



SAINT LOUIS UNIVERSITY  
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OFFICE OF UNIVERSITY COMPLIANCE

# Spring 2018 Compliance Newsletter

## Opioid Cough and Cold Medicines No Longer Indicated for Children, says FDA

Published 1/22/2018

The U.S. Food and Drug Administration (FDA) announced that it is requiring labeling changes to restrict the use of prescription opioid cough and cold medicines that contain codeine or hydrocodone to only patients age 18 years or older, according to a [January 11, 2018, FDA news release](#). The products will no longer be indicated to treat cough in any pediatric patient because the risks of using prescription opioid cough products in children of all ages generally outweigh the potential benefits. FDA suggests that providers counsel parents to carefully read labels because a few over-the-counter products sold in some states may contain codeine or may be inappropriate for young children. The label changes are part of FDA's ongoing efforts to combat the epidemic of opioid addiction by decreasing exposure to the drugs.

## Upcoming Billers' Meetings

10:00-11:00am

Law Clinic Annex 321 Spring Ave

April 10, 2018

May 8, 2018

June 12, 2018

## IMPORTANT TEACHING PHYSICIAN DOCUMENTATION CHANGE

As of February 02, 2018; Effective March 5, 2018

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3971CP.pdf>

Change Request (CR) 10412 revises the Medicare Claims Processing **Manual to allow the teaching physician to verify in the medical record any student documentation of components of E/M services, rather than re-documenting the work. Make sure your billing staffs are aware of the changes.**

**Previously**, the attending physician had to perform or re-perform the physical exam and medical decision making activities in the E/M services being billed in order to bill the service.

**NOW**, the attending physician may verify any student documentation rather than re-documenting the work.

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10412.pdf>

It is very important that we call it a "verification" statement and not an "attestation". Teaching physicians must attest to the resident and this process only applies in the teacher/resident context.

Example of a medical student verification statement to be signed by the attending physician:

"I verify the medical student's documentation/findings including history, physical exam and/or medical decision making. I have personally performed a physical exam and medical decision making (or other relevant process) for this service."

## COMPLIANCE REQUIREMENTS:

Annual Compliance Update 2018 will launch during the summer of 2018. Please watch for further announcements.

As always please be sure to regularly check the Home tab of [myslu.slu.edu](http://myslu.slu.edu) for current compliance requirements.

## Welcome New Employees!

All new employees of SLU are required to complete compliance training within 30 days of their start date. The module can be found on the "Compliance Requirements" section of your mySLU homepage.

# The CODING CORNER

ICD-10 March 2018



March 17 is the celebration day of St. Patrick, the patron saint of Ireland, also known as St. Paddy's Day, It is now celebrated around the world with feasting, drinking, and partying.

The color green has long been associated with St Patrick's Day, the origins for the association is unclear but, some of the more common theories are: St Patrick used the shamrock to illustrate the doctrine of the Trinity to the Irish, Ireland is often referred to as 'the Emerald Isle,' or, leprechauns, which are mischievous little creatures, pinch anyone they see. According to folklore, leprechauns can't see green, and thus became the tradition of wearing green.

Here are some ICD-10 codes that should help keep you clear of pinching leprechauns.

**I25.810 Coronary Artery Bypass.** Corned beef and cabbage are staples at any St. Patrick's Day celebration. But if eating too much red meat requires a different kind of CABG, use this code.

**L25.2 Unspecified Contact Dermatitis.** Due to Dyes Green beer, green clothes, green...well, everything. If someone's skin is sensitive to the color of the holiday, this code could end up in his or her chart.

**H53.50 Unspecified Color Vision Deficiencies.** Legend has it that leprechauns hide their gold at the end of the colorful rainbow. Color blindness may make finding the treasure difficult.

**D50.8 Hypochromic Anemia** No doubt you may get sick of seeing all the green this St. Patrick's Day. However, if a patient exhibits a greenish discoloration of skin, he or she may have the real "green sickness"—Hypochromic Anemia.

**R44.1 Visual Hallucinations.** Leprechauns are a fanciful legend for children. But if you see little green men running around, your doc may use this ICD-10 code.

**F40.11 Social Phobia, Generalized.** The Irish celebrate St. Paddy's Day by gathering for large parties and parades. Not everyone loves the chaos of large groups, however. This ICD-10 code is perfect for anyone missing out on festivities due to their fear of crowds.

**B27 Infectious mononucleosis.** With so many shirts and pins reading "Kiss Me, I'm Irish", there is bound to be some smooching going on. Irish or not, not all St. Patrick Day partiers will be lucky enough to avoid the "kissing disease."

**I42.6 Alcoholic cardiomyopathy.** Drinking green beers year after year may put a stop future St. Paddy's Days. This code is used for what's been called "beer-drinker's heart."

**Y92.22 Religious Institution as Place of Occurrence.** Some celebrants may observe the religious day of Saint Patrick in a more traditional way. This code may get some use if a trip to the cathedral results in injury.

As an Irish grandma used to say "*May you live as long as you want and never want as long as you live.*"

## Happy St. Patrick's Day!

<http://www.keystonehp.com/blog/luck-othe-irish-green-icd-10-codes>

<https://www.advancedmd.com/learn/celebrate-st-paddys-day-icd-10-codes/>



## Department of Justice (DOJ) Settlement with 2 Physician Groups - Whistleblowers walk away with Millions

Recently, on December 19, 2017, the DOJ announced settlements with two physician groups, EmCare Inc. (EmCare) and Physician's Alliance Ltd (PAL), for allegedly receiving illegal remuneration in exchange for patient referrals to hospitals owned by the now-defunct Health Management Associates (HMA).

EmCare provides physicians to hospitals to staff their Emergency Departments (EDs). Under the settlement with EmCare, the physician group will pay \$29.6 million to resolve allegations that, from 2008 through 2012, EmCare received remuneration from HMA to recommend patients be admitted to HMA hospitals on an inpatient basis when the patients should have been treated on an outpatient basis.

On average, Medicare pays at least three times as much for an inpatient admission as it does for outpatient care. As part of the alleged scheme, HMA made certain bonus payments to EmCare ED physicians and tied EmCare's retention of existing contracts and receipt of new contracts to increased admissions of patients who came to the ED.

Under the qui tam, or whistleblower provisions of the False Claims Act, private individuals may sue on behalf of the government for false claims and share in any recovery. The EmCare settlement resolves a qui tam lawsuit filed by Drs. Thomas Mason and Stephen Folstad, whose medical practice, MEMA, previously supplied ED physicians to two HMA hospitals in North Carolina.

The EmCare settlement resolves a qui tam lawsuit filed by Drs. Thomas Mason and Stephen Folstad, whose medical practice, MEMA, previously supplied ED physicians to two HMA hospitals in North Carolina. In connection with the settlement, Drs. Mason and Folstad will receive **\$6,222,907**.

### Impact of Cyberattacks

From the January 2018 American Institute of Healthcare Compliance, Inc. Newsletter:

Cyberattacks constitute a HIPAA breach and have the potential to put all electronic protected health information at risk.

The Office of Civil Rights (OCR) reported that in a recent government survey, 61% of respondents had experienced a data breach within the past two years, including unauthorized access, denial of service, and malware infections. In addition, a U.S. Government inter-agency report indicated that there were, on average, over 4,000 ransomware attacks every day in 2016, a 300% increase from the previous year.

According to the [Identity Theft Resource Center](#), in 2016 almost 16 million health care records were affected by data breaches, 43% of the total records affected by data breaches that year.

The Ponemon Institute, which conducts independent research on privacy, data protection, and information security, noted in their [2016 Cost of Data Breaches Study](#) that the average cost-per-record for a health care breach was about \$402. This means that in 2016, with 16 million healthcare records affected, the total amount lost to data breaches could be estimated at over \$6 billion.

[Click Here](#) to read more about this topic.

## Justice Department Recovers Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017

The Department of Justice (DOJ) reports achieving more than \$3.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2017. This announcement was made by acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than **\$56 billion**.

\$2.4 billion of the \$3.7 billion in settlements and judgments, involved the health care industry, which includes false claims from drug companies, hospitals, pharmacies, laboratories, and physicians.

This is the eighth consecutive year that the department's civil health care fraud settlements and judgments have exceeded \$2 billion. The recoveries included in the \$2.4 billion reflect only federal losses. In many of these cases, the department was instrumental in recovering additional millions of dollars for state Medicaid programs.

### LARGEST 2017 HEALTH CARE RECOVERIES

The largest recoveries involving the health care industry this past year - over \$900 million - came from the drug and medical device industry:

**Shire Pharmaceuticals LLC** paid \$350 million to resolve allegations that Shire and the company it acquired in 2011, Advanced BioHealing (ABH), induced clinics and physicians to use or overuse its bioengineered human skin substitute by offering lavish dinners, drinks, entertainment and travel; medical equipment and supplies; unwarranted payments for purported speaking engagements and bogus case studies; and cash, credits and rebates. In addition to these kickback allegations, the settlement also resolved allegations brought by relators that Shire and ABH unlawfully marketed the skin substitute for uses not approved by the FDA, made false statements to inflate the price of the product, and caused improper coding, verification, or certification of claims for the product and related services.

- The settlement included \$343.9 million in federal recoveries, and another \$6.1 million in recoveries to state Medicaid programs.

**EpiPen Drug manufacturer Mylan Inc.** paid approximately \$465 million to resolve allegations that it underpaid rebates owed under the Medicaid Drug Rebate Program by erroneously classifying its patented, brand name drug EpiPen - which has no therapeutic equivalents or generic competition - as a generic drug to avoid its obligation to pay higher rebates. Between 2010 and 2016, Mylan increased the price of EpiPen by approximately 400 percent yet paid only a fixed 13 percent rebate to Medicaid during the same period based on EpiPen's misclassification as a generic drug.

- Mylan paid approximately \$231.7 million to the federal government and \$213.9 million to state Medicaid programs.

The department also reported substantial recoveries from other health care providers, listing the recoveries below to show-case which includes a major EHR software company:

**Life Care Centers of America Inc.**, and its owner agreed to pay \$145 million to settle allegations that it caused skilled nursing facilities to submit false claims for rehabilitation therapy services that were not reasonable, necessary, or skilled. This was the largest civil settlement with a skilled nursing facility chain in the history of the False Claims Act. The government alleged that Life Care instituted corporate-wide policies and practices designed to place beneficiaries in the highest level of Medicare reimbursement - known as "Ultra High" - irrespective of the clinical needs of the patients, resulting in the provision of unreasonable and unnecessary therapy to many beneficiaries. Life Care also allegedly sought to keep patients longer than necessary in order to continue billing for rehabilitation therapy.

### **eClinicalWorks (ECW)**

- **a national electronic health records software vendor** and certain of its employees paid \$155 million to resolve allegations that they falsely obtained certification for the company's electronic health records software by concealing from its certifying entity that its software did not comply with the requirements for certification. For example, rather than programming all the required standardized drug codes into its software, the company allegedly "hardcoded" into its software only the drug codes required for testing. As a result of the deficiencies in its software, ECW allegedly caused physicians who used its software to submit false claims for federal incentive payments. The United States also alleged that ECW paid unlawful kickbacks to certain customers in exchange for promoting its product.

[Click Here](#) to read the entire Justice News Article.

## **The Olympic Sport of Export Control Compliance**

Michael A. Reeves

As you watched the Olympics in South Korea last month, much attention was paid to the unified Korean team. The inclusion of North Korean athletes created a complex situation for Olympic organizers, as they attempted diplomacy while complying with Export Control regulations.

The roughly 3,000 athletes that participated in the Olympic games received gifts for participation, including a new Samsung smart phone. However, the 26 athletes from North Korea and Iran did not receive these phones over concerns of violating the Department of Commerce's Export Administration Regulations (EAR). The EAR restricts providing "dual-use" items to sanctioned countries without a license due to potential military use.

The sanctions even impacted the uniforms worn by the Korean team. The Department of Treasury Office of Foreign Assets (OFAC) sanction countries, organizations, and individuals, these sanctions restrict the ability to "provide benefit" to an entity on the list. Nike would be in violation of these OFAC sanctions by providing uniforms to a team that includes North Korean athletes.

While these sanctions may seem trivial, they are the same sanctions that Saint Louis University must review and adhere to when traveling internationally, entering agreements, and hosting visitors. If you have any questions, comments, or concerns regarding Export Controls, please contact the Export Control Officer, Michael Reeves; [michael.reeves@health.slu.edu](mailto:michael.reeves@health.slu.edu), 977-5880.

**SAINT LOUIS UNIVERSITY COMPLIANCE  
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