



University of Louisville

Research Billing Compliance (RBC) Review Process

What is clinical research billing compliance (RBC)?

- Medicare can only be billed for items and services that are part of **routine** clinical care

Conventional care

Administration of investigational product

Diagnosis & treatment of complications

- Research sponsor must pay for items and services that are done solely for data collection purposes
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What is clinical research billing compliance?

- Patients who enroll in a clinical trial must be fully and accurately informed of the costs associated with participating
- CTA/budget, MCA/billing plan, and ICF must all reflect this and be aligned

Rules that govern clinical research billing





This is just a sampling... there are more!



- Medicare Clinical Trial Policy (NCD 310.1)
- Medicare Benefit Policy Manual (Ch 14)
- Common Rule (45 CFR 46)



To assure compliance

-  Do not bill for services the sponsor is already paying for (double billing)
 -  Do not bill for services that were promised free to the participant
 -  Do not bill for services that are for research purposes only
 -  Only bill for services that have no external funding source and are medically necessary
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RBC Reviews

What is reviewed?

Why is it reviewed?

What are the steps?

Timeline

Who reviews it?

RBC Reviews - What is reviewed?

Starting from July 1, 2019

- ★ All new clinical projects with patient billing (i.e. CTA, CTR...)
- ★ All contract amendments requiring budget change



RBC Reviews - What is reviewed?

- Qualifying Clinical Trial status
- Final draft budget
- Medicare coverage analysis (MCA)
- Internal budget document, if applicable
- Current version of the Informed Consent Form (ICF)
- Provider pricing (admin fees, technical & professional components, pharmacy fees, etc)
- Final Protocol

RBC Reviews - Why is it reviewed?

To ensure that the budget and the payment terms are compliant with research billing rules and regulations, and that the research costs of conducting the trial are being covered by the Sponsor

- All documents are aligned to ensure compliance with billing standards
- F&A is appropriately budgeted
- Required institutional fees are included in the budget
- All provider costs are covered



RBC Reviews - What are the steps?

1

Submit TRIA/IBED as usual

- You may copy ccdfin@louisville.edu on the submission (optional)
- You will receive an acknowledgement email from reviewer

2

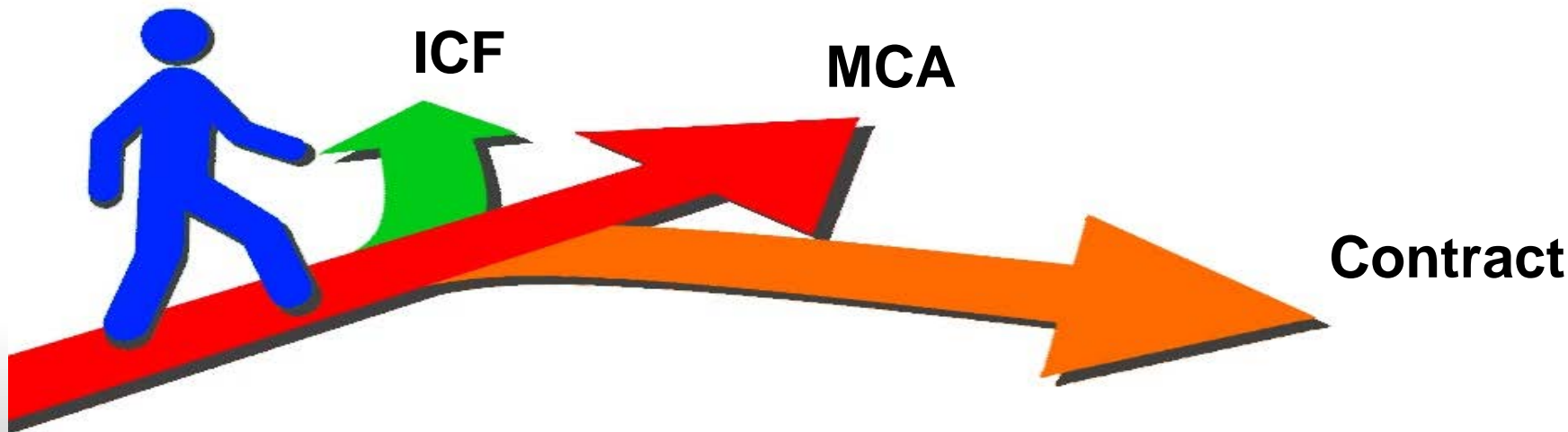
Negotiate your budget with Sponsor as usual



DON'T FINALIZE YOUR BUDGET WITH SPONSOR

RBC Reviews - What are the steps?

Make sure that your documents are in synch



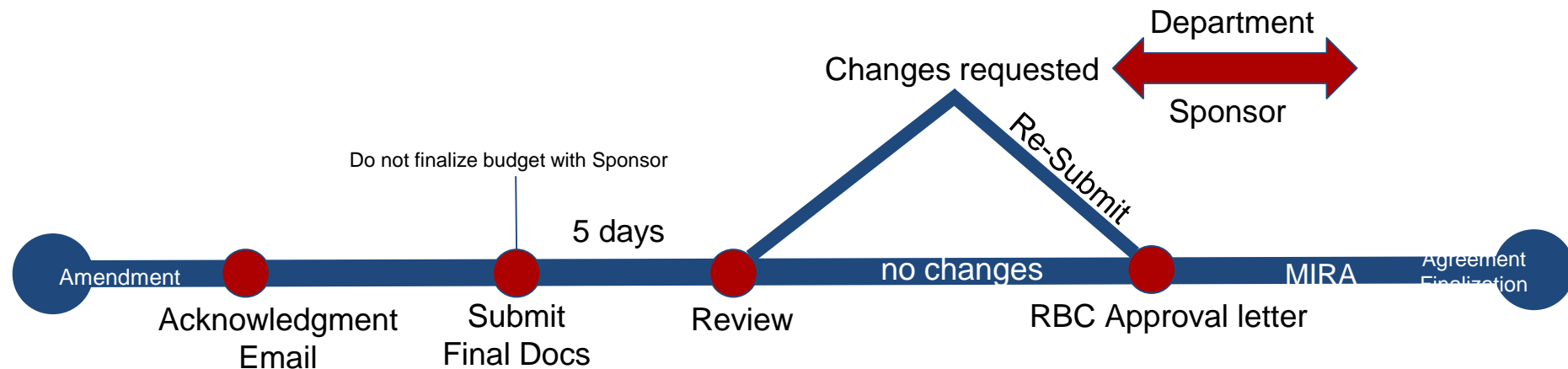
RBC Reviews - Submission

- Final draft budget
- Final draft ICF
- Final MCA
- Final internal budget
- Provider price request forms
- Final Protocol
- UMC QCT form, if applicable



Submit all documents to ccdfin@louisville.edu

RBC Reviews - timeline



What are some common compliance issues?

Examples

Medical Coverage Analysis (MCA)

- Items paid by the sponsor in the contract are not correctly stated in MCA
- Items promised free of charge to the participant in ICF are not correctly stated in MCA or the sponsor budget
- Remaining items that are “routine costs” and their billable status do not match the sponsor budget

Examples

Medical Coverage Analysis (MCA)

- Site location and billing references/guidelines are missing
 - National Coverage Determinations (NCDs)
 - E.g. - NCD 310.1: Routine Costs in clinical trials
 - Local Coverage Determinations (LCDs) for CGS Administrators
 - E.g. - L 33959: Cardiac Catheterization and Coronary Angiography
 - Guidelines
 - National Comprehensive Cancer Network (NCCN)
 - Associations, Societies, Networks, etc.

Examples

Informed Consent Form- Cost language submitted version

You will not be billed for

- The study drug (XXXXXX)
- Additional visits, tests or procedures that are required solely for this study (ask the study staff to discuss these with you)

The charges for these items will be paid for by the Sponsor.

The study contract budget and MCA state the Sponsor is not covering the cost of study drug administration. The sponsor is only supplying the study drug free of charge.

Examples

Informed Consent Form- Cost language revised version



You will not be billed for

- The study drug (XXXXXX) – *please note, the cost for the IV administration of the drug will be billed to you or your insurance company*
- Additional visits, tests or procedures that are required solely for this study (ask the study staff to discuss these with you)

The charges for these items will be paid for by the Sponsor.

Examples

Informed Consent Form- Subject injury language

Conditional Language:

“The sponsor shall pay for all medically necessary services to diagnose and treat injury arising from participation in the trial if the subject’s insurance rejects coverage of the service.”

Conditional payment language has been typical in Sponsor draft contracts



Never

NEVER ACCEPT CONDITIONAL LANGUAGE!



Never

Examples

Informed Consent Form- Subject Injury Language

“Subject injury” language should be consistent in the CTA and ICF:

- Sponsor pays (no conditional payment language) for any reasonable medical costs related to the treatment of the injury



- Medical treatment will be provided
- Insurance or participant will be billed for the medical treatment provided

Examples

Informed Consent Form- Stipend

- Important question to ask when a stipend is being offered and the amount
 - Stipend amount and time points in ICF do not match the contract budget exhibit or the exhibit does not show any information about the stipend payments or the budget does not include stipend payments at all
 - Stipend is not included in the “Internal Budget Document” if the sponsor is not providing a line item budget
 - Stipend amounts in the budget do not include card processing fees and/or institutional overhead

Examples

Sponsor Budget- Provider Pricing

- Hospital procedure costs, radiology costs, admin fees, technical & professional components, pharmacy fees, etc. are not fully covered in sponsor's budget
- Institutional overhead is not added on top of provider's costs and fees

RBC Reviews - reviewers



ccdfin@louisville.edu

Serra Bayraktar 852-6993

Melissa VanArsdale 852-2158

Allyson Turner 852-3808



Questions?