Clinical Trials – Budgeting and Billing

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Rules and Regulations

- Medicare Clinical Trials Coverage Policy - National Coverage Decision (NCD)
  - Originated in September 2000 and was called the Clinical Trial Policy NCD
  - Renamed the Clinical Research Policy and revised July 9, 2007

Issues Relating To The Costs of Clinical Research

- **Billing Medicare (or the patient) for items or services that are otherwise reimbursable (or free) to the hospital through federal or private grant funds – *a.k.a. "double billing"***
- Billing Medicare for experimental drugs, devices or procedures
- Charging for an investigational drug in a clinical trial under an investigational new drug application without approval of the FDA
- Waiving Medicare co-payments and deductible obligations for study participants
- Up-coding of billable services
- Receiving remuneration from research sponsors that could be viewed by Medicare as kickbacks
- Coding and billing for non-covered items or services as a covered benefit by an insurer
- Billing for items and services solely to satisfy data collection needs
- **Billing for items and services provided solely to determine trial eligibility**
- Inadequate medical record documentation for items or services billed

National Coverage Decision (NCD)

Basic rule:

- Medicare covers routine costs during qualifying clinical trials
  - Coverage is not automatic (don't assume)
  - Insurer and/or Contractor may deny
  - Does not affect device billing category (A & B)
- Qualifying Trials
  - 3 Requirements; 7 desirable characteristics
  - Federal and IND studies qualify, others by agency qualification

Routine Clinical Services

- Routine clinical service costs are associated with patients enrolled in qualifying clinical trials and include:
  - Items and services otherwise available to beneficiaries;
  - Not statutorily excluded by Medicare;
  - No national non-coverage decision.
- Routine costs includes items and services that are:
  - **Typically furnished absent clinical trial (SOC)**
  - Necessary to provide investigational item/service;
  - Required for clinically appropriate monitoring of effect of investigational item/service or for prevention or treatment of complications

Costs that are not considered routine:

- Investigational item/service itself
  - *But* NCD does not supersede Local Coverage Determinations (LCDs) or Category B device rules
- **Items and services furnished solely to determine trial eligibility or satisfy data collection and analysis needs not used in clinical management of patient**
- Items and services **customarily** provided by research sponsors free of charge for **any** enrollee in the trial.

NCD – Qualifying Requirements

Part 1: The 3 "necessary requirements"

- The study must investigate an item or service that is in a Medicare benefit category
  - Note: NCD does not supercede local coverage determinations (LCD)—if Item or service is excluded by LCDs, study doesn't qualify
- The study must enroll patients with diagnosed diseases
- The study must have therapeutic intent – it must not be designed solely to test the safety or toxicity of the investigational item or service

Part 2: The study must be "deemed" to meet the 7 "desirable characteristics" – only certain types of studies are "deemed":

- Funded by certain government agencies (NIH, DOD, VA)
- Funded by co-op groups that receive funding from government
- Conducted under an FDA-approved IND application
- Exempt from IND requirements

Compliance Settlements

U. of Alabama at Birmingham ($3.39 M)

- Allegations
  - Falsely billed Medicare for:
    - Researcher's time spent on patient care when no patients had been seen; and
    - Clinical research trials that were also billed to the sponsor of the research grants
  - Overstated percentage of effort devoted to the grants and falsely reported T/E of employees who did not work on the grants

Prior to Award

- Determine routine services vs research related
- Obtain correct pricing for services
- Create a budget and billing grid with a list of all patient services required in protocol, include all CPT codes
- Make sure everything is in the contract

Routine vs. Research Related Services

- Determination should come from the PI:
  - Examine each procedure in the protocol and the frequency it is being performed
  - Use CRP definition of routine clinical services to help guide you
  - Do not just go with what the sponsor is telling you

Where do I get prices?

- Technical Fees- Research rates are posted on website (Fed and non-Fed), contact CTFA
- Professional Fees- Each professional group determines pricing
- Investigational Drug Services- annual fee charged to the study, IDS will give an estimate
- IRB fees- standard rates set by IRB and WIRB
- Time and Effort- Comes from the department
- Indirect Costs- Check with BMC or BU grants office
- Other-Storage fee, shipping, dry ice, central lab fees, pass thru fees, patient stipends, etc

Hospital rates

- Federally negotiated rates apply, charges revised annually
- Industry rates are set at either the Federal level or 38%, whichever is higher. Example:

	Federal	Industry
Radiology	36.1%	38%
Pulmonary	65.9%	65.9%

- Research prices are posted on internal website
- Build your budget

Budget Worksheet

Clinical Trial Budget

	CPT4 Codes	Unit Cost	Baseline	Treatment				Follow-Up	
				Week 1	Week 2	Week 3	Week 4	Month 2	Month 4
Procedures									
Initial Visit (MD Visit Level4)	99204	$ 181.28	SOC						
Physical Exam (MD Visit Level 2)	99242	$ 154.15					SOC	SOC	SOC
Vital Signs (RN Level 1)	99211	$ 41.72	SOC	$41.72	$41.72	$41.72	SOC	SOC	SOC
ECG	93000	$ 86.31	$86.31						
HIV	87536	$ 104.25	$104.25						
Hep A Ab	86708	$ 85.29	$85.29						
Hep B Ab	86706	$ 71.46	$71.46						
Hep C Ab	86803	$ 112.95	$112.95						
Complete CBC Auto	85025	$ 35.54	SOC				$35.54		
Creatinine	82565	$ 27.65	SOC				$27.65		
AST	84450	$ 28.39	SOC				$28.39		
ALT	84460	$ 28.39	SOC				$28.39		
Sodium	84295	$ 25.73	$25.73				$25.73	$25.73	
Potassium	84132	$ 25.73	$25.73				$25.73	$25.73	
Serum Pregnancy Test (HCG)	84702	$ 87.36	$87.36						
Chest CT	71270	$ 1,463.40	SOC					SOC	SOC
Pelvis CT	72194	$ 1,180.73	SOC					SOC	SOC
Abdomen CT	74170	$ 1,484.19	SOC					SOC	SOC
Concomitant Medication	N/A	N/A	SOC	SOC	SOC	SOC	SOC		
Study Drug Admin (IV Infusion 30 min)	96410	$ 185.33		$ 185.33	$ 185.33	$ 185.33	$ 185.33		
Personnel									
Principal Investigator			$150.79	$150.79	$150.79	$150.79	$150.79	$150.79	$150.79
Research Nurse			$282.71	$282.71	$282.71	$282.71	$282.71	$282.71	$282.71
Study Coordinator			$278.94	$278.94	$278.94	$278.94	$278.94	$278.94	$278.94
Other									
Misc Admin			$75.00						
Totals									
Total Direct Cost / Visit			$1,386.52	$939.49	$939.49	$939.49	$1,069.20	$763.90	$712.44
Indirect Cost @ 30%			$415.96	$281.85	$281.85	$281.85	$320.76	$229.17	$213.73
Total Cost Per Visit			**$1,802.48**	**$1,221.34**	**$1,221.34**	**$1,221.34**	**$1,389.96**	**$993.07**	**$926.17**
Total Cost of Baseline, Treatment, & Follow-Up For Each Patient							**$8,775.69**		

Billing Grid

- Details patient procedures performed during each subject visit
- Drives where the service should be billed, who is financially responsible
- Each charge clearly identified as SOC or Research
- Billing grid should be used for each study participant
- Vital tool when reconciling studies

Billing Grid

Clinical Trial Budget

	CPT4 Codes	Baseline	Treatment				Follow-Up	
			Week 1	Week 2	Week 3	Week 4	Month 2	Month 4
Procedures								
Initial Visit (MD Visit Level4)	99204	SOC						
Physical Exam (MD Visit Level 2)	99242					SOC	SOC	SOC
Vital Signs (RN Level 1)	99211	SOC	GRANT	GRANT	GRANT	SOC	SOC	SOC
ECG	93000	GRANT						
HIV	87536	GRANT						
Hep A Ab	86708	GRANT						
Hep B Ab	86706	GRANT						
Hep C Ab	86803	GRANT						
Complete CBC Auto	85025	SOC				GRANT		
Creatinine	82565	SOC				GRANT		
AST	84450	SOC				GRANT		
ALT	84460	SOC				GRANT		
Sodium	84295	GRANT				GRANT	GRANT	
Potassium	84132	GRANT				GRANT	GRANT	
Serum Pregnancy Test (HCG)	84702	GRANT						
Chest CT	71270	SOC					SOC	SOC
Pelvis CT	72194	SOC					SOC	SOC
Abdomen CT	74170	SOC					SOC	SOC
Concomitant Medication	N/A	SOC	SOC	SOC	SOC	SOC		
Study Drug Admin (IV Infusion 30 min)	96410		GRANT	GRANT	GRANT	GRANT		

SOC - Billed to the Patient's Insurance

GRANT - Billed to the Research Grant & Paid by the Sponsor

**If any SOC procedures are denied by a patient's insurance, please contact the clinical trial financial analyst as soon as possible.*

Are you ready to start?

- Contract has been signed.
- Budget has been approved.
- IRB approval letter received.
- Account number has been assigned by BMC/BU.
- Study team is ready to begin research protocol.
  - **What's next???**

Set Up Research Study in SDK

Prior to enrolling first patient, the study must be set up in SDK.

New Research Carrier Request Form for SDK

This sets up the specific study in SDK as a type of insurance so patients and 3rd party payors are not billed for research related services.

New Research Carrier Request Form For SDK

Boston Medical Center

New Research Insurance Carrier Request for SDK

Date:

Form initiated by:

Phone:

Admin/Study Coordinator:

Email:

Grant Title:

PI:

IRB #

Department: Section:

What would you like to name this study in SDK? (up to 16 characters):

Is this Inpatient, Outpatient or Both? drop down

Is this a Federal agreement? drop down

Payor ID# (the 7-digit AU for BMC or 10-digit Internal Order# for BU):

Effective Start Date: Effective End Date:

Where will study take place?

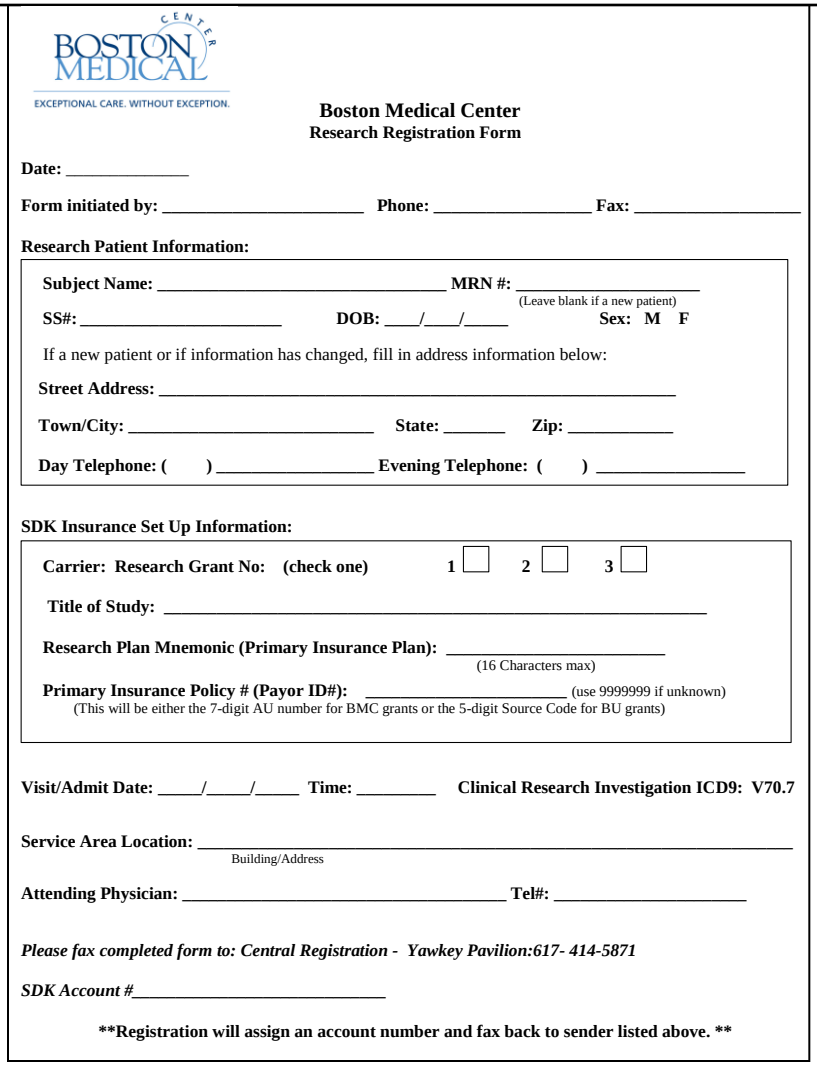
Building: Floor: Room:

**Please attach a copy of the budget with all the clinical tests being performed **

Scheduling and Registration

- Call department for the appointment
- Give them the research information as the insurance
- Registration is decentralized, anyone can register, staff may not understand what a research insurance is

Outpatient Registration Form



BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Boston Medical Center
Research Registration Form

Date: _____

Form initiated by: _____ **Phone:** _____ **Fax:** _____

Research Patient Information:

Subject Name: _____ **MRN #:** _____
(Leave blank if a new patient)

SS#: _____ **DOB:** ____/____/_____ **Sex: M F**

If a new patient or if information has changed, fill in address information below:

Street Address: _____

Town/City: _____ **State:** _____ **Zip:** _____

Day Telephone: ( ) _____ Evening Telephone: ( ) _____

SDK Insurance Set Up Information:

Carrier: Research Grant No: (check one) **1** ☐ **2** ☐ **3** ☐

Title of Study: _____

Research Plan Mnemonic (Primary Insurance Plan): _____
(16 Characters max)

Primary Insurance Policy # (Payor ID#): _____ (use 9999999 if unknown)
(This will be either the 7-digit AU number for BMC grants or the 5-digit Source Code for BU grants)

Visit/Admit Date: _____/_____/_____ **Time:** _____ **Clinical Research Investigation ICD9: V70.7**

Service Area Location: _____
Building/Address

Attending Physician: _____ **Tel#:** _____

Please fax completed form to: Central Registration - Yawkey Pavilion:617- 414-5871

SDK Account #_____

****Registration will assign an account number and fax back to sender listed above. ****

Patient Care Report and Invoice

- A monthly patient care report is generated and distributed to the Administrator of each study. This report contains:
  - Detail grant charges for each date of service
  - Detail grant charges for each patient
- Compare these reports to Billing Grid – only Grant charges should appear on these reports
- Verify accuracy of charges
  - Are SOC charges being charged to Grant?
  - Are Grant charges being charged to SOC?
- Problems!! - Contact the CTFA

What to Watch Out For!

- Are these patients truly part of the study?
- Are there any patients that you do not see on your list that you know participated?
- Are there any charges missing?
- Are some of these charges not grant related?
  - **Contact the CTFA if there are any issues**

Example Patient Care Report

INSURANCE CARRIER	INSURANCE PLAN	INSURANCE POLICY NUMBER	ACCOUNT NUMBER	PATIENT NAME	ADMIT DATE	AMOUNT	PAID VIA JE OR BU SOURCE	ADJ.	BALANCE	COMMENT	SERVICE CODE	SERVICE CODE DESCRIPTION	CPT CODE	REVENUE CODE	REVENUE CODE DESCIPTION	INSURANCE PLAN PAYOR ID	
RESEARCH GRANT #2	STUDY 1234	4567-8	115076655	JANE SMITH	3/11/2005	240.00	240.00		-	Approved by Alex	71020880	CHEST;2V,AP&LAT	71020	320	DX X-RAY	4567-8	ACTIVE
RESEARCH GRANT #2	STUDY 1234	4567-8	115472151	RUSSELL LEE	3/23/2005	240.00	240.00		-	Approved by Alex	71020880	CHEST;2V,AP&LAT	71020	320	DX X-RAY	4567-8	ACTIVE
RESEARCH GRANT #2	STUDY 1234	4567-8	113064851	JOHN KING	1/18/2005	240.00	240.00		-	Approved by Alex	71020880	CHEST;2V,AP&LAT	71020	320	DX X-RAY	4567-8	ACTIVE
RESEARCH GRANT #2	STUDY 1234	4567-8	120778956	BRAD PITT	8/1/2005	240.00	240.00		-	Approved by Alex	71020880	CHEST;2V,AP&LAT	71020	320	DX X-RAY	4567-8	ACTIVE
				subtotal		960.00	960.00	-	-								
				Total Amount to charge the grant			960.00										

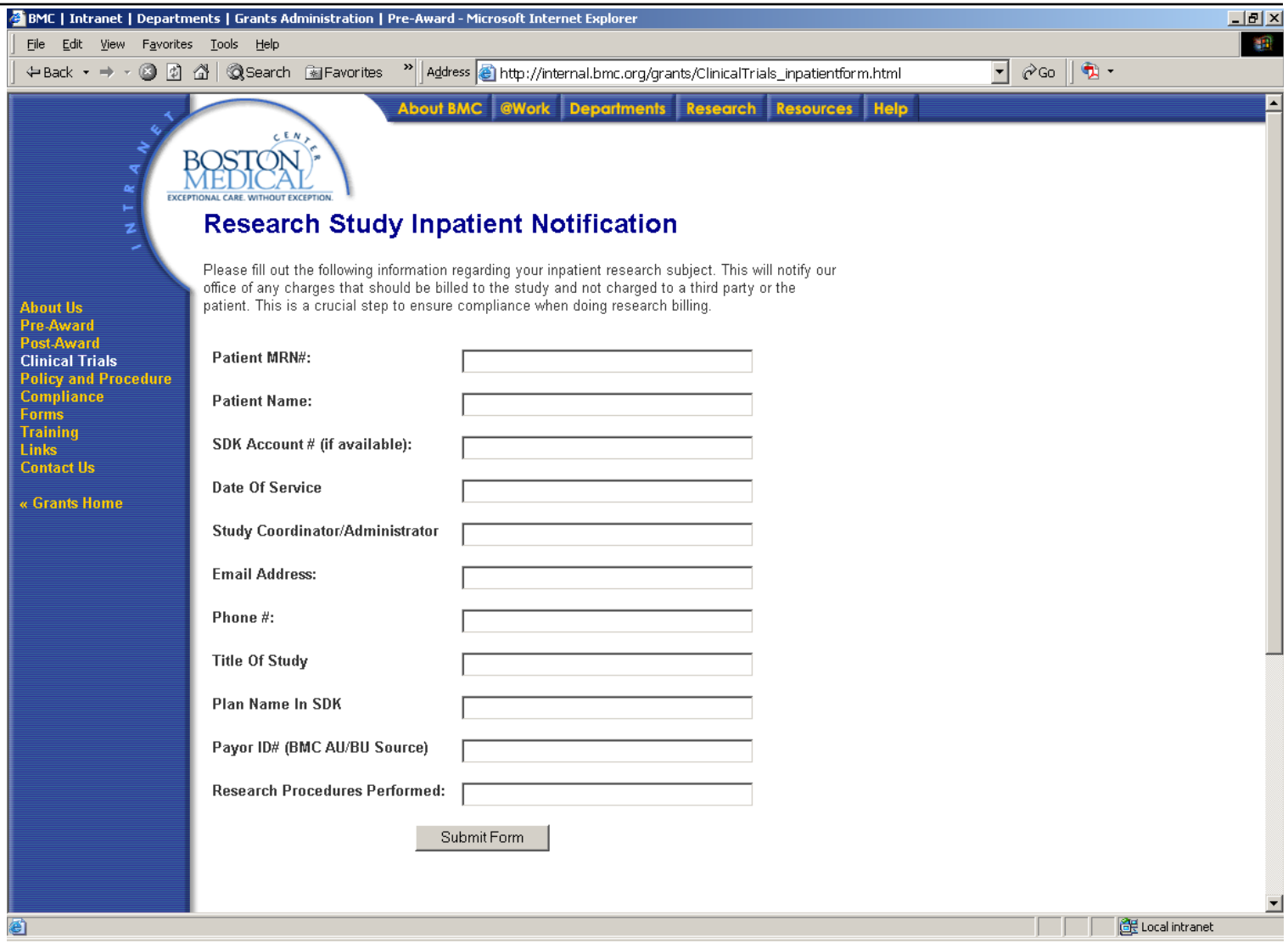
What if routine clinical care and research services are performed on the same day?

- 2 visits must be created in SDK
  - Patient's insurance or self pay
  - Research study insurance
- Charges must be separated in SDK and allocated to the correct visit number

Inpatient Registration

- Charges related to inpatient stays are usually covered by third party payors, **unless** the patient is also part of a clinical research study.
- Research charges **must be flagged** in the system so they are not released with the regular inpatient claims to third party payors
- Study Coordinators must inform the CTFA of any research charges by using the **Inpatient Notification Form**
- Communication between the Study Coordinator and the CTFA is vital!

Inpatient Notification Form



Financial Close Out

- Has everything been billed to the sponsor? All payments received?
- Have salaries been allocated properly?
- Patient reconciliation completed?
- All vendors have been paid? Professional groups, IDS, GCRC, etc.

- **Cash balance after everything should be close to break even point**

Any Questions???