Saint Louis University
Office of Compliance & Ethics
Summer 2019 Newsletter

Compliance Office Location Update

The Office of University Compliance & Ethics has added a location to better serve the entire University. The Vice President (Jessica Evenson), the Privacy Officer (Ron Rawson), and Chief Policy and Export Control Officer (Michael Reeves) will be located at 33 DuBourg on the North Campus. The research Auditor (Kerry Borawski), the Privacy Analyst (Christian Allen), and the Coding, Educator and Compliance Auditor (Mickey Coriell), will remain at M229 Schwitalla Hall on the South Campus. The main phone number for compliance remains the same: 314-977-5545

Annual Compliance Update to launch July 1, 2019

Federal guidelines and our third-party contracts insist that individuals complete annual Fraud, Waste, and Abuse and General Compliance Training. CMS does not distinguish employment status or contracting terms. Their definition includes every employee, temporary employee, volunteer, consultant, governing board member, and downstream entity that support (directly or indirectly) the healthcare encounter. Working with department business managers and leadership, our office has identified those individuals within the School of Medicine, CADE, and DCHS who are required to complete the training. The deadline for completion is **July 31, 2019**. Beginning July 1, the Modules can be found at **myslu.slu.edu/home** under Training Requirements. You must complete the modules through Banner to have your participation recorded in Banner.

Attention New Employees

New employees of SLU*Care*, SOM, CADE, & DCHS who directly or indirectly support healthcare encounters are required by Federal law to complete Fraud, Waste, and Abuse, and General Compliance training within 45 days of their start date. Beginning in **August of 2019** The module **NEWEMPCUFY2020** can be found on the "Training Requirements" section of your mySLU Home page.

Do you have a Coding Question? SLU*Care* has a new coding help line! Call or email the coding specialists at 314-977-6323 or email medicalcoding@health.slu.edu

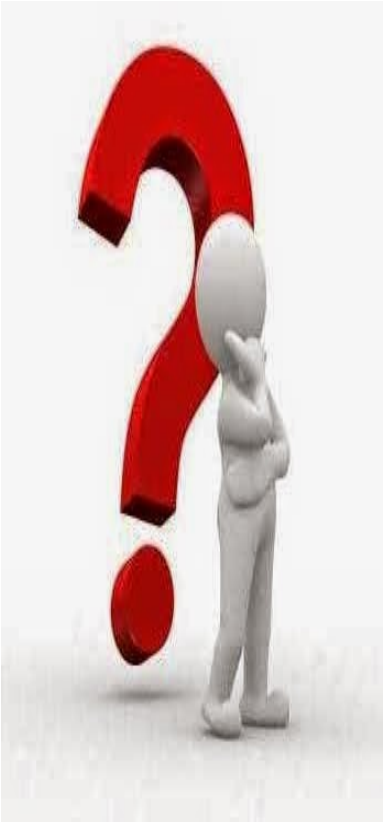
Did you Know?

The Saint Louis University Office of Compliance and Ethics has a hotline available and answered 24/7? Caller/Reporter may remain **anonymous.** Please call 877-525-5669 if you wish to report any compliance concerns, such as a HIPAA violation, potential Conflict of Interest, export control violation, or a physician billing violation.

Did you know??

When documenting a patient "has six siblings", this is counted as social history. We have had providers count this as 'family history'. When counting history elements, its important to remember the 'past, family and social history' are regarding the patients personal past medical history, the patient's family medical history and the patient's social history.

When documenting allergies, you may count this as past medical history or in the review of systems area but, you may not count it towards both areas.



What will you score on these commonly asked documentation questions??

1. What is the most important factor when billing for services?

2. What are the critical or key portions of a procedure?

3. When a resident sees patient and the attending sees the patient on the next day, what date is used for billing?

4. Can you report an E&M visit and Medicare Wellness Visit on the same date of service?

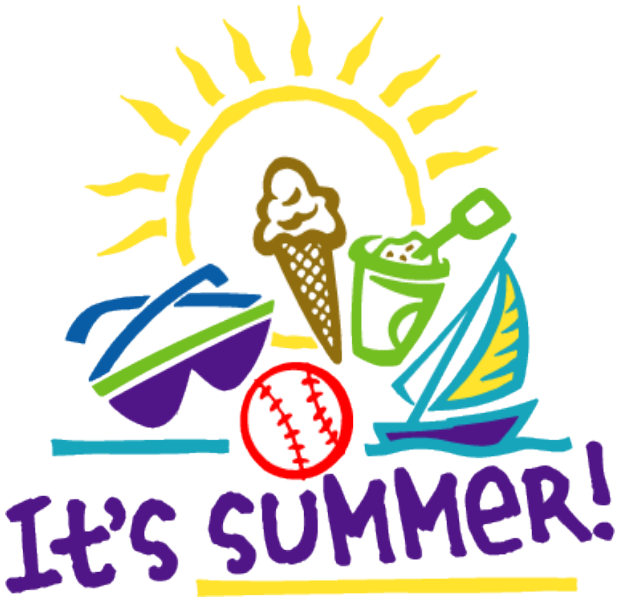
5. Does SLUCare allow Incident-to or Split Shared Billing?

Answers located on the last page.

Foreign Travel review by Export Control requirement

The federal government restricts what information, technology, and software can be shared with foreign nationals without a license or prior authorization. To maintain compliance with these federal regulations, all SLU personnel who are traveling on SLU business or taking equipment out of the country are required to contact the Export Control Office prior to international travel.

Please contact Michael Reeves, Ph.D., Chief Policy and Export Control Officer at michael.reeves@health.slu.edu or 977-5880



New University Policy Process

The University has adopted a new process for policy approval, this process is applicable to University wide policies, although Units and Departments wishing to follow best practices in policy implementation are welcome to reach out to the Chief Policy Officer for assistance.
The new process approval provides some structure and clarity to the review and approval process for policies at the University. New additions to the policy review process include:

- Policy owners will be designated to ensure review by appropriate parties has been conducted and to present policies to the committees for approval.
- A policy must be sponsored by a Responsible University Official, someone at the Vice-President or Provost level, this will ensure adequate buy-in at the top with new policies.
- Policies will use standard University template, old policies as they are updated will change to the new format.
- Policies will be moved into PolicyStat, the centralized policy library, found within myS-LU:Tools.
- New and updated policies will be presented to the Policy Review Committee, after approval they will be presented to the University Leadership Council, before being approved and signed by the President.
- All new policies will be posted on-line for a 30-day feedback period, allowing the University community an opportunity to comment.

SLUCare's Clarification of 1995 & 1997 Examination Documentation Guidelines

Determining Expanded Problem Focused Exam –VS- Detailed Exam

The 1995 & 1997 documentation guidelines specify a difference between expanded problem focused exam –VS- detailed exam.

1997 Guidelines specify:

Expanded Problem Focused (EPF) exam - General Multi System exam requires at least 6 elements identified by a bullet.

Detailed exam - General Multi System exam requires at least 2 bullets from each of 6 areas or at least 12 in two or more areas.

1995 Guidelines specify:

Expanded Problem Focused (EPF) exam - 2 -7 body areas or organ systems must be documented.

Detailed exam – at least 2, but less than 7 organ systems or body areas must be documented. 2 organ systems/body areas must have at least 3 descriptors each.

Examination									
Body Areas:									
❑ Head, Including face	❑ Chest, including breasts and axillae	❑ Abdomen	❑ Back, including spine	❑ 1 body area or system '95:Limited to affected body area or organ system (one body area or system related to problem) '97=Specialty and GMS: 1-5 elements identified by bullet	❑ 2 to 7 systems '95:Affected body area or organ system and other symptomatic or related organ system(s) '97=Specialty and GMS: At least 6 elements identified by bullet	❑ 2 to 7 system '95: Extended exam of affected area(s) and other symptomatic or related organ system(s) with at least 2 systems 3 descriptors each. '97=Specialty: At least 12 elements identified by bullet (9 for eye and psych) GMS= At least 2 bullets from each of 6 areas or at least 12 in 2 or areas	❑ 8 or >systems '95:General multi-system exam (8 or more systems) or complete exam of a single organ system (complete single system exam not defined in these instructions) '97=Specialty: All elements with bullet in shaded areas and at least 1 in non-shaded area. GMS: At least 2 elements with bullet from each of 9 areas/systems
❑ Neck		❑ Genitalia, groin, buttocks	❑ Each extremity				
Organ Systems:							
❑ Constitutional (wt loss, etc)	❑ Cardio/vasc	❑ GU	❑ Neuro				
❑ Eyes	❑ Resp	❑ Musculo-skeletal	❑ Psych				
❑ Ears, nose, mouth, throat	❑ GI	❑ Skin	❑ Hematologic/ Lymph/Immu				
				PROBLEM FOCUSED	EXP. PROB. FOCUSED	DETAILED	COMPREHENSIVE

Examples: Two very similar exams, one EPF, the other Detailed.

EPF Exam: Vitals: 120/80, 88, 98.6
General appearance: NAD, conversant
Lungs: Clear to auscultation
CV: RRR, no MRGs
Abdomen: Soft, nontender
Extremities: No peripheral edema

Detailed Exam: *Vitals: 120/80, 84, 98.3*

General Appearance: Flat affect, stooped posture, facial expression appropriate to situation **

Lungs: Clear to auscultation

CV: RRR, No MRGs, 2+ jugular venous distention **

Abdomen: Soft, nontender

Extremities: No peripheral edema

** **3 or more descriptors**

When to Contact the Compliance Department about Privacy?

The Compliance Department or Privacy Officer is the first point of contact for issues related to HIPAA. If you have questions or concerns related to data privacy, including health information privacy and security at the University, please contact us at 314-977-5545.

We're your resource to answer questions, offer guidance, and provide assistance or advice on privacy matters. Whether you're unsure about a disclosure, have a unique patient privacy situation, or just have doubt about HIPAA requirements for handling a certain matter, we're here to help.

Please remember, it's also your responsibility to report privacy and security incidents. If you witness a HIPAA violation or something that doesn't seem appropriate, contact the Compliance Department or the Privacy Officer immediately. We're here to answer your questions and address your concerns before they become major issues.

Reporting a potential HIPAA issue? What if you just want advice or have questions?

You can report a potential HIPAA violation or suspicious activity through the Integrity Hotline at 1-877-525-5669. This toll-free number allows you the option of staying completely anonymous and is monitored by a third-party call center.

You can also contact SLU Privacy at HIPAA@health.slu.edu or you may speak to the Privacy Officer directly at 314-977-5884.

Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations

April 4, 2019

The Department of Justice today announced that three pharmaceutical companies – Jazz Pharmaceuticals plc (Jazz), Lundbeck LLC (Lundbeck), and Alexion Pharmaceuticals Inc. (Alexion) – have agreed to pay a total of $122.6 million to resolve allegations that they each violated the False Claims Act by illegally paying the Medicare or Civilian Health and Medical Program (ChampVA) copays for their own products, through purportedly independent foundations that the companies used as mere conduits.

When a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may be required to make a partial payment, which may take the form of a copayment, coinsurance, or a deductible (collectively "copays"). Similarly, under ChampVA, patients may be required to pay a copay for medications. Congress included copay requirements in the Medicare program, in part, to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration — which includes money or any other thing of value — to induce Medicare or ChampVA patients to purchase the company's drugs. This prohibition extends to the payment of patients' copay obligations.

"Pharmaceutical companies undercut a key safeguard against rising drug costs when they create assistance funds to serve as conduits for the companies to subsidize the copays of their own drugs," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "These enforcement actions make clear that the government will hold accountable drug companies that directly or indirectly pay illegal kickbacks."

"We are committed to ensuring that pharmaceutical companies do not use third-party foundations to pay kickbacks masking the high prices those companies charge for their drugs," said U.S. Attorney Andrew E. Lelling. "This misconduct is widespread, and enforcement will continue until pharmaceutical companies stop circumventing the anti-kickback laws to artificially bolster high drug prices, all at the expense of American taxpayers."

Jazz and Lundbeck each entered five-year corporate integrity agreements (CIAs) with OIG as part of their respective settlements. The CIAs require the companies to implement measures, controls, and monitoring designed to promote independence from any patient assistance programs to which they donate. In addition, the companies agreed to implement risk assessment programs and to obtain compliance-related certifications from company executives and Board members.

"These kickback schemes harm Medicare and the public," said Gregory E. Demske, Chief Counsel to the Inspector General. "OIG CIAs, such as those with Jazz and Lundbeck, are designed to reduce future risks to patients and taxpayer-funded programs. OIG decided not to require a CIA with Alexion because it made sweeping and fundamental organizational changes following the bad conduct. The changes included hiring a new eight-member executive leadership team and changing half of the members of its Board of Directors. In addition, 40 percent of Alexion's employees are new and the company relocated its corporate headquarters."

In the DogHouse Continued

"These settlements demonstrate the FBI's commitment to safeguard the Medicare program and ensure that patients receive treatment solely based on their medical needs," said Joseph R. Bonavolonta, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division. "Not only did these companies undermine a program that was set up to assist patients in decreasing the cost of their drugs, but they threatened the financial integrity of the Medicare program to which we all contribute and on which we all depend."

"Kickback schemes undermine the integrity our nation's healthcare system, including healthcare benefits administered by the U.S. Department of Veterans Affairs," said Special Agent-in-Charge Sean Smith, VA Office of Inspector General, Northeast Field Office. "The VA Office of Inspector General, along with our law enforcement partners, will continue to aggressively pursue these investigations and exhaust all efforts to uncover these schemes."

Please see the full story at : https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay total-over-122-million-resolve-allegations-they-paid

Are you "Bidding Adieu to SLU"?

During the final month of the academic year, we may have an opportunity to offer a fond farewell to friends and colleagues who are following their own career paths into retirement, private practice, or new academic or corporate endeavors. For the convenience of members of the SLU research community heading into their next chapter, we have compiled a list of items to consider for a compliant transition forward.

This list benefited from collaborative efforts from the Office of General Counsel, Research Integrity and Safety Group, Research Innovation and Commercialization, Grant Operations (GO) Center, and the Clinical Trials Office, and is intended for SLU professionals engaged in the design, conduct or reporting of research. This list should not be considered an all-inclusive checklist, but may be used to accompany other off-boarding guidance provided elsewhere.

The Principal Investigator (PI) has three options available to them when leaving the University:

1. Close their study at SLU and submit a Final Report Form in eIRB (if human subjects were involved); or
2. Transfer the IRB protocol to another SLU Investigator via a formal Protocol Amendment; or
3. Request a transfer of research outside of SLU in accordance with the Policy on Research Records and Biological Specimens: Ownership, Retention, Transfer, and Destruction. Industry-sponsored clinical trials typically will not be allowed to transfer outside of SLU unless it is proven to be in the patients' best interests.

No Research Records are to be removed from Saint Louis University premises or shared with other investigators without appropriate approval and compliance with federal and University regulations. "Research Records" are defined in the policy link above and include both original and copied content.

Please click here for a checklist.

1. The medical necessity of a service is the overarching criterion for payment. Do not submit a higher level of E/M service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which the service is submitted. Select the code for the service based upon the content of the service. The service furnished and submitted must meet the definition of the code.https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/

2. The part or parts of a service the teaching physician determines are a critical or key portion.

3. Billing is for the teaching physician services. The date of service used is always the date the teaching physician saw the patient.

4. Yes, the E/M visit should be separate from the wellness visit. If the physician treats and documents an acute or chronic problem during the same encounter as a wellness visit, bill for both. If the patient's condition is not stable, or there is an acute problem, report the E/M visit separately. The E/M visit should contain a chief complaint, HPI, Exam and assessment and treatment plan. The treatment plan should show either a change in treatment or a plan to monitor the condition.

5. No, SLU*Care* recently revised our Billing and Reimbursement Compliance Policy to prohibit billing Incident To services. "Incident To" is the scenario in which an MD and a Non-Physician Provider (NPP) from the same provider group each perform individual E/M services for the same patient on the same calendar day service under the MD's identifier if certain criteria were met and appropriately documented. As of 9/15/2018, CMS will no longer allow inpatient split-shared billing.

Office of University Compliance & Ethics

North Campus—DuBourg Hall, Room 33:

Vice President	Jessica Evenson	977-5774	jessica.evenson@slu.edu
Privacy Officer	Ron Rawson, CHPC	977-5884	ron.rawson@health.slu.edu
Chief Policy & Export Control Ofcr	Michael Reeves, Ph.D	977-5880	michael.reeves@health.slu.edu
Executive Assistant	Janet Flach	977-5772	janet.flach@slu.edu

South Campus — Schwitalla Hall, Room M229

Privacy Analyst	Christian Allen, JD	977-5889	christian.d.allen@health.slu.edu
Research Compliance Auditor	Kerry Borawski, CPA	977-7720	kerry.borawski@health.slu.edu
Coding Educator, Compliance Auditor	Mickey Coriell, CPC, CPMA	977-5886	mickey.coriell@health.slu.edu