Compliance Round-Up

November 12, 2013

Physician Sunshine Act Implementation (Open Payments);
Clinical Research Billing Claims Processing Rule Changes

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Continuing Goals

The goals of the Compliance Round-Up Webinars:

- Teaching/knowledge transfer
- Keep you up to date on compliance rules
- Practical points
- Assist organizations to develop in-house methods of managing
- Please share your thoughts, suggestions (and criticisms)

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Compliance Round-Up: Webinar Overview

<u>Administrative Matters</u>

- Monthly on the 2nd Tuesday of the month
- No charge! (feel free to spread the word….)
- Each session will be 60-75 minutes in duration
- Each session will begin at 12:00 PM CT
- If you are unable to participate in the live discussion, each session will be recorded and made available in MP3 format

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Today's Topics/Agenda

1. The expansion of clinical research beyond the academic setting

2. Clinical Research Billing (CRB) claims processing changes beginning January 1, 2014

3. Closing out the year with the Physician Sunshine Act reporting rules

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Research – Not just an academic issue anymore!

Movement of clinical research into the community setting

- For many years, clinical research has been the domain of academic medical centers…not anymore.

- Some estimates peg 40% of clinical research is performed at a community hospital or in independent physician practices

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Research – Not just an academic issue anymore!

What does this mean for community health care?

- Examine the legal relationships:
  - Who are the parties to the clinical trial agreement?
  - Who is receiving the money and for what?
  - Does the institution receiving the money have contracts in place with all the parties the institution will pay?

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Research – Not just an academic issue anymore!

What does this mean for community health care?

- Coordinating information:
  - What research is approved for your institution?
  - Who are the research patients?
  - Is there a mechanism for the principal investigator to tell other providers that a patient is in a research study?

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Why is it important to coordinate research information?

1. Services which cannot be billed to insurance must be charged to the study – potential for false claims

2. *Beginning January 1, 2014*, all claims containing research-related services billed to Medicare, must have a clinical trials number placed on the claim

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CRB Claims Processing

- CMS issued Transmittal 2805/CR 8401 on August 9, 2013, then revised and reissued it on October 30, 2013
  - MLN Matters document reissued November 6, 2013
- The Transmittal requires “effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items/services provided in clinical trials that are qualified for coverage in [NCD 310.1].”
- It also warns: “Claims submitted without the clinical trials number that were once paid will now be returned for reprocessing….”
- The number to use: “the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov website….”

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CRB Claims Processing

- What other CRB claims processing requirement?
  - V70.7 ICD-9 code in secondary position
    - ICD-10: Z00.6
  - Condition Code 30
  - Q0/Q1 Modifier for outpatient claims (hospital, physician, IDTF, etc)
- The codes are only used for certain claims after the patient enrolls in a research study – not for any and all claims
- The codes and the clinical trial number are used for claims that contain “routine costs” during either a “qualifying clinical trial” under NCD 310.1 or an “approved research study” under device trial regulations

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CRB Claims Processing

- What are the implications of these new CRB rules?
  - CMS and its contractors will have an enormous amount of information about specific studies
  - CMS may deny claims if it does not believe the study is a qualifying clinical trial
  - The government will be able to compare providers within the same study and compare patients within the same study

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CRB Claims Processing

- What to do?
  - Do not “over-code” claims with the CRB codes merely because the patient is enrolled in a research study
  - Be judicious – apply only to claims containing clinical research “routine cost” charges (services required by the schedule of events or to treat complications)
  - All the more reason to do a Coverage Analysis for the research study!
  - Examine your process flow of clinical research information to determine how to focus on applying the codes to the right claims

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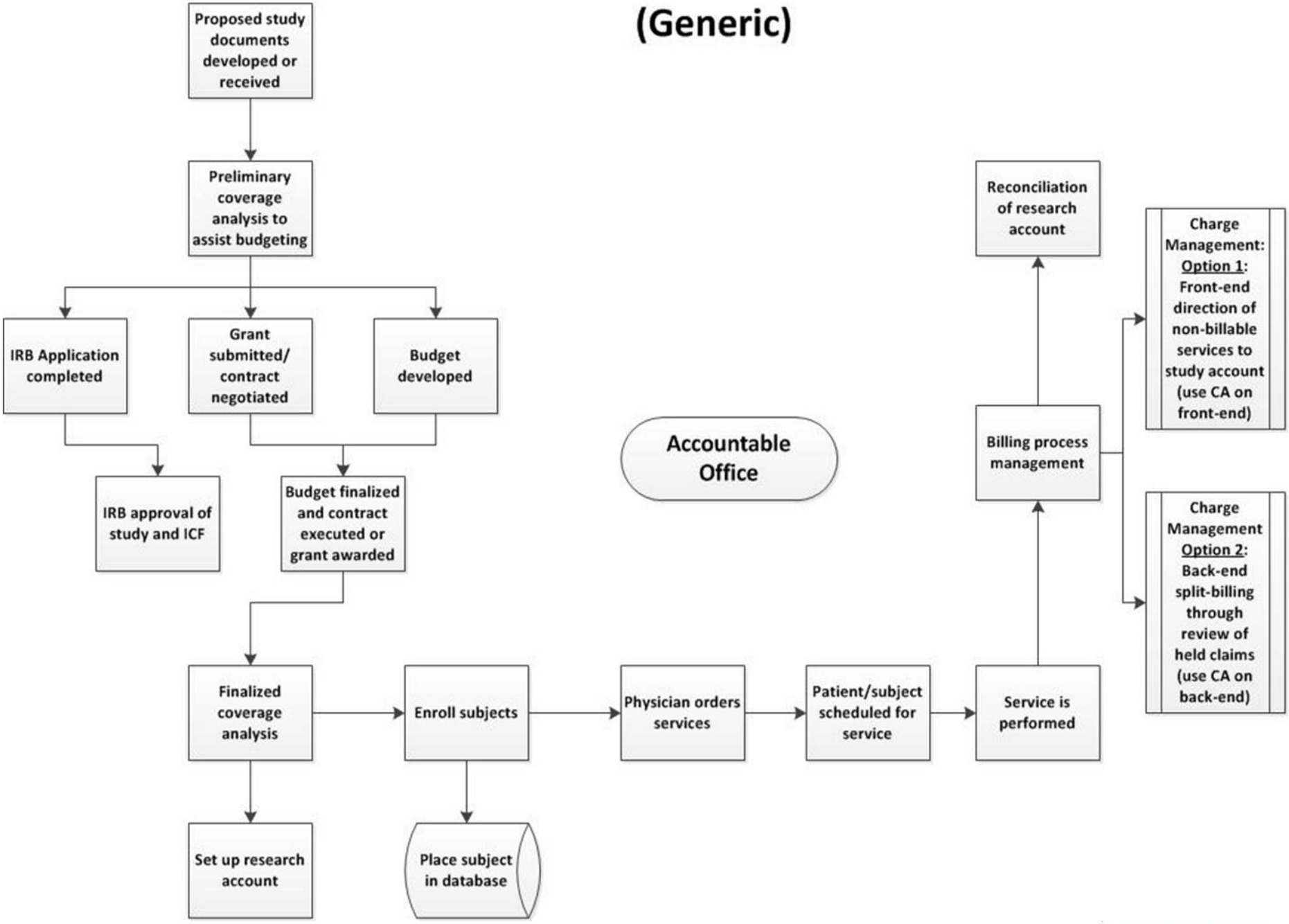
Clinical Research Billing Process (Generic)



Physician Sunshine Act Implementation

- Adopted as part of the Affordable Care Act of 2010
- Final Rule issued February 8, 2013
  - 42 CFR 403.900-910
- First reporting period:
  - August 1, 2013-December 31, 2013
- CMS now referring to the program as:
  - **"Open Payments"**
  - http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html

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Open Payments Program

- Tagline:
  - “Creating public transparency of industry-physician financial relationships”
- Key Dates:
  - Transfers and ownerships began tracking August 1, 2013
  - Reports by Manufacturers and GPOs due to CMS by March 31, 2014
  - First publication by CMS by September 30, 2014
- Note: Final Rule is “definition heavy”
  - 23 significant definitions

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Open Payments: The Basics

"These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value provided to covered recipients…

…as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities."

42 CFR 403.900 (emphasis added)

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Open Payments: The Basics

Who is covered?

1. For Transfers of Value:

   "Covered Recipients"

   - Physicians
   - Teaching Hospitals

   Note: Includes transfers made to Third Parties but intended for benefit of a covered recipient

2. For Ownership or Investment Interests:

   - Physicians
   - Immediate Family Members

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Open Payments: The Basics

Who reports?

1. Applicable Manufacturers
   - Produces, prepares, compounds…drug, device, biologic or supply that is reimbursable under Medicare or Medicaid; and
   - Is not being used by itself for its own patients

2. Applicable Group Purchase Organizations
   - Purchase, arranges, negotiates a covered drug, device, biologic or supply reimbursable under Medicare or Medicaid; and
   - Not used by the GPO itself.

Note 1: Physicians do not have reporting responsibility

Note 2: Check detailed definitions and exceptions

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Open Payments: The Basics

What is reported?

- Transfers of Value:
  - Anything over $10
  - Under $10 if aggregate is over $100
  - *Very broad*
  - "Form" and "nature" of payment or transfer needs to be disclosed

- Exclusion:
  - Speaking fees at accredited education events if not paid directly to the physician by a reporting entity

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Open Payments: Process of Reporting

- Applicable Manufacturer or Applicable GPO submits report to CMS by March 31 for preceding calendar year
  - Note: Reports are due by March 30 in leap-years!
- CMS must provide the reporting entities, physicians and teaching hospitals opportunity to review material for at least 45 days before posting on CMS website
  - First posting: By September 30, 2014
  - Thereafter: By June 30 of each year
- Physician may certify accuracy or register a dispute

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Open Payments: Research Funds

- Research funds must be reported if provided to:
  - Physician;
  - Teaching hospital; or
  - Third Party for the benefit of the physician or teaching hospital

- To be reported includes (but not limited to)
  - Study name
  - Amount of funding

- Delay in publication allowed if requested by sponsor under certain circumstances
  - Delay can be no longer than 4 years

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Open Payments: Implications

- Interaction with Conflicts of Interest Policy
  - What is the physician required to report at your organization?
  - Does it match the Sunshine reports?
  - Some payments exempt from Sunshine reporting but may be required by your COI policy
  - Are you a State entity and the physician's COI disclosure is public?
  - Watchdog groups will likely be matching up reports

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Open Payments: Implications

- Will physicians (personally) have responsibility for reviewing “response time” reports?
- Will a central office at your organization coordinate with the physician?
- Will you check reports against COI disclosures to identify differences?

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Open Payments: Implications

- If your organization has multiple sites and there is no common contracting process, how will you handle reports of research funds for the same study which may be different for different PI/sites?

- Prepare public relations office for handling press inquiries when reports are made public

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Follow-Up

Questions?

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Next Lecture:

Tuesday, December 10, 2013

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