SAINT LOUIS UNIVERSITY
OFFICE OF UNIVERSITY COMPLIANCE

COMPLIANCE E-NEWSLETTER JANUARY 2016

What's in store by the Office of Inspector General

Every year the Office of Inspector General publishes their "Work Plan" for the upcoming year. This is a great resource that everyone involved in providing healthcare services should review to be informed of what services will be under their microscope and considered vulnerable to fraud, waste and abuse. In 2015 the OIG reports that they have expected recoveries in the amount of $3 billion (oig.hhs.gov)! It is our responsibility as University staff and faculty to make sure that we stay up to date with the current laws and regulations to keep the University and ourselves safe from becoming part of that statistic.

The OIG states, "The majority of our resources are directed towards safeguarding the integrity of the Medicare and Medicaid programs." This does not mean patients who hold commercial and other private healthcare plans are safe from these types of reviews. We should uphold the same standard of care for all of our patients as they are often times held to the same level of scrutiny as Medicare participants.

There are several sections to the Work Plan that provide details of what services will be under review for the upcoming year. The Work Plan is usually updated mid-year so it is beneficial to periodically check in to see if there are any updates. The areas listed in the current year's Work Plan may be what have been identified as a higher risk areas, however, services under previous review and in prior Work Plans may also be called on for review during the current year. The following areas are what the OIG has added for this year's Work Plan. This list is not all inclusive. Further details can found by downloading the Work Plan from the OIG's website.

- Medical device credits for replaced medical devices
- Medicare payments during MS-DRG payment window
- CMS validation of hospital-submitted quality reporting data
- Skilled nursing facility prospective payment system requirements
- Orthotic braces – reasonableness of Medicare payment compared to amounts paid by other payers
- Orthotic braces – supplier compliance with payment requirements
- Increased billing for ventilators (Respiratory Assist Devices, and Continuous Positive Airway pressure devices)
- Physicians – referring/ordering Medicare services and supplies
- Anesthesia services – non-covered Services
- Physician home visits – reasonableness of services
- Prolonged services – reasonableness of services
- Accountable Care Organizations (ACO)
- Medicare payments for unlawfully present beneficiaries in the US
- Medicare payments for incarcerated beneficiaries
- CMS management of ICD-10 implementation
- Medicare Part D Beneficiaries' exposure to inappropriate drug pairs
- Increase in prices for brand name drugs under Part D

Cindy's Coding Corner

It's easy to lean toward choosing a diagnosis for every sign and symptom the patient is experiencing at the time of the visit. However, keep in mind the ICD-10-CM Official Guidelines for Coding and Reporting 2016:

- Codes that describe symptoms and signs, as opposed to diagnoses, are acceptable for reporting purposes **when a relative definitive diagnosis has not been established (confirmed)** by the provider
- Signs and symptoms that are associated routinely with a disease process **should not** be assigned as additional codes, **unless** otherwise instructed by the classification
- Additional signs and symptoms that **may not be associated routinely with a disease process** should be coded when present

Recent FAA Site Visit

The Federal Aviation Administration (FAA) visited a research lab during the month of January to conduct a site inspection of the research team's handling of hazardous materials. The visit was a keen reminder of the responsibility each of us has to identify the wide range of hazardous materials we may encounter while performing our job. We need to be knowledgeable of how these materials must be packaged and familiar with the required markings, labels, and/or placards that must be applied to hazardous materials shipments to ensure their safe transportation.

Hazardous materials are substances or materials with the potential to cause injury or harm to people, property, or the environment including when transported. They include materials such as blood specimens being sent to a sponsor according to the research protocol, as well as infectious substances, radioactive items, and lithium batteries.

The US Department of Transportation (DOT) is responsible for developing and issuing the Hazardous Materials Regulations (HMR) that govern the transportation of hazardous materials in interstate, intrastate, and foreign commerce, and can be found in Title 49 of the Code of Federal Regulations (49 CFR), Parts 100 – 185. In addition, the FAA is responsible for all hazardous materials shipments made by air transportation, and related guidance that is enforced as regulation by the FAA, known as the International Air Transportation (IATA) Dangerous Goods Regulations (DGR).

The recent FAA Site Inspection reminded us of the training requirements applicable to all employees who perform work functions subject to the HMR and DGR. The requirements include initial training as well as periodic recurrent training to ensure they maintain the required knowledge and skill sets. The specific areas of training & the frequency for which they must be completed are included in the accompanying reference table.

Type of Training	Frequency of Training	Format of Training	Where to Find Training?
Laboratory Safety & Compliance Training Includes: ***General Awareness, Safety, Function Specific & Security Awareness***	Annual	Face-to-Face	Hosted by Environmental Safety every other Tuesday http://www.slu.edu/office-of-environmental-health-and-safety/training/lab-safety-training-sign-up
IATA (Shipment of hazardous materials packages by air) Includes: ***General Awareness, Safety, Function Specific, Security Awareness & In-Depth Security (if a Security Plan is required)***	Every Two Years	Biohazards – Online Chemicals – Online and in conjunction with Environmental Safety approval	Skillsoft
DOT (Shipment of hazardous materials by ground only)	Every Three Years	Biohazards – Online Chemicals – Online and in conjunction with Environmental Safety approval	Skillsoft
Radiation Safety Orientation	Upon arrival or prior to use of radioactive materials	Face-to-Face	Hosted by Environmental Safety the 2nd Thursday of every month

The University's Office of Environmental Health and Safety coordinates the training efforts necessary to satisfy the DOT's and FAA's expectations. They make every effort to ensure that each employee is trained and tested, and they assist in the development and retention of training records for each employee. Their office recommends that each research lab on campus create a "Laboratory Training Binder" as a central repository for all hazmat training documents. The Laboratory Training Binder should include the following for each member of the research team: name of the employee; completion date of most recent training; description, copy, or location of the materials used to conduct the training; name and address of person providing training; and certification that the hazmat employee was trained and tested.

Please contact the Office of Environmental Health and Safety (http://www.slu.edu/office-of-environmental-health-and-safety, or type into your browser "oehs.slu.edu") or call 314-977-8608 (main number) with your questions about their many training initiatives, and to confirm that your research lab training is current.

Why is Research Compliance Necessary?

Conducting human subject research can be a scary scenario for investigators, institutional review boards (IRBs), and institutions in light of increasing scrutiny from government entities. The scrutiny is due, in part, to recent media coverage of patients who were harmed while participating in research. Oversight of research activities has increased drastically; for those failing to comply with the vast and complex network of legal and regulatory requirements, the consequences are severe. In the past few years, the federal Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA) have suspended the authority to conduct research at a growing number of well-known institutions. In addition, noncompliance has resulted in the withdrawal of funding from investigators, fines and prison sentences.

The current environment has motivated organizations involved in human research to foster research compliance programs to reduce risks. Both institutions and investigators may benefit from these compliance efforts. An effective research compliance program is one that identifies legal and regulatory problems, corrects deficiencies, and assists in preventing future problems. In order to be effective, certain basic elements must be in place, including established standards of conduct in research, training, disciplinary procedures, auditing, monitoring, and corrective action. With an effective compliance program, the risks for both human subjects and research personnel are greatly reduced.

Identifying the Risks

The primary risk factors in conducting both basic and clinical research are

- Lack of proper oversight by the institution and investigator
- Inadequate training
- Inappropriately handled conflicts of interest
- Improper expenditure of federal funds and residual funds
- Improper billing of research items

Keys to Successful Research Compliance

With a thorough understanding of the regulations, ongoing monitoring, the correction of identified deficiencies, and administrative support for compliance efforts, compliance in research conduct may be obtained. Coupled with quick responses to problems, research compliance efforts at Saint Louis University will continue to be an affirmative move toward promoting a high level of ethical and lawful conduct in all aspects of research.

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877-525-KNOW

Please feel free to contact the Office of University Compliance at (314) 977-5545 or at slucompliance@slu.edu

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If you need to reference past newsletters, upcoming education dates or need more information on Compliance visit our website.

2016 Biller's Meeting Schedule

All meetings will be from 10:00-11:00am

February 9, 2016--LRC Rm 112/113

March 8, 2016--LRC Auditorium C

April 12, 2016--LRC Auditorium C

May 10, 2016--LRC Auditorium C

June 14, 2016--LRC Auditorium C