

The University of Texas Systemwide  
Compliance Office  
Systemwide Compliance Academy  
Emerging Trends in Research

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# Agenda

- A Year-in-Review and Special Topics: What should you know?
  - 2011 OIG Work Plan (with continuing investigations from 2010)
  - The Administration's Policies & Initiatives
  - Affordable Care Act & Clinical Research
  - American Recovery and Reinvestment Act (ARRA) - A Major Influx of Federal Dollars Toward Research
  - Human Subjects Research Protections
  - HIPAA & HITECH
  - Conflicts of Interest and Financial Disclosure (OIG Recommendation re: Institutional COI)
  - Off-Label Marketing & Promotion
  - Export Controls
  - Medicare Advantage Clinical Research Billing Update
  - May 2010 MSP Guidance
- Closing Remarks / Q&A

# OIG Work Plan FY 2011

# DHHS OIG FY 2011 Work Plan Initiatives

## *Research Oversight*

The following OIG work plan initiatives include both ongoing and planned reviews. Additionally, OIG planned reviews related to the American Recovery and Reinvestment Act of 2009 (Recovery Act) are also provided.

- The Food and Drug Administration's Oversight of Investigational New Drug Applications
  - The OIG “will review FDA's process for evaluating investigational new drug (IND) applications.”
    - Drug sponsors submit IND applications to FDA for review, and the agency has 30 days from receipt of the applications to review them, after which the sponsors may start clinical trials without FDA's approval.
  - They “will assess FDA's timeliness and identify challenges to the IND review process.”

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

# DHHS OIG FY 2011 Work Plan Initiatives

## *Research Oversight*

- FDA's Policies and Procedures for Resolving Scientific Disputes
- FDA's 510K Process for Device Approval
- FDA's Oversight of Postmarketing Surveillance Studies of Medical Devices
- Submission of Electronic Drug Labels

# DHHS OIG FY 2011 Work Plan Initiatives

## *Research Oversight*

- National Institute of Environmental Health Science's Grant Process
  - The OIG “will review issues related to grants made by NIEHS to determine whether it complied with the HHS “Grants Administration Manual” and whether FY 2005 to 2007 expenses incurred by its Director’s office were in accordance with NIH policies.”

*(OAS; W-00-10-50036; expected issue date: FY 2010; **new start**)*

- Colleges' and Universities' Compliance With Cost Principles
  - The OIG “will review colleges' and universities' compliance with selected cost principles issued by OMB Circular A-21, Cost Principles for Educational Institutions.”
  - They will also “conduct reviews at selected schools based on the dollar value of Federal grants received and on input from HHS operating divisions and the offices of the Assistant Secretary for Resources and Technology (ASRT) and the Assistant Secretary for Administration and Management (ASAM).”

*(OAS; W-00-10-50037; various reviews; expected issue date: FY 2010; **new start**)*

# DHHS OIG FY 2011 Work Plan Initiatives

## *Research Oversight*

- Review of Extra Service Compensation Payments Made By Education Institutions
- Recharge Centers at Colleges and Universities
- Use of Data and Safety Monitoring Boards in Clinical Trials
- National Institute of Allergy and Infectious Diseases' Oversight of Project BioShield Grants
- National Center for Research Resources' Oversight of Clinical and Translational Science Awards

# DHHS OIG FY 2010 Work Plan Initiatives

## *Research Oversight*

- Use of Data and Safety Monitoring Boards in Clinical Trials
  - The OIG “will review the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials.”
    - A DSMB is a group of individuals with pertinent expertise that regularly reviews accumulated data from one or more ongoing clinical trials to ensure the safety of participants in the trials and the validity and integrity of the scientific data generated.
    - The NIH “Policy for Data and Safety Monitoring,” set forth in June 1998, requires that all NIH-funded clinical trials establish data- and safety-monitoring plans.
    - A variety of types of monitoring, including DSMBs, are used depending on the risk, nature, size, and complexity of the clinical trial.
    - This requirement sets minimum responsibilities that sponsoring Institutes and Centers must meet to ensure and oversee data and safety monitoring.
  - They “will also determine how and to what extent NIH is ensuring that grantees comply with the NIH policy for DSMBs in multisite clinical trials.”

*(OEI; 00-00-00000; expected issue date: FY 2011; **new start**)*

# DHHS OIG FY 2010 Work Plan Initiatives

## *Research Oversight*

- National Center for Research Resources' Oversight of Clinical and Translational Science Awards
  - The OIG “will review the National Center for Research Resources (NCRR) process for overseeing Clinical and Translational Science Award (CTSA) grantees.”
    - The CTSA program began in 2006 (to be fully implemented in 2012) to encourage intellectual discussion and dissemination of clinical research results and technologies among scientific investigators at 60 institutions that facilitate the creation of translational science networks and biomedical informatics tools.
    - The CTSA program awards 5-year grants to 12 academic health centers annually.
    - NCRR oversees this program and its milestones for compliance with CTSA program objectives and HHS grant administration requirements at 45 CFR pt. 74.
    - Congress awarded over \$300 million during the first 2 years of this program, with funding of the full CTSA initiative expected to exceed \$500 million annually by 2012.
  - They “will also examine the types of innovative information-sharing techniques developed through the CTSA program.”

*(OEI; 07-09-00300; expected issue date: FY 2010; **work in progress**)*

# DHHS OIG FY 2010 Work Plan Initiatives

## *Research Oversight*

- National Institute of Allergy and Infectious Diseases Oversight of Project BioShield Grants
  - The OIG “will review the processes that the National Institute of Allergy and Infectious Diseases (NIAID) uses to monitor Project BioShield grantees’ compliance with Federal laws, regulations, and policies.”
    - Project BioShield, created by the Project BioShield Act of 2004, authorizes the Federal Government to research, develop, and procure medical countermeasures, such as vaccines, therapeutics, and diagnostics.
    - It has lead responsibility for research and development of such medical countermeasures.
  - They will also “review NIAID’s oversight of grantees that have received awards under NIAID’s Project BioShield funding.”
  - They “will also examine how NIAID ensures that grantees are aware of required security measures as well as the consequences of noncompliance with the requirements during the research and development of Project BioShield products.”

*(OEI; 00-00-00000; expected issue date: FY 2010; **new start**)*

# DHHS OIG FY 2011 Work Plan Initiatives

## *ARRA/Recovery Act “Cross-Cutting” Investigations*

- Conflict of Interest Waivers at the Department of Health and Human Services
- Integrity of Recovery Act Expenditures
  - “We will review and evaluate credible allegations relating to improper expenditures of Recovery Act funds to identify cases in which criminal investigations will be opened and appropriate enforcement actions pursued.”
    - The Recovery Act funding will result in a significant increase in the number of grants and contracts awarded by HHS.
    - Accordingly, we anticipate an increase in the number of complaints and referrals of grant- and contract-related fraud allegations.
    - The Recovery Act requires transparency and accountability in the awarding and spending of funds.

*(OI; various reviews; expected issue dates: FY 2009 through FY 2012; work in progress; Recovery Act)*

# The Administration's Policies & Initiatives

# The Administration's Initiatives

- The Administration's initiatives have included:
  - Comparative effectiveness reviews and research<sup>2</sup>
    - “One of the keys to eliminating waste and missed opportunities is to increase our investment in comparative effectiveness reviews and research.”
    - Establish an independent institute to guide reviews and research on comparative effectiveness
  - *Consistent with his 2007 Senate vote in favor of the [embryonic] Stem Cell Research Enhancement Act, President Obama's....*
    - Investing in biomedical research, as well as medical education and training in health-related fields
    - Providing more than \$1 billion in federal funding for autism research
    - Creating an independent institute to guide reviews and research on comparative effectiveness of treatments
  - Establishing a Drug Development Center within NIH (the National Center for Advancing Translational Sciences)

1. <http://www.barackobama.com/issues/healthcare/index.php>

2. <http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf>

# Embryonic Stem Cell Research

- March 9th 2009 – Obama signs executive order to reverse President Bush’s policy on embryonic stem cell research: (EO) 13505—Removing Barriers to Responsible Scientific Research Involving Human Stem Cells
- Subsequent Bills (referred to Committee):
  - 111th Congress, House Bills
    - H.R. 110—Human Cloning Prohibition Act of 2009
    - H.R. 872—Stem Cell Research Improvement Act of 2009
    - H.R. 873—Stem Cell Research Enhancement Act of 2009
    - H.R. 877—Patients First Act of 2009
    - H.R. 1050—Human Cloning Prohibition Act of 2009
    - HR. 1654—Cures Can Be Found Act of 2009
    - HR. 2107—Cord Blood Education and Awareness Act of 2009
  - 111th Congress, Senate Bills
    - S. 99—Ethical Stem Cell Research Tax Credit Act of 2009
    - S. 487—Stem Cell Research Enhancement Act of 2009

# Embryonic Stem Cell Research

## *Expectations for Research Institutions*

- The Guardian newspaper article titled “Obama overturns Bush policy on stem cell research,” published on March 9th, 2009, suggested: <sup>1</sup>
  - “For Harvard University scientists, Obama's repeal today of Bush's restrictions on federal funding will have dramatic practical effects.”
    - “This will mean the end of the quite onerous bookkeeping and segregation of supplies, equipment and people that were necessary under the Bush executive order,” said BD Colen, spokesman for the institute in Cambridge, Massachusetts.”
    - “Harvard stem cell institute co-director Doug Melton will apply for federal grants to research ways to turn stem cells into heart cells, pancreatic cells to treat diabetes, and neurons that could someday yield a cure for Parkinson's and Alzheimer's diseases.”
- Glaxo Gives Harvard \$25 Million for Stem Cell Study <sup>2</sup>
  - July 24 (Bloomberg) -- GlaxoSmithKline Plc, Europe's largest drugmaker, will give the Harvard Stem Cell Institute at least \$25 million over five years to speed development of treatments using the technology.

1. <http://www.guardian.co.uk/world/2009/mar/09/obama-administration-stem-cell-funding>

2. <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aFl5sOcXjDxo>

# Embryonic Stem Cell Research

## *NIH Guidelines for Research Using Human Stem Cells*

- Principles:
  - Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover new ways to prevent and/or treat illness.
  - Individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.
- Protection of Human Subjects:
  - “*When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 C.F.R. 46, Subpart A. Applicants should consult <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.*”
  - “...the HHS regulation, *Protection of Human Subjects*, 45 C.F.R. Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 C.F.R. § 46.102(f).”

# Embryonic Stem Cell Research

## *NIH Guidelines for Research Using Human Stem Cells*

- Use of NIH Funds
  - “Prior to the use of NIH funds, funding recipients should provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs are listed on the NIH registry.”
- Research Using hESCs and/or Human Induced Pluripotent Stem Cells Ineligible for NIH Funding
  - “Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.”
  - “Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.”

# Embryonic Stem Cell Research

## Constitutionality of Executive Order

- The reversal in the Executive Order went further than overturning a policy of the previous Administration. It may have attempted to overturn specific 1995 legislation prohibiting federal funding of embryonic stem cell research.
- Basic principle: Executive Orders may only be used to establish rules which either the Constitution or legislation provides authority to the Executive Branch to act on a matter.
- A federal trial court in Maryland (August 2010) has held the Executive Order an unconstitutional exercise of power in contradiction to federal legislation. The 4<sup>th</sup> Circuit Court of Appeals (Jan 2011) reversed the trial court on technical grounds of the plaintiff's standing. The legal status of the current Administration's policy is in limbo.

# False Claim Act Amendments

*FERA 2009*

- Fraud Enforcement and Recovery Act of 2009
  - In May 2009 President Obama signed FERA into law. It is a tool created to allow the federal government greater ability to recover funds lost to mortgage, securities and commodities, financial institution, and other “frauds” related to federal assistance programs.
  - Section 4 of FERA, “Clarification to the False Claims Act to Reflect the Original Intent of the Law” amends the False Claims Act by:
    - Broadening the definition of “claim”
    - Expanding liability for retentions and overpayments
    - Requiring violators to reimburse the federal government for the costs of civil action to recover penalties or damages.
    - Establishing a retroactive effective date of June 7, 2008

# False Claim Act Amendments

*FERA 2009*

- Impact on Clinical Research:
  - The False Claims Act Amendments are far-reaching for health care organizations and it is important to note:
    - Any claim to the federal government is potentially subject to the FCA – this includes grant applications and any reporting on use of research funds
    - The FCA also applies to claims submitted to contractors the federal government
    - FCA risk exists for both federal grants and claims to federal health care programs for clinical services during research studies
    - Keep in mind that sub-contracts and multi-center sites for a federal research grant are covered by the FCA
    - Co-op studies are funded by NCI and are also covered by FCA
- The FERA amendments had a retroactive effect – numerous federal courts are considering the constitutionality of retroactive effect, and several have already declared it unconstitutional

# Affordable Care Act & Clinical Research

# Affordable Care Act & Clinical Research

- New 42 USC 300gg–8:
  - A health plan using the “exchange”:
    - (A) may not deny the individual participation in [an approved] clinical trial....;
    - (B) [...]may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
    - (C) may not discriminate against the individual on the basis of the individual’s participation in such trial.
- Effective: 2014
  - Does not apply to Medicare & Medicaid
  - Does not preempt State laws

# Affordable Care Act & Clinical Research

- Definition:

(2) ROUTINE PATIENT COSTS...routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

# Affordable Care Act & Clinical Research

- Definition:

QUALIFIED INDIVIDUAL: Is a person who meets the criteria of an “approved clinical trial.”

# Affordable Care Act & Clinical Trials

- **Definition:**

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term ‘approved clinical trial’ means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

[Contains list similar to CMS CTP: Studies funded by NIH, CDC, AHCRQ, CHC, center supported by NIH, VA, DOD, and studies in the FDA IND process, or exempt from IND process]

[Also adds: DOE]

# American Recovery and Reinvestment Act

# American Recovery and Reinvestment Act

- American Recovery and Reinvestment Act of 2009 was passed on February 13, 2009 by the House and Senate and signed into law February 17, 2009
- Three stated goals of the ARRA at the time were to<sup>1</sup>:
  - Create new jobs as well as save existing ones
  - Spur economic activity and invest in long-term economic growth
  - Foster increased levels of accountability and transparency in government spending
- Grant recipient reporting began on October 1, 2009.
  - “The second reporting period has ended. The next reporting period begins on April 1, 2010.”
  - “Beginning on February 2 and continuing through March 15, federal agencies will have the ability to comment on recipient's reports. Prime and sub-recipients will be able correct and revise their reports.”<sup>2</sup>

1. [http://www.recovery.gov/About/Pages/The\\_Act.aspx](http://www.recovery.gov/About/Pages/The_Act.aspx)

2. [http://www.recovery.gov/FAQ/recipient/Pages/Recipient\\_Reporting.aspx](http://www.recovery.gov/FAQ/recipient/Pages/Recipient_Reporting.aspx)

# American Recovery and Reinvestment Act

- Federal Coordinating Council for Comparative Effectiveness Research<sup>1</sup>
  - ARRA created the Federal Coordinating Council for Comparative Effectiveness Research to coordinate comparative effectiveness research across the Federal government. \$1.1 billion has been appropriated for comparative effectiveness research.
- National Institutes of Health<sup>2</sup>
  - ARRA provides \$10.4 billion, available for two years through September 2010. Expectations to spend as much as possible in FY 2009.
    - Unprecedented \$8.2 billion in extramural funding (13,784 Grants as of 2/21/2010)
- National Institute of Standards and Technology<sup>3</sup>
  - ARRA provides \$610 million in funding to NIST
    - Covers lab research, measurements, competitive grants, research fellowships, and advanced measurement equipment, supplies and the expansion and development of EMR technology.

1.<http://www.hhs.gov/recovery/programs/os/cerbios.html>

2.[http://www.nih.gov/about/director/02252009statement\\_arra.htm](http://www.nih.gov/about/director/02252009statement_arra.htm)

3.<http://www.nist.gov/recovery/>

# American Recovery and Reinvestment Act

## *Expectations for Research Institutions*

- NIH will invest in projects that will stimulate the economy, create or retain jobs, and have the potential for making scientific progress in 2 years.
- Under ARRA NIH:
  - “Expand the pay line” and select recently peer-reviewed and approved, highly-meritorious research grant applications (\$5.7 Billion)
    - R01s and others that were not funded in FY 2008, as well as grant applications that would not otherwise likely be funded in FY 2009 or FY 2010.
  - Fund new research applications
  - Provide targeted supplements to current grants (approximately \$1 billion)
    - Competitive Revisions (NOT-OD-09-058) and Administrative Supplements (NOT-OD-09-056)
  - Support new types of activities such as the NIH Recovery Act Challenge Grant program to focus on health and science problems, including cancer and autism, where significant progress can be made in a two year time frame.
    - Challenge Grants (NOT-OD-09-058) (at least \$200 million / 200 grants)

# American Recovery and Reinvestment Act

## *Expectations for Research Institutions*

- Under ARRA NIH will:
  - Use other funding mechanisms as appropriate, including:
    - Grant Opportunity Program, or “GO grants” (RFA-OD-09-004) (at least \$200 million) to support high impact ideas requiring significant funding
    - New Faculty (RFA-OD-09-005) (approximately \$100 million) to support the recruitment of new faculty to conduct research at institutions across the country.
    - Summer Research Experiences for Students and Science Educators (NOT-OD-09-060) (approximately \$20 million) to provide summer jobs for high school/college students and teachers to work in science labs.
    - NIH Signature Initiatives to support exceptionally creative and innovative projects and programs, including: “nanotechnology, genome-wide association studies, health disparities, arthritis, diabetes, autism, the genetic risk for Alzheimer’s disease, regenerative medicine, oral fluids as biomarkers, and HIV vaccine research.”

# American Recovery and Reinvestment Act

## *Guidelines for Research Institutions*

- Consistent with statutory and OMB guidance, NIH is supposed to be open and transparent in its spending of ARRA funding. Measures include:
  - Making public (on Recovery.gov) quarterly recipient reporting, as required by Section 1512 of the Recovery Act and OMB guidance.
  - Informing recipients of their reporting obligations, using standard terms and conditions, grant announcements, contract solicitations, and other program guidance.
  - Ensuring that appropriate processes by which an organization's resources are directed, monitored, and measured are in place throughout the entire funding cycle.
  - Providing more technical assistance to recipients.
  - Utilizing Project Officers to ensure compliance with reporting requirements.
  - Ensuring recipient cost and performance reporting requirements by issuing Recovery Act awards with special accounting numbers and codes to better track the funds and awards.

**All Recovery Act funds must be awarded separately from the normal appropriation funds and all awards must comply with both existing NIH reporting requirements and the Recovery Act reporting requirements.**

# American Recovery and Reinvestment Act

*Federal Oversight (not specific to research funding)*

- “The Recovery Board encourages citizens to report suspected fraud, waste, or abuse.
  - All reports are closely reviewed, and if any warrant investigation, they are referred to the appropriate Inspector General.
- As of December 31, 2009, the Recovery Board and the federal Inspectors General had received 1,501 complaints (up from 1,006 at the end of November) of wrongdoing associated with Recovery funds
  - 141 triggered active investigations
  - 27 cases resulted in a prosecutor's office opening a file and continuing to work with an investigator on the matter.
- The federal Inspectors General had also completed 324 reviews of activity involving Recovery funds
  - Many of these reviews have resulted in recommendations on improving the use of these funds.”

# **Human Subjects Research Protections**

# Human Subjects Research Protections

## *Laws, Regulations, & Responsibilities*

### 21 CFR 56 Institutional Review Boards (FDA)

- Effective July 14, 2009 – The FDA final rule (21 CFR 56.106) requires IRBs to register through a system maintained by the Department of Health and Human Services (HHS).
  - Registration information includes:
    - Contact information (such as addresses and telephone numbers),
    - The number of active protocols involving FDA-regulated products reviewed during the preceding 12 months, and
    - A description of the types of FDA-regulated products involved in the protocols reviewed.
  - The IRB registration requirements will make it easier for FDA to inspect IRBs and to convey information to IRBs.
  - All IRBs must comply with the initial registration requirement and, if necessary, make required revisions to their registrations by September 14, 2009.

# Human Subjects Research Protections

## *Proposed Amendment to Informed Consent Regulations*

### 21 CFR 50 Informed Consent Elements (FDA)

- In December 2009 the FDA issued proposed rules for public comment related to informed consent documents and processes:
  - Requirement that informed consent documents to state that clinical trial information for such investigations has been or will be submitted to the National Institutes of Health/National Library of Medicine (NIH/NLM) for inclusion in the clinical trial registry databank ([www.clinicaltrials.gov](http://www.clinicaltrials.gov))
  - Requirement for a descriptive explanation of the registry databank
  - The proposed amendment applies to clinical investigations of drugs, devices and biologics
  - Comment period concludes March 2010

# Human Subjects Research Protections

## *Laws, Regulations, & Responsibilities*

### 21 CFR 312.300 Expanded Access to Investigational Drugs (FDA)

- In August 14, 2009 The FDA announced changes to expanded access regulations that permit the use of investigational drugs for the treatment of patients despite the fact that safety and effectiveness has not been fully established
  - Explains standards and procedures for submission for expanded access
  - Describes the types of expanded access programs and criteria:
    - Individual patient
    - Intermediate sized patient populations
    - Treatment IND or Treatment Protocols
  - Clarifies when a drug manufacturer can charge for an investigational drug used in a clinical trial or in an expanded access program
  - Clarifies what costs manufacturers can recover when charging

# Human Subjects Research Protections

*Draft Guidance Issued by OHRP and FDA*

- October 2009 – OHRP circulated draft guidance to institutional review boards (IRBs) The document provides recommendations regarding the criteria, process, and frequency of continuing review<sup>1</sup>:
  - Use of IRB staff for preliminary review, primary reviewers, continuing review approval with conditions
  - Types of information for consideration at continuing review- risk assessment & monitoring, adequacy of informed consent process, investigator and institutional issues
  - Use of cooperative review agreements or centralized IRB for continuing review of multi-site research
  - Recommendations on appropriate utilization of expedited review procedures under categories 8 and 9 for continuing research
- The draft guidance offers clarification on determination of continuing review dates and lapse in IRB approval
- The FDA guidance comports with OHRP's and was released January 2010<sup>2</sup>

1. [http://www.hhs.gov/ohrp/requests/200911guidance\\_rev.pdf](http://www.hhs.gov/ohrp/requests/200911guidance_rev.pdf)

2. <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM197347.pdf>

# Human Subjects Research Protections

## *Recent Headlines*

- March 26, 2009 – GAO: Undercover Tests Show the Institutional Review Board System Is Vulnerable to Unethical Manipulation<sup>1</sup>
  - “The IRB system is vulnerable to unethical manipulation, which elevates the risk that experimental products are approved for human subject tests without full and appropriate review.”
  - “GAO investigators created fictitious companies, used counterfeit documents, and invented a fictitious medical device to investigate three key aspects of the IRB system.”

### **Results:**

- GAO succeeded in getting approval from an actual IRB to test a fictitious medical device (with fake specifications that matched several examples of “significant risk” devices from FDA guidance) on human subjects.
- The IRB did not verify the false information that FDA had already cleared GAO’s device for marketing.
- June 30, 2009 – Coast IRB closed its doors and ceased operations following GAO sting and FDA warning.<sup>2</sup>

1. <http://www.gao.gov/new.items/d09448t.pdf>

2. [http://www.coastirb.com/coastirb\\_fda](http://www.coastirb.com/coastirb_fda)

# Human Subjects Research Protections

## *Recent Headlines*

- Fifth Circuit Says Clinical Investigators Can Be Criminally Liable For Violating FDA Record-Keeping Requirements
  - In *United States v. Palazzo* (reported at 558 F. 3d 400)<sup>1</sup>, a licensed medical doctor specializing in psychiatry was a Medicare provider authorized to submit bills for reimbursement for certain medical services provided to eligible Medicare beneficiaries.
  - Plaintiff-Appellant, the United States (“the Government”), brought charges against Dr. Palazzo for health care fraud and failure to maintain records of the clinical drug studies.
  - In its appellate review of FDA Regulations and 21 C.F.R. § 312.62(b), the Fifth Circuit clinical investigators to be subjected to criminal liability for the failure to adhere to recording keeping and reporting requirements.
  - Palazzo was then denied both a petition for rehearing on March 20, 2009 (Pet. App, 46-47) and writ for certiorari on October 5, 2009 (2009 WL1883419)<sup>2</sup>.
  - While her appeal was pending, the petitioner was tried by a jury on the remaining counts of the original indictment, except for one count that was dismissed on the motion of the government. The jury found petitioner guilty on all counts, and she was sentenced to 87 months of imprisonment.

1. [http://www.circare.org/lex/palazzo\\_0731119.pdf](http://www.circare.org/lex/palazzo_0731119.pdf)

2. <http://www.usdoj.gov/osg/briefs/2009/0responses/2008-1536.resp.html>

# Human Subjects Research Protections

## *Recent Headlines*

- On August 16, 2009, the FDA published two rules that seek to clarify the methods available to seriously ill patients interested in gaining access to investigational drugs and biologics when ineligible to participate in clinical trials and without satisfactory treatment options.
  - Found at 21 CFR Parts 312 and 316, respectively, are:
    - "Expanded Access to Investigational Drugs for Treatment Use," makes investigational drugs more widely available to patients by clarifying procedures and standards and
    - "Charging for Investigational Drugs Under an Investigational New Drug Application." The latter describes the specific circumstances and types of costs for which manufacturers can charge patients for investigational drugs when used as part of a clinical trial or outside the scope of a clinical trial.
  - "The final rules balance access to promising new therapies against the need to protect patient safety and seek to ensure that expanded access does not discourage participation in clinical trials or otherwise interfere with the drug development process," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

# HIPAA & HITECH

# Health Insurance Portability & Accountability Act

## *Laws, Regulations, & Responsibilities*

- The HIPAA Privacy Rule was the first comprehensive Federal protection for the privacy of personal health information (PHI).
  - Research institutions and investigators may or may not be covered by the HIPAA Privacy Rule.
  - **<http://privacyruleandresearch.nih.gov/> provides all the information you need to know on the HIPAA Privacy Rule and its relationship to research.**
- Prior to HIPAA, investigators were already required to take measures to protect PHI from inappropriate use or disclosure.
  - As we discussed, these measures are included in the HHS and FDA Protection of Human Subjects regulations 45 CFR part 46 or 21 CFR parts 50 and 56, respectively.
- HITECH Act (part of ARRA) supplemented and/or modified certain provisions of the HIPAA Privacy Rule
  - State Attorneys General may bring civil actions in federal court on behalf of the state's residents.
  - Civil monetary penalties for HIPAA violations have increased.

# HIPAA

## *Laws, Regulations, & Responsibilities*

- Authorization for Research Purposes
  - Pertains only to a specific research study, not to future, unspecified projects.
  - An Authorization is different than Informed Consent
    - An Authorization is an individual's permission for a covered entity to use or disclose PHI for a certain purpose, such as a research study.
    - Informed Consent is the individual's permission to participate in the study.
  - An Authorization can be combined with an Informed Consent Form (ICF)
    - Must include the core elements and required statements. See <http://privacyruleandresearch.nih.gov/authorization.asp#samplelang>

# HIPAA

## *Laws, Regulations, & Responsibilities*

- Covered entities may permit researchers to review PHI in medical records or elsewhere during reviews preparatory to research, as long as the covered entity receives representations from the researcher that:
  - The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes.
  - No PHI will be removed from the covered entity during the review.
  - The PHI that the researcher seeks to access is necessary for the research purposes.

# HIPAA

## *Recent Headlines*

### **Institute of Medicine**

- February 2009 – IOM: “Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Research”
  - IOM committee concludes that the HIPAA Privacy Rule does not protect privacy as well as it should, and that, as currently implemented, it impedes health research.
  - Recommended that federal policymakers develop a new privacy framework apart from HIPAA for health research that standardizes ethical oversight and emphasizes strong security protections.
  - Recommended extending the Common Rule to all interventional research regardless of funding source.

# Conflicts of Interest & Financial Disclosure

# Conflicts of Interest & Financial Disclosure

## *Context*

- **OIG FY 2009 Work Plan Initiative (Recap):**
  - Financial Conflicts of Interest in Research Funded by the National Institutes of Health
    - Review NIH's oversight of grantees' compliance with financial conflict-of-interest requirements.  
Federal regulations at 42 CFR pt. 50, subpart F
    - Review NIH's processes for reviewing the nature and management of financial conflict of interest reported by grantee institutions during FY 2006.
- **OIG FY 2010 Work Plan Initiative (Recap):**
  - Examination of CMS process for oversight of contractor COI disclosures
  - Examination of institutional financial conflicts of interest for NIH grant recipients
  - Review of conflicts of interest reported by special government employees who serve on HHS Federal Advisory Committees

# Conflicts of Interest & Financial Disclosure

## *General Definition*

- A conflict of interest involves the abuse -- actual, apparent, or potential -- of the trust that people have in professionals.
- Simple Working Definition:
  - “An **actual conflict of interest** is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.”
  - An **apparent conflict of interest** is one in which a reasonable person would think that the professional’s judgment is likely to be compromised.
  - A **potential conflict of interest** involves a situation that may develop into an actual conflict of interest.
- Note:
  - A conflict of interest exists whether or not decisions are affected by a personal interest.
  - A conflict of interest implies only the potential for bias, not a likelihood.
  - Conflicts may involve both individuals and institutions

# Conflicts of Interest & Financial Disclosure

## *Proposed PHS Legislation*

- On May 8, 2009, The National Institutes of Health (NIH) issued an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register.
  - The purpose was to gain public input on whether modifications are needed to the PHS regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94).
- The NIH is specifically interested in comments regarding the:
  - Expansion of the scope of the regulation and disclosure of interests;
  - Definition of “significant financial interest”;
  - Identification and management of conflicts by institutions;
  - Assurance of institutional compliance;
  - Provision of additional information to federal officials by research institutions; and
  - Broadening of the regulations to address institutional conflicts of interest.

# Conflicts of Interest & Financial Disclosure

## *Industry Trends*

- Increased transparency and plans for public disclosure of payments to physicians
  - Eli Lilly & Company to post in an online database all its payments to doctors for speaking and consulting services in 2009.
    - July 31, 2009 – New “faculty registry” lists payments to all the doctors who served as consultants in the first quarter of this year
  - Merck & Company also said that it would disclose speaking fees it pays to doctors, beginning in 2009.
  - Johnson & Johnson said that the company supported a “revised version” of the Physician Payments Sunshine Act, and is committed to disclosing payments for educational grants and to patient-advocacy organizations by early 2009. <sup>1</sup>

1. <http://www.nytimes.com/2008/09/25/health/policy/25drug.html>

# Conflicts of Interest & Financial Disclosure

## *Industry Trends*

- What should providers do in light of this? Reconcile with sponsors?
- February 9, 2009 – Pfizer Inc. announced that it will publicly disclose online payments made to healthcare providers, principal investigators, major academic institutions, and clinical research sites. This will include payments made for consulting services, speaking engagements, and conducting clinical trials.<sup>1</sup>
  - Plans to first publish on its website in 2010, but will include all payments made after July 1, 2009.
  - Pfizer also supports the Physician Payments Sunshine Act.

1. <http://www.healthlawyers.org/News/HLWArchive/Pages/2009/February%202009/February%2013%202009/PfizerAnnouncesPhysicianPaymentDisclosureProgram.aspx>

# Conflicts of Interest & Financial Disclosure

## *Industry Trends*

- Strengthening ethical standards governing vendor gift-giving and marketing practices through adoption of voluntary codes and policies
  - April 28, 2009 – Institute of Medicine (IOM) issues a report called “Conflict of Interest in Medical Research, Education, and Practice. “
  - The goal of the report was to conduct a comprehensive examination of conflicts of interest in medicine and provide recommendations on policies and practices for medical institutions.
    - Argues for voluntary and regulatory measures to reduce conflicts of interest.
    - Stresses the importance of preventing bias and mistrust
    - Focuses specifically on financial conflicts of interest involving pharmaceutical, medical device, and biotechnology companies, and
    - Recommends the implementation of policies and procedures to reduce the risk of conflicts of interest that can jeopardize research integrity, objective medical education, quality of care, and public trust.

# Conflicts of Interest & Financial Disclosure

*Clinical Investigator Responsibilities -FDA*

- 21 CFR Part 54, Financial Disclosure by Clinical Investigators
  - This federal regulation affects clinical investigators linked to clinical data submitted to the FDA in marketing applications for drugs, biological products, and devices.
  - Applicants must disclose or certify information concerning the financial interests of a of all clinical investigators who conducted covered clinical studies:
    - (a) Attestation to the absence of financial interest and arrangements (completed FDA Form 3454)
    - (b) Disclosure (FDA Form 3455) of:
      - financial arrangements between sponsor and investigator,
      - significant payments from sponsor to investigator
      - proprietary interest (patent, trademark) in the test product held by the i
      - significant equity interest held by investigator
  - PIs must provide the sponsor with accurate financial information during disclosure process.
  - FDA may refuse to file a marketing application if there was no certification or disclosure of financial information.

**Significant payments are more than \$25,000. Significant equity interest is any ownership interest, stock options, or other financial interest in a public corporation that exceeds \$50,000. These thresholds are applicable during the time project and for 1 year after completion of the study.**

# Conflicts of Interest & Financial Disclosure

## *Industry Trends – Interactions with Healthcare Providers*

- July 10, 2008 – Pharmaceutical Research and Manufacturers of America (PhRMA) revised Code on Interactions with Healthcare Professionals (Effective January 2009)
  - New Provisions & Revisions
    - Prohibit giving non-educational items (e.g. pens, mugs and other “reminder” objects adorned with a company or product logo) to healthcare providers and their staff.
    - Prohibit sales representatives from “wining and dining” (providing restaurant meals to healthcare professionals).
    - Require companies ensure that their sales reps are sufficiently trained about applicable laws, regulations, and industry codes of practice that govern interactions with healthcare professionals.

# Conflicts of Interest & Financial Disclosure

## *Industry Trends – Interactions with Healthcare Providers*

- PhRMA Code (continued)
  - Recommends that companies assess compliance with relevant standards of conduct.
  - Requires yearly certification by company CEOs and CCOs that they have processes in place to comply with the revised Code.
    - Disclosure requirements for healthcare providers who help set formularies or develop clinical practice guidelines and who serve as speakers or consultants for a pharmaceutical company.
  - More comprehensive guidance regarding speaking and consulting arrangements with healthcare professionals.
  - Accordance with the revised Physician Payments Sunshine Act (S. 2029).

# Conflicts of Interest & Financial Disclosure

## *Industry Trends – Interactions with Healthcare Providers*

- December 18, 2008 – Advanced Medical Technology Association (AdvaMed), a national trade association of medical technology manufacturers, issued a revised Code of Ethics on Interactions with Healthcare Professionals. (Effective July 2009)
  - Contains changes that will impact the AdvaMed members in the medical device industry, as well as non-members who may chose to adopt the ethical standards. Changes include:
    - AdvaMed’s public website will list companies that certify their adoption of the Code.
    - A ban on providing restaurant meals, entertainment or recreation, and gifts of *any* type to Healthcare professionals (HCPs).
    - Additional guidelines for royalty payments to Healthcare Professionals in exchange for substantial contributions that improve medical technologies.
    - A new section addressing Evaluation and Demonstration Products that sets forth appropriate parameters under which companies may provide no-charge products intended to educate both HCPs and patients on newer or improved medical technologies.

# OIG Guidance on Institutional Conflicts of Interest

- In 2010, the DHHS OIG promulgated guidance to research sites regarding implementation of policies, procedures and disclosure mechanisms related to institutional conflicts of interests
- Institutional Conflicts of Interest include company ownership or proprietary interests in patents, research discoveries, new technologies
- It is clear that government agencies demand transparency in the area of conflicts of interest and the industry will need to respond

# Conflicts of Interest & Financial Disclosure

*DHHS Guidance*

Financial Interests and the Safety/Welfare of Human Subjects Points of Consideration		
Institutions	IRBs	Investigators
Establish a Conflicts of Interest Committee and Policies/Procedures on its Operation and Communication with the IRB	Determine If Methods to Manage Conflicts Adequately Protects Human Subjects or Whether Additional Actions are Necessary	Modify the informed consent process when a potential or actual financial conflict exists, by either <ul style="list-style-type: none"> <li>• Having a another individual involved in the consent process or,</li> <li>• Using independent monitoring of the research.</li> </ul>
Determine What Constitutes an Institutional Conflict of Interest	Determine the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.	
Develop Policies/Procedures on the Financial Relationships that may/may not be held by those involved in research		

# Conflicts of Interest & Financial Disclosure

*DHHS Guidance (continued)*

- Research institutions and academic medical centers must adopt and enforce conflict of interest policies that counterbalance often competing priorities and anticipate difficult deliberations. Examples:
  - An individual has significant financial interest (e.g. a consulting relationship or intellectual property) but may be essential to the conduct of the forecasted research.
- Entities such as conflict of interest committees (COIC) – made up of ex-officio members (Compliance, General Counsel) and voting members (department heads, community members, faculty researchers) – are well situated to determine how best to manage the conflict and protect the integrity of the research.

# Conflicts of Interest & Financial Disclosure

*DHHS Guidance (continued)*

- Every institution or organization should first assess whether it encounters conflicts of interest and the appropriate infrastructure to cope with assessing and managing them.
- Policies, procedures and process flows need to be developed, vetted and disseminated organization wide
- Prioritize federally regulated areas such mechanisms to ensure as research contributors are disclosing “significant financial interests” on an annual basis.
- If such policies, procedures and process flows do already exist, it is advisable to review and update them periodically to ensure they remain operationally relevant.

# Conflicts of Interest & Financial Disclosure

*DHHS Guidance (continued)*

- Institutions should prioritize implementing a reporting, evaluation and management process reliant on review by either:
  - An internal conflict of interest committee (COIC) or, if a smaller entity with limited resources, an external reviewer.
  - COIC should ideally have an administrative arm that assists with tasks such as documenting minutes, collection of annual disclosures, maintenance of records (e.g. issued management plans) and coordinates meeting with Principal Investigators.
  - Reporting of conflicts of interests can be effectuated by use of either a manual or electronic/automated solution.

# Off Label Marketing & Promotion

# Off-Label Marketing and Promotion

## *Context*

- Increasing Trends:
  - More state False Claim Acts enacted over recent years
  - More off-label use and promotion by physicians
  - More investigations and litigation
  - More legal uncertainty and risk for the pharmaceutical industry
- While the number of post-marketing studies are increasing, there still remains a need for clarifying the laws and regulations that apply to “non-registrational” (i.e. non-IND/IDE) vs. “registrational” studies (i.e. studies with IND/IDE).
  - “Use of a marketed product... when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an IRB”
  - Thus, different rules apply when investigators prescribe drugs for off-label use not covered under an IND, but receive payment from pharmaceutical companies for participating in the post-marketing study of the drug.

# Off-Label Marketing and Promotion

## *Laws, Regulations, & Responsibilities*

- The two major laws that generally apply to allegations of improper, off-label promotion of approved drugs are:
  - The Anti-kickback Statute, and the False Claims Act (both Federal and State laws)
- In some cases, other applicable laws and regulations that can apply are:
  - HIPAA
  - The Common Rule
  - Food and Drug Administration Modernization Act (FDMA)
  - Generic Drug Enforcement Act (for investigators on the FDA’s Debarment List)
  - Reporting Post-marketing Adverse Drug Experiences and Unanticipated Side Effects (21 CFR 314.80)
- Laws that do not generally apply to off-label (“non-registrational”), post-marketing studies:
  - 21 CFR 54 (Financial Disclosure)
  - 21 CFR 312 (IND Requirements)
  - Physician Self-referral (“Stark”)

# Off-Label Marketing and Promotion

## *New State Laws*

- June 8, 2009 – Gov. Douglas of Vermont signs into law an act relating to the marketing of prescribed products (Act No. 59)
  - Similar to the Massachusetts law
  - *Effective July 1, 2009*, the Vermont Act companies from paying for any food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider.
  - Annually required disclosure of all payments by companies to providers with prescribing authority

# Off-Label Marketing and Promotion

*Proposed Federal Legislation (referred to Committee)*

- January 22, 2009 – Senators Grassley (R-IA) and Kohl (D-WI) introduce The Physician Payments Sunshine Act of 2009, to require drug and device manufacturers to publicly report payments (over \$100) to physicians every year.
  - Companies will be required to report items, such as:
    - Consulting Fees
    - Compensation for services other than consulting
    - *Honoraria*
    - Current or prospective ownership or investment interests
    - Compensation for serving as a faculty member / speaker for CME program
    - Grants
    - Any other payment or transfer of value as defined by the secretary
    - Food
    - Gifts
    - Entertainment
    - Travel
    - Education
    - Research
    - Charitable Contributions
    - Royalties or licenses

# Off-Label Marketing and Promotion

## *Proposed Federal Legislation*

- The Physician Payments Sunshine Act of 2009 also included:
  - Required reporting of research payments
  - Required reporting of physician ownership interests in private companies
  - Unintentional failure to report: penalties to include fines from \$1,000 - \$10,000 for each payment not reported with a cap of \$150,000/year
  - Intentional failure to report: penalties to include fines from \$10,000 - \$100,000 for each payment not reported with a cap of \$1 million/year
- March 11, 2009 – Promoting Innovation and Access to Life-Saving Medicine Act<sup>2</sup>
  - Provide for the licensing of biosimilar and interchangeable biological products
  - Allows any person to file an abbreviated biological product application with the Secretary of HHS
  - Requires applications to demonstrate a high degree of similarity or interchangeability between the biological product and the licensed biological product (reference product)

1. <http://www.policymed.com/2009/01/physician-payment-sunshine-act-2009-introduced.html>

2. <http://www.opencongress.org/bill/111-h1427/show>

# Off-Label Marketing and Promotion

## *Proposed Federal Legislation*

- March 23, 2010: Affordable Care Act Sec. 6002
  - Incorporated most aspects of the proposed sunshine law
  - Provisions begin in 2012: Start date for recording is January 1, 2012
  - Start date for reporting: March 31, 2013
  - Included in disclosure:
    - Name of physician
    - Business address of physician
    - Physician specialty
    - NPI
    - Value of the payment or transfer of value
    - Name of related drug, device or supply
    - Description of form of payment
    - Drug sample data

# Off-Label Marketing and Promotion

## *Recent Headlines*

- September 2, 2009 – Pfizer to Pay \$2.3 Billion for Fraudulent Marketing<sup>2</sup>
  - To settle a federal investigation into its alleged off-label marketing of the now-withdrawn painkiller Bextra.
  - Largest settlement of improper off-label marketing practices
  - **Largest health care fraud settlement in the history of the Department of Justice**
  - Already in a 5 year CIA from 2004 for off-label promotion of Neurontin<sup>3,4</sup>

1. <http://www.usdoj.gov/opa/pr/2008/September/08-civ-860.html>  
2. <http://www.usdoj.gov/opa/pr/2009/September/09-aag-900.html>  
3. [http://oig.hhs.gov/fraud/cia/agreements/pfizer\\_5\\_11\\_2004.pdf](http://oig.hhs.gov/fraud/cia/agreements/pfizer_5_11_2004.pdf)  
4. [http://www.usdoj.gov/opa/pr/2004/May/04\\_civ\\_322.htm](http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm)

# Off-Label Marketing and Promotion

## *Recent Headlines*

- July 14, 2009 – Endoscopic Technologies Inc. (Estech) agrees to pay U.S. \$1.4 million to resolve allegations of Medicare fraud, including:<sup>1</sup>
  - Off-label marketing its medical devices to treat atrial fibrillation, a use that is not approved by the FDA.
  - Promoting expensive heart surgeries using the company's devices when less invasive alternatives were appropriate,
  - Advising hospitals to up-code surgical procedures using the company's devices to inflate Medicare reimbursements, and
  - Paying kickbacks to healthcare providers to use its devices.

1. <http://www.usdoj.gov/opa/pr/2009/July/09-civ-681.html>

2. <http://www.usdoj.gov/opa/pr/2008/November/08-civ-1012.html>

# Export Controls

# Export Controls

## *What You Need to Know*

- Export control regulations are intended to protect national security and to secure both domestic and foreign policy initiatives.
- Each of academic medical center, hospital, pharmaceutical or device maker should be able to satisfactorily answer the following questions:
  - *Who works here and collaboratively with our employees?*
  - *What is in my research portfolio/ under development?*
  - *Where will the devices, technologies, drugs, etc. head next?*
  - *What types of technical data or items in-coming to our laboratories?*
- As industries – including health care – become increasingly enmeshed in a global economy, planning and developing an infrastructure to mindfully accommodate and compliantly manage research initiatives and the exchange of information and technologies is critical.
- Such an approach not only protects an organization from onerous civil and criminal penalties, but, ultimately, for long term success.

# Export Controls

## *Recent Headlines*

- August 6, 2009: DHL Settles Iranian Transactions Regulations, Sudanese Sanctions Regulations, Reporting, Procedures and Penalties Regulations, and Export Administration Regulations Allegations with OFAC and the Department of Commerce's Bureau of Industry and Security (BIS):
  - DPWN Holdings (USA), Inc. and DHL Express (USA), Inc. (collectively "DHL") have agreed to remit \$9,444,744 to settle allegations of violations of the Iranian Transactions Regulations, the Sudanese Sanctions Regulations, the Reporting, Procedures and Penalties Regulations (collectively, the "OFAC Regulations") and the Export Administration Regulations ("EAR").
  - OFAC alleged that, between August 2002 and March 2007, DHL made numerous shipments to Iran and Sudan in violation of the OFAC Regulations and that the company failed to maintain records with respect to other shipments to those countries.
  - BIS alleged that between June 2004 and September 2004, DHL made certain unlicensed exports to Syria in violation of the EAR and in connection with a number of other exports to Syria failed to retain airway bills and other export control documents in violation of the EAR.
  - DHL did not voluntarily disclose this matter to OFAC or BIS. It was resolved according to the prior enforcement guidelines published by OFAC at 68 Fed. Reg. 4422.

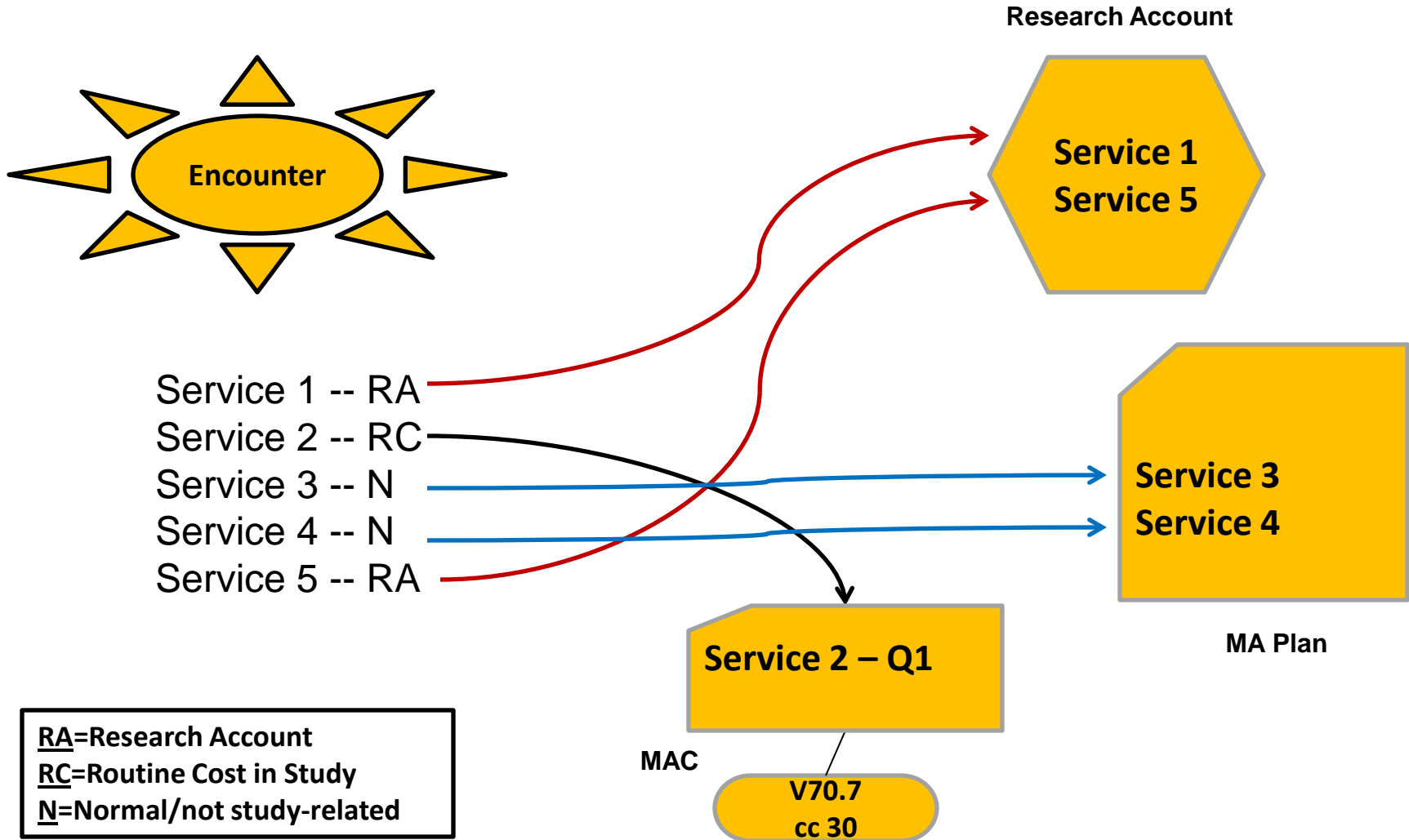
# **CMS Managed Care & Clinical Research Billing Update**

# CMS Managed Care & Clinical Research Billing

## *Update*

- In October 2009 CMS issued clinical trial billing guidance through MLN Matters Article Number MM6455 (Revised).
- The guidance provides clarification related to processing and billing claims outpatient clinical trials services to managed care beneficiaries (Medicare Advantage, etc.):
  - Institutional providers, must not bill outpatient clinical trial services and non-clinical trial services on the same claim.
  - When covered outpatient services unrelated to the clinical trial are rendered during the same day/stay for a Medicare managed care patient, clinical trial services must **ONLY** be billed to Medicare to be processed as though the services were rendered to a Medicare fee-for-service (FFS) patient.
  - Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.

# Managing Claims for Medicare Advantage



# Clinical Research & Medicare Secondary Payer

- In 2010, CMS issued an “alert” regarding clinical trials and MSP rules
- Only one thing is known for certain with clinical trials and MSP rules: confusion reigns!

## MSP 2007 Amendments: Preface to 2010

- Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 sets out a host of MSP reporting requirements
- Elaborate registration process and reporting obligations for an entity that is considered a primary payer for a Medicare beneficiary
- “Responsible Reporting Entity” (RRE) must register and report on ongoing responsibilities

## May/July 2010 MSP Alert

“When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported. The appropriate Responsible Reporting Entity (RRE) should report the date that the injury/complication first arose as the Date of Incident (DOI). The situation should also be reported as one involving Ongoing Responsibility for Medicals (ORM).”

## 2010 MSP Alert

“When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported.”

- Implication:

When these circumstances occur, the MSP Rule is triggered

- Therefore:

When do these circumstances occur?

## 2010 Alert

“When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported.”

## 2010 Alert

“When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported.”

# 2010 Alert

- Conditions:
  - When complications or injuries arise out of the trial; and
  - Payments are made by the sponsor

# 2010 Alert

- Conditions:
  - CONDITION 1:  
When complications or injuries arise out of the trial
  - CONDITION 2:  
Payments are made by the sponsor

# 2010 Alert

## CONDITION 1:

When complications or injuries arise out of the trial

- What is a complication?
- What is an injury?

# 2010 Alert

## Injury:

- The 2004 CMS letter identified “research-related injury” as triggering MSP Rule if the sponsor agreed to pay for treatment of the injury or conditionally agreed to pay for treatment if subject’s insurance denied coverage.
- CMS argued that sponsor constituted a liability plan when it contemplates payment for treating injury
- Injury assumes legal liability (e.g., negligence)

# 2010 Alert

## Complications:

- No one knows what this term means
- Presumably more than “injury”
- Does it include known potential complications and side effects?
- Does it include all adverse events/serious adverse events?

Postulate: CMS did not define the term “complications” and used it imprecisely and on par with “injury.” A liability plan assumes legal liability (otherwise it would be health insurance) and known potential complications that are disclosed to the subject cannot be negligence when the complications occur.

# Lingering Questions

- Is a sponsor really a “liability plan” under the MSP statute?
- What authority does CMS have to determine through an “Alert” what constitutes “liability insurance”?
- What is the legal posture of a CMS “Alert”?

# Clinical Trial Agreement Language

- Examples for Discussion:
  - “If the subject’s insurance denies coverage for any imaging service, then the Institution may invoice Sponsor using rates set out below.”
  - “If the subject experiences injury from the study device, then the Institution may invoice Sponsor for the costs associated with the Institution providing treatment and care to the Subject.”

## Additional Questions:

### Does the Informed Consent Form Trigger MSP Rules?

- Assume the clinical trial agreement is silent, but ICF discusses subject injury treatment, does this make the Institution a “Responsible Reporting Entity”?
  - “In the event of injury resulting from your participation in this research study, the facilities at XYZ Hospital will be made available to you and you will be provided reasonable care at no cost to you. If you seek care from other healthcare providers, you must do so at your own expense.”
  - “The sponsor or XYZ Hospital will pay for the cost of treatment for injuries, complications and side effects related to your participation in this study.”

# Some Situations (Discussion)

- Scenario 1:
  - The sponsor has agreed to pay for all imaging services required by the study if the subject's insurance rejects coverage of the service
- Scenario 2:
  - The sponsor has agreed to pay for treatment of any complications arising from use of the study drug.
- Scenario 3:
  - The informed consent has promised that treatment for complications will not be the responsibility of the subject. [But sponsor has not agreed to such terms)

# Questions?

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