SAINT LOUIS UNIVERSITY

OFFICE OF UNIVERSITY COMPLIANCE

August 2017 Compliance Newsletter

New FDA Guidance for Informed Consent Waivers

In designing a research project involving human subjects, one of the essential ethical considerations is the adoption an IRB-approved Informed Consent Document designed to protect one's research subjects. A well-written Informed Consent Document should enable the subject's complete understanding of the study's purpose, procedures employed by the research team, the risks involved, and the demands that may be made upon them. The subject must be offered the freedom to participate, to decline to participate, and to withdraw from the research at any time without penalty. The Informed Consent Document has long been regarded as the fundamental tool in which a research team can both inform and protect their research subjects. However, Informed Consent Documents aren't always practical.

While the Department of Health and Human Services' regulations have long allowed IRB's to grant waivers of consent for certain minimal risk research, to date, waivers of consent have only been allowed by the Food and Drug Administration (FDA) under two exceptions (1- in life-threatening situations and 2- for emergency research). However, the U.S. Congress signed the 21st Century Cures Act into law on December 13, 2016, and in part, the law allows exceptions from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes safeguards to protect the rights, safety, and welfare of the human subject. Last month, the FDA published guidance for sponsors, investigators, and institutional review boards which adjusted FDA regulations governing informed consent requirements for certain minimal risk clinical investigations. The FDA expects their guidance will support minimal risk clinical research that may be important to addressing significant public health needs without compromising the rights, safety, or welfare of human subjects.

The July 2017 FDA Guidance adds the following waiver under appropriate human subject protection safeguards to the two existing exceptions from informed consent, when the IRB finds and documents that:

- The clinical investigation involves no more than minimal risk to the subjects;
- The waiver will not adversely affect the rights and welfare of the subjects;
- The clinical investigation could not practicably be carried out without the waiver; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Minimal Risk is defined in 21 CFR 50.3(k) and 56.102(i) as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

If you feel that your proposed clinical research meets the conditions for waiving consent above, you can justify the request in the consent section of the IRB Application. You may also consult with the IRB at irb@slu.edu; (314) 977-7744, Caroline Building C110 with any questions/concerns.

2017 Billers' Meeting Schedule

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

September 12, 2017
October 10, 2017
November 14, 2017
December 12, 2017

COMPLIANCE REQUIREMENTS

The Deadline to complete **Annual Compliance Update 2017 (ACU2017) is August 31, 2017**. Please go to myslu.slu.edu/home to make sure you have completed this required training. **After the deadline, access to other programs within Banner will be suspended until this requirement is satisfied.**

NOTICE

It is a violation of University Policy to forward to/or use personal email for University business. Do not use your personal email for business purposes, or allow others to do so. Please call Compliance with any questions regarding this policy at 977-5545

The CODING CORNER

David Schindler and Kelly Pratt both shared an article:

On June 30, the United States Department of Justice Office of Public Affairs released information regarding a Detroit area medical biller who was sentenced to 50 months in prison for her role in a $7.3 million Medicare and Medicaid fraud scheme involving medical services that were billed to Medicare and Medicaid but not rendered as billed.

According to the evidence presented at trial, the biller knowingly submitted fraudulent bills on behalf of a co-conspirator physician for services she knew could not have been rendered, and for services she knew had not been rendered as billed.

Refer to the article here for more information:

https://www.justice.gov/opa/pr/detroit-area-medical-biller-sentenced-50-months-prison-her-role-73-million-dollar-healthcare

Thanks David & Kelly!
Please continue to send us articles of interest!

Back to the Basics of documentation:

Not long ago, providers hand wrote every step of their physical exam. Now, with a click of a button, a normal comprehensive physical exam is documented. Another click brings up a normal review of systems and a series of screening questions regarding anything from anxiety to Zika exposure.

Providers are paid by how much they document, not on how well they listen, or how hard they think about what could be wrong. The rules for what they have to document are convoluted: 87 pages is what it takes for Medicare to explain how to document the highest level office visit. A provider must document several aspects of the main problem, screen at least 10 organ systems, write something regarding the patient's past, family and social history, as well as a lengthy physical exam. Further, documentation must demonstrate that medical decision making was very complicated. This high level visit is expected to take about 40 minutes.

We will never go back to the old days of lost charts, illegible writing and manual prescription refills. Electronic medical records help us avoid dangerous drug interactions and medical ordering errors, they remind us to provide preventive care and allow us to view data trends. But, they also increase our risk of cultivating erroneous documentation.

Take a look at the documentation errors most often found on audit.

Chief Complaint: Very often, a provider's note does not contain a Chief Complaint (CC). There must be a reason that you are seeing the patient. This needs to be documented. F/U or Follow up is not acceptable. F/U What??

The **History** area is often found lacking: A provider will submit a bill for a comprehensive visit but, a comprehensive exam must include a comprehensive history. The provider must document something on the three history elements, past, family and social. Documenting "Reviewed" or "see history tab in EPIC" is not sufficient.

Medical Decision Making takes into account what "the provider writing the note" is deciding. A provider cannot count what a consulting provider is doing or has prescribed or what another service is taking care of.

If you have questions about your documentation, reach out to your coder/biller for clarification.