



Clinical Research Billing Compliance

ROLE OF OFFICE

The Clinical Research Billing Compliance (CRBC) department assures compliance with regulations and policies at the federal, state and health system level during our review of all billing for patients associated with clinical trials taking place within Johns Hopkins Medicine facilities. Working closely with study team personnel, Clinical Research Support Services, Revenue Cycle Management, the Epic Project team and other key stakeholders we ensure orderable, chargeable items correctly route to patient insurance coverages or the study account

Leadership

Scott A. Streibich, Director

Liza Rodriguez, Associate Director

Pat Robertson, Manager

PERFORMANCE IN THE PAST YEAR

Our compliance function serves any clinical trial that may incur a physician or hospital related charge at a Baltimore/DC area academic/community hospital or outpatient site. In FY2018, the CRBC adjudicated over \$260M in charges for studies with a Prospective Reimbursement Analysis (PRA). The 27,282 active patients subject to review represent a 24.5% increase over FY2017. In FY2018 1,237 studies with PRAs fell under our review, representing 528 Principal Investigators.

While our workflow activities continue to grow over the last 12 months, our team has improved efficiency and accuracy. In addition, since the beginning of the Epic implementation in 2013 we have slashed our average days of revenue held from 13.5 overall to 7.7 in the last six-month period. This improvement represents an increase of \$2.5M per day released from review compared to the five-year average since Epic became our billing environment.

Clinical Research Billing Compliance staff developed and maintain the online training in MyLearning called "Clinical Research Billing Orientation." Passing the orientation module is a requirement for all study team members if the study has a PRA. In the past twelve months, 879 individuals completed training - a 13.9% increase over FY2017, when 772 study team personnel completed the training activity.

CRBC Management team members present portions of the Clinical Research Revenue Cycle Training, a half-day "deep dive" for study coordinators and Investigators providing an interactive format to learn about crucial compliance and billing processes at Johns Hopkins Medicine.

CHANGES IN THE PAST YEAR

Our team recently enacted JHM policy on ensuring compliance with the CMS 60-Day Overpayment Rule. Recent US Senate hearings highlight government efforts to ensure recipients of Medicare and Medicaid funds promptly report and return overpayment funds.

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

Epic's Single Billing Office will go live in July 23, 2018 and will bring new challenges to our workflows. Statements for Hospital and Physician services charged to research study budgets have undergone redesign, combining both elements into one document sent to study financial personnel for payment.

A pilot effort is underway using Epic's Encounter Linking workflow to trigger the prospective review of research related charges instead of the patient-level hold now in existence. A sample of all PRA=YES studies will be evaluated on encounter linking compliance to determine enterprise readiness for the change. All study teams should continue to use the encounter linking processes that were part of their initial training needed to secure an Epic research security template role.

This change will allow for improved identification of encounters, orders and charge level data for reporting purposes related to research participation. A key revenue cycle improvement will be a reduction in charges unrelated to research from hold and review, further improving financial performance through faster collection of payments from insurance company and patient co-payments.

BEST WAY TO WORK WITH PROGRAM

We have a process in place to perform a focused review of study related billing, insurance clearance, compliance workflows and best practices with your study team when your first study patient charge is identified for our review. The goal is to support patient enrollment and satisfaction while at the same time ensuring adherence to all compliance requirements.

Our department maintains a website of essential contacts, resources and links accessible at: <https://www.hopkinsmedicine.org/research/resources/offices-policies/CRBC/resources.html>. Please reach out to us for help with any research billing related concern about a patient.