(NOT) JUST A BILL
The Ins and Outs of UAB Clinical Research Billing
Responsible Parties

- **Clinical Billing Review (CBR)**
  - Coverage Analysis
  - Coding

- **OnCore**
  - Clinical Trials Management System (CTMS)
  - Clinical Trials Billing Notice (CTBN) Report

- **Ancillary Area**
  - The area where a service is being performed (ex. Chest X-Ray will be performed by UAB Radiology or a Comprehensive Metabolic Panel may be performed by Hospital Labs) and charges are captured

- **Clinical Billing Offices (CBO) - MSO (Professional) and PFS (Hospital) Billing Offices**
  - Receives charges from ancillary areas and sends bills to insurance/patients or study based on CTBN

- **Study Team**
  - Patient interaction and CTBN creation in the Clinical Trials Management System
What is a “Clinical Billable”?

- A “Clinical Billable” (defined by UAB Research) is a protocol required clinical activity performed during the conduct of a clinical trial that is billed through HSF (MSO) and/or UAB Hospital (PFS) billing offices.
  - Ask yourself, “Are any of the items on your Protocol Schedule of Events billed through the UAB Billing Offices?” If yes, then that item is a clinical billable.
  - Clinical Billables can be both bill to study and/or SOC.

Why does it matter?

- When subject has completed the procedure, the charges are captured and sent by the Ancillary Area (ex. Radiology, Outreach Lab, Echocardiography, etc) to MSO and PFS to be billed accordingly.
- If you do not occur the visit accurately and in a timely fashion in OnCore, generating the Clinical Trials Billing Notice (CTBN), charges will be billed to the subject or the subject’s insurance in the usual manner. The item or service will be captured and billed regardless of entry into OnCore.
Clinical Billing Review (CBR) – The First Step in the Process

- **Submission Requirements** –
  - Research Studies with Clinical Billable Services are required to be submitted for review through Clinical Billing Review (CBR)

- **Coverage Analysis** –
  - National Coverage Determination (NCD) 310.1 – Routine Costs in Qualifying Clinical Trials
    - NCD 310.1: “Effective for items and services furnished on or after July 9, 2007, 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.”
    - CBR Performs Targeted Coverage Analysis
      - To determine the Study Type – Is the trial Qualifying?
      - To confirm Medicare rules and document routine care for standard of care items/services
      - To confirm CMS Approval for Category A, Category B Device trials and CED trials

- **Coding – Collaboration between CBR, Revenue Integrity, Billing Offices, and Departmental Submitters**
  - Once coding has been determined, pricing is pulled directly from the OnCore Chargemaster for the billable items/services

- **CBR/FAP Approval**
  - When Coverage Analysis is complete, CBR Approval (including approved billing designations, study type, and coding) is sent to the submitter, the OnCore Calendar Builders, and PowerTrials Team
OnCore Calendar Services – The Next Step

- **CBR/FAP Approval** - OCS registers the study in OnCore and builds the calendar once CBR approval is received.

- **Billing Designations** - OCS then uses the FAP Approved Billing Plan to designate the items/services at each visit as either Bill to Study (X) or Bill to Insurance (S).

- **OnCore Chargemaster** - OCS links the billables to the OnCore Chargemaster so that they will appear on the CTBN after the study visit is “Occurred”.

- **Study Type** - OCS adds the Study Type from our approved billing plan into OnCore. The Study Type will then appear on the CTBN after the study visit is “Occurred”.

- **Calendar Validation** - OCS sends the calendar to the study team for their review and validation. The study team will review the PC Console information in OnCore, the drafted calendar, and the billing designations in the calendar (S = SOC, X = Bill-to-Study).
  
  - Not validating thoroughly can lead to billing errors and corrections that can involve additional work from your study team, the billing office, and the OnCore team. It is important to have the calendar correct in OnCore and ready to go when you screen your first subject.

- **Calendar Released** - Calendar is released by the study team after the SIV.
CTBN Creation – The VERY Important Step

- **Occurred the Visit in OnCore**
  - Study team reviews the visit details to determine if all billable items/services occurred at that visit
  - Study team may need to add procedures. Contact the OnCore team for assistance because procedures must be added appropriately in order for them to appear on the CTBN
    - Please note MSO and PFS billing offices cannot assist with OnCore questions
  - Study team marks the visit as “Occurred” generating an electronic CTBN for the date of service
CTBN Example

**Report Date:** Date the visit was occurred in OnCore

**Visit Date:** Date of visit

**NCT#:** Required on claim to insurance for Study Type Q

**IRB#:** Used to locate institutional account number to post the charges

**Study Type:** Informs CBO if codes/modifiers needed on claim to insurance.

**Contact Info:** Used to contact dept for queries (ensure contact info in OnCore Staff Tab is correct and updated in real time)

**Clinical Billables:** Linked to chargemaster at visit by Calendar Builders
CTBNs & The MSO/PFS Billing Offices (CBO)

What the CBO does
CBO receives charges and reviews services on CTBNs which drives where the charges are billed

What the CBO needs
CTBNs need to include Study Type, and all study protocol driven billable services with billing designation, as well as protocol related SOC billed to insurance

Helpful reminders
- Ensure study visits are in OnCore and occurred in a timely fashion (24-48 hours after visit has taken place)
- Reference Coding Works Aids created by the CBR to assist with reconciling payments

Potential Risk Factors of Study Related Billing Errors
- Reportable compliance issues occur when charges are billed to insurance in error for study related services that should have been billed to the study
- Risk of exceeding insurance timely filing limits. These denials will result in loss of revenue
- Billing errors lowers patient satisfaction experiences
- All of the above effects our Pillar Goals enterprise wide
### IDX Charge Example:

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<th>Patient</th>
<th>Proc</th>
<th>Desc</th>
<th>Created</th>
<th>User</th>
<th>Status</th>
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</thead>
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<tr>
<td></td>
<td>71046</td>
<td>RADIOLGY EXAM, CHEST 2 VIEWS</td>
<td>02/05/20</td>
<td>6:20A</td>
<td>TESN1</td>
</tr>
</tbody>
</table>
Overview of Research Billing Process
What Could Go Wrong?

- **Nothing** -
  - Visits are managed carefully (checking for correctness) in OnCore in a timely manner (24-48 hours after visit occurred)
  - Charges drop and CTBN is created with all appropriate items/services on the CTBN, so billing offices have clear instructions on how to bill for the date of service

- **Everything** -
  - Visits are not marked Occurred in OnCore
  - Charges drop and no CTBN is created
  - Billing offices bill everything to insurance (some things are meant to be billed to study and/or it is a qualifying trial with no codes/modifiers on the claim)
  - Sponsor pays for services and insurance has also paid – Double-Billing!!

- **Common Things** -
  - Visits not marked Occurred
  - Calendar was not validated, visits are incorrect
  - Visits are not managed in a timely manner, meaning charge corrections
    - Charge corrections requires sending money back to insurance companies and/or submitting claims past timely filing limits
    - A large number of charge corrections can trigger an audit resulting in large fines for UAB
  - Visits are kept with incorrect information, generating queries from billing offices
  - Additional procedures occurred that were not entered into OnCore or entered incorrectly, therefore not producing a CTBN
  - Participants are not educated about costs in clinical trials
  - Sponsor cannot pay for item/service if insurance denies – patients are responsible
Qualifying Trials and Medicare Beneficiaries

- **Qualifying Clinical Trials and Medicare Beneficiaries**
  - If study participants are Medicare beneficiaries, items/services billed to participants on Qualifying clinical trials may generate higher copays and deductibles, as the claim will go to Original Medicare and not their advantage plan
  - Participants need to be aware of this and contact their plan before enrolling in the trial
  - Medicare beneficiaries may be reimbursed for the copays/deductibles
HELP! Who do I contact?

What type of Question/Concern do you have?

- **Questions about using OnCore?** (ex. how to occur visits, add a procedure, problems with the CTBN not generating)
  - OnCore Administrators
- **Questions about the OnCore Calendar?** (ex. procedure needs to be added to a visit, amendment affects the schedule of events, etc.)
  - OnCore Calendar Builders
- **Questions about bills?** (ex. subject received a bill, bill is incorrect, etc)
  - MSO and PFS Billing Offices
- **Questions about CPT Codes or billing designations?** (ex. changing something from bill to insurance to bill to study (or vice versa))
  - CBR
Contact Information:

- **CBR**
  - *Ashley Specht (General Queries):*
    - Email: aspecht@uabmc.edu; Phone: (205)996-7573
  - *Mackenzie Roberts (Coding Queries):*
    - Email: mstanford@uabmc.edu; Phone: (205) 934-3187
  - *Office Email Address: FAP@uab.edu*

- **CBO (MSO and PFS Billing Offices)**
  - *Bonnie Fowler (MSO):*
    - Email: bflowler@uabmc.edu; Phone: (205) 731-5629
  - *Donna Simpson (PFS):*
    - Email: dsimpson@uabmc.edu; Phone: (205) 934-9711

- **OnCore Administrators**
  - Oncore@uabmc.edu

- **OnCore Calendar Builders**
  - OncoreCalendars@uabmc.edu