

Clinical Research Billing Compliance: Truths, Myths and eNOTIS/eSPRV updates

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Summary

- What is Clinical Research Billing (CRB) Compliance?
- Northwestern Medicine CRB Systems, Tools and Processes
- Northwestern Medicine Roles and Responsibilities (PI versus Institution)
- eNOTIS and eSPRV updates

How is CRB Compliance defined?

- General billing compliance: Adherence to the billing, coding & documentation rules/regulations set forth by Center for Medicare and Medicaid services
- Research billing compliance is essentially a subset of general billing compliance
 - Identifying services that can or cannot be billed to 3rd party payers
 - Ensuring processes are in place to bill the appropriate party (sponsor versus insurance)
 - Ensuring that study documents are in alignment with billing regulations
- In the context of a research study CMS rules are often applied as the 'Gold Standard' regardless of the patient's insurance

CRB Compliance Importance

Benefits of CRB compliance include, but are not limited to.....

- Within regulatory boundaries it clearly delineates the roles and responsibilities:
 - WHO IS PAYING FOR WHAT? SPONSOR, INSTITUTION, MEDICARE OR OTHER PAYER, PATIENT
- Helps to establish a solid budget and may be helpful in negotiation with Sponsors
- Provides transparency to the Patient during the Informed Consent Process
- Ensures consistency in research and financial documentation
- Helps to ensure equal treatment of all patients and payers

CRB Compliance Importance

- Increased Regulatory Scrutiny on CRB compliance
- Office of Inspector General (OIG) Work Plans have often included Clinical Trial Billing in its top compliance initiatives.
- Remains an element in current and proposed enforcement agenda.

“A problem related to the failure to accurately and completely report support from other financial sources in the charging of both award funds and Medicare and other health care insurers for performing the same service. This is clearly improper and has subject institutions to fraud investigations.”

(Draft OIG Guidance for Recipients of PHS Research Awards 11/28/2005)

CRB Compliance Importance

False Claims Act

Title 31 USC 3729-3733 passed Congress on 3/2/1863

The False Claims Act provides that liability may be imposed:

- On any person who knowingly presents
- Or causes to be presented to the United States,
- A false or fraudulent claim for payment or approval

CRB Compliance Importance

False Claims Act may be triggered by inaccurate billing:

- Double Billing (Sponsor and Medicare/Insurance/Patient)
- Billing for services that are not qualifying, promised for free in IC, research only
- Billing Medicare Advantage plans instead of the Medicare Contractor

Variety of risks that may affect:

- Research Participant
- Success of current and future Research studies
- Research Investigator
- Research Staff
- Institution

CRB Non-Compliance Risks

Participant: Overall Patient Dissatisfaction and undue financial burden

Current and Future Studies: Research patient withdrawal from studies and longer term repercussions for study enrollment due to research subject dissatisfaction

Institution, Principal Investigator, Research Staff:

- Loss of Research Funding
- Criminal/Civil sanctions
- Fines and Penalties
- Marred Reputation
- Suspension of Operations
- Exclusion from Federal programs
- Rework for all campus partners
- Research Staff Dissatisfaction
- Qui Tam

CRB Regulations

THE FOUNDATION:

The Clinical Trials National Coverage Decision (NCD) was issued in September 19, 2000 after a presidential directive to develop rules allowing for the coverage of services during clinical trials.

NCD for Routine Costs in Clinical Trials (310.1)...

Medicare will cover 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.

CRB Regulations

Clinical Trial NCD 310.1 continued.....

Routine Costs:

- Conventional care items and services typically provided absent a trial
- Administration of the investigational item or clinically appropriate monitoring of the effects of the item or service or the prevention of complications
- Items and services for the diagnosis or treatment of complications

Non-Routine Costs:

- Investigational item and service itself (unless covered outside a trial)
- Items and services provided solely to satisfy data collection and analysis; not used in the direct clinical mgmt of the patient
- Items/Services provided for free or paid for by the sponsor

Basic Components of CRB Compliance

Must have a mechanism for identifying :

- (What) **Research Study**
- (What) **Clinical items/services administered under the protocol**
 - Protocol requirements
 - Study Budget, Consent, CTA
- (Who) **Research Participant**
 - Consent and Tracking
- (Who, Where and When) **Encounter**
 - Registration/Scheduling and Tracking
- (What , Who ,Where and When) **Clinical items/services administered under the protocol**
 - Patient Study Calendar
 - Charge separation
 - Coding and Billing

Tools and Processes: NMH

NMH Protocol Review Form- Medicare Qualifying determination:

Uploaded in eIRB at time of New Project submission

All of A) and one of B)

A) 3 Necessary Requirements

- Does study have a therapeutic intent? (not only toxicity)
- Does the investigational item/service fall in a Medicare benefit category?
- Do the subjects enrolled have a disease diagnosis?

B) Deemed to have 7 Desirable Characteristics

- Funded by NIH, CDC, AHRQ, CMS, DOD or VA
- Supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD or VA
- Conducted under IND
- Exempt from having an IND

Tools and Processes: NMH

NMH Research Account Activation:

- **NMH Research Budget Form**

- Submitted to NMH Office of Research in parallel with New Project Submission
- 70XXXX NMH research account # issued after IRB approval
- A Special (S) registration (associated with the 70XXXX) is created by NMH staff if the outpatient encounter involves charges conducted under a research protocol that are not billable to patient/insurance
- Research charges are posted to the (S) account associated with the 70XXXX

Tools and Processes: NMFF

NMFF Research Account Activation:

- **NMFF Study Account Budget Registration Form (SABR)**

- Submitted to NMFF Physician Billing Department via email (nmffclinicaltrialbilling@nmff.org)

- Study account information verified (CPT codes, fees, contact info, etc.)

- 60XXXX or 000070XXXX NMFF research account # issued after IRB approval

- The research team is notified by email that the study account is active and is entered in eNOTIS

- EPIC generates a research guarantor account for billing (listed by NU IRB #)

- Research services (CPT Codes) from the SABR are entered in EPIC for charge capture

- Charges are posted to the study account by NMFF Billing Staff

Tools and Processes: NMH

NMH Receipt of Encounter Notification:

•**NMH Research Registration Form-** Inpatient/Bedded Outpatient

- Study Coordinator completes the appropriate registration form (CRU or non-CRU) for every research patient admitted to a bed and faxes the form to NMH Admitting and Registration at 6-8111
- This form enables NMH to identify the patient as research (using a research “Co-Plan” number- 09-400) so the individual’s bill will be held until the research charges can be appropriately separated from the standard of care charges.
- PI/Study Coordinator will receive copy of itemized bill to identify research charges
- Research charges are separated and invoiced to PI
- Conventional care items are billed to patient’s insurance

Tools and Processes: NMH & NMFF

NMH & NMFF Receipt of Encounter Notification:

- **e-Study Participant Research Voucher (eSPRV)-Outpatient**

- Study Coordinator completes the eSPRV form for every outpatient encounter date for each patient for both NMH and NMFF services
- To be completed for each patient at every outpatient encounter and submitted within 1 business day of the NMH/NMFF service being performed.
- Form Notifies NMH and NMFF of patient identity, encounter date and research service(s).
- eSPRV template can be mocked up to mimic NMH/NMFF research budget. At each encounter, patient information can be filled in and appropriate services/sites checked off.

Tools and Processes: NMH

Receipt of Encounter Notification cont'd:

- **eNOTIS/PRIMES Report**

- All research participants registered in eNOTIS that had an NMH encounter within the last 24 hours
- Report also includes 24 hr encounter activity of patients with prior history on NMH research accounts in PRIMES.

- Results in encounter flagging and bill hold processes

- **Bill Hold Report**

- Charge verification and separation processes
- Research services billed to Research Account

Tools and Processes: NMFF

Receipt of Encounter Notification cont'd:

- eNOTIS-EPIC Interface

- Essential for research teams to enter study information such as Study Name, PI Department, and Submission Preparer in eNOTIS

- All research participants properly entered in eNOTIS will be associated to the study guarantor account in EPIC

- Results in encounter flagging and bill hold processes in EPIC

- EPIC will associate a patient to a study and hold charges when:

- Patient is identified as clinical trial participant on a study in eNOTIS based on the following criteria:

- Valid NMFF MRN

- Patient name

- Date of birth

- Study Status (subjects not listed as Withdrawn, Deceased, Completed)

Tools and Processes: NMFF (cont'd)

- CPT code matches code(s) listed on study budget, AND
- Pending charge is queued to bill the patient or to the patient's insurance
- Charge verification and separation processes
 - Verified research charges will be billed to the research 'guarantor' (study account)
 - Verification will occur via SPRV/eSPRV or CRC confirmation of research charges
- Research services billed to Research Account (a guarantor in EPIC)

July 19th 2011 Memorandum

Participants in clinical research studies are one of the most important components of our research enterprise. One of our foremost obligations to them is to make our best efforts to protect them from harm, whether physical, emotional or financial. A key element of this protection is to better identify them during clinical encounters where appropriate knowledge of their participation might be required to allow the best clinical care and to incorporate this information into our financial systems to assure they or their insurance providers are not inappropriately billed for services that are part of the research study. It is clear that we can and must improve our current practices.

A wide range of faculty, research staff and administrative staff from Northwestern University (NU), Feinberg School of Medicine (FSM), Northwestern Memorial Hospital (NMH), and Northwestern Medical Faculty Foundation (NMFF) have been working together to develop processes for improving our ability to identify participants in clinical trials and other clinical studies to assure proper billing. Based on this input the eNOTIS tool will be used as the central repository for all individuals enrolled in clinical trials or clinical studies. The goal of this system is to allow NMH and NMFF to identify patients participating in clinical studies in their clinical and financial systems. In order for NMH and NMFF to have an accurate list of clinical research subjects - **all research participants in active clinical studies using NMH and/or NMFF medical services must be entered into eNOTIS by 8/31/11.** Medical services include all research related billable tests or procedures used for research eligibility screening and diagnosing or treating disease. Research personnel will be required to enter a medical record number or a limited amount of demographic data into eNOTIS for all research subjects. In addition, **a new standardized Study Participant Research Voucher (SPRV) will be instituted and**

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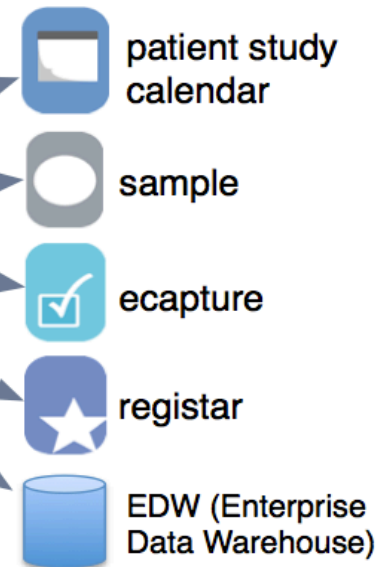
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Tools and Processes: NU

The benefits of eNOTIS

- Storing participant name, DOB, MRN, Case #
- Capturing NIH-coded gender, race, and ethnicity and generating NIH Inclusion Enrollment report
- Tracking participant status (consented, etc...)
- Exporting a study participant list to CSV
- Help identify if participants are on multiple trials
- **Participants enrolled in eNOTIS can be accessed by other NUBIC systems**

Other NUBIC systems can schedule visits, track samples, collect data, or generate EDW reports based off eNOTIS)




eNOTIS/eSPRV Updates:

- All MRNs are now validated against NMH/NMFF EMRs
- All MRNs that could not be validated are have been purged from the system
- eNOTIS no longer permits manual entry/editing of MRNs
- We provide a search facility that allows MRN cross walking as well as searching by Name/DOB

eNOTIS/eSPRV Updates:

 Subjects  Reports/Export  Settings  Charts

Search Medical Record

NMH  85862232 Find

-OR-

Warren Kibbe 2013-06-13 Find

eNOTIS/eSPRV Updates (Dashboard):

eNOTIS	Dashboard	Reports ▾	<input type="text" value="irb number/title"/>	<input type="button" value="search"/>
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Alerts

Studies

Urgent

- [SPRV Action Required for NJENGA, JAMES Date of Service - 2013-02-05](#)

To Do

- [SPRV Pending for ZZ, TOP Date of Service - 2013-08-12](#)

eNOTIS v6.1.0 — created by [NUBIC](#) for Northwestern University

eNOTIS/eSPRV Updates(coming soon)

- Research Budgets/SABRs
- Calendar

Per current mandate, what research subjects need to be entered into eNOTIS?

1. Patients using NMH services only
2. Patients using NMFF services only
3. All patients in active clinical research studies using services at NMH and NMFF
4. I think it depends

Within what timeframe must I enter my research subjects into eNOTIS?

1. At the time of signing consent
2. No later than 1 business day after signing consent
3. I am busy- I will enter them whenever I get to it

Should screen fails be entered into eNOTIS?

1. Yes
2. No
3. Unsure

My study is an observational study with medical services at NMH, but the services are all standard of care. Do I need to put my patients into eNOTIS?

1. Yes
2. No
3. Maybe

When do I need to submit an eSPRV for research services at NMH/NMFF?

1. Before the service is rendered.
2. No later than 1 business day of service rendered.
3. I am busy. I can enter them whenever I get to it.
4. Both A and B

My patient is getting specimen collected (eg. blood draw) at their clinic visit, but it will be processed at an off-site facility.

Do I need to submit an eSPRV?

1. Yes
2. No
3. Maybe

I still need to submit a SPRV if my study will be conducted exclusively in the Clinical Research Unit.

1. True
2. False
3. Unsure

My study only uses inpatient services.
Is it required by the current policy for me
to submit a SPRV?

1. Yes
2. No
3. Unsure

Roles and Responsibilities

PI and Research Staff:

- Perform preliminary Medicare Qualifying determination (NMH Protocol Review Form checklist)
- Ensure non-conventional care and research items/services are clearly identified as being paid for by sponsor in study budget, NMH/NMFF budgets, IRB approved consents & executed CTA; **Ensure all documents are in alignment**
- Obtain NMH/NMFF Research Accounts before initiating clinical activities
- Promptly submit updates to NMH/NMFF budgets and responsible study personnel
- Enter consented research participants into eNOTIS
- Place research consent in the Medical Records
- Notify NMH/NMFF of encounters (Registration Forms & eSPRVs) and provide timely response to verification requests

Roles and Responsibilities

Clinical Service Providers (NMH and NMFF):

- Validate Medicare Qualifying status
- Activate Research Account and issue # to study team
- Process research encounter notifications
 - Registration Forms
 - eSPRVs
 - eNOTIS reports
- Flag/Bill hold encounter
- Review, Verify and separate charges
- Perform appropriate coding and billing

Q&A Session