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MGB Clinical Research Billing Compliance Manual

In order to comply with federal, state, and institutional regulations, Mass General Brigham and its member institutions are responsible for establishing effective processes to ensure that all study-related services are billed properly. These processes are often complex as costs associated with research-related clinical services can be incurred at multiple MGB organizations over the course of a trial. In addition, clinical research often takes place in conjunction with routine care visits for patients in trials, making it essential that billing for each service is appropriate and accurate. Research billing compliance requires a coordinated effort between the Principal Investigator (PI), study staff, department administrators, and research compliance. This manual provides a step-by-step guide to assist investigators and research staff with conducting research billing accordingly.

Clinical Research Billing Compliance

Clinical research billing compliance is the process of ensuring that all clinical services related to a research study are billed appropriately and in accordance with

- All applicable federal, state, and third-party regulations
- All study-related materials, including the sponsored agreement, informed consent form, and study budget
- All MGB policies and procedures

The convergence of research and clinical care reimbursement in clinical research trials necessitates regulations to prevent improper billing of federal health care programs and violating the Federal False Claims Act, the penalties of which are severe. Ensuring compliance with billing regulations is essential to maintaining MGB's commitment to achieving the highest ethical and legal standards in the conduct of research. The regulations stipulate

- Do not bill for services that have already been paid by the sponsor (double billing)
- Do not bill for services that are required for research purposes only
- Do not bill for services that were promised free to the subject in the informed consent form

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Medicare Qualifying Trial Determination

At MGB, the Clinical Trials Office (CTO) is tasked with determining if a study meets the requirements of a Medicare Qualifying Trial (MQT) before billing for any routine costs associated with the study.

According to the CMS Clinical Trial Policy (CTP) National Coverage Determination (NCD) 310.1, a study is considered qualifying if it meets three requirements

- The purpose of the study must be to investigate an item or service that falls within a Medicare benefit category.
- The study must have therapeutic intent.
- The study must enroll patients with a diagnosed disease.

Medicare may cover the routine costs of qualifying clinical trials if the costs are

- Typically covered outside of the context of a research study, e.g., conventional care
- Reasonable for the prevention, detection, and treatment of complications
- Required for the administration of the investigational item

For Medicare qualifying device trials, CMS requires an application be approved prior to any Medicare billing associated with the trial.

- For Category A Investigational Device Exemption (IDE) studies, coverage for routine care and services provided in the study is allowed, but costs of the device itself are excluded.
- For Category B IDE studies, coverage is allowed for the device itself and any routine items or services provided in the study.

Medicare Coverage Analysis

The CTO is responsible for conducting a Medicare Coverage Analysis (MCA) to determine eligibility for coverage of study-related items or services. The MCA is a detailed independent review of clinical research items and services to be provided

as part of a trial to establish the appropriate payor for each. MGB requires the MCA be completed before the IRB study protocol can be activated.

The CTO is notified through the MGB IRB that an MCA is needed if the protocol requires routine care. The CTO reviews the protocol to determine whether the study is qualifying, and if so, determines coverage eligibility for each item or service specified in the protocol based on local and national Medicare rules. Routine Costs are determined through a review of the protocol and standard treatment guidelines in consultation with the Principal Investigator and study staff.

The CTO creates a billing grid that mirrors the protocol schedule of events and includes notations of what should be billed to the research sponsor and what may be billed to Medicare. This billing grid becomes the guide for appropriately directing clinical research charges. The CTO reviews the study budget, sponsor agreement, and informed consent form to ensure language regarding any financial responsibilities delegated to the sponsor or study subjects is consistent and reflected accurately in the billing grid.

For those studies deemed ***not*** qualifying, ***all research-related clinical items or services must be billed to the research study fund.*** Usual and routine clinical services provided around and during the trial may be billed to Medicare in the usual manner.

For IDE studies, the CTO prepares and submits a petition to the CMS Fiscal Intermediary for review and approval. No Medicare patient may be enrolled in the trial until the CMS Fiscal Intermediary has approved the study or an alternative funding source has been identified for research-related expenses.

Epic Integration

Research charge allocation occurs in Epic. Epic must have an active study code before patients receive any research-related patient care services. The Epic study code is the IRB protocol number + study fund number. To generate a study code in Epic, the study fund must be linked to the associated IRB protocol in Insight and the status of the IRB protocol must be active. If the linkage did not occur at the time of IRB

submission, the study team will have to submit an amendment to the IRB in Insight to link the protocol to the fund. Once the linkage is active, Insight automatically sends the information to Epic to create a new record with the study code.

If you are activating a DFCI protocol that is NOT overseen by the CCPO, you must submit a ticket to the DHeC Research Team with your fund number in order to activate your study.

Charge Direction in Epic

The process of ensuring appropriate patient care charge allocation involves four steps.

Enrolling the subject to the study in Epic. As soon as the subject signs the informed consent form to indicate their willingness to participate in the trial, they need to be associated with the study in Epic. The subject is added to the research study by locating the study code in the "Add new research study" button in Epic and updating their status to "Enrolled". Identifying a subject as enrolled in the study in Epic allows for research-related patient care charges to be associated with the study. A signed copy of the informed consent form will need to be uploaded to the patient's Epic record using the Media Manager import function.

Linking research-related encounters to the study in Epic. Once the patient is associated with the study in Epic, all research-related patient care encounters and orders must be linked to the study. This includes any standard of care encounters that will be used for research. Linking the encounters to the study lets Epic know that the charges are associated with research and should not be released until after the study team reviews them. Upcoming encounters can be linked to the study by highlighting the relevant encounter, clicking the "Link to Research Study" button, and selecting the appropriate study from the pop-up box. Orders associated with the encounter can be placed on the Encounter Visit Task Bar by selecting the "Add Order" tab. The Research Association button is located in the "Options" menu in the Order Composer.

Of note, it is common for clinical research and usual care services to be performed in conjunction with one another. If even a single research-related service is to occur during an

otherwise usual care encounter, the entire encounter must be linked.

Reviewing and approving charge allocation. If there are any encounters linked to the study in Epic, the system will hold all the patient's charges for that date of service (or for the duration of the admission, if the subject is inpatient at the time) in the study's "Research Billing Review" (RBR). A member of the study team will run the RBR report, and, using the study billing grid as a reference, review the charges and direct each to bill insurance/patient or the study fund, as appropriate. Once accurate charge direction is confirmed, select "Mark Account as Reviewed". This releases all the charges for that patient to the appropriate payer. Charges should be reviewed within 7 days of posting to Epic. Study staff should run the Research Billing Review Report 2-3 times a week.

Confirming accurate charge direction in Insight. All charges directed to the study fund will be viewable in the "Patient Care Charges" page in the Agreements module in Insight. A member of the study staff with access to the "Patient Care Charges" page should confirm accurate charge direction in Insight every month.

Research Discount for Pro and Tech Charges. The research discount for patient care charges is applied to each charge once it is posted to Insight. Research discount rates are institution-specific and are based on the hospital providing the service and not the hospital where the patient is enrolled into the study if the two sites differ. If different discount rates are observed during the review of charges in Insight, research staff should confirm the location of the services provided by either reviewing the Research Billing Review in Epic or reviewing the patient's EPIC record.

Charge Direction Error

Suspected or discovered errors in research-related patient care charge allocation can be corrected via a Patient Care Corrections (PCC) request in the Agreements module in Insight. Any member of the study staff team who has access to the "Patient Care Charges" page can submit the correction.

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If there are any concerns about any patient care charges associated with the study, contact MGB Clinical Trial Billing (mgbclinicaltrialbilling@mgb.org) to request an audit of the study's billing history.

Change in Study Fund Number

If the study fund is updated for any reason, e.g., contract amendment or new enrollment period, an IRB amendment will have to be submitted in Insight to link the protocol to the new study fund number. When the amendment is approved, Insight will automatically send the updated information to Epic to create the new Study Code.

If there are currently patients enrolled to the study and charges have been applied to the old fund, those patients will need to be enrolled to the new study code in Epic and their status updated to "Complete" in the old/expired study code.

Before updating patient status to "Complete" for the old study code, make sure all outstanding charges from patients who are enrolled have been cleared. The old Study Code in Epic will then need to be closed using the procedures below.

Epic Study Fund Closeout

When the research fund has ended, the Epic study record needs to be inactivated to prevent any future costs from being erroneously charged to the fund. The Epic study record should be closed when its associated fund is ending as part of the award close out process. Once the project has expired, the fund account can be inactivated after all payments have been received, all expenses have been charged appropriately, and the fund balance is zero dollars.

Prior to initiating close out of the Epic study record, a member of the study team must first confirm that all outstanding charges from patients who are enrolled have been cleared and the enrollment status for all patients associated with the study in Epic has been updated to "Complete".

To close the Epic study record, open a Service Now ticket from the Digital Service Hub homepage to request the study record be completed in Epic.

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The protocol number, study fund number, and study code number are required to complete the request. In the detail request field, include statements confirming that the Epic study record needs to be closed, that all patients have had their enrollment status changed to completed, and that all research billing has been processed on patients enrolled to this study. A confirmation email will be sent confirming that the record closure has been completed. This email should be forwarded to the department administrator so that this can be documented as part of the overall award closure process.