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All These Rules, Why Do We Have to Follow Them?

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Learning Objectives

1. Understand the Medicare criteria for determining what studies allow patient billing
2. Know the difference between the PI's and Medicare's definitions of 'Standard of Care'
3. Identify the most common billing compliance mistakes
4. Discuss the mechanisms and tools for compliant research billing

Research Billing Compliance History

"Reasonable and Necessary"

- From the inception of Medicare in the mid-1960s, the phrase "reasonable and necessary" guided Medicare reimbursement. Though little explicit policy was issued, this clause was the basis for excluding reimbursement for services in clinical trials.

- The Medicare interpretation reflected the private insurance sector, whose policies in the 1960s though the implementation of the Affordable Care Act in March 2010, excluded coverage of services in clinical trials.

Research Billing Compliance History

"Reasonable and Necessary"

- Most private insurance plans excluded coverage of services in clinical trials on the basis that the treatment is "experimental" or "investigational," although the language does not explicitly mention clinical trials. However, Medical Directors reported that they often approved payment for care in clinical trials on a case-by-case basis.

- In addition, private insurers have been involved in supporting specific trials (e.g., the Blue Cross/Blue Shield Association was instrumental in initiating a trial of high-dose chemotherapy with bone marrow transplant rescue for women with advanced breast cancer).

Important Dates for Clinical Research Billing

Prior to 2000 – Medicare does not pay for care associated with clinical trials

2000 – Medicare National Coverage Decision (NCD) allowed coverage of some costs associated with Qualifying Clinical Trials (QCTs)

2003 – Medicare Prescription Drug, Improvement, and Modernization Act (MMA) allowed Medicare payment of the routine costs of care furnished to Medicare beneficiaries in certain categories of Investigational Device Exemption (IDE) studies

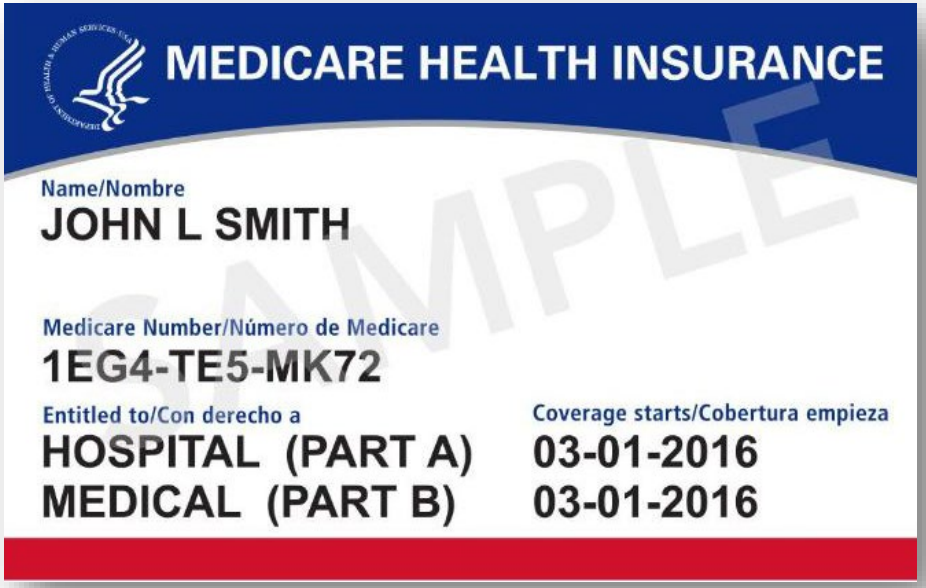
2010 – Affordable Care Act goes into effect, codifying reimbursement by private insurance for some clinical research activities

Medicare Motivation

History of Medicare and Clinical Research

Who typically receives Medicare coverage?

- People aged 65 and over
- Younger people with disabilities
- People diagnosed with End Stage Renal Disease

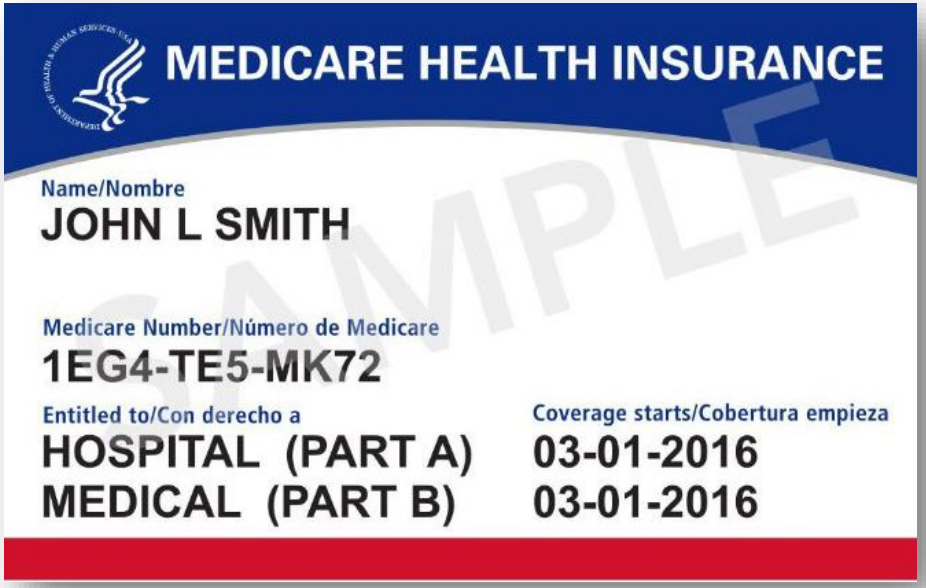


Medicare Motivation

History of Medicare and Clinical Research

Many of the patients who participate in clinical research have Medicare as their health insurance.

Because of its complicated nature, and the possibility of expensive fines, Medicare's policies drive much of the methodology regarding billing for clinical research.



So How Does a Study "Qualify"

- It fulfills 3 basic requirement for Medicare coverage

And…

- It possesses 7 desirable characteristics, or is assumed to have those characteristics, mostly because of its funding source

How Do Investigational New Drug Studies Qualify?

Must meet all three necessary requirements

Evaluate an item or service that falls within a Medicare benefit category

Have therapeutic intent

Enroll patients with diagnosed disease

Must be at least one of these 4 types of trials

Funded by NIH, CDC, AHRQ, CMS, DOD or VA

Supported by center or cooperative group funded by NIH, CDC, AHRQ, CMS, DOD or VA

Conducted under an Investigational New Drug application (IND) reviewed by the FDA, DOD or VA

IND exempt under FDA regulation 21 CFR 312.2(b)(1)

How Do Device Studies Qualify?

Investigational Device Studies have different criteria.

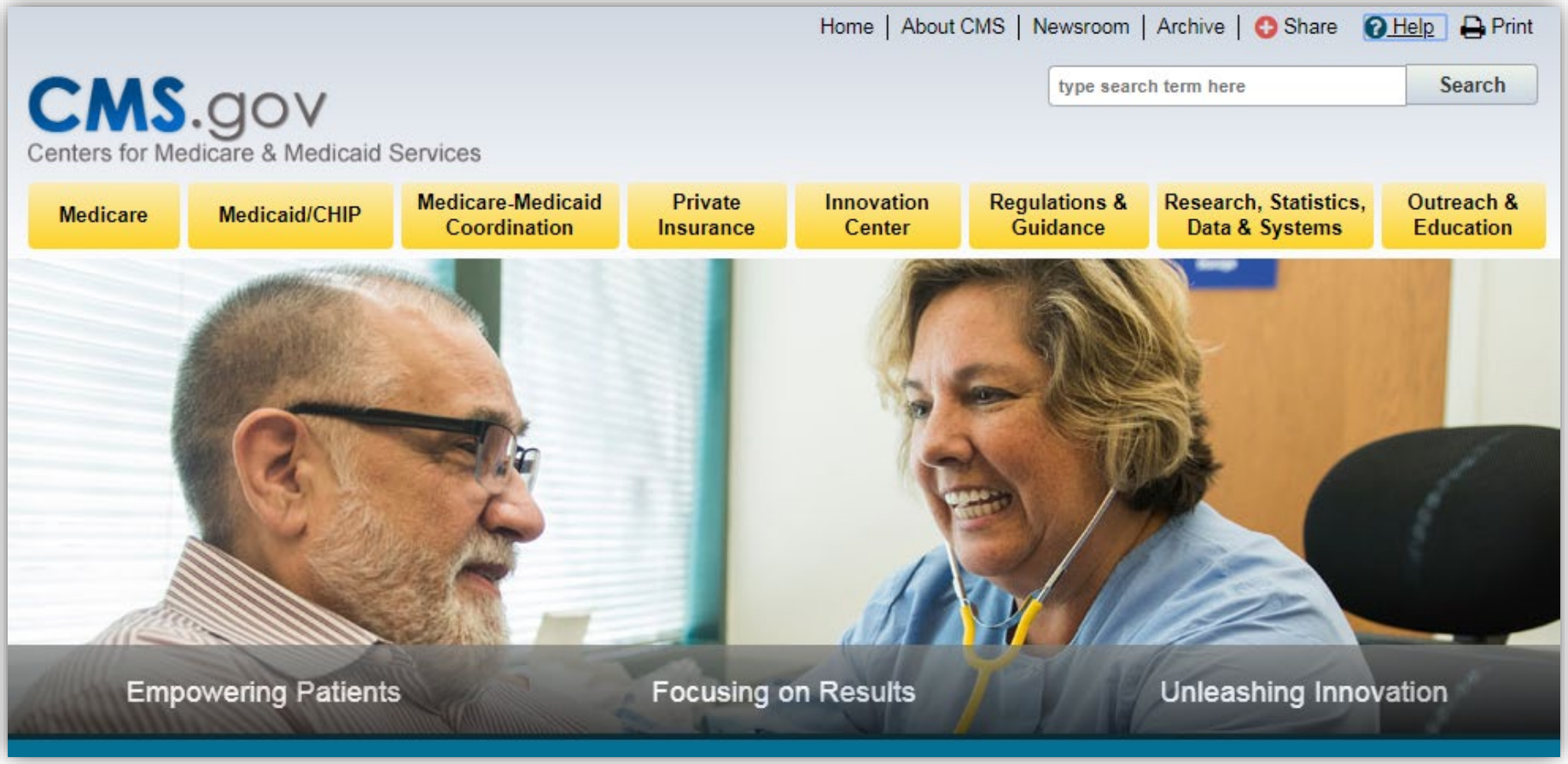
1. The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
2. The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The study results are not anticipated to unjustifiably duplicate existing knowledge.
4. The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
5. The study is sponsored by an organization or individual capable of successfully completing the study.
6. The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.

How Do Device Studies Qualify? (Cont.)

7. Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studies is life threatening and the patient has no other viable treatment options.
8. The study is registered with the National Institutes of Health National Library of Medicine's ClinicalTrials.gov.
9. The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.
10. The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

How Do Device Studies Qualify?

The **Center for Medicare and Medicaid Services (CMS)** provides a checklist and application instructions on their website at: https://www.cms.gov/Medicare/Coverage/IDE/Downloads/IDE-Study-Criteria-Crosswalk-Sep-2014.pdf



If You Qualify, What's Next?

Coverage Analysis

Coverage Analysis evaluates protocols to determine how services, items, and tests can be billed according to Medicare National and Local Coverage Determinations.

- National Coverage Determinations – set at national level by Medicare
- Local Coverage Determinations –
  - Determined by **Medicare Administrative Contractors (MACs)**
  - Locate your area's MAC via the CMS website at https://www.cms.gov/medicare-coverage-database/indexes/lcd-state-index.aspx

If You Qualify, What's Next?

Local Coverage Determinations

LCDs by State Index Results [5 Contractors]

Selection Criteria:

States(s): Washington
Document Type(s): All LCDs

Print Report

Expand All | Collapse All

Washington [5 Contractors]

MAC PART B	MAC PART A	HOME HEALTH AND HOSPICE MAC	DURABLE MEDICAL EQUIPMENT MACs	Part A and B - Medicare Administrative Contractor	Part A and B and Home Health and Hospice- Medicare Administrative Contractor
	Wisconsin Physicians Service Insurance Corporation (05901, MAC - Part A, J - 05)	National Government Services, Inc. (06004, HHH MAC, J - 06)	Noridian Healthcare Solutions, LLC (19003, DME MAC, J-D)	Noridian Healthcare Solutions, LLC (02401, A and B MAC, J - F)	
				Noridian Healthcare Solutions, LLC (02402, A and B MAC, J - F)	

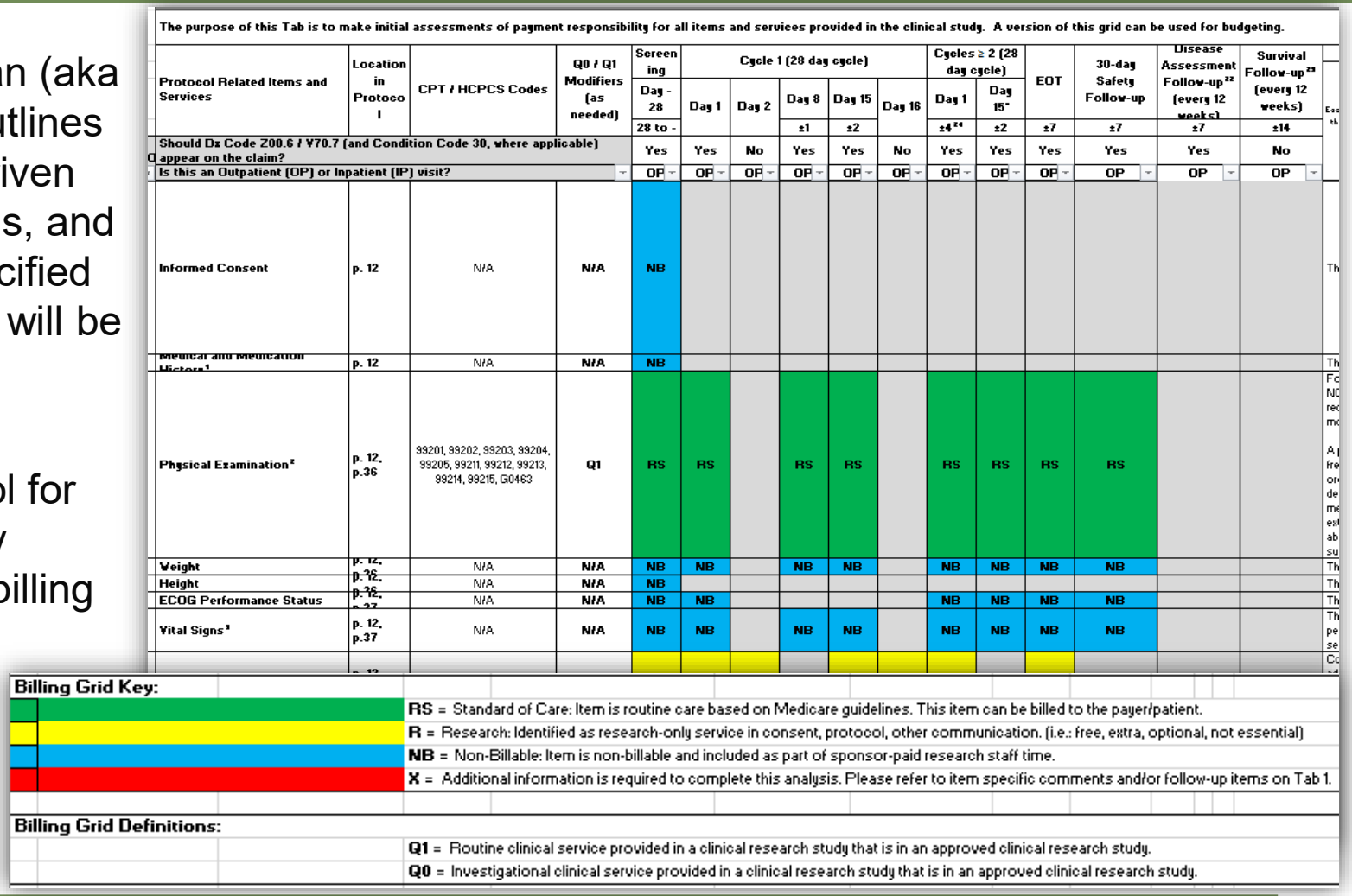
Billing Plan

- Determined if the study is a Qualified Clinical Trial
- Completed coverage analysis to evaluate what Medicare will and won't pay for
- Time to create a billing plan

Billing Plan as Roadmap

The billing plan (aka billing grid) outlines all protocol-driven services, items, and tests and specified to whom they will be billed.

Invaluable tool for creating study budgets and billing compliance.



The purpose of this Tab is to make initial assessments of payment responsibility for all items and services provided in the clinical study. A version of this grid can be used for budgeting.

Protocol Related Items and Services	Location in Protocol	CPT / HCPCS Codes	Q0 / Q1 Modifiers (as needed)	Screening	Cycle 1 (28 day cycle)					Cycles ≥ 2 (28 day cycle)		EOT	30-day Safety Follow-up	Disease Assessment Follow-up[22] (every 12 weeks)	Survival Follow-up[23] (every 12 weeks)	Ea th
				Day -28	Day 1	Day 2	Day 8	Day 15	Day 16	Day 1	Day 15*					
				28 to -			±1	±2		±4[24]	±2	±7	±7	±7	±14	
Should Dx Code Z00.6 / V70.7 (and Condition Code 30, where applicable) appear on the claim?				Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	
Is this an Outpatient (OP) or Inpatient (IP) visit?				OP	OP	OP	OP	OP	OP	OP	OP	OP	OP	OP	OP	
Informed Consent	p. 12	N/A	N/A	NB												Th
Medical and Medication History[1]	p. 12	N/A	N/A	NB												Th
Physical Examination[2]	p. 12, p.36	99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, G0463	Q1	RS	RS		RS	RS		RS	RS	RS	RS			Fo NC rec mo A fre or de me ex ab su
Weight	p. 12, p.36	N/A	N/A	NB	NB		NB	NB		NB	NB	NB	NB			Th
Height	p. 12, p.36	N/A	N/A	NB												Th
ECOG Performance Status	p. 12, p.37	N/A	N/A	NB	NB					NB	NB	NB	NB			Th
Vital Signs[3]	p. 12, p.37	N/A	N/A	NB	NB		NB	NB		NB	NB	NB	NB			Th pe se
	p. 12															Co

Billing Grid Key:

RS =	Standard of Care: Item is routine care based on Medicare guidelines. This item can be billed to the payer/patient.
R =	Research: Identified as research-only service in consent, protocol, other communication. (i.e.: free, extra, optional, not essential)
NB =	Non-Billable: Item is non-billable and included as part of sponsor-paid research staff time.
X =	Additional information is required to complete this analysis. Please refer to item specific comments and/or follow-up items on Tab 1.

Billing Grid Definitions:

Q1 =	Routine clinical service provided in a clinical research study that is in an approved clinical research study.
Q0 =	Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

Billing Plan

- Determined if the study is a Qualified Clinical Trial
- Completed coverage analysis to evaluate what Medicare will and won't pay for
- Time to create a billing plan
- Compliant billing at the time of service

Compliant Billing at the Time of Service

- Where does your research take place?
  - Is it a single department or team?
  - A variety of clinical environments?
- What systems are available?
  - Electronic Medical Record (EMR)
  - Electronic orders
  - Paper orders
- Build relationships with the people who touch billing related activities
  - Insert yourself in the revenue cycle/billing discussion
  - Invite them into your discussions

Research Billing Risks

Research billing is a priority for the DOJ Health Care Fraud Strike Force.

The Strike Force is comprised of resources from the FBI, OIG, US Attorney's Offices, and other law enforcement agencies.

Research Billing Risks

- Random audits
  - Recovery Audit Contractor Audits
  - Certified Error Rate Testing
- Probe audits
  - Not random
  - Focused audits when there is suspicion of abuse
  - Risk-based algorithms
- Institutions self-reporting
- Whistle-blower complaints

Research Billing Risks

Double-billing research services by accepting sponsor funding, then billing patient (Medicare) for the same services.

Requires that we identify up front the appropriate payer for each service and budget accordingly.

Research Billing Risks

Billing non-covered research services to Medicare, or billing covered services incorrectly.

Requires clear billing plan for each service (billing grid)

Requires that charges are directed accurately **at the point of care**

DOJ – OIG Consequences

- **2005 Rush University Medical Center- $1M**
  - Self disclosure
  - Improperly billed $670,000 in services that are not reimbursable as routine care
- **2005 University of Alabama at Birmingham $3.39M**
  - Falsely billed Medicare for services also billed to the sponsor
  - Falsely billed researcher's time spent on patient care when no patients were seen.
- **2013 Emory - $1.5M**
  - Billed Medicare and Medicaid for services paid by the clinical trial sponsor
- **2019 GenomeDx Biosciences Corp - $1.99M**
  - Whistleblower
  - Submitted claims for reimbursement for the Decipher test that were not medically reasonable and necessary
  - Patients did not have risk factors that required the test

DOJ – OIG Consequences

- **2010 USC – Norris Cancer Center/Tenet Healthcare- $1.9M**
  - Improperly billed for:
    - items or services that were paid for by clinical research sponsors or grants under which the clinical research was conducted;
    - items or services intended to be free of charge in the research informed consent;
    - items or services that were for research purposes only and not for the clinical management of the patient; and/or
    - items or services that were otherwise not covered under the …(CMS) Clinical Trial Policy."

Summary

- Are you a Qualified Clinical Trial?
- Documented Coverage Analysis
  - Coverage determinations are not written in stone
  - Don't rely on the determinations of previous studies
- Have a documented Billing Plan/Billing Grid
- Follow the Billing Plan
  - Know how your institution directs clinical research charges
  - Nurture relationships with the finance side of clinical care

References and Resources:

- Slides 4-5, Medicare Reimbursement History: 2000, National Academy of Sciences, 'Extending Medicare Reimbursement in Clinical Trials, Paying for Patient Care in Clinical Trials', accessed January 2020. https://www.ncbi.nlm.nih.gov/books/NBK225267/
- Slide 13: Criteria checklist for device studies when determining if Qualified Clinical Trial, https://www.cms.gov/Medicare/Coverage/IDE/Downloads/IDE-Study-Criteria-Crosswalk-Sep-2014.pdf
- Slides 14-15, Medicare Coverage Determination Process: https://www.cms.gov/Medicare/Coverage/DeterminationProcess
- Slide 14, LCD Lookup By State: https://www.cms.gov/medicare-coverage-database/indexes/lcd-state-index.aspx
- Slides 9-13, Medicare Clinical Trials Policies: https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies
- Slide 24, GenomeDX Biosciences article, https://www.genomeweb.com/regulatory-news/genomedx-biosciences-pay-2m-settle-allegations-improper-medicare-billing#.XiihIf5KjmE
- Slide 25, Clinical Research Reimbursement: What You Need to Know to Plan and Execute Trials Without Creating Legal Issues, Amy B. Judge-Prein, https://www.faegrebd.com/webfiles/Full%20Slides_3-3-15.pdf, page 37

Questions?

Thank You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