




Clinical Research Billing: Constructing Complimentary Operational and Compliance Models

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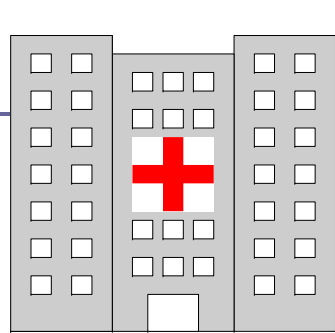
Agenda

- Background
- Elements of a Compliant Research Billing Operation
- Research Billing Audit Program

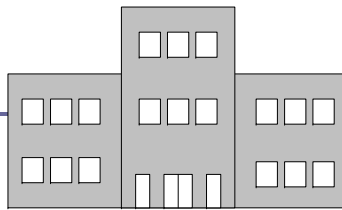




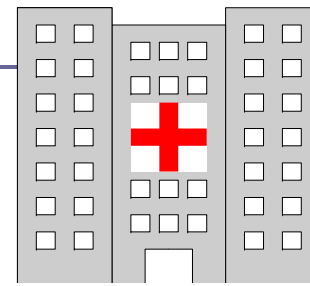
Background



University of Washington Medical Center and Clinics



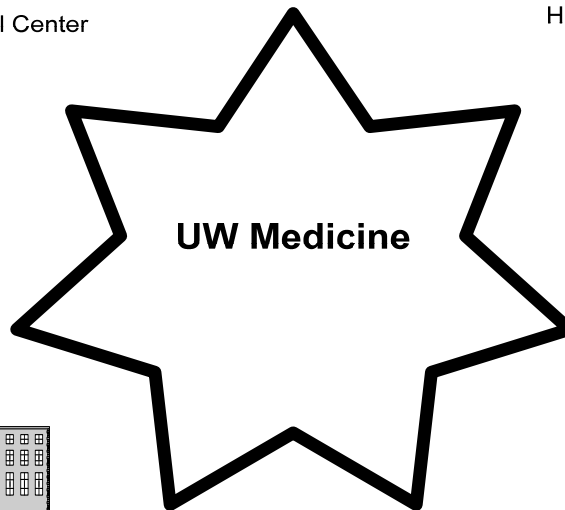
University of Washington School of Medicine



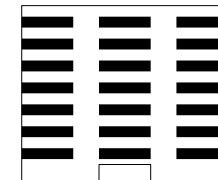
Harborview Medical Center and Clinics



UW Medicine Neighborhood Clinics (University of Washington Physicians Network)



UW Medicine

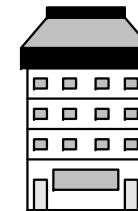


University of Washington Physicians

UW Physicians Sports Medicine Clinic



UW Physicians Eastside Specialty Center



Hall Health Primary Care Center

Research at UW Medicine

- Seattle Cancer Care Alliance
- About 700 studies
- About 700 study staff
- Over \$1 billion in research
- **\$250,000** in Clinical Trials Research



Medicare regulatory landscape

- National Coverage Decision (NCD)
September 2000
 - Coverage for Medicare beneficiaries on clinical trials costs for “usual” or “conventional” care
- 2005 Rush settles with Federal Government for \$1 million.



Medicare regulatory landscape

- Medicare Clinical Trials Policy (CTP) October 2007
 - Affirmed original NCD w/modifications and provided clarification on existing requirements
 - Expanded coverage for studies that are “deemed qualified”
 - Required identification of all study services that are billed, even usual care
- Issued new billing codes, January 2008



UW Medicine Timeline

- 2002 Task Force on Billing Compliance in Clinical Trials formed (reported 2003)
- 2003 – Transitional Task Force formed to develop an implementation plan (report 2004)
- 2005 – Clinical Research Budget & Billing Office (CRBB) established, issued policy on Clinical Research Billing which established consistent study budget planning, review and data collection across School of Medicine (SOM)
- 2006 – Probe audit started

UW Medicine Timeline



- 2007 – Probe audit report issued
- 2007 – Audit program established
- 2007 – Process improvement project implemented to separate study charges from patient charges
- 2008 – Medicare’s clarified Clinical Trials Policy (CTP) implemented
- 2010 – Epic Hospital Billing conversion

Clinical Research Billing Risks


■ Compliance Risks

- Billing non-covered research services to patient/Medicare
- Double billing research services by accepting sponsor funding and billing patient/Medicare, including faculty effort

■ Other Risks

- Not billing for all services provided
- Improper coding on research services billed to Medicare in the context of a clinical trial





Elements of a
Compliant Research Billing Operation

Elements of Compliant Research Billing

- Research billing compliance tasks are required at each stage of the study life cycle :
 - Study planning and pre-implementation
 - On Study phase
 - Post-implementation phase



Planning for Research Billing Compliance

- Accurate research billing requires:
 - Close collaboration amongst individuals in multiple roles throughout the University and the Health System
 - Office of Sponsored Programs
 - Human Subjects Division
 - School of Medicine faculty and staff
 - Hospital and clinic staff
 - Practice plans
 - Intelligent, interfaced study management and billing systems
 - Manual processes where systems don't exist
 - Active intervention at multiple steps in the clinical revenue cycle



Planning for Research Billing Compliance

- No central authority over all the pieces
- No individual or department with responsibility for end-to-end process
- Need for research support across the entity led to the creation of a centralized office: Clinical Research Budget and Billing (CRBB)

Planning for Research Billing Compliance: CRBB

- Established CRBB in 2005
- Located in Research and Graduate Education, part of the Dean's Office in the School of Medicine
- Created to support UW Medicine investigators in :
 - Sound budgeting
 - Policy compliance
 - Operational assistance
 - Education and training





CRBB FUNCTIONAL RESPONSIBILITIES

- Review industry funded clinical research budgets
- Negotiate study budgets with sponsors
- Develop study billing grids
- Perform Clinical Trials Policy (MCA) analyses
- Create and maintain RRR study accounts
- Manage study and enrolled subject databases
- Invoice hospital services to research studies
- Outreach, training and education to SoM staff and faculty
- Clinical research study start up process improvement
- Customer relations and communications
- Research billing oversight and policy development
- Compliance support and audit remediation
- Administer research care plan documentation process and policy

Information Systems & Administration Team

INFORMATION SYSTEMS

- Budget tool development and support
- Document storage and access management
- CRBB database design, development, management and maintenance
- Study and subject inventories
- Campus systems interface design, development and support
- Epic Facility Billing conversion

ADMINISTRATION

- Office administration and finance

1 program coordinator + 1 manager + 1 director = 3 FTE

Budgeting and Outreach Team

BUDGETING

- New study intake and workflow management
- Facility and professional services coding and pricing liaison
- Clinical Trials Policy analysis and financial language reconciliation
- Budget and billing grid development and review

- Study budget negotiations
- Audit support
- Customer service

OUTREACH

- Faculty and Clinical Research Staff training programs
- CRBB website, eNews and customer communications
- Website design and maintenance

1 program coordinator + 5 budget specialists + 1 manager = 7 FTE

Revenue Cycle and Billing Team

BILLING

- Hospital research charge review and routing
- Research facility billing and invoicing
- Accounts receivable follow up and collections
- Epic business systems analysis
- Hospital revenue cycle liaison
- Study subject data collection and management
- Research billing audit support and remediation

2 program coordinators + 1 supervisor + 1 manager = 4 FTE

Compliance Throughout the Study Lifespan

- Research billing compliance tasks are required at each stage of the study:
 - Pre-implementation
 - On Study
 - Post-implementation

Compliance Throughout the Study Lifespan

- **Pre-implementation**
- On study phase
- Post-implementation phase



Compliance Throughout the Study Lifespan: Pre-Implementation

3 Pre-implementation Steps:

- Coverage analysis
- Billing grid/plan
- Budget

Pre-Implementation Tasks: Coverage Analysis

- Medicare Coverage/CTP Analysis
 - Collects study demographic information for clinical trials inventory
 - Co-signed by PI and department director
 - Tells institution and regulators that necessary planning was performed by the study Principal Investigator with department support



Medicare Coverage Analysis

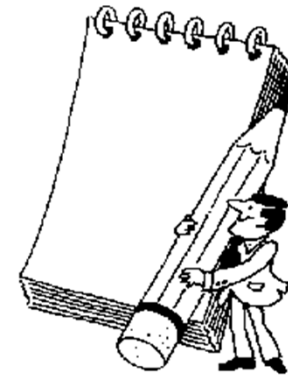
- Tells CRBB what type of study and billing rules
 - Qualifying?
 - Investigational device?
- Tells investigators and sponsors
 - Which services are billable and which aren't?



Compliance Throughout the Study Lifespan: Pre-Implementation

3 Pre-implementation Steps:

- Coverage analysis
- **Billing grid/plan**
- Budget



Pre-Implementation Tasks: Billing Grid

- Billing Grid
 - Detailed by visit, service type, CPT and payer
 - Bill to study/sponsor
 - Bill to participant
 - Drug, device or supply is provided by sponsor
- Researchers work with hospitals to code and price patient care services
 - Informs and substantiates billing grids/plans

Billing Grid Arm 1 All patients

Practice Site (select)	Location of Item/Service (select)	In/Outpt (select)	CPT/HCPCS Code (enter)	Item/Service CPT/HCPCS Description (enter)	Note (optional)	BL			C1D1			C1D15			C2,3D1			
						Service Type	Quantity	Sponsor Paying (Y/N)	Service Type	Quantity	Sponsor Paying (Y/N)	Service Type	Quantity	Sponsor Paying (Y/N)	Service Type	Quantity	Sponsor Paying (Y/N)	
UWMC	453-GENERAL UROLOGY	Outpt	99213	Level 3 visit, established pt	Assessment, approach (ICF)	U	1	N										
UWMC	453-GENERAL UROLOGY	Outpt	99212	Level 2 visit, established pt	PE, Cycle Day 1				U	1	N					U	1	N
UWP - UWMC	453-GENERAL UROLOGY	Outpt		Level 2-3 visit, profee	Profee	U	1	N	U	1	N					U	1	N
UWMC	453-GENERAL UROLOGY	Outpt	38415	Venipuncture	Urology or LabMed	U	1	N	U	1	N	U	1	N	U	1	N	
UWMC	403-CLIN HEMATOLOGY	Outpt	85025	CBC-Differential, smear eval	CBD	U	1	N										
UWMC	403-CLIN HEMATOLOGY	Outpt	85027	CBC	CBC				U	1	N					U	1	N
UWMC	401-CLIN CHEMISTRY	Outpt	80053	Comprehensive Metabolic Panel	COMP	U	1	N	U	1	N					U	1	N
UWMC	401-CLIN CHEMISTRY	Outpt	80076	Hepatic Function Panel	HFPA							U	1	N				
UWMC	653-STEROID LAB.	Outpt	84153	PSA	PSA	U	1	N	U	1	N					U	1	N
UWMC	650-COAGULATION LAB	Outpt	85610	PT (as needed)	PT	E	1	N										
UWMC	650-COAGULATION LAB	Outpt	85730	PTT (as needed)	PTT	E	1	N										
UWMC	506-COMPUTED TOMOGRAPHY	Outpt	71275	CT Chest, or Chest Xray	or 71020	U	1	N										
UWMC	506-COMPUTED TOMOGRAPHY	Outpt	74170	CT Abdomen	or MRI Abdomen	U	1	N										
UWMC	506-COMPUTED TOMOGRAPHY	Outpt	72194	CT Pelvis	or MRI Pelvis	U	1	N										
UWMC	506-COMPUTED TOMOGRAPHY	Outpt	Q9967	CT Contrast material	CT Contrast	U	1	N										
UWMC	546-NUCLEAR MEDICINE	Outpt	78306	Bone Scan, Total		U	1	N										
UWMC	546-NUCLEAR MEDICINE	Outpt	A9540	Tc99	Tc-99 for Bone Scan	U	1	N										
UWMC	546-NUCLEAR MEDICINE	Outpt	78472	MUGA (or Echocardiogram)		E	1	N										
UWP - UWMC	546-NUCLEAR MEDICINE	Outpt		MUGA (or Echocardiogram)	PROFEE	E	1	N										
UWMC	408-CARDIOLOGY EKG	Outpt	93005	EKG		E	1	N										
UWP - UWMC	408-CARDIOLOGY EKG	Outpt	93005	EKG	Profee	E	1	N										
UWP - UWMC	506-COMPUTED TOMOGRAPHY	Outpt		CT Chest, or Chest Xray	PROFEE	U	1	N										
UWP - UWMC	506-COMPUTED TOMOGRAPHY	Outpt		CT Abdomen/or Pelvis	PROFEE	U	1	N										
UWMC	OTHER	Outpt		Abiraterone acetate dispense	IDS Abi, SvcCtr 569				E	1	N					E	1	N
UWMC	OTHER	Outpt		Dutasteride dispense (start Cycle 3)	IDS Avodart start Cycle 3 Day 1											E	1	N
HMC	506-COMPUTED TOMOGRAPHY	Outpt	20225	Bone biopsy, vertebral	Facility fee	R	1	Y										
UWP - HMC	506-COMPUTED TOMOGRAPHY	Outpt	20225	Bone biopsy, vertebral	Profee	R	1	Y										
HMC	506-COMPUTED TOMOGRAPHY	Outpt	77012	CT guidance	Facility fee	R	1	Y										
UWP - HMC	506-COMPUTED TOMOGRAPHY	Outpt	77012	CT guidance	Profee	R	1	Y										
HMC	506-COMPUTED TOMOGRAPHY	Outpt	99144	Conscious sedation, first 30 min	Sedation, 30min	R	1	Y										
HMC	506-COMPUTED TOMOGRAPHY	Outpt	99145	Conscious sedation,each additional	Sedation, ea +15min	R	1	Y										
HMC	other	Outpt		Sedation medication dispensing**	IDS, SvcCtr 569	R	1	Y										
UWMC	other	Outpt		Abiraterone Acetate drug	Provided by Sponsor				I	1	Y					I	1	Y
UWMC	other	Outpt		Dutasteride drug (start C3D1)	Provided by Sponsor											I	1	Y
UWMC	other	Outpt		Prednisone drug (local pharmacy)	pt cost / insurance				E	1	N							
UWP - UWMC	546-NUCLEAR MEDICINE	Outpt	78306	Bone Scan, Total	PROFEE	U	1	N										

NOTES

Hide Notes Section

Biopsy comment: Each pt will only have one type of biopsy, whether prostate-CPT 55700 (Urology Clinic), CPT 76872 US Transrectal, CPT 76942 US Guided needle Bx, Soft tissue CPT 20206 (CT guidance at HMC).
Biopsy occurs at Baseline and EOT. Only pts who receive >3 cycles of Abiraterone will have EOT bx.
 CT-guided bone bx is most likely, then iliac crest CPT 20220, then CT-guided soft tissue.
 Prostate biopsy is unlikely in this population.

****Iliac crest biopsy may be performed in Urology Clinic during a routine visit. Profee is Effort.**

****Sedation medication may be any of the following:** Versed injection, Fentanyl injection up to 500mg IV, Fentanyl oral or Lidocaine.
 No antibiotics are required for CT-guided bx, per Radiology.
 If Prostate Biopsy occur, Cipro and Gentamicin will be used.

R = Research only: Research-only items and services provided solely to satisfy data collection and analysis needs and which are not used in the direct clinical management of the patient. **Note: Research only services may never be billed to the patient or patient's insurance.**

U = Usual: Medically reasonable and necessary items and/or services used in the clinical management of the patient which would be provided absent the research study.

E = Expanded: Items or services required for the provision of the investigational item or service itself (e.g., administration of a non-covered chemo-therapeutic agent); items or services required for the clinically appropriate monitoring of the effects of the investigational item or service; items or services needed for reasonable and necessary care arising from the provision of the investigational, item or service, such as the prevention, diagnosis or treatment of complications.

I = Investigational: The investigational item or service which is a subject of the research study. **Note: Expanded and Investigational services may be billed to the patient or patient's insurance only if the study is an oncology study which is "Deemed Qualified" under Medicare's Clinical Trials Policy (CTP). Refer to the "CTP Coverage Analysis Checklist" for this study or call CRBB for further information.**

Compliance Throughout the Study Lifespan: Pre-Implementation

3 Pre-implementation Steps:

- Coverage analysis
- Billing grid/plan
- **Budget**



Pre-Implementation Tasks: Budgeting

- Study team drafts in UW Medicine Detailed Budget Tool
 - Prompts full accounting of all possible study team tasks and patient care services required to implement the protocol
- CRBB reviews
 - Ensure concurrence of financial language with draft contracts and Informed Consents
 - Notify Office of Sponsored Programs and/or IRB when discrepancies are found

Pre-Implementation Tasks: Budgeting

■ Budget Negotiation

- CRBB or study team negotiates budget exhibit and payment terms for all industry funded clinical research contracts
- Ensure no Medicare Secondary Payer language is creeps into the contract or budget



Compliance Throughout the Study Lifespan

- Next study phase:
 - Pre-implementation
 - **On Study**
 - Post-implementation



Compliance Throughout the Study Lifespan: On-Study Tasks

4 On-Study Steps:

- Research account creation
- Enrollment reporting
- Research and the EMR
- Billing



Compliance Throughout the Study Lifespan: On-study Tasks

- **Research account creation**
- Enrollment reporting
- Research and the EMR
- Billing



On-study Tasks: Research account creation

- Epic research account
 - Study can't schedule research visits or order hospital services without a research billing account
 - Account established by CRBB after:
 - all pre-implementation tasks are complete
 - study budget is established
 - training is complete

Compliance Throughout the Study Lifespan: On-study Tasks

- 4 On-Study Steps:
 - Research account creation
 - **Enrollment reporting**
 - Research and the EMR
 - Billing



On-Study Tasks: Enrollment Reporting

- Research billing compliance relies on identifying study participants
 - Start and end dates of participation
- Per internal auditing and monitoring, this is one compliance element with significant room for improvement.

Why?

On-Study Tasks: Enrollment Reporting

1. No hard stops
2. Researchers have multiple reporting requirements
 - IRBs
 - Monitors
 - Funding entities

Now Billing office?



3. Definitions of “enrolled” and “disenrolled” are different for billing purposes

Compliance Throughout the Study Lifespan: Medical Record Documentation

■ 4 On-Study Steps:

- Research account creation
- Enrollment reporting

■ **Research and the EMR**

- Billing

On-study Tasks: Medical Record Documentation

- Documenting research participation in the EMR
 - Dual drivers:
 - Medicare billing requirements
 - Patient safety



On-study Tasks: Medical Record Documentation

- EMR Research Care Plan (RCP)
 - Study demographic information or Care Plan entered into each participant's hospital record
 - Triggers a pop up Clinical Alert indicating patient is enrolled in a study
 - Meets Medicare billing requirements
 - Supports patient safety

PowerChart Organizer for Reilly, MD, Dominic Francis

Task Edit View Inbox Help

In-Box Patient List View Scheduling

DREILLY

Sign and Review (1 new)

Inbox Messages (0 new)

Results to Endorse (0 new)

Orders to Approve (0 new)

Sign and Review

	Patient Name
1	Sign and Review
2	Documents to Dictate
3	Sign
4	Review
5	Saved Documents(1)
6	ZZSTORM, SEATTLE

Discern: Open Chart - ZZSHAKESPEARE, WILLIAM PAVILION

Clinical Alert

The patient has the following clinical alert(s):

STUDY: Enrolled in a clinical research study

Please refer to the Alerts Tab for additional detail.

OK

Since: 2/2/2008

Com... From

Compliance Throughout the Study Lifespan: On-Study Tasks

- Research account creation
- Enrollment reporting
- Research and the EMR
- **Billing**



On-Study Tasks: Billing

- Accurate coding and presentation of research “claims” depends on several factors:
 - Study type
 - Service type
 - Provider role
 - Participant type

Billing: Type of Study



■ Study type

- Medicare requires different claim data for studies that are:
 - Qualifying/non-qualifying
 - Investigational Device Exemption Category A
 - Investigational Device Exemption Category B
 - Coverage with Evidence Development (CED)
 - In some cases Post Marketing Surveillance studies and Humanitarian Use Devices

Billing: Type of Study

- At UW Medicine, we flag patient accounts according to the type of study they're enrolled in, "Qual," "Nqual," IDEB, etc.
 - Determined by Clinical Trials Policy Analysis Checklist (MCA)
 - Tells CRBB and billing system how to edit and present participant's claims

Billing: Type of Service

■ Service type

- Medicare asks providers to distinguish between clinical services, items or tests they consider “routine costs”
 - Q1 modifier at the line item level
- And the investigational service or item itself
 - Q0 modifier
 - Investigational device number assigned by the FDA

Billing: Role of Provider



■ Provider role

- UW Medicine Clinical Research Effort and Professional Services Policy states:
 - Faculty must fully account for their work in clinical research:
 - Principal investigators and key personnel must charge either effort to the grant or contract *or* a professional fee to the study participant
 - PIs and KP don't drop pro fees to study account
 - Other non-study providers must bill pro fees to participant or study

Billing: Type of Participant

■ Participant type

- Medicare has different rules for reporting diagnosis codes for healthy volunteers
 - Diagnosed disease absent
 - V70.7 in first DX FLD
- Created a patient level identifier “HLVL” to facilitate correct professional services coding

On-Study Tasks: Billing



- Depending on study type, service type, provider role, type of participant and payer, accurate research billing requires unique actions at each point in the hospital revenue cycle
 - No individual or department with knowledge of all the elements and their variables
 - No individual or department with responsibility for end-to-end process
 - No central authority over all the pieces

On-Study Tasks: The Research Revenue Cycle

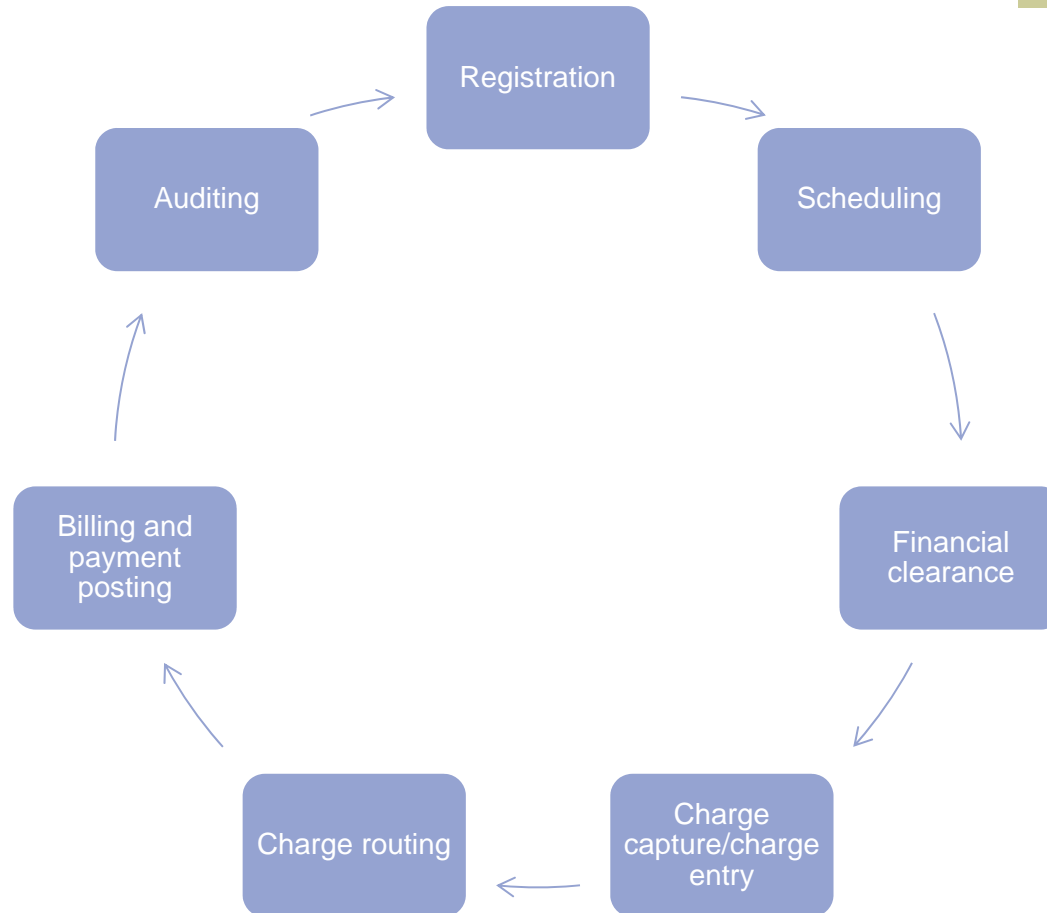
- Roles: **20**
- Systems: **11**
- Steps/interventions: **14**



On-Study Tasks: The Research Revenue Cycle

- 14 Steps can be grouped into 7 touchpoints:
 - Patient/subject registration
 - Visit scheduling
 - Financial clearance
 - Charge capture/charge entry
 - Charge routing
 - Billing
 - Auditing

The Research Revenue Cycle



On-Study Tasks: The Research Revenue Cycle

- Patient/subject registration and enrollment
 - Hospital registration is mandatory
 - Billing system flags
 - Research care plan
- Visit scheduling
 - Link study to encounter
 - Billing visit directional flag
 - All to study, all to patient, some of each



On-Study Tasks: The Research Revenue Cycle

- Financial clearance
 - When billing participants for research services, we have a responsibility to confirm coverage
 - Can't plan for sponsor to pay when insurance denies

On-Study Tasks: The Research Revenue Cycle

- Charge capture/charge entry
 - Research fee sheets, orders and requisition forms
 - Internal indicators to route charges in mixed visits
 - Medical record documentation

On-Study Tasks: The Research Revenue Cycle

- Charge routing
 - Pre bill review workqueues

- Billing
 - Invoicing studies and billing participants
 - Applying research rates
 - Ensuring proper Medicare coding
 - Research collections

- Auditing



Compliance Throughout the Study Lifespan

- Next study phase:

- Pre-implementation

- On Study

- Post-implementation**



Post-Implementation Study Tasks: Disenrollment and Close Out

- Accurate research billing requires knowledge of study and participant end dates
- Study end and subject disenrollment reports from study teams trigger CRBB to remove billing system indicators
 - Prevents over-coding
 - Discourages re-use of research accounts
- EMR research care plans are permanent; pop up alerts are disabled

Last step in the Research Revenue Cycle: Auditing

■ Auditing

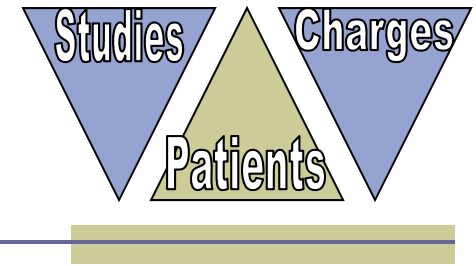
- Tells us how we're performing
- Facilitates correction of identified billing errors
- Points to areas needing process improvements
- Identifies topics on which faculty and staff need additional training

Questions



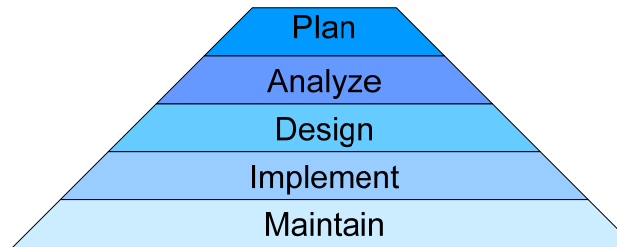


Clinical Research Billing Audit Program



- Scope
- Study Selection and Inclusion Criteria
- Study Audit Process
- Audit Reporting

Scope



- Ensure that researchers are complying with UW Medicine Policies
 - Billing Compliance in Clinical Research

- Ensure that subject's research related clinical services are billed appropriately and according to applicable regulations

Elements of the audits



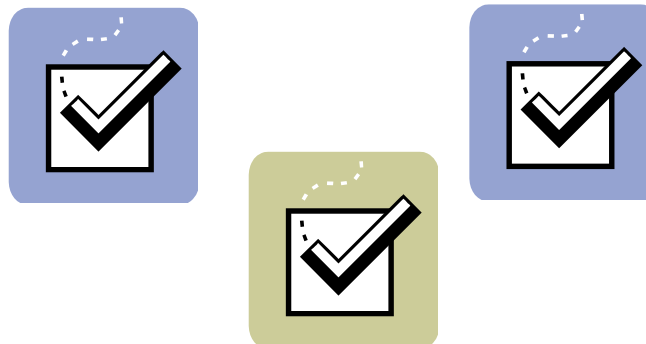
1. Registration with the CRBB in advance of initiating the study.
2. Consistency in payment terms across study related documents, including the protocol, Informed Consent Form (ICF), contract with sponsors (or Award Letter), billing plan , and budget.
3. Whether research subjects have been reported to the CRBB.
4. Whether costs to the subjects associated with their participation in the research study are disclosed in the ICF.

Elements of the audits

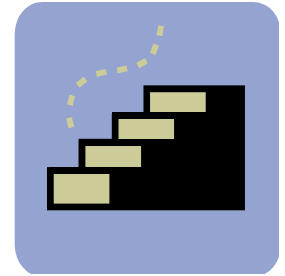
5. Whether appropriate research care plan documentation and study alerts are present in EMR.
6. Whether a CTP analysis has been completed.
7. Whether billing is in accordance with the proposed billing plan.
 - a. Only the last year of billing data is audited
 - b. Sample of 20% of total study subjects or five subjects, whichever is greater
8. Whether the RS indicator has been added appropriately to documentation of all research-related usual care services provided in the context of a qualifying clinical study.

Study Selection and Inclusion Criteria

- Department/Division Selection
 - The order in which Departments/Divisions were audited was based on the total award amounts and subjects enrolled



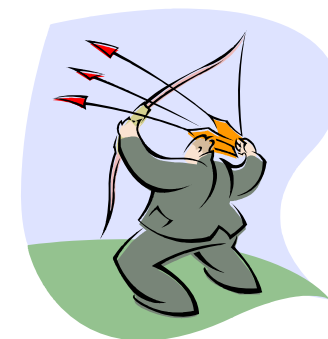
Department/Division Meeting



- Clinical Research Billing Audit team meets with Chair/Chief and Director/Administrator
- Audit plan is shared
- Study Inventory reviewed for possible studies to be audited
- Communication template provided to Chair/Chief for them to communicate to the PIs who will be audited

Auditing One Research Study per PI (Based on Risk to the Organization)

- Studies with a large volume of clinical services in the budget
- A previous history of compliance concerns
- Studies expected to have high enrollment
- No research coordinator or few study personnel associated with study
- Studies begun prior to April 2005
- Implantable device studies



Study Audit Process

- Communicate/meet with PI and study staff
- Obtain pertinent study documentation
 - Protocol
 - Consent
 - Billing grid
 - Contract
 - Budget
 - Billing data
 - Subject inventory
- Audit performed



Study Audit Process (cont.)



- Draft report reviewed with PI and study staff
- Final report provided to Research Coordinator, PI, Compliance Officer, Department/Division Leadership, Ancillary Departments Leadership
- Department is provided summary of all study findings from their department

Additional Auditing

- Studies that have an audit finding error rate greater than 5% of billing transactions (line items) undergo further analysis.



Audit Results Analyzed to Determine:

- The need for repayments, adjustments, disclosures, policy modifications, procedural changes and/or training
- Information that will help refine operational processes
- UW Medicine's comprehensive long-range plan for auditing clinical research billing activities



Program Reporting

- Simi-Annually - UW Medicine Board Compliance Committee
- Bi-Monthly – Executive Compliance Committee





Program Results

General Observations



- Studies are not being closed with CRBB
- Study subjects not reported to subject inventory
- Billing plans are not updated when protocols or billing codes change

Program Status Since 2008

- Completed 137 audits
- Less than 5% error rate for
 - Patient accounts incorrectly charged (\$30K)
 - Research accounts incorrectly charged (\$5K)
 - Services unbilled (\$81K)



Overall Audit Results



- Radiology Charges
- ECG Professional Billing
- Effort accounting
- Professional Fee Charges

Questions



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