Healthcare Reform and The Clinical Research Industry

David Vulcano, LCSW, MBA, CIP, RAC
AVP & Responsible Executive, Clinical Research @ HCA
HCCA Research Compliance Conference
June 4, 2014
Austin, TX

Conflict of Interest Disclosure
David Vulcano, LCSW, MBA, CIP, RAC

Has no real or apparent conflicts of interest to report.
Other Disclaimers

• This presentation is a combination of lecture and slides. Neither the audio or visual portion are intended to be construed as a stand-alone presentation.
• Opinions that may be put forth in this session are not to be construed as opinions of any agency that the speaker is affiliated with.
• Some opinions put forth may not be the opinions of the speaker himself.

Learning Objectives

Participants will be able to…
1. Name major pieces of legislation impacting the research industry as a whole.
2. Predict how the changes in legislation may impact their operations.
3. Organize a plan to adhere to new laws, regulations and policy.
Disclosure

I have no relevant financial relationship in relation to this educational activity

Disclaimers

• This is a high level summary. Many details/exceptions etc have been omitted for the sake of brevity.
• This presentation is a combination of lecture and slides. Neither the audio or visual portion are intended to be construed as a stand-alone presentation.
• Opinions that may be purported in this session are not to be construed as opinions of any agency (or persons) that the speaker is affiliated with.
• Opinions presented may not even be the opinions of the presenter.
Section 1
The Continuing Saga Of The PPACA & HCEARA (a.k.a. “Obamacare”) Legislation

“This is a big !@#$%^& deal.”

May 23, 2010 - Vice President Joe Biden, caught on open mic congratulating President Obama on the passage of the PPACA.
PPACA Goal: More People Insured

• Immediate
  • Elimination of Lifetime/Annual Caps, Pre-Existing Conditions;
  • The “Adult Child Coverage” coverage on parent’s plan until age 26;

• Beginning 2014
  • State Medicaid Expansion:
    • Increases availability of Medicaid (to 133% poverty);
    • 100% Paid by Federal Government until 2016, then states have to start taking over their portion unless they don’t.
  • State/Federal “Insurance Exchanges” Begin but delayed until 2015
  • Individual Mandates to Buy Insurance (Or Pay Fine Tax)
  • Premium assistance (Tax Credit) from Insurance Exchange for up to 400% poverty level;
  • Other Tax Credits To Individuals based on:
    • % premium paid by employer (i.e. <60% paid by employer)
    • % of income the premium is (i.e. more that 8% or more than 9.5% income)
  • $2k-$3k per employee (with adjustments) penalty to employer (excludes companies with <50 FTEs) for not offering or for “underpaving” insurance

2014: Obtaining Insurance Through Employer Or Available Medicaid Expansion And/Or Exchanges
Presumed Coverage Migration Patterns

- Medicare
  - Traditional
  - Advantage

- Medicaid

- Insured
  - Private

- Uninsured

- Medicare
  - Traditional
  - Advantage

- Medicaid
  - Traditional
  - Expanded

- Insured
  - Private
  - Exchanges

- Uninsured

Status of Exchange Participation (02/25/2014)

http://kff.org/health-reform/state-indicator/health-insurance-exchanges/#map
Requires Some Insurance Coverage of Some Clinical Trials

- PPACA Section 10103 adds new section (Section 2709) to the Public Health Service Act entitled “Coverage For Individuals Participating In Approved Clinical Trials”
- **Effective 2014**
- Group and Individual Health Plans **cannot deny or limit coverage** of **routine patient costs** for items and services furnished in connection with **approved trial**.
  - Except: Plans **Governed under ERISA** (i.e. Self-Insured Plans)
  - Except: “Grandfathered” Plans (where the person was enrolled on/before March 23, 2010)
- **Criteria remarkably similar to Medicare**
  - i.e. “**Routine Costs**” = items typically covered absent a study and doesn’t include investigational item, items for data analysis, services inconsistent with standards of care etc.;
  - i.e. “**Approved Trials**” = Federally Funded Trial, IND application trials etc.
- Unlike Medicare, limited to clinical trials of **“Cancer or other life-threatening disease or condition”**.
- **Cannot discriminate on basis of individual’s participation** in trial.
Some Notable Limitations To Mandated Clinical Trial Coverage

- Insurer can require subjects to use “In-Network” providers that are investigators, if the PI will accept the subject.
- Must Include “Out Of State” providers in “Out Of Network” Benefits if trial is conducted out of State
  - But doesn’t change Out-Of-Network benefits if any (i.e. subjects must pay Out-Of-Network rates if provided...If not, they will have to pay Out Of Pocket).
- Additional Criteria- “eligible to participate...according to the trial protocol...”

The Tax Man Cometh
PPACA Sec. 9008: Annual Fee for Rx Drug Manufacturers

Your Company’s Portion Of The Base Fee

Money Allocated For Medicare Part B (Outpatient Benefits), Not Part D (Prescription Drug Benefits)

Your % Sales of Branded Non-Orphan Prescription Drugs/Biologics to Specified Government Programs

Your Sales / Everyone’s Sales

Sliding Scale adjustment for sales <$5M (0% of sales) to Sales >$400M (100% of sales)

Base Fee

2011 = $2.5B; 2012 - 2013 = $2.8B; 2014 - 2016 = $3.0B; 2017 = $4.0B; 2018 = $4.3B; 2019 and thereafter = $2.8B.

Adjustments for HCEARA Added “Joint And Several Liability” clause.

HCEARA Section 1405: Excise Tax on Medical Device Manufacturers

• 2.3% tax on all devices except
  • Eyeglasses;
  • Contact Lenses;
  • Hearing Aids;
  • Others TBD by HHS (using criteria “generally purchased by general public at retail for individual use”).

• Effective Jan 1, 2013.
• Expected $25.5B from 2012-2021 (PwC Report)
Individual/Business Impacts Beginning in 2013

- **Higher Medical Expense itemized deduction threshold.**
  - Threshold For Tax Deduction (i.e. IRS Schedule A) medical expenses has increased from 7.5% of AGI to 10% of AGI.
  - Except, in the years 2013–2016, if either the taxpayer or the taxpayer’s spouse has turned 65 before the end of the tax year, the threshold remains at 7.5% of AGI.

- **Salary reduction contributions to FSAs now capped at $2,500**

- **New 3.8% Medicare Tax on Unearned Income** (i.e. investments)
  - Income criteria determined annually (See Current ➔)

- **.9% Increase in Employee Portion Of Medicare Tax**
  - From 1.45% to 2.35% (or from 2.9% to 3.8% For Self-Employed)
  - Income criteria determined annually (See Current ➔)
  - Still Must Be Withheld By Employer
    - Note, to do so they need to know your filing status and spouse income

<table>
<thead>
<tr>
<th>Filing Status</th>
<th>Threshold Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married, Filing Jointly</td>
<td>$250,000</td>
</tr>
<tr>
<td>Married, Filing Separately</td>
<td>$125,000</td>
</tr>
<tr>
<td>Single, Head of Household or Qualifying Widow(er)</td>
<td>$200,000</td>
</tr>
<tr>
<td>with dependent child</td>
<td></td>
</tr>
</tbody>
</table>

Section 2

Transparency Reports: Morning Sunshine or Mourning Sunshine?
Amended & Restated Disclosure

I have no relevant financial relationship in relation to this educational activity

And neither (to my knowledge) do any of these:

| My (Only) Spouse and (Only) 2 Children, Extended Family & Inlaws | The Vulcano Family Foundation, Inc. | HCA |
| Angel Capital Group, LLC (and affiliated investments) | Front Gate Films, LLC | Ardent Health Services, LLC |
| Health Improvement Institute or HealthTech Council | Trainingcampus.org | HCCA (and related entities) |
| Williamson County 100 | Middle Tennessee Boy Scout Troop #418 | The Andrewz Sisterz |

History and Future of the “National Physician Payment Transparency Program” (a.k.a. “Open Payments”)

- “Physician Payments Sunshine Act of 2007” Died In Congress
- “Physician Payments Sunshine Act of 2009” Died In Congress
- Passed not as “Sunshine Act” but as Section 6002 of Patient Protection and Affordable Care Act entitled “Transparency Reports And Reporting Of Physician Ownership Or Investment Interests”
- Regulations Due But Not Done. Implementation Delayed.
- Draft Regulations Finally Posted For Comment
- February: Regulations Finalized
- Sample reports/tools posted
- Officially Named “Open Payments”
- August 1: Tracking Begins
- March 31: First Report Due (and Annually Thereafter)
- September 30: Website Go-Live (and June 30th annually thereafter)
The Essential Summary

“Applicable manufacturers must disclose certain payments or other transfers of value to covered recipients.”

“Applicable Manufacturers and Applicable GPOs must report ownership and investment interests held by physicians and immediate family members of physicians.”

“This information is to be aggregated and posted publically by CMS on a searchable website.”

CMS Publishing 3 Data Collection Templates Later in 2013

1. Physician Ownership Template (29 Fields Per Interest)
2. General Payments (Non-Research) Template (46 Fields Per Payment)
3. Research Payment Template (59 Fields Per Payment + 16 Fields For Each Additional “Multiple Investigator” up to 4)

• The Debated Research “Expenditure Category” Field (Item #36 “Expenditure Category”).
  – “Contextual category for this research payment or transfer of value. There can be multiple contextual categories for this research reported; however, for every Expenditure Category reported, an Expenditure Category percentage must also be reported. Category and percent represented as a single number for the category followed by the 2 or 3 digit percentage value (eg. 1-90 or 1-100) "01" = Professional Salary Support;"02" = Medical Research Writing or Publication;"03" = Patient Care;"04" = Non-patient Care;"05" = Overhead;"06" = Other”
  – This is an OPTIONAL field.
Definition of Physician’s “Immediate Family” As Owner

(1) Spouse.
(2) Natural or adoptive parent, child, or sibling.
(3) Stepparent, stepchild, stepbrother, or stepsister.
(4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.
(5) Grandparent or grandchild.
(6) Spouse of a grandparent or grandchild

Types of “Payments Or Other Transfers Of Value” Can Be.....

- “Direct Payment”
- “Indirect Payment”
- “Third Party Payment”
“Direct Payment” to Physician or Teaching Hospital

“Indirect Payment” to Physician or Teaching Hospital

CRO
SMO
TMO
Society
Agency
Other 3rd Party
“Third Party Payments” Directed By Physician

Don’t Pay Me, Pay My...
- Practice
- Favorite Charity
- Side Company
- Foundation
- Ex-Spouse
- Girlfriend

Sample of Similar Website Under a CIA

<table>
<thead>
<tr>
<th>#</th>
<th>ENTITY PAID</th>
<th>PHYSICIAN AND/OR PRINCIPAL INVESTIGATOR</th>
<th>PAYMENTS</th>
<th>NON-CASH</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name</td>
<td>City</td>
<td>State</td>
<td>Name</td>
<td>Research Related Payments</td>
</tr>
<tr>
<td>1</td>
<td>SARAH CANNON RESEARCH INSTITUTE LLC</td>
<td>ATLANTA</td>
<td>GA</td>
<td>BENDELL, JOHANNA</td>
<td>$452,536</td>
</tr>
<tr>
<td>2</td>
<td>SARAH CANNON RESEARCH INSTITUTE LLC</td>
<td>ATLANTA</td>
<td>GA</td>
<td>YARDLEY, DENISE</td>
<td>$178,167</td>
</tr>
<tr>
<td>3</td>
<td>SARAH CANNON RESEARCH INSTITUTE LLC</td>
<td>ATLANTA</td>
<td>GA</td>
<td>SPIGEL, DAVID</td>
<td>$164,686</td>
</tr>
<tr>
<td>4</td>
<td>SARAH CANNON RESEARCH INSTITUTE LLC</td>
<td>ATLANTA</td>
<td>GA</td>
<td>MOORE, KATHLEEN</td>
<td>$147,716</td>
</tr>
</tbody>
</table>

Important Note: Research related payments for clinical studies do not reflect the actual compensation, if any, received by the physician listed as the principal investigator at the site. In some instances, the registry reports clinical study payments made to institutions (e.g., academic research organizations [AROs]) that oversee the study across multiple sites.
### Some Notable Exclusions

- Manufacturers with <10% Revenue From Covered Products Only Report Transactions on Covered Products
- Certain items for patient use/education
  - Samples, coupon/vouchers-charity care etc.
- Items when the covered recipient is a patient or research subject
- Payments/Transfers of Value of <$10 each provided <$100 in aggregate (for 2013 and adjusted annually by CPI)
- Several Other Exclusions

### Exclusions Pertaining To Conferences Or Similar Large Scale Events

- Where it would be difficult to definitively establish the identities of those who accept...
- Not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants.
  - Note: “Invited” meals means you know who they are.
- Not required to report or track items of <$10 given away.
  - Note: Assume is giveaway if >=$10 you will know who it is.
Final Category List

• (i) Consulting fee.
• (ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.
• (iii) Honoraria.
• (iv) Gift
• (v) Entertainment.
• (vi) Food and beverage.
• (vii) Travel and lodging (including the specified destinations).
• (viii) Education.
• (ix) Research. [Special Reporting Rule]
• (x) Charitable contribution.
• (xii) Royalty or license.
• (xiii) Current or prospective ownership or investment interest.
• (xiv) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
• (xv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
• (xvi) Grant.
• (xvii) Space rental or facility fees (teaching hospital only).

Final Rule: Food and Beverage Category

• Allocated To Partaking Covered Recipients Only
• Rep does not have to stay
• Note- just because it is not reported on the website, does not mean it does not have to be tracked. It still does and then reported if >$100 aggregate over the year.

Q: A catered lunch costing $165 is brought to a 10 physician practice. 3 physicians and 8 support staff participated. What is reported?

– Draft Rule: $16.50 Per Each 10 Physicians (even if not partaking)
– Final Rule: $15 Per Each 3 Physicians Partaking
  • $165/11 = $15 per person and non-covered providers are not reported.
  • Note, if all 10 MDs and 8 non-MDs partook, it would be <$10.
The Calcul-EATER

Before you eat....Calcul-EAT!

Reporting Research Payments

- All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.
- Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.
- May request Delayed Publication on website (reporting still due each year) For the sooner of 4 years or FDA approval.
The “Research Payment Template”

- Fields
  - DE #
  - Data Element Name
  - Definition / Description
  - Data Type
  - Format
  - Required?
  - Field Size
  - Validation
  - Publicly Displayed

- 59 Items Per Payment (+16 items for each “Multiple PI” for the same payment)

Several Unique Requirements About Research Reporting

- Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.
- Name/Info of the research study.
  - ClinicalTrials.gov Number is Optional
  - Identification as “Pre-Clinical” excludes some required fields
- Information about each physician covered recipient principal investigator
- Request for delayed reporting (Yes/No)
Determining If Subject To “Delayed Publication Rule”

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.”

“Clinical investigation means any experiment involving one or more human subjects, or materials derived from human subjects in which a drug, device, biological or medical supply is administered, dispensed or used.”

Can Delay Publication (Not Reporting) for 4 years (or until FDA approval) if….

1. Research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.
2. Clinical investigations regarding a new drug, device, biological, or medical supply (but not clinical investigations for new applications of existing covered products.

The Steps

- Presubmission Review
  - Optional, to cut down errors/disputes
- Report Submission
  - By March 31st each year
- 45 Day (+15) Review And Corrections
  - Covered Recipient has 45 days to dispute
  - Payee does not get registration/password access
  - Unresolved disputes are just marked as “Disputed”
  - Note: Can get one more chance to dispute during second year.
- Publishing Information To Public
  - CMS Website
  - Reports To States/Congress
  - Mechanisms to obtain “non-public” information via FOIA
For more Information, go to the OpenPayments site at.......

- http://go.cms.gov/openpayments
- All Reporting Templates
- FAQ
- Other Support/Educational Tools

CMS has provided a “Patient Brochure”...

Information patients can use:

Open Payments

What is the Open Payments program?
Open Payments is a federal, voluntary transparency program that will collect and make available publicly information about financial relationships between health care providers, pharmacies, and teaching hospitals. The Centers for Medicare and Medicaid Services (CMS) will publicly report information from over 80 million payments made by manufacturers and others to health care providers, pharmacies, and teaching hospitals.

Why is this program important?
Open Payments helps ensure players in the health care industry are fair to the patients they serve. The payments reported to CMS are not necessarily payments that health care providers can accept or utilize. The payments are reported to ensure transparency and help strengthen the relationship between health care providers, pharmacies, and teaching hospitals. This transparency will help patients understand how these relationships affect their care and how their health care providers are compensated.

What kinds of payments will be reported?
Payments or other transfers of value made to health care providers, pharmacies, and teaching hospitals that exceed $10 and are reported to CMS. These payments include payments for the purchase of equipment, supplies, or services; payment of travel costs; and other transfers of value.

Can I see how much is paid to my doctor each year?
Yes, CMS will publish this information each year on a publicly accessible website starting in the fall of 2014.

Will this have any effect on my insurance coverage?
No. Your insurance plan is not affected by the Open Payments program.

Will my doctor change any of my prescriptions or treatments because of this program?
No. A doctor’s decision about which treatment to use is based on scientific evidence and the patient’s needs. The Open Payments program will not alter the treatment your doctor prescribes or recommends to you. Your doctor will make decisions about your care based on the best scientific evidence available.

Where can I find more information?
Visit Open Payments to learn more about the Open Payments program. The Open Payments website is also linked from the CMS HealthCare.gov website.
...and two SmartPhone Apps!

Section 3

“Pay For Performance”
“Pay for Performance” Provisions

• “Performance “= Compliance with Select Evidence Based Pathways
  • Initial 4 “Core Measures”
    – Acute Myocardial Infarction;
    – Heart Failure;
    – Pneumonia;
    – Surgical Care Improvement Project (SCIP).
    – >70 More on the way!!!
      • Inpatient AND Outpatient.
  • Compliance Stats...
    – ...Posted on Public HHS Websites
    – ...Will effect Medicare (and likely Private Insurance) reimbursement
      • Only get full payment if above a certain percentile
      • “Non-Pay for Non-Performance”
      • “Tier and Steer” Provider Lists (i.e. higher copays for lower scoring physicians )

Primary Quality Reporting Drivers

• “Hospital Inpatient Quality Reporting Program”
  – Formerly Known As “Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)”.
• Hospital Outpatient Quality Data Reporting Program (HOPQDRP).
• Physician Quality Reporting Initiative (PQRI).
Sample (Abbreviated) Core Measure Pathway (for AMI)

- Aspirin at Arrival
- Fibrinolytic Medication Within 30 Minutes Of Arrival
- PCI Received Within 90 Minutes of Hospital Arrival
- ACE Inhibitor or ARB for Left Ventricular Systolic Dysfunction
- Aspirin & Beta Blocker at Discharge

# Patients that received the intervention
# Patients that should have received the intervention  = Compliance Rate

One Graph From HHS’s “HospitalCompare” Website on 3 Indianapolis Hospital’s Performance On Sample Measure
The Either/Or of a Clinical Trial Admission

Follow Core Measure Pathway

Follow Clinical Trial Protocol

Excluding Clinical Trial Subjects From Equation.
1) “There is documentation that the patient was involved in a clinical trial during this hospital stay relevant to the measure set for this admission.”
2) Only documentation accepted is signed ICD on Hospital Chart (i.e. in PI’s office does not count)

What’s the Impact?

• Heightened importance on hospitals identifying patients on trials
  – Need for signed ICD on Medical Record;
  – Expected need to put Protocol’s NCT number on bill.
• Pathway gears in place affecting individualized treatment
  – Sooner identified as a research subject, the better.
• Potential for “Gaming” system.
Section 4
Research Funding Bubble

Miscellaneous PPACA
Funding/Mandates for Clinical Research

<table>
<thead>
<tr>
<th>Area</th>
<th>Amount of Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Delivery System Research</td>
<td>$20M (FY 2010-2014)</td>
</tr>
<tr>
<td>Emergency Medicine Research (Including separate category for Pediatric)</td>
<td>“Sums as may be necessary” (FY 2010-2014)</td>
</tr>
<tr>
<td>Public Health Services Delivery</td>
<td>No additional funding, just a mandate</td>
</tr>
<tr>
<td>Pain (Causes and Treatment)</td>
<td>“Sums as may be necessary” (FY 2010-2012)</td>
</tr>
<tr>
<td>Post-Partum Depression (Includes Support, Education and Research)</td>
<td>$3M in 2010, “Sums as may be necessary” (FY 2011-2012)</td>
</tr>
<tr>
<td>Establish Goals for Woman’s Health Research (AHRQ)</td>
<td>No additional funding, just a mandate</td>
</tr>
<tr>
<td>Establishes “Prevention and Public Health Fund” (some of which to be used for research)</td>
<td>$500M (FY2010) increasing to $2B (in FY 2015)</td>
</tr>
</tbody>
</table>
Patient-Centered Outcome Research Institute (PCORI)

- Formerly “Federal Coordinating Center for Comparative Effectiveness Research (FCCCER)”.
- Duties
  - Identify Research Priorities;
  - Establish Agenda;
  - Carry Out Agenda.
- Funding
  - $10M in 2010;
  - $50M in 2011;
  - $150M in 2012;
  - $150M + Fees in 2013+ (charging insurers $2 per year per covered life, increased annually by a product of National Healthcare Expenditures inflation).
- Oh, and BTW….. “[AHRQ] shall build capacity for CER by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing literature and primary research such as clinical trials.”

4 Quartiles of IOM’s 100 Priorities

- Example of “First Quartile” Priority
  - Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment.
- Example of “Fourth Quartile” Priority
  - Compare the effectiveness of smoking cessation strategies (e.g., medication, individual or quitline counseling, combinations of these) in smokers from understudied populations such as minorities, individuals with mental illness, and adolescents.
### PCORI Activity So Far

- Established First Four Advisory Panels
  - Patient Engagement
  - Assessment of Prevention, Diagnosis, and Treatment Options;
  - Improving Healthcare Systems; and
  - Addressing Disparities
- 279 awards totaling more than $464.4 million

### Section 5

**HIPAA Privacy 10th Birthday**

**Present: A HITECH Suit**
The New HIPAA Omnibus Rule

Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule (January 25, 2013)
a.k.a. “HIPAA Omnibus Final Rule”

Summary Of Significant Dates

• Published: January 25, 2013
• Effective Date: March 26, 2013
• Compliance Date: September 23, 2013 (180 days)
• Several Other Transition Dates
Business Associates (BA)

- An entity that “creates, receives, maintains, or transmits protected health information on behalf of the covered entity.”
- BAs and BA Subcontractors are now directly liable for HIPAA violations (Privacy & Security)
- An organization can now be classified as a BA (or BA Subcontractor) even if no agreement is in place (although a BA agreement is still required).
- Each BA agreement down the chain of sub-contractors must be as or more stringent than those up the chain.
- Have until March 26, 2014 to revise BA Agreements with new requirements.

Reconfirmed That Researchers Are NOT “Business Associates”

- “A person or entity is a business associate only in cases where the person or entity is conducting a function or activity regulated by the HIPAA Rules on behalf of a covered entity, such as payment or health care operations, or providing one of the services listed in the definition of “business associate,” and in the performance of such duties the person or entity has access to protected health information. Thus, an external researcher is not a business associate of a covered entity by virtue of its research activities, even if the covered entity has hired the researcher to perform the research. Similarly, an external or independent Institutional Review Board is not a business associate of a covered entity by virtue of its performing research review, approval, and continuing oversight functions.”
Confirms That Creating De-IDs and LDSs Is a BA Activity (And Can be the Researcher Under Circumstances)

• “However, a researcher may be a business associate if the researcher performs a function, activity, or service for a covered entity that does fall within the definition of business associate, such as the health care operations function of creating a de-identified or limited data set for the covered entity... Where the researcher is also the intended recipient of the de-identified data or limited data set, the researcher must return or destroy the identifiers at the time the business associate relationship to create the data set terminates and the researcher now wishes to use the deidentified data or limited data set (subject to a data use agreement) for a research purpose.”

Final Rule For “Sale of PHI”

• Sale is “A disclosure of protected health information by a covered entity or business associate, if applicable, where the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information.”

• Cannot sell PHI without individual’s authorization with some exceptions.
  – Can for sell for research but only if remuneration received is a “reasonable, cost-based fee to cover the cost to prepare and transmit the data for such purposes”. 
When is Research “Sale”? 

• “In addition, we do not consider sale of protected health information in this provision to encompass payments a covered entity may receive in the form of grants, or contracts or other arrangements to perform programs or activities, such as a research study, because any provision of protected health information to the payer is a byproduct of the service being provided. Thus, the payment by a research sponsor to a covered entity to conduct a research study is not considered a sale of protected health information even if research results that may include protected health information are disclosed to the sponsor in the course of the study.”
• “A disclosure of protected health information by a covered entity to a third party researcher that is conducting the research in exchange for remuneration would [not be permissible], unless the only remuneration received is a reasonable, cost-based fee to cover the cost to prepare and transmit the data for such purposes.”

Not A “Sale”: Paid To Do Research. Data is Byproduct

Covered Entity

Researcher

Research Results Including PHI
A “Sale”, Subject To “Cost Only”

Answer To IRB’s Role In Validating Fees

• Q: “Clarify that the Institutional Review Board is not responsible for making a determination regarding the permissibility of the fees paid in exchange for a disclosure of protected health information for research purposes.”

• A: “We clarify that a covered entity, or business associate if applicable, is responsible for determining whether any fees paid to the entity in exchange for protected health information covers the covered entity’s or business associate’s costs to prepare and transmit protected health information for research.”
Subsequent “Sale” By A Receiving Party

• If receiving party is a covered entity, requires:
  – Subsequent Authorization From Individual OR
  – Original Authorization is sufficiently clear that subsequent sale can occur

• If receiving party is a not a covered entity, it is not subject to HIPAA.
  – Note: Authorization forms still must have statement that once disclosed, no longer covered by HIPAA thus restrictions on sale do not apply.
  – Note: Waiver of Authorizations are still allowed here (for a non-sale by the covered entity) so if waived, individuals may still never be informed of this subsequent risk of “sale”.

Grandfathered “Sale” Activities

• Authorizations signed prior to March 26, 2013
• Waivers of Authorizations obtained prior to March 26, 2013
• Limited Data Sets (under Data Use Agreements) until the sooner of:
  – Renewal Date of Data Use Agreement
  – March 26, 2014 (One Year after Compliance Date)
Right To Restrict Disclosures To Insurer

• Effective March 26, 2013- Covered Entities must (no longer optional) honor request to not have PHI sent/accessible to insurer (or their business associate) if they pay out of pocket.
  – Includes withholding from Medicare
  – For HMO physicians prohibited from accepting payment from an HMO member, will have to refer to an “Out-of-Network” provider
  – State laws (i.e. that require bills to be sent and no self-pay i.e. Medicaid) may trump this and allow disclosure
• This law trumps contracts to the contrary.

Right To Restrict Disclosures

• Providers need to employ methods to flag or make notation with respect to restricted PHI.
  – Not sent for payments
  – Not provided during audits
  – Regulation makes it clear that impermissible disclosures are subject to penalties.
• Providers need to inform that the request does not carry to downstream providers (i.e. the local pharmacy filling the script, the lab processing the sample) and the requestor must make their own effort to inform downstream providers.
Right To Have A Copy Of ALL PHI

• “If an individual requests an electronic copy of protected health information that is maintained electronically in one or more designated record sets, the covered entity must provide the individual with access to the electronic information in the electronic form and format requested by the individual, if it is readily producible, or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.”

• This includes both EHR and non-EHR data.
  – Research Records
  – Note: Can still restrict access of information “in the course of research that involves treatment” during the study if agreed to in Authorization

Effective March 26, 2013 Can Combine Research Authorizations

• Must Clearly Differentiate What is Conditioned (Main Study) and What Is Not Conditioned (Sub-Study)
• Must Be “Opt-In”, not “Opt Out”
• Free To Decide “Opt In” Methodology such as
  – E.g. Check Box, One Signature
  – E.g. Separate Section, Second Signature
  – E.g. Check Box + One Signature but referencing separate (unsigned) form describing substudy
  – E.g. Old way (i.e. Two forms)
• Do not have to change previously signed two+ forms after effective date if you do not want to. Two forms will still be good.
Pre-Amended Rule Status of HIPAA Authorizations
= Study-Centric

**Informed Consent Form**
- Main Study Consent
- Main Study **Authorization**
- Sub-Study #1 Consent
- Sub-Study #2 Consent

Sign Here: __________
Date: ________

**HIPAA Authorization Form**
- Sub- Study #1 **Authorization**

Sign Here: __________
Date: ________

**HIPAA Authorization Form**
- Sub- Study #2 **Authorization**

Sign Here: __________
Date: ________

One “Combined Authorization” Option: Opt
In Check Boxes, One Signature

- Main Study Consent
- Main Study Authorization
- Sub-Study#1 Consent Language
  - [ ] Sub- Study#1 Authorization Opt-In
- Sub-Study #2 Consent Language
  - [ ] Sub-Study #2 Authorization Opt-In

Sign Here: __________
Date: ________
Another “Combined Authorization: Option: Second Signature

• Main Study Consent
• Main Study Authorization
• Sub-Study#1 Consent Language
  Sign Here To Participate:
• Sub-Study #2 Consent Language
  Sign Here To Participate:

Sign Here: __________
Date: ______

Miscellaneous Issues of Combined Authorizations

• Excludes: Research that involves psychotherapy notes.
  – May only be combined with other authorizations for psychotherapy notes
• Revoking
  – Seek clarification on what sections are asked to be revoked.
  – Absent clarity, the entire authorization is considered revoked.
• Includes things like:
  – Sub-studies
  – Biospecimen Banking
  – Future/Secondary Use
Future/Secondary Use: Original Interpretation

- Previous Interpretation of Research Authorizations Purpose
  - Must be study specific
  - Must include a description of each purpose of the requested use or disclosure.
- Future Use Then Required
  - Subsequent Authorizations
  - Waiver of Authorization
  - Using De-Identified Data or Limited Data Sets

Future/Secondary Use: Interpretation
Effective March 26, 2013

- Future/Unspecified Use Now Allowed as a “Purpose”
- Authorization must “adequately describe such purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research.”
- Note, All Required Elements Of Authorizations Are Still Required
  - The Who, What’s Where, Whens etc.
50 Year Post-Mortem Expiration Of Protections Under HIPAA

- 50 Years Decided On Based on Multiple Inputs From Varying Stakeholders
- Does not override more restrictive State laws or other professional responsibilities
- Not a 50 year record retention requirement

Redefining “Breach”

- “Breach” Changes from a “Harm Standard” to a “Compromised Standard” based on Risk Assessment
- Encryption and destruction technologies are a safe harbor
  - Firewalls and passwords do not render data unreadable
  - If individual wants unencrypted email, CE has duty to notify them of risks
- Note: BREACH ALSO INCLUDES
  - Breach of Limited Data Sets
  - Breach of data considered “More than Minimum Necessary”
Breach Notification Logistics

- Must Be In Writing And Contain Certain Information
  - For those that only want voice communication, must document the call and disclose option to “pick it up”.
- If there is insufficient contact information for 10 or more individuals, a substitute notice of conspicuous posting on the home page of the covered entity’s Web site or notice in major print or broadcast media in the geographic areas is required.

Additional Obligations For Breach of “Unsecured” PHI

- “Unsecured” = “not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance”
- Notify Prominent Media Outlets
  - If >500 per covered entity and in a given State
    - 200 individuals in FL and 400 individuals in GA from one covered entity = No report to media
    - BA breach affects 800 individuals, 450 from one CE and 350 from another = No report to media
- Notify DHHS “immediately” if >500, regardless of distribution across States
  - Will post on website
Genetic Information Nondiscrimination Act (GINA)

• GINA prohibits discrimination based on an individual’s genetic information in both the health coverage and employment contexts.
  – Prohibition on a health plan’s use or disclosure of genetic information is for underwriting purposes.
  – Can use/disclose to determine medical appropriateness of a benefit.
• Clarified “Long Term Care Plans” are considered excluded from the prohibition.
• No applicability for Life Insurance and other discriminations

What Is Considered “Genetic Information”?

• “Genetic information” generally means:
  – individual’s genetic tests or that of their family members (including fetus and embryos)
  – the manifestation of a disease or disorder in family members of such individual (i.e., family medical history).
  – any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or family member, specifically:
    • A genetic test;
    • genetic counseling (including obtaining, interpreting, or assessing genetic information); or
    • genetic education.
• “Genetic information” shall not include information about the sex or age of any individual.
Section 6

I Don’t Mean To (Medi)Scare You But…..

NCT Number To Be Required On Medicare Claims Effective January 1, 2014

<table>
<thead>
<tr>
<th>CMS Manual System</th>
<th>Department of Health &amp; Human Services (DHHS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pub 100-04 Medicare Claims Processing</td>
<td>Centers for Medicare &amp; Medicaid Services (CMS)</td>
</tr>
<tr>
<td>Transmittal 2758</td>
<td>Date: August 9, 2013</td>
</tr>
<tr>
<td></td>
<td>Change Request 8401</td>
</tr>
</tbody>
</table>

SUBJECT: Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to inform providers and suppliers that 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 as specified in the Medicare National Coverage Determination (NCD) Manual, Publication 100-03, section 310.1. The clinical trial number that the Centers for Medicare & Medicaid Services (CMS) is making mandatory is the same number that has been reported voluntarily since the implementation of CR5790, TR310, dated January 18, 2008 - the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov website when a new study appears in the NLM Clinical Trials database.

EFFECTIVE DATE: January 1, 2014
IMPLEMENTATION DATE: January 6, 2014
What CMS Will See When NCD Number Is Placed On Bill: Inconsistent Research Billing Across Country

<table>
<thead>
<tr>
<th>SITE #1</th>
<th>SITE #2</th>
<th>SITE #3</th>
<th>SITE #4</th>
<th>SITE #5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Billed for X, Y &amp; Z</td>
<td>Didn’t Bill For X, Y &amp; Z</td>
<td>Billed for X, Y &amp; Z</td>
<td>Billed For X &amp; Y but not Z</td>
<td>Didn’t Bill For X, Y &amp; Z</td>
</tr>
</tbody>
</table>

- Creates opportunities for CMS to audit sites for potential recovery of funds if you billed for things other sites didn’t.

“Doc Fix” in Past 3 Years

- Postponed SGR cuts for one more month.
- PPACA Bill Passed
  - Section 3101: Amends Social Security Act to Increase Physician Medicare Payment by .5%.
  - Section 10310 (527 Pages Later): “The provisions of, and the amendment made by, section 3101 are repealed.”
  - Sec. 5501: Primary Care Bonus
    - Defines “Primary Care”, Offers 10% Medicare “Bonus” for provision of “Primary Care”;
    - “Half the cost of the bonuses would be offset through an across-the-board reduction in all other services”
- HCEARA Bill Passed
  - Sec. 1202 required Medicaid rates to equal Medicare for primary care services for years 2013 and 2014.

- Began from 2009 decision to postpone 21% SGR cuts to March 1st.
“Doc Fix” in Past 3 Years

Postponed SGR cuts for one more month.

- November 29, Postponed SGR cuts until January 1, 2011
- Postponed SGR cuts until January 1, 2012, then a 25% cut

“Doc Fix” in Past 4 Years

2011
- December 2011: Postponed Until March 1, 2012 then a ~27.4% cut

2012
- February 24, 2012: Postponed Until January 1, 2013 then (expected) 32%
- American Taxpayer Relief Act postpones cuts to January 1, 2014.
  - Exact amount unknown (24.4%?)

2013
- Postponed to March 31, 2014 then 24% cut.

2014
- Postponed to March 31, 2015 then 24% cut.
Research Reimbursement Rates Tied to Medicare Rates Will Change as the Medicare Rates Change.

New Centralized Process For CMS Approval of IDE Clinical Trials Begins January 1, 2015

• CMS Will Provide Central Review/Approval for IDE studies as “Qualifying Studies”
  – Eliminates Need To Submit To Contractor but...
  – Claims Still Go To Subcontractor
• Will List Approved Protocols on CMS Website by NCT number
Formalized Approval Criteria (Still No Self-Certification)

• Submit
  1. FDA Approval Letter
  2. Protocol
  3. IRB Approval Letter (Note: 1 Letter Suffices for Any Site In Multisite Protocols)
  4. Clinicaltrials.gov Identifier

• CMS Promises a 30 Day Turnaround Time
• ONE submittal per NCT Number (i.e. only sponsor or one site needs to submit for multisite protocols.)

New (Revised) Criteria for IDE Protocols

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 answer the research question(s) being asked in the study.

5. The study is sponsored by an organization or individual capable of completing it successfully.

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.

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 studied is life threatening and the patient has no other viable treatment options.

8. The study is registered with the National Institutes of Health’s National Library of Medicine’s ClinicalTrials.gov.

9. The study protocol describes the method and timing of release of results on all prespecified 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.
Questions Unanswered

• Grandfathering?
• Protocol Amendments?
• Did not address
  – “Routine Costs”
  – Medicare Secondary Payer
  – Other Issues

Section 6

I C D Future…
…And It’s a 10!
ICD-10 Conversion

- HIPAA Covered Entities may no longer bill with ICD-9 codes effective this date (even to private insurance).
- Increase from ~14,000 codes to ~68,000 codes.
- Rearranges existing codes as well (i.e. not just adding codes).
  - Converts from mostly 3-5 numeric digits to 5-7 alphanumeric characters
  - Multiple “One To Many” ICD-9 to ICD-10 relationships
- Does not change CPT codes.

Impact of ICD-10

- Change of Coding/Systems
  - Healthcare Billing and EHRs
  - Add-n Research Systems That Use ICD-9
- More Precise Clinical Documentation To Support Codes
Examples of More Detailed Codes

- **Laterality (Left, Right, Bilateral)**
  - C50.511 – Malignant neoplasm of lower-outer quadrant of right female breast
  - H16.013 – Central corneal ulcer, bilateral;
- **Combined and Expanded Codes**
  - E11.341 – Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema;
  - T42.3x2S – Poisoning by barbiturates, intentional self-harm, sequela.
  - T82.02xA – Displacement of heart valve prosthesis, initial encounter.
  - 125 codes for “pressure ulcer” depending on location and depth

More Examples of ICD-10 Level Specificity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>W5921XA</td>
<td>Bitten by turtle, initial encounter</td>
</tr>
<tr>
<td>W5921XD</td>
<td>Bitten by turtle, subsequent encounter</td>
</tr>
<tr>
<td>W5921XS</td>
<td>Bitten by turtle, sequela</td>
</tr>
<tr>
<td>W5922XA</td>
<td>Struck by turtle, initial encounter</td>
</tr>
<tr>
<td>W5922XD</td>
<td>Struck by turtle, subsequent encounter</td>
</tr>
<tr>
<td>W5922XS</td>
<td>Struck by turtle, sequela</td>
</tr>
<tr>
<td>W5929XA</td>
<td>Other contact with turtle, initial encounter</td>
</tr>
<tr>
<td>W5929XD</td>
<td>Other contact with turtle, subsequent encounter</td>
</tr>
<tr>
<td>W5929XS</td>
<td>Other contact with turtle, sequela</td>
</tr>
</tbody>
</table>

Similar codes for parrot, macaw, chicken, turkey, goose, duck, alligator, crocodile, dolphin, sea lion, shark, orca, raccoon, pig, horse, dog etc. as well as coding differently for football, softball, volleyball, baseball, golf ball, golf club, hockey stick, baseball bat, shoe cleat, football helmet etc.
### More Examples of ICD-10 Level Specificity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V9027XA</td>
<td>Drowning and submersion due to falling or jumping from burning water-skis, initial encounter</td>
</tr>
<tr>
<td>V9027XD</td>
<td>Drowning and submersion due to falling or jumping from burning water-skis, subsequent encounter</td>
</tr>
<tr>
<td>V9027XS</td>
<td>Drowning and submersion due to falling or jumping from burning water-skis, sequela</td>
</tr>
<tr>
<td>V9037XA</td>
<td>Drowning and submersion due to falling or jumping from crushed water-skis, initial encounter</td>
</tr>
<tr>
<td>V9037XD</td>
<td>Drowning and submersion due to falling or jumping from crushed water-skis, subsequent encounter</td>
</tr>
<tr>
<td>V9037XS</td>
<td>Drowning and submersion due to falling or jumping from crushed water-skis, sequela</td>
</tr>
<tr>
<td>V9087XA</td>
<td>Drowning and submersion due to other accident to water-skis, initial encounter</td>
</tr>
<tr>
<td>V9087XD</td>
<td>Drowning and submersion due to other accident to water-skis, subsequent encounter</td>
</tr>
<tr>
<td>V9087XS</td>
<td>Drowning and submersion due to other accident to water-skis, sequela</td>
</tr>
<tr>
<td>V9107XA</td>
<td>Burn due to water-skis on fire, initial encounter</td>
</tr>
<tr>
<td>V9107XD</td>
<td>Burn due to water-skis on fire, subsequent encounter</td>
</tr>
<tr>
<td>V9107XS</td>
<td>Burn due to water-skis on fire, sequela</td>
</tr>
<tr>
<td>V9137XA</td>
<td>Hit or struck by falling object due to accident to water-skis, initial encounter</td>
</tr>
<tr>
<td>V9137XD</td>
<td>Hit or struck by falling object due to accident to water-skis, subsequent encounter</td>
</tr>
<tr>
<td>V9137XS</td>
<td>Hit or struck by falling object due to accident to water-skis, sequela</td>
</tr>
</tbody>
</table>

And 12 more....

### More Examples of Specificity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y92020</td>
<td>Kitchen in mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92021</td>
<td>Dining room in mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92022</td>
<td>Bathroom in mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92023</td>
<td>Bedroom in mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92024</td>
<td>Driveway of mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92025</td>
<td>Garage of mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92026</td>
<td>Swimming-pool of mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92027</td>
<td>Garden or yard of mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92028</td>
<td>Other place in mobile home as the place of occurrence of the external cause</td>
</tr>
<tr>
<td>Y92029</td>
<td>Unspecified place in mobile home as the place of occurrence of the external cause</td>
</tr>
</tbody>
</table>
More Examples of More Detailed Codes

R46.1 is “bizarre personal appearance”
R46.0 is “very low level of personal hygiene”
W22.02XA, “walked into lamppost, initial encounter
W22.02XD, “walked into lamppost, subsequent encounter”
Y93D1, “Activity, knitting and crocheting”
Y93D2, “Activity, sewing”
Y93J1, “Activity, piano playing”
Y93J2, “Activity, drum and other percussion instrument playing”
Y93J3, “Activity, string instrument playing”
Y93J4, “Activity, winds and brass instrument”
Y93C2, “Activity, hand held interactive electronic device”

Coding Change Relevant To Research Code

• Change of ICD-9 Research Code
  – From: V70.7 Examination of participant in clinical trial
  – To: Z00.6 Encounter for examination for normal comparison and control in clinical research program (Applicable To: Examination of participant or control in clinical research program)
• All Other Non-ICD Billing Codes (i.e. Condition Code 30, Q0/Q1 Modifiers etc.) remain same
• Don’t Forget 8 Digit Clinical Trial Number Effective January 1, 2014
Most Sponsors of Research Not Legally Required To Convert to ICD-10

• Continued submission may be requested to remain in ICD-9
  – Contractual Obligation
  – Data Consistency
• If protocols are written using ICD-9 codes, actions will be necessary such as...
  – Protocol Update to ICD-10 and/or
  – Site justify the back-conversion to assure protocol compliance

....And Much More!!!!!