DOCR Study Initiation Process

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December 11th, 2013 | Duke North 2001

What is it?
- The DOCR review process for new studies
- The goal: to foster a collaborative environment assisting study teams in navigating all regulatory and institutional requirements for clinical research
- Effort to break down silos

Historical process
- Prior to July 8th, 2013, a billing grid and fund code were the only requirements for DOCR review
  - Study teams built grids and submitted them to DOCR for review – limited conversation
  - DOCR provided approved grid and fund code to PRMO for manual review of research charges
Transition to new process

- Need for a collaborative system study start-up, and an opportunity to bring the expertise of other offices to the study review process:
  - DUHS Compliance
  - SOM Ethics and Compliance
  - SOM Finance
  - PRMO
  - Contracts (ORA)
  - Study Teams/CRU

Transition to new process (cont.)

- The implementation of Maestro Care provided opportunity for change
  - Building of MC billing calendars, order sets, and treatment plans
    - Demands more accuracy
    - Provides more transparency

Maestro Care implementation

- Maestro Care build needed to facilitate study enrollment activities
- Coordinated effort between study team, investigational pharmacy, and DOCR
Understanding the lingo

- RSH record: the study’s research administration record in MC
  - Users and providers
  - Fund code and other billing groupers
  - Linked to the billing calendar
- Billing calendar: the “behind-the-scenes” interface that directs charges
  - The “timeline” to which research encounters should be linked

Maestro Care migration

- For already existing studies, the approved grids were converted into “grillendars” from which billing calendars and order sets were built
- Once built, require face-to-face validation
- Validation sessions still ongoing

Evolution of the grid

- The Excel spreadsheet of study activities and charge assignments has evolved.
New Study Initiation Process

- Facilitate new study start up within DUHS
- Identify study related clinical activities and Maestro care needs
- Qualifying status and Medicare coverage analysis
- Review billing requirements and charge assignment
- Identify opportunities for organizational improvement

The Review Process: Nuts and Bolts

Identifying studies for review

- DOCR regularly queries eIRB for newly submitted studies and performs a preliminary review of study documents to determine if a Maestro Care build may be required
- An email to the CRC and PI (with the RPM and FPM copied) is sent to the study team
  - “Response Requested: Pro000XXXXX PI Last Name/Sponsor DOCR Study Set-up”
- A preliminary assessment of MC build needs is made, with option for study team to appeal
Preliminary Assessment

- Three categories of studies:
  1) Study not requiring MC billing calendar or order set, and not consenting Duke patients
    • Retrospective studies
    • Analyses of banked specimens
    • No MC component is required for these.

Preliminary Assessment (cont.)

2) Study not requiring MC billing calendar or order set, but consenting Duke patients
   • Interviews/Questionnaires
   • Research blood drawn by study staff
   • An RSH record is created in MC so that subjects may be associated.
   • Fund code requested for RSH creation.

Preliminary Assessment (cont.)

3) Study requiring MC billing calendar and/or order set
   • All studies with investigational drugs or devices
   • Labs resulted at Duke
   • Any other billing activity within DUHS system
   RSH record, billing calendar, and order set (if applicable) are created at DOCR’s direction after review is performed.
Documents needed for DOCR review
If the study appears to require a Maestro Care build, the following documents are requested from the study team:
1. Schedule of study activities if not included in protocol
2. Internal Cost Assessment
3. Study Budget (can be a draft if budget has not been approved).
4. Clinical Trial Agreement (contract) and associated exhibit(s) for Industry Sponsored trials (can be a draft if final version is not available).

Initial review
- Upon receipt of the requested documents, DOCR contacts the study coordinator to arrange a meeting with the study team
  - A simplified (email-only) review may be conducted for less complex studies
    - Singular or few clinical activities
    - Studies using designated research spaces
  - Study teams can always request a meeting instead.

Initial Review (cont.)
- Best to have meeting as soon as possible after major details of the protocol have been finalized
- In preparation for meeting, DOCR makes a preliminary “qualifying trial” determination and drafts a research charge router using the provided documents
  - Both open to discussion
Qualifying status

- A trial must be considered “qualifying” in order to bill Medicare and other third-party payors for routine costs:
  - From CMS:
    - “Items or services that are typically provided absent a clinical trial (e.g., conventional care);
    - Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
    - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.”

Qualifying status (cont.)

In order to be classified as a “qualifying clinical trial,” a study must meet the following three requirements.

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent; and
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. (Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.)

Qualifying status (cont.)

- The following studies may be automatically “deemed” qualifying:
  - Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
  - Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
  - Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
  - Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)
**Qualifying status in a nutshell**

- A trial has to be qualifying in order for any activities on the research charge router (and therefore the billing calendar) to be coded as billable to insurance.
- Non-qualifying trials must have all research charges coded as billable to the study.

**Research Charge Router**

- All activities generating a DUHS patient charge are represented.
- Timing of events, types of orders, and charge assignments are represented with as much detail as possible.
  - Serves as the basis of both the MC order set and billing calendar.
Study Initiation Meeting

- Qualifying status is discussed
- The details of the research charge router (timepoints, MC orderables and chargeables) are clarified
  - DOCR and DUHS compliance provide Medicare coverage analysis, if applicable
- Timing and expectations for MC build are discussed

Study Initiation Meeting (cont.)

- Ethics and Compliance performs QA review of study documents
  - Consistency among documents and eIRB application
- SOM Finance and DOCR provide input on budget and contract
  - Payment terms
  - Does budget cover expenses?
- PRMO weighs in on any billing questions

After the meeting...

- DOCR provides the approved research charge router to PRMO for billing calendar build and the MC builders for order set build.
- If the study has a drug dispensed from an investigational pharmacy (IDS, IDR, or ICS), DOCR makes sure the drug is on their list for medication profile build
Medication Profile

- Dosing, dispensing, and administration information
- Completion of the medication profile is the necessary first step before the study drug (eRx) can be built in Willow
  - The eRx must be built before the order set and billing calendar can be completed

Medication profile (cont.)

- To facilitate completion of the medication profile, the study team should provide their investigational pharmacist with as much information about the drug as possible
  - The drug itself (or a sample), if available
  - Pharmacy manual
  - Label/dispensing information
  - Product picture

Order set completion

- The order set is built using the approved research charge router
- Once complete (with eRx, if applicable), an email is sent to the PI and CRC to validate the order set
  - Subject line: “Validate Pro000XXXXX”
- The order set can be moved into MC production only after it has been approved by the study team
RSH record and billing calendar
- PRMO begins building the billing calendar after the approved research charge router is provided to them
- In order for PRMO to move the RSH record and billing calendar into production, several things are needed:
  - eRx (if there is a study drug)
  - Fund code
  - NCT code (if any charges are going to insurance)

DOCR Approval
- DOCR will release approval in eIRB after the following requirements are met
  - RSH record and billing calendar in MC production
  - Order set (or Beacon treatment plan) in MC production
  - Clinicaltrials.gov registration (for applicable clinical trials)
  - All key personnel have completed HSR training

Clinicaltrials.gov
- Registration is required for Applicable Clinical Trials (ACTs)
  - Interventional trials (drugs, biologics, devices)
  - Phase 2 – 4 (not phase 1 drug; not small feasibility device)
  - US FDA jurisdiction (e.g. IND/IDE or US site)
- Also required for all qualifying trials with research charges going to insurance
Human Subjects Research Training

- Required for all Duke personnel listed as key personnel in eIRB

Instructions:
- Using Internet Explorer, go to https://bcw-lmsa.duhs.duke.edu/SabaLogin (log in with Net ID and password)
- Look under “in progress learning” and click on the course title “DOCR HSR at Duke”
- Click “launch” next to the DOCR Mandatory Quiz

Summary

Beacon

- Treatment Plan vs Order set
- DOCR facilitating MC build
- Processes being evaluated and refined
In Summary

1) Studies not requiring MC billing calendar or order set and not consenting Duke patients
   - HSR training
2) Studies not requiring MC billing calendar or order set and consenting Duke patients
   - HSR training
   - Fund code for RSH record creation
   - Clinicaltrials.gov registration (if applicable)

Summary (cont.)

3) Studies requiring a Maestro Care billing calendar and/or order set
   - HSR training
   - Clinical trials.gov registration (if applicable)
   - RSH record, billing calendar, and order set live in MC production
     - Fund code for RSH record
     - NCT code for RSH record (if any charges are going to insurance)
     - eRx for study drugs

Helpful Hints

- Send documents to DOCR as early in the process as possible (once protocol is not likely to change)
- If there is a study drug, reach out to investigational pharmacists to find out what information they need and to communicate enrollment timeline
- SIVs and drug shipment may occur between IRB approval and full institutional approval
Helpful Hints (cont.)

▪ Register on clinicaltrials.gov (if not being done by external sponsor)
▪ Make sure all key personnel have completed HSR training
▪ Keep an open line of communication with DOCR
  ▫ Anticipated enrollment
  ▫ Any changes to protocol, budget, or contract after review has been completed

Looking Forward

▪ Database of studies in review to become accessible to study teams
  ▫ Will be able to track status of DOCR review and MC build components
▪ Research charge router to evolve
▪ Continued identification of needs, gaps, and practice variations among CRUs

Questions?

If you have questions about the study initiation process or about the status of a particular study, you may write to DOCR.help, or feel free to contact us directly:

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