Research Billing Compliance: Bridging the Gap

ASSESSMENT OF POTENTIAL RESEARCH BILLING COMPLIANCE RISKS AND IMPLEMENTATION OF PROCESSES TO MITIGATE RISKS

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BACKGROUND

Intermountain Healthcare is a not-for-profit health system with a robust clinical research program. The Office of Research consists of administrative staff with responsibility to oversee research operations and provide support services, including research billing compliance oversight. The current research billing team is relatively new (ranging between 5-18 months in the role). With little knowledge transfer from the previous team and few written procedures for guidance, it was necessary to re-examine institutional processes to ensure Research Billing Compliance.

METHOD

Existing resources were reviewed to assess the current status of Research Billing Compliance and identify potential risks. New processes were then implemented to address these risks and improve accuracy and compliance. As more information becomes available, processes are updated or refined further.

REVIEW AND IMPLEMENTATION

RESEARCH ACCOUNT HOLDS

SOURCE: Weekly report of research account holds. This report includes data from our Clinical Trial Management System (CTMS) identifying research patients by Medical Record Number (MRN) who have completed study visits in the previous week, compared to data from Electronic Medical Records (EMR) on accounts that have been placed on a research hold during the same time period. A list for review was generated based on patients who had a research visit, but no account held.

ASSESSMENT: Initial review showed a very low rate of missed account holds (<1%). However, further scrutiny of account data showed that it did not include patients who had an account held. Thus, it could not be verified for this larger group of patients whether the account placed on hold was the correct or only study-related account.

MANAGEMENT: Report was expanded to review all accounts during the report period that had not been held, for patients who had completed a study visit in that same time period. Over a period of one year, the expanded review has continued to show a very low rate of missed account holds (<0.5%).

DOCUMENT ALIGNMENT AND CTMS CONFIGURATION

SOURCE: Internal audit. Institution's internal audit department conducted an audit to assess billing accuracy for sponsored clinical trials. Audit was performed in accordance with the Institute of Internal Auditors International Standards for the Professional Practice of Internal Auditing.

ASSESSMENT: Audit revealed multiple areas for improvement, including lack of a standard process for document and CTMS reconciliation and insufficient oversight of billing processes for new study implementation.

MANAGEMENT: A new intake form was created for coverage analysis review. This allowed for upload of supporting documents—contract/budget, informed consent form (ICF), and protocol, to be reviewed alongside the coverage analysis to ensure alignment. Procedures or items that are paid by the sponsor in the budget are verified as study-paid in the billing grid. The cost language of the ICF is reviewed to confirm that it is consistent with the coverage analysis. The protocol is reviewed to ensure that billable procedures at all timepoints are accounted for in the billing grid.

To further validate the CTMS study set up, it is audited against the coverage analysis. Any inconsistencies between the two must be resolved prior to activating a new study in CTMS. Additional monitoring of the first patient enrolled was also implemented. The research billing team reviews several factors, including verifying that billing notifications are sent, that procedures are correctly allocated as study-paid or standard of care (SOC) for the visit, that the correct account information and date of service is documented, and that the account hold is placed in a timely manner.

REVIEW
Source Information

- Research patient accounts and account holds data from EMR
- Study visits completed in CTMS
- Compliance audit of claims
- Internal audit
- Billing errors reported by study staff

IDENTIFY
Potential Risks

- Discrepancies between coverage analysis, ICF, contract/budget
- Account holds
- Charge review and itemization of study-paid/SOC charges
- CTMS set-up

IMPLEMENT
Processes to Address Gaps

- New intake process to facilitate review of document alignment
- Audit of CTMS set-up
- Monitoring billing for the first patient enrolled in each trial
- Expanded monitoring of research accounts
- Second review of charge itemization
- Education to address most frequently reported errors

EVALUATE
and Refine

- Are new processes effective?
- Are they feasible to maintain?
- Are new issues identified after additional monitoring?
- With new information, continue to identify risks and update processes as needed.

REVIEW AND IMPLEMENTATION CONT.

TIMELY COMMUNICATION OF BILLING INFORMATION

SOURCE: Monthly report of CTMS visit entry times. Completing visit entry in CTMS results in an automatic notification to billing staff, prompting them to address study-related accounts. Thus, timely entry of these visits is critical to routing charges correctly. Institutional standard operating procedure states that visits should be entered within one business day of completion. Reports pulled on the first of the month include all visits occurring within the past month.

ASSESSMENT: Average times of around 2-3 days seen on reports were not initially considered a significant risk. But it was later realized that visits occurring within the month but entered in a later month were not accounted for. Reports were revised to capture all visits entered within the month, which would include visits occurring in a previous month. This revealed some late entry times that could have resulted in incorrect initial billing and a correction required.

MANAGEMENT: Report is disseminated to research department managers on a monthly basis, with late entries and studies showing trends toward late entries highlighted. This feedback is shared with their study teams to increase awareness and correct for recurring issues.

CHARGE REVIEW AND ALLOCATION

SOURCE: Compliance audit of claims. The institution's compliance department completed an audit of charges for 3 studies. No errors were found on review of two of the studies, but a slightly higher than acceptable error rate was found on the third study reviewed. This led to auditing a fourth study of the same type, with similar results.

ASSESSMENT: The research billing team reviewed the errors and categorized by error type. The most prevalent error seen was incorrect itemization of charges; charges that should have been study-paid were not marked as such in the charge review, resulting in incorrect billing.

MANAGEMENT: In addition to correcting the charge errors, a second review of charges was implemented. After the charges are assessed and allocated as either study-paid or SOC, another study coordinator verifies accuracy. The research billing team also began monitoring a percentage of the itemizations to further ensure accuracy. If errors are found, corrections are requested and feedback is provided to the study team.

STUDY COORDINATOR TRAINING

SOURCE: Billing error tracking and coverage analysis. The research billing team tracks reported errors to look for trends and areas of concerns.

ASSESSMENT: The majority of errors reported fell into three categories—study account not flagged; late or missed CTMS entry of a study visit; or wrong account information listed in CTMS. These areas are generally the responsibility of the study coordinator. Recent turnover in study staff may have contributed to a lack of understanding in these areas.

MANAGEMENT: Training was developed to educate study coordinators on research billing processes and the importance of correct and timely entry of CTMS visits and flagging study accounts. Study coordinators across all research departments participated in this training.

OUTCOME

Monitoring, oversight, and education have helped bridge the gaps in Research Billing Compliance processes and knowledge at our institution. Continued surveillance will aid in identifying and correcting issues early. As new issues arise, processes can be adapted to better ensure billing compliance in the research program.