RELATED SETTLEMENTS



- Rush University Medical Center agreed to a \$1 million settlement after self-disclosing that it had billed Medicare for services performed in cancer research studies that were not reimbursable as routine care costs.
- The University of Alabama at Birmingham paid a \$3.39 million settlement for billing Medicare for clinical research trials that were also billed to the sponsor of research grants (and overstating the percentage of work effort the researchers were able to devote to the grants).
- Emory University agreed to a \$1.5 million settlement for falsely billing Medicare and Medicaid for clinical trial services the clinical trial sponsor agreed to pay.



AUDITING AND MONITORING

RESEARCH-BILLING FLOW



HOW TO FACILITATE COMPLIANT BILLING



- Develop a multi-disciplinary taskforce to communicate and collaborate on research billing processes and issues
- Implement operational processes to comply with research billing rules
 - Perform a comprehensive coverage analysis
 - Appropriately identify research subjects and research-related visits
 - Hold research charges for review prior to billing
 - Implement billing edits to ensure the appropriate codes are included on research claims
- Establish clear billing roles and responsibilities
- Perform ongoing routine auditing and monitoring of research claims and processes
- Conduct ongoing education of research billing rules and procedures



RESEARCH BILLING AUDIT GOALS



- Identify and correct process errors and gaps that may lead (or have led) to non-compliant billing
- Take the appropriate steps to remediate identified errors (e.g., issue refunds for overpayment)
- Identify process improvement opportunities
- Identify training opportunities
- Identify documentation opportunities



STEPS TO PERFORM A BILLING AUDIT



1. Develop audit scope
2. Select audit sample
3. Compile study documents
4. Conduct interviews and testing
5. Validate testing exceptions and observations
6. Document observations and develop recommendations
7. Request action plans and follow-up



1. DEVELOP AUDIT SCOPE

Develop scope

- Which facilities will be included?
- Drug or device studies?
- Will hospital billing and/or professional billing be included?
- What timeframe of studies and accounts will be audited?
- Will the studies and accounts be targeted or randomly selected?
- Are there recent findings or concerns related to non-compliance?



2. SELECT AUDIT SAMPLE

Study sample

- Drug or device studies
- Coverage across in-scope entities
- Studies with enrolled subjects or expected enrollment
- Studies with a history of compliance concerns
- Complex studies with a high volume of clinical services
- Random sample of studies

Subject sample

- Select a sample of subject visits from each study to audit
- Select a sample of enrolled subjects and audit all associated visits for the selected subjects



3. COMPILE STUDY DOCUMENTS

Study documents

- Contract
- Protocol
- Budget
- Informed Consent Form
- Coverage Analysis

Systems

- EMR
- Clinical Trial Management System (CTMS)



4. CONDUCT TESTING – STUDY LEVEL

The testing process for study level testing includes the following steps:

- Develop a testing sheet to organize the testing population and findings
- Confirm all documentation exists (protocol, budget, Coverage Analysis, ICF)
- Perform a document concordance review
 - Do any discrepancies exist between the documents (e.g., the informed consent states that certain services are free of charge to the patient and the billing grid indicates the item as standard of care)?
- Review the accuracy of the Coverage Analysis
 - For studies with billable services, has a Coverage Analysis been developed?
 - Does the study qualify for billing?
 - Is the Coverage Analysis consistent with other study documents?
 - Is the billing grid accurate and complete?



STUDY LEVEL – TESTING SHEET

A testing sheet will help organize the testing population and findings. Key attributes to incorporate include:

- Are all documents present (protocol, budget, ICF, Coverage Analysis)? (Y/N)
- Is the QCT accurate and complete? (Y/N)
- Is the Billing Grid present? (Y/N)
- Are the CPT codes included on the billing grid accurate and complete? (Y/N)
- Are the Q1/Q0 modifier designations accurate and complete? (Y/N)
- Are all services reflected in the study protocol included on the billing grid? (Y/N)
- Is the Coverage Analysis concordant with study documents? (Y/N)
- Issues identified (free text)



STUDY LEVEL – SAMPLE FINDINGS

- The Coverage Analysis was not developed.
- Inconsistencies were noted in study documentation (e.g., the ICF indicated a service as promised free and the billing grid indicated the service as billable to a third-party payer).
- The billing grid included incorrect/incomplete CPT codes and modifiers for study services (e.g., the Q0 modifier was indicated on the billing grid instead of the appropriate Q1 modifier).
- The billing grid did not include all study-related services outlined in the protocol (e.g., a lab draw indicated on the protocol was not included in the billing grid).
- The billing grid indicated the incorrect responsible party for study services (e.g., the billing grid indicated a service as billable to a third-party payer when all other study documents indicate the service as paid for by the sponsor).



4. CONDUCT TESTING – SUBJECT/ENCOUNTER LEVEL

The testing process for subject or encounter level testing includes the following steps:

- Develop a testing sheet to organize the testing population and findings
- Utilize the study documents (protocol, ICF, Coverage Analysis) to determine the expected services and billable party for each service rendered on the visit date
- Pull up each account within the billing system and verify the following:
 - A research flag was appended to the subject's account
 - The research visit was appropriately identified as such
 - Charges were segregated appropriately according to the Coverage Analysis
 - The appropriate billing indicators are appended on the account (NCT number, condition code, Z00.6 diagnosis code, Q1/Q0 modifier)



SUBJECT/ENCOUNTER LEVEL – TESTING SHEET

A testing sheet will help organize the testing population and findings. Key attributes to incorporate include:

- Was a clinical research flag appended to the encounter in the EMR? (Y/N)
- Do the services rendered match the services listed in the billing grid for the specified visit? (Y/N)
- What is the expected funding for the specified service? (Sponsor, patient, third-party payer)
- Was the service billed to the appropriate party? (Y/N)
- Was the appropriate Q0/Q1 modifier included on the claim, if applicable? (Y/N)
- Was the Z00.6 ICD-10 diagnosis code included on the claim? (Y/N)
- Was condition code 30 included on the claim? (Y/N)
- Was the correct NCT number included on the claim? (Y/N)
- Was the Research Billing Review (RBR) completed? (Y/N)
- How many days after the date of service was the RBR completed? (number of days)
- Issues identified (free text)



SUBJECT/ENCOUNTER LEVEL – SAMPLE FINDINGS

- The wrong payer is billed for a service (e.g., Medicare is billed for a service that the sponsor agreed to pay).
- Two parties are billed for the same charges (e.g., both Medicare and the sponsor are billed for the same MRI).
- The NCT number is not included on a claim for standard of care services rendered for a qualifying clinical trial.
- Research routine charges lack the ICD-10 Z00.6 code.
- Insufficient guidance in the policies and procedures as well as the training materials. Reliance on staff for knowledge of the billing process.
- Research subjects are not identified or flagged in the EMR.



5. VALIDATE TESTING EXCEPTIONS AND OBSERVATIONS

- Meet with process owners to discuss exceptions identified through testing and process improvement observations.
- Clear exceptions that are no longer valid after review with process owners (e.g., an exception for a missing NCT number is cleared after identifying that system access issues prevented it from being visible to the auditor).
- Process owners should work to immediately take corrective action and rebill or refund government payers for claims identified to be billed in error.



6. DOCUMENT OBSERVATIONS AND DEVELOP RECOMMENDATIONS

Analyze the identified findings and develop recommendations based on the root cause issue.

- What caused the problem?
 - Lack of internal controls
 - Lack of policies and procedures
 - Lack of education and training
 - Lack of communication
- How can the issue be resolved?
 - Implement system controls
 - Develop/implement policies and procedures
 - Clarify billing roles and responsibilities
 - Improve inter-departmental communication
 - Provide training and education



7. REQUEST ACTION PLANS AND FOLLOW-UP

- Action plans should be developed by process owners for each observation group identified through the audit
- Action plans should address the root cause(s) of the finding
- Target completion dates should be reasonable and allow sufficient time to implement the necessary controls, education, and/or process improvements
- Follow-up should be performed to ensure action plans have been completed and that they were effective in remediating finding(s)



CLINICAL RESEARCH BILLING COMPLIANCE AUDIT: A CASE STUDY

CLIENT BACKGROUND

Show-Me State Health System (SMSHS)


- 20+ Hospitals
- 70+ Outpatient clinics

Research Program


- 3 Hospitals
- 15 Outpatient clinics



AUDIT OBJECTIVES



Policy and Procedure Review: Validate the sufficiency of select policies and procedures related to key areas of clinical research legal and regulatory compliance risk.



Billing Compliance Testing: Validate that the appropriate mechanisms are in place to ensure compliant billing of human subject related-medical procedures and validate that consistent and compliant billing is occurring via an audit of a sample of claims.

PROJECT TIMELINE

Preliminary Project Schedule		Estimated Dates	
●	Initial Kick-off Meeting	●	Week beginning 7/22/2019
●	Initial Fieldwork Commencement	●	Week beginning 7/22/2019
●	Estimated Completion of Fieldwork	●	Week beginning 08/12/2019
●	DRAFT Report Issued for Findings Validation	●	Two Weeks After Fieldwork Completion (Responses Due within 5 days)
●	Management Action Plans Requested	●	One Week After Findings Validated (Responses Due within 10 days)
●	Final Report Issued	●	One Week After Management Action Plan's Accepted

DOCUMENTATION REQUEST

- Policies, procedures, methodologies, existing flow charts or other process documentation related to clinical research and research-related billing
- A list of all completed and active clinical trials at SMSHS, inclusive of their status, from January 2019 to present
- Training documents, including validation of attendance associated with clinical research-related (e.g., Human subject research, COI, Informed Consent, etc.) compliance risk areas
- Findings from any previous reviews, audits, and incidents (including severe adverse events (SAEs))
- Additional relevant documentation will be identified during the audit (e.g., clinical trial folders, Medicare coverage analyses, etc.)

AUDIT PROCESS - START- UP

1. Audit Kick-Off Meeting

- Introductions
- Audit Background
- Scope & Objective
- Project Timeline

2. Review and Assess Policies and Procedures – Review SMSHS policies, procedures, performance indicators, management reports, and prior audit findings to understand the current environment, required operations, and assess for sufficiency and reasonableness

AUDIT PROCESS - FIELD WORK

3. Schedule and Conduct Interviews – Interview key SMSHS clinical research and clinical trial personnel and other applicable departments to understand the current expected operations, including manual and automated system processes and controls. Interview subjects included:

- Chief Compliance Officer
- Clinical Trial Administration
- Regional Directors of Research
- Patient Access Administration
- Revenue Cycle personnel involved in research billing
- Others, as necessary

4. Perform Walkthroughs – Perform on-site walkthroughs of the billing process to:

- Understand the current actual operations, including when and how the processes are performed
- Validate effective implementation of controls
- Identify areas of potential compliance risk, process inefficiencies, and processes not operating as described (e.g., by policy, law, regulation, expected practice, etc.).

AUDIT PROCESS - PROCESS EVALUATION

5. Evaluate Design Effectiveness – Evaluate the mechanisms in place to ensure consistent and compliant billing for human subject related-medical procedures within SMSHS CBO and Regions.

- Billing Grids: Evaluate the process for creating, approving, and utilizing research-billing grids.
- Medicare Coverage Analyses (MCAs): Evaluate process for creating and using MCAs for research billing.
- Research Patient Identification: Evaluate the process of identifying SMSHS patients who are participating in a research study.
- Research Participant Tracking: Evaluate the process for tracking research participant visits.
- Auditing and Monitoring: Evaluate the process and frequency of conducting clinical trial billing audits for compliance
- Billing Training: Evaluate the process of training and educating new or existing employees into Alocasia's clinical trial billing processes.

AUDIT PROCESS - TESTING – STUDY LEVEL & ENCOUNTER LEVEL

6. Test Operating Effectiveness – Test the operating effectiveness of key internal controls related to clinical research and clinical trials billing compliance. A sample of 50 clinical trial accounts was selected to evaluate the process for billing those accounts to ensure appropriate and compliant billing is occurring.

- Determine whether research-related charges are consistently identified as such
- Determine whether charges were correctly billed to the appropriate payer(s)
- Determine whether research-related claims include the appropriate modifier, diagnosis code, and National Clinical Trial identifier

7. Validate Testing Exceptions – Submit all testing exceptions to key process owners for review and validation.

AUDIT PROCESS - REPORTING

8. Identify Findings - Identify process gaps based on policies and procedures review, inquiry, walkthroughs, and testing results to identify process improvement opportunities.

9. Create Recommendations – Discuss findings and process improvement opportunities with internal management and then key process owners to verify accuracy and discuss the feasibility of recommendations, including consistent standards and controls to be implemented within the facility, region, department, and/or system office (corporate).

10. Develop Audit Report

- Executive Summary
 - Background
 - Scope and Objectives
 - Summary of Findings
- Audit Findings and Recommendations

FINDING #1 - LACK OF DOCUMENTED CLINICAL RESEARCH BILLING PROCESSES AND PATIENT IDENTIFICATION MECHANISM

- An enterprise-wide clinical research billing process has not been documented or developed. Adequate controls have not been established to facilitate appropriate and compliant billing of research-related services.
- Research billing roles and responsibilities have not been defined and formal, management-level communication channels have not been established.
- Communication pathways have not been established to provide feedback on issues resulting in research-related billing errors.
- Revenue Cycle, Research, and Compliance have not developed an approach for ongoing monitoring and auditing of research billing compliance.
- SMSHS does not leverage EMR functionality to append a research flag within the EMR to indicate that a patient is enrolled in a clinical research study. Lack of a clinical research alert on a patient's medical chart can pose a patient safety risk.

FINDING #1 RECOMMENDATION

SMSHS should form a multidisciplinary task force to include representation from Revenue Cycle, Compliance and Research to focus on improving communication and collaboratively developing an effective process for clinical research-related charge identification and billing. Processes should be documented in formalized policies and procedures and should address the following:

- **Billing Roles and Responsibilities:** Define roles and responsibilities within the clinical research billing process and educate staff members on their role in facilitating compliant billing.
- **Research Billing Monitoring and Auditing:** Develop a plan to establish ongoing monitoring and auditing of research billing compliance to include:
 - Validating that research-related charges are consistently identified as such.
 - Validating that charges were billed to the appropriate payer(s).
 - Validating that charges were billed with the appropriate research codes. Ongoing education should be provided to communicate feedback on identified billing
- **Research Patient Identification:** Establish a mechanism to consistently and effectively identify patients enrolled in clinical research studies and patients scheduled for research-related visits. SMSHS should investigate opportunities to leverage the electronic health record system to improve billing efficiencies using automation, flags, and notification alerts.

FINDING # 2 - RESEARCH COVERAGE ANALYSIS

SMSHS has not consistently developed Research Coverage Analyses (RCAs). A sample of 15 studies and reviewed the associated RCAs (if created). Undeveloped or inaccurate RCAs were observed in 6 of 15 (40%) studies.

- 2 of 15 (~14%) studies did not have a Research Coverage Analysis completed, although the protocol included routine care charges billable to third party payers.
- 1 of 15 (~7%) studies billing grid did not include CPT codes for all applicable study services.
- 1 of 15 (~7%) studies billing grid included incorrect/incomplete CPT codes
- 1 of 15 (~7%) studies included an RCA which incorrectly indicated routine care procedures as non-billable.
- 1 of 15 (~7%) studies included a Qualifying Clinical Trial Questionnaire with the incorrect protocol description of the study populated in the form.

STUDY LEVEL - FINDING

The billing grid did not include CPT codes for all applicable study services.

Items and Services	Protocol Location	CPT/HCPCS Codes	Q1/Q0 Modifiers	Screening	Enrollment	Assessment
Time & Effort						
Evaluate Preliminary	Prot. P. 72	N/A	N/A	R		
Identify Eligible Candidates	Prot. P. 72	N/A	N/A	R		
Preliminary Density	Prot. P. 72	N/A	N/A	R		
Assign Consent Number	Prot. P. 72	N/A	N/A	R		
Collect Participant	Prot. P. 72	N/A	N/A		R	
PI Or Sub-I: Review SoftVue, Complete SV Workstation	Prot. P. 72	N/A	N/A			R RADIOLOGY TO COMPLETE
Procedures						
Perform PinkView Scan	Prot. P. 72	N/A	N/A		R	
Digital Breast Tomosynthesis &	Prot. P. 72	77065-77067	N/A	S RADIOLOGY TO COMPLETE		
Perform Diagnostic Imaging	Prot. P. 72	XXXXX	N/A		S RADIOLOGY TO COMPLETE	
Perform Biopsy or Excision/Path Review	Prot. P. 72	19100-19101	N/A			
Digital Breast Tomosynthesis &	Prot. P. 72	77065-77067	N/A			
Study Device						
PinkView	Prot. P. 72	XXXXX	N/A		R	
Coverage Code Key						
R: Research/Paid for by Sponsor						
R-Inv: Research/Invoice to Sponsor						
S: Billable to Patient/Insurance (Standard of Care)						

STUDY LEVEL - FINDING

The billing grid included incorrect/incomplete CPT codes.

Items and Services	Protocol Location	CPT/HCPCS Codes	Q1/Q0 Modifiers	Enrollment	Programing to Assigned Treatment Arm		
				≤ 60 calendar days post successful implant	Day of Randomization. Cannot exceed 60 calendar days post implant	Month 6	Month 12
						Day 180 (±60)	Day 360 (±60)
Time & Effort							
Informed Consent	Prot. P. 38	N/A	N/A	R			
Inclusion/Exclusion	Prot. P. 38	N/A	N/A	R			
Cardiac Medications	Prot. P. 38	N/A	N/A		R	R ²	R ²
Arrhythmia Episodes	Prot. P. 38	N/A	N/A		R	R	R
Cardiology Read Fee and Submission	Prot. P. 38	N/A	N/A		R		
Device Follow-up and Settings Report, Save	Prot. P. 38	N/A	N/A		R	R	R
Device Programming	Prot. P. 38	N/A	N/A		R		
Data Collection (Physical Assessment and	Prot. P. 38	N/A	N/A		R		
Evaluation & Management							
Physical Assessment (data collection only)	Prot. P. 38	99201-99205; 99211-99215 G0463	N/A		S		
Medical History	Prot. P. 38	N/A	N/A		S		
Scans/Procedures							
Device Interrogation	Prot. P. 38	93288-93292 (93282 was billed)	N/A		S	S	S
Coverage Code Key							
R: Research/Paid for by Sponsor							
R-Inv: Research/Invoice to Sponsor							
S: Billable to Patient/Insurance (Standard of Care)							

STUDY LEVEL - FINDING

The billing grid included incorrect/incomplete CPT codes.

Protocol

As part of screening/baseline, all patients will undergo the standard of care anti-reflux surgery work-up. The anti-reflux surgery work-up used for the study enrollment should be completed within the 1-year time period prior to signing of the study ICF. For purposes of the study, the questionnaires and other related surgery work-up procedures will be **paid by the sponsor**.

Items and Services	Protocol Location	CPT/HCPCS Codes	Q1/Q0 Modifiers	Screening / Baseline	Implant / Discharge
Scans/Procedures					
SYNC System Procedure	Prot. P. 18	43284	N/A		R
Esophageal pH Measurements	Prot. P. 5	91035	Q1	S	
Esophageal pH Measurements	Prot. P. 5	91034	Q1	S	
Endoscopy (LA Grade Classification)	Prot. P. 5	43237	Q1	S	
Manometry/Motility	Prot. P. 5	91010	Q1	S	
Barium Esophagram	Prot. P. 5	74230	Q1 (outpatient only)	S	R
Upright Bi-Planar X-Rays (AP and Lateral)	Prot. P. 5	71020	Q1 (outpatient only)		R
Study Medications					
SYNC System Procedure	Prot. P. 18	L8699	Q0		R
Coverage Code Key					
R: Research/Paid for by Sponsor					
R-Inv: Research/Invoice to Sponsor					
S: Billable to Patient/Insurance (Standard of Care)					

Billing Grid

FINDING # 2 - RECOMMENDATION

SMSHS Clinical Research Administration and Finance should address the following:

- The SMSHS Research Finance should take corrective action on both the inaccurate and the undeveloped RCAs identified by Internal Audit.
- SMSHS should also facilitate development of RCAs for all active studies for which the patients and/or their insurances are responsible for payment of some/all related procedures.
- Management should continue to identify additional areas of improvement and develop new processes as needed.
- SMSHS should develop a plan to establish ongoing monitoring and validation of timely and accurate completion of RCAs.

FINDING AND RECOMMENDATION # 3 - NON-COMPLIANT CLINICAL TRIAL BILLING

Finding - Internal Audit reviewed a sample of 50 research subject accounts from all 7 of the in-scope drug and device studies active in 2019 with enrolled patients. The following billing errors were identified:

- Sponsor Charges Billed to Third Party Payer - 5 of 50 (10%) accounts, totaling \$50,740, included sponsor-covered charges billed inappropriately to third party payers.
- Routine Care Charges Billed without Research Codes - 5 of 50 (30%) accounts, totaling \$202,654 for routine care procedures associated with research protocols, were billed without the research modifier, research diagnosis and condition codes, or NCT number included on claims as required by Medicare and some commercial payors.
- Incorrect Modifier on a Routine Care Charge - 1 of 50 (2%) accounts for \$500 was billed to Medicare with a Q0 modifier indicating an investigational clinical service, instead of the appropriate Q1 modifier to represent a routine care charge.

Recommendation - SMSHS should take the necessary corrective actions for each billing error identified in this review that resulted in incorrect third-party payments for sponsor covered charges

DISCUSSION / Q & A



SHOOT THE MESSENGERS: Q&A

Please feel free to contact us if you have additional questions. Thank you again for your time!

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