Medicare Coverage Analysis

BWH qualifying study training and discussion

Research Compliance at BWH

- At BWH, Research Compliance ensures study teams and institution follow governing authorities
  - interprets federal guidelines
  - requires oversight boards and committees
  - develops policy
  - implements process
  - educates and audits
  - collaborates with Partners Corporate and other affiliates

- Two departments directly relate to research billing compliance
  - Research Administration and Compliance- Allison Moriarty, VP
  - Billing Compliance- Jim Bryant, VP and CCO

BWH BRIGHAM AND WOMEN'S HOSPITAL

Clinical Research Compliance at BWH

➢ Research Administration and Compliance applicable divisions

- Research Subject Welfare and Lab Safety
  - e.g.Informed consent
- Sponsored Programs and Compliance (unique contracts)
  - e.g. Contract/budget negotiations
- Clinical and Translational Research Support (CCI)

➢ Billing Compliance department, Research Billing division

- Specified Epic support: charge routing and correction assistance
- Audits and educates on research billing processes
- Bridge between academic and hospital/professional worlds
- Centralized resource for DFCI related billing issues
- Maintain relationships with: Partners Corporate, MGH, other affiliates, and DFCI

Research Administration: https://partnershealthcare.sharepoint.com/sites/phrmdepartments/hd/bwh/bra

Billing Compliance: https://www.bwhpikenotes.org/employee_resources/compliance/billing/default.aspx

BWH BRIGHAM AND WOMEN'S HOSPITAL

Focus: Processes Supporting GCP

➢ Clinical research billing

- Direct and monitor charges for patient care services, required by a protocol, and rendered to a subject, the subject's insurance, or a research fund

➢ Importance of clinical research billing

- Incorrect billing of Medicare, insurance or a federal sponsor may be viewed as insurance fraud or a false claim[1]
  - charging patient's insurance and study fund for the same procedure e.g. double billing
  - claim formatting requirements, e.g. Medicare Coverage Analysis (MCA)
- Ensure ethical obligation to research subjects are not billed for services expected to be paid for by the study[1]
- Maintain institutional reputation for research excellence, trust of our patients who volunteer to participate in research studies[1]

[1] Source: The CITI PI presentation – An Overview of Clinical Trials Billing

Process in practice, cont.

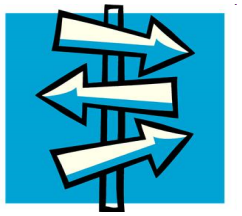
Clinical research charge routing encounters

1. Routine/usual care will occur in parallel with clinical research and will not be related to a study protocol
   Outcome: encounters are billed as usual to patient or patient's insurance

2. Routine/usual care that may be required by the protocol
   Outcome: special billing requirements may apply, need billing review
   - Medicare Coverage Analysis (MCA)- qualifying or non-qualifying

3. Clinical research only procedures must be charged to study fund
   Outcome: cannot bill to insurance, study must pay, need billing review

Medicare Coverage Analysis



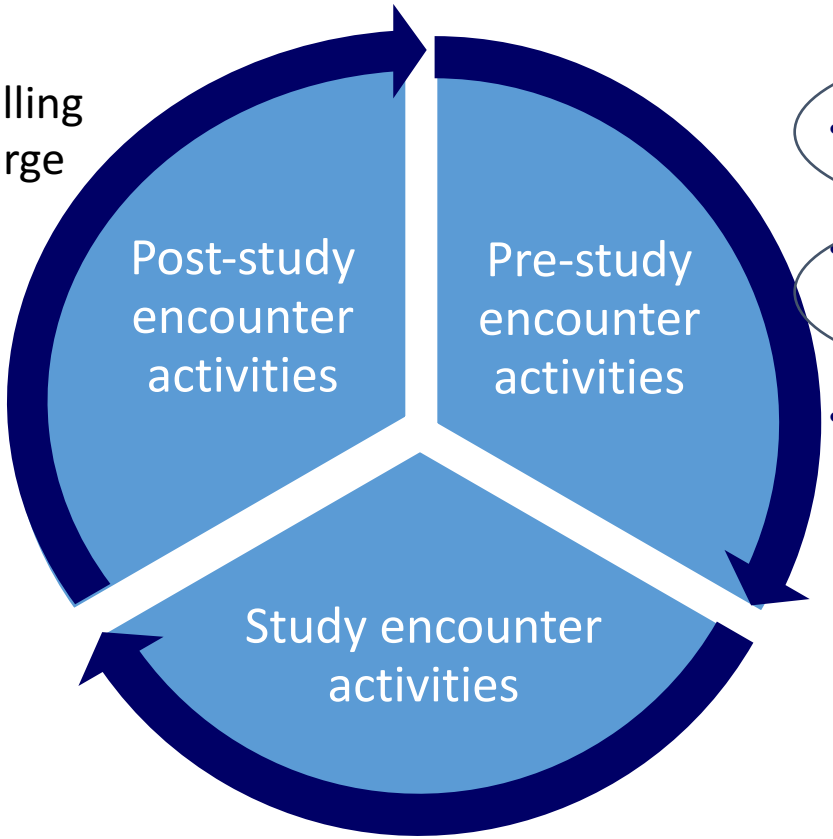
Partners Clinical Trials Office (PCTO):

- Is notified, through the Partners IRB process, to begin an MCA review if protocol requires routine/usual care
- Develops billing calendar: research procedures and payment methods
- Reviews all clinical research studies to determine if the study meets the definition of a Qualifying Clinical Trial
- Contacts the PI if their study is undergoing an MCA, may request the PI to participate in routine billing practice discussions, will send an MCA summary letter describing which services may/may not be billed to Medicare, and, when applicable, updates Insight with qualifying status
- If the protocol is non-qualifying, then the study fund must cover all research specific charges
- **PI of the protocol** and **PI of the fund** (if not the same) are **equally responsible** to monitor **study** related **charges**

BWH BRIGHAM AND WOMEN'S HOSPITAL

Process in practice

- Run Epic's "Research Billing Review Report" for charge validation
- Review charges within 7 days of posting in Epic
- Delinquent charge review may result in leadership email escalations



- Identify research specific encounters
- Financial responsibility confirmation: consent & contract match
- Active study code in Epic

- Consent and enroll subject to Epic's applicable study code
- Schedule, order, and link research services to study code in Epic

BWH BRIGHAM AND WOMEN'S HOSPITAL

Process in practice, cont.

14.1. Appendix 1: Schedule of Assessments

Procedure	Pre-Screen[1]	Screen	Baseline (Randomization)	Up-Titration[11]		Maintenance			Down-Titration		Follow Up	Early Withdrawal
	P	S	R	T	End T	IMV[12]	M3 (12 wks)	M6 (24 wks)	DT1	End DT[13]	FU	EW
Signed Informed Consent	X											
Inclusion and exclusion criteria	X	X	X[9]									
Medical History	X	X										
Complete Phys Exam[2]		SOC/M			RS			SOC /M				RS
Chest X-Ray		X[6]										
ECG (Standard 12-Lead)		X	X[10]					X				X
Urine Pregnancy Test		X										
Vital Signs (BP/HR)	X[4]	X	X	X	X	X	X	X	X	X	X	X
FPG/ HbA1c/insulin/c-peptide		X[7]	X				X	X				X[15]
New Onset Diabetes								X				X
Fasting lipid panel[3] /inflammatory markers	X[5]	X[8]	X				X	X				X[15]
Concomitant Medications	X	X	X	X	X	X	X	X	X	X		X
Hematology and Clin Chem, Urinalysis (Safety)		X	X				X	X			X[14]	X
AEs/ Serious AEs		X	X	X	X	X	X	X	X	X	X	X
Assessment of Tolerability			X	X	X							
Study Medication Compliance				X	X		X	X	X	X		X

BRIGHAM AND WOMEN'S HOSPITAL

Process in practice, cont.

Procedure	Professional billing		Hospital billing	
New pt E&M	99203	Q1	6000204	Q1
Est. pt E&M	99214	$43.93 x 2	6000831	$80.00 x 2
Chest x-ray	71010	$21.35 x 1	4000254	$59.37 x 1
ECG 12-lead	93005	$78.47 x 4	93010	$8.96 x 4
Urine pregnancy			0020229	$8.96 x 1
HbA1 c-peptide			0070426	$13.75 x 5
Fasting lipid panel			0020421	$18.97 x 6
Hematology-CBC			0040003	$7.49 x 6
Chemistry panel-CMP			0020408	$14.97 x 6
Urinalysis			0020350	$4.48 x 6

Note:

- 7 procedures listed on protocol, exploded into 10 procedures with 14 different associated codes and costs
- “Schedule of Assessments” from the protocol may not include billing route, refer to contract/consent
- Cost may vary depending on the sponsor type and institutional commercial mark-up
- Cost ≠ sponsor reimbursement (could be reimbursed less, equal to, or more)
- Cost many vary over the course of the study, inflation is recommended

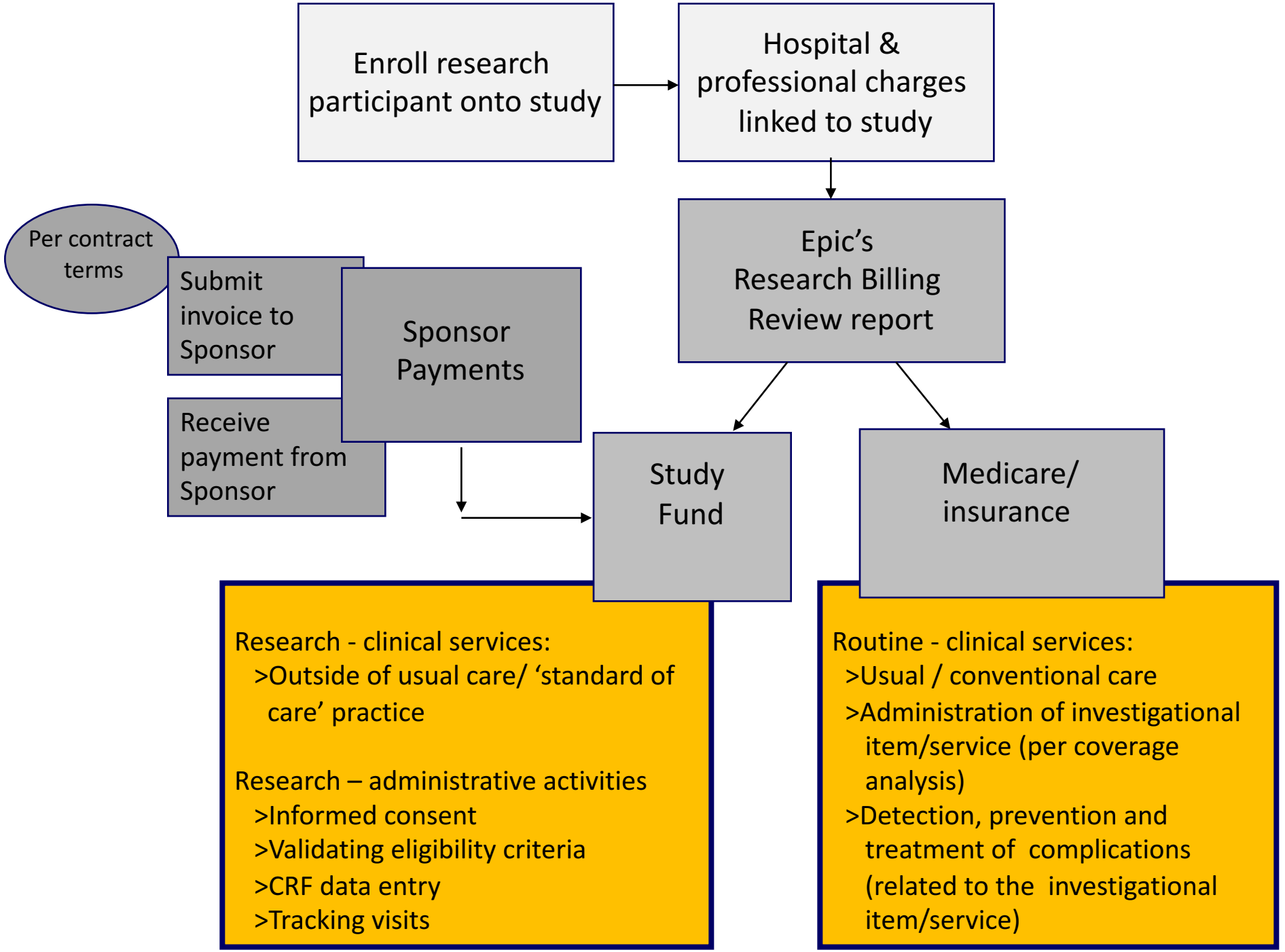
BWH BRIGHAM AND WOMEN'S HOSPITAL

Charge direction in Epic

- PI enters Active study code in Epic (auto-populated from Insight)
- Insight auto-populates Epic with study information
- Enroll subject to applicable study code
- Link research encounters/orders/admissions to study
- Run Epic's "Research Billing Review Report" for accurate charge review
  - review charges within 7 days of posting in Epic
  - check Research Billing review report 2-3 times per week
  - delinquent charge review could result in leadership email escalations

Accurate charge allocation is **YOUR** responsibility!

BWH BRIGHAM AND WOMEN'S HOSPITAL


Enroll research participant onto study
Hospital & professional charges linked to study
Epic's Research Billing Review report
Per contract terms
Submit invoice to Sponsor
Sponsor Payments
Receive payment from Sponsor
Study Fund
Medicare/ insurance
Research - clinical services:
>Outside of usual care/ 'standard of care' practice
Research – administrative activities
>Informed consent
>Validating eligibility criteria
>CRF data entry
>Tracking visits
Routine - clinical services:
>Usual / conventional care
>Administration of investigational item/service (per coverage analysis)
>Detection, prevention and treatment of complications (related to the investigational item/service)

Managing the Study Fund(s)

The PI and/or delegated study team member(s) must:

1. Ensure the fiscal health of his/her study fund

2. Develop a budget prior to the start of the study that encompasses all activities related to the research; use this list of activities to track if items are being billed appropriately

3. Link all studies, with patient care charges, to the research fund(s) used to cover patient care costs

4. Define roles and responsibilities and ensure all study staff are trained on ordering, charge direction, and monitoring of study services and associated charges

BWH BRIGHAM AND WOMEN'S HOSPITAL

Managing the Study Fund(s), cont.

5. Contact Department Administrator monthly to monitor study funds in a timely manner

6. Promptly submit and monitor Patient Care Correction request in Insight's Agreements module if charges are:
   - missing that should be billed to the fund (could have gone to patient's insurance)
   - appearing and should be billed to insurance/patient
   - needing to be transferred to a different fund

7. Protocol amendments that affect the informed consent and participant's clinical care, should be evaluated by PCTO for possible revision of the MCA and update in Epic

Study team is accountable to protect the research participants and the institution from misbilling

BWH BRIGHAM AND WOMEN'S HOSPITAL