Details Matter - Take the Time to Do It Right

By Stephanie Walkley, JD, BSN

The Taylor[1] family had a history of prostate cancer throughout the last couple of generations of their family tree. When Moses Taylor, age 63, received his prostate cancer diagnosis, he finally convinced his brother Malachi, age 59, and his son Martin, age 42, to see the local family medicine physician for a physical exam. Neither Malachi nor Martin were keen to go to the doctor unless they were acutely ill, which rarely happened. Reluctantly, both men scheduled appointments to see Dr. Benjamin Howard the following month.

It had been at least two years since Malachi had seen a healthcare provider, and he had never had a comprehensive physical exam. At Malachi's appointment, Dr. Howard performed a physical exam, which revealed an enlarged prostate. Dr. Howard ordered a battery of tests, including a PSA, based on Malachi's age, presentation, and family history.

A few days later, Martin went to see Dr. Howard for his physical examination. Knowing of Martin's extensive family history of prostate cancer, Dr. Howard decided to perform a prostate exam and order a PSA for this 42 year-old patient. Overall, the physical examination was unremarkable with the exception of a small palpable nodule on the prostate. Dr. Howard decided to wait until Martin's PSA results came back for review before determining whether to refer him to a urologist for biopsy.

Within a couple of weeks, the PSA results came back for both Malachi and Martin. Dr. Howard saw that each man had elevated PSA levels for their respective ages. Due to the

shared family history, elevated PSA levels, and Malachi's abnormal exam finding, Dr. Howard decided that both should be seen by a urologist for further evaluation; he referred the gentlemen to Dr. Kevin Davis.

Coincidentally, Malachi and Martin were scheduled to see Dr. Davis on the same day. They both went to their appointments as scheduled — Malachi in the morning and Martin in the afternoon. Each man had an examination by Dr. Davis followed by a biopsy of his prostate. Return appointments were made for each of them to receive their results within a couple of weeks.

Malachi was the first of the two Taylor men to have his follow-up appointment and receive his results. Much to his relief, Dr. Davis informed Malachi that his biopsy was negative. Malachi was instructed to continue seeing Dr. Howard, his PCP, for periodic monitoring of his PSA.

Martin, however, had a much more somber visit with Dr. Davis. At his appointment, Dr. Davis told Martin that his biopsy showed an unusually aggressive form of cancer. Dr. Davis discussed the need for a radical prostatectomy and offered to schedule the surgery. Overwhelmed by all of the information, Martin decided to wait on scheduling surgery so he could discuss the biopsy results and treatment recommendations with his family. Martin's father, Moses, suggested going to a major academic medical center in a nearby metropolitan area for the surgery.

Heeding his father's advice, Martin made an appointment with the urological department at the academic medical center. Three weeks later, Martin saw urologist Dr. Daniel Marsh. Based on the biopsy results, Dr. Marsh also recommended a radical prostatectomy as the appropriate surgical intervention for Martin's aggressive form of prostate cancer. Martin underwent the procedure two weeks later at the academic medical center.

While still in the hospital recovering from surgery, Martin received unexpected news. The pathology report from his surgery had returned, and his prostate showed no signs of cancer. At first Martin was elated, as this seemed to be a miracle. However, his joy and relief soon turned to confusion and anger. Martin asked Dr. Marsh how that could be possible, and Dr. Marsh could not offer an explanation.

In the days and weeks following surgery, Martin began experiencing a whole host of problems related to the radical prostatectomy, including urinary incontinence and erectile dysfunction. At his first post-operative visit with Dr. Marsh, he had many questions and concerns related to his surgery and subsequent issues.

Dr. Marsh informed Martin that he had contacted Dr. Davis about the surgical pathology results. After speaking with Dr. Davis and Martin, the decision was made to do DNA testing on Martin's original biopsy specimen. Results from the testing concluded that the prostate specimen with the aggressive cancer did not come from Martin.

Confirmation that the biopsy specimen labeled as "Martin" did not actually belong to Martin

prompted further investigation and testing. The biopsy specimen that had been labeled as “Malachi,” Martin’s uncle, positively matched a blood sample provided by Martin. Martin’s biopsy specimen had been misidentified as Malachi’s. The question now — to whom did the cancerous specimen belong?

The obvious next step was to see if the biopsy labeled as Martin’s belonged to Malachi. DNA confirmed that it did indeed. Martin had undergone unnecessary surgery, and Malachi had his treatment delayed by a couple of months. Not only did Martin have unnecessary surgery, he had severe problems related to the surgery that were getting worse, rather than better, with time. Martin and Malachi retained an attorney, and soon thereafter, Dr. Davis and the laboratory responsible for processing the biopsy specimens received letters advising them of impending litigation.

At this point, defense attorneys were retained to investigate the matter further. Meticulous accession logs and other documentation from the laboratory exonerated it from responsibility for the specimen mix-up. What came to light was a history of mix-ups and mistakes from Dr. Davis’ office – the laboratory had notified the office of problems in the past regarding matters such as incomplete labels and empty specimen boxes. There had even been a couple of occasions when specimens had been mislabeled, but the errors had been discovered due to the fact that female tissue had been labeled as “male,” and conversely, male had been labeled as “female.”

Learning from prior mistakes and proactively handling issues as they became apparent would have hopefully prevented these incidents and, at a minimum, put Dr. Davis in a more defensible position. As the facts developed during the pre-suit investigation, it became apparent that there was little in the way of a defense for Dr. Davis. The parties reached a pre-suit settlement of these claims.

Dr. Davis should have established a system for completing requisition forms, labels, and specimens. Clear guidelines were necessary to help prevent this type of error. Dr. Davis should have trained, educated, and supervised his staff more closely. The staff should have been instructed to:

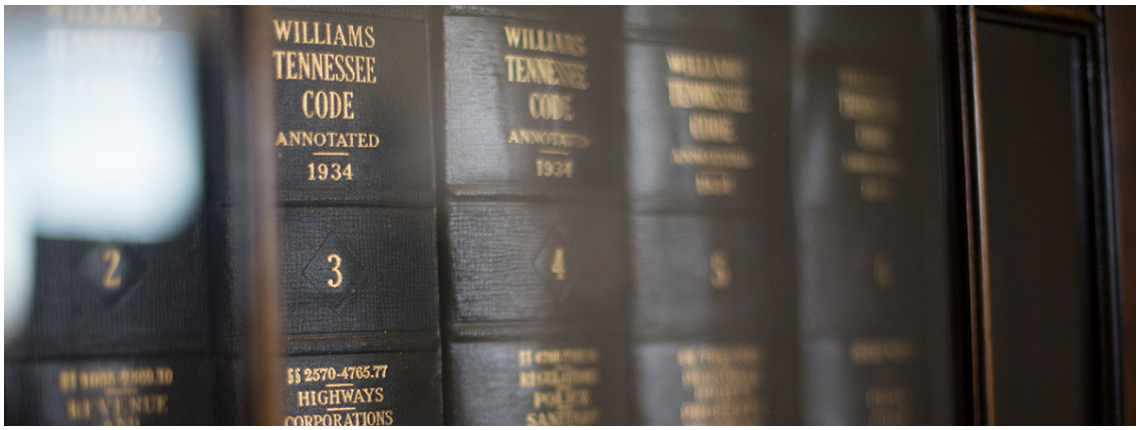
1) Verify the identity of the patient and the type of specimen;
2) Check for completeness on labels and forms (date and time taken, surgeon’s name, type of specimen);
3) Use more than one identifier on every requisition and specimen (never assume that a last name or even a last name with a first initial is sufficient);
4) Label the specimen container immediately upon collecting the specimen (never pre-label specimen containers); and
5) Minimize distractions during collection and labeling.

In a high-volume clinic where there are multiple specimens going out each day, it is too easy for errors to occur if everyone is not mindful of what a profound impact an incorrect label can make. Although in this instance the patients had very similar names and happened to be related, the staff should have been “on alert” and diligent in their labeling

and processing for each and every patient.

1) The names of all involved parties have been changed.

The False Claims Act



By Wendy Longmire, JD

The False Claims Act (FCA) is a federal law which imposes liability on any person or entity who knowingly presents false or fraudulent claims for payments to the United States government or the Armed Forces of the United States; knowingly makes, uses, or causes to be made a false record or statement to get a false or fraudulent claim paid for by the government; conspires to defraud the government by having a false or fraudulent claim paid or approved by the government; or knowingly makes, uses, or causes to be made a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the government.[1]

There are several penalties associated with the FCA, which, on the surface, do not appear to be that significant. The law maintains a civil penalty of no less than $5,000 and no more than $10,000 per violation.[2] However, the civil monetary penalties associated with a violation of the FCA adjust with inflation, which would make the penalties for a violation higher than the stated amount in the statute.[3] If a healthcare provider is submitting invoices and has essentially overbilled the federal government, each presentation of a bill is considered a violation. However, the crucial part of the law is that there is a penalty in addition to that for three times the amount of damages that the government sustained [4] - this is known as treble damages. Therefore, if a healthcare company were found to have overbilled Medicare for services that were not rendered, then that overage would be the amount of damages the government has suffered and would be subject to trebling. Finally, there is a Criminal False Claims Act [5], where healthcare providers can be criminally charged for submitting false healthcare claims.[6]

You may have noticed the term “knowingly makes” in the above-mentioned statute.

Generally, one believes that those terms are aligned with intent to defraud. It is worth noting that the statute defines “knowingly” with respect to information as, “a person having actual knowledge of that information or one who acts in deliberate ignorance of the truth or falsity of that information or acts in reckless disregard of the truth or falsity of the information.” [7] Therefore, the law does not require specific intent to defraud.[8]

However, an entity does not violate the FCA by submitting a false claim, if, in fact, they do not have knowledge of the falsity pursuant to the aforementioned definition.[9]

Congress created the FCA in 1863, during the Civil War, out of concern that suppliers of goods to the Union were defrauding it.[10] Thus, the law was passed which provided that any person who knowingly submitted false claims to the government was liable for double the government’s damages, plus a penalty of $2,000 for each false claim.[11] In 1986, damages increased from double to treble damages and penalties raised from $2,000 to a range of $5,000-$10,000.[12] In the past 156 years, there have been only minimal modifications to this law.

Any healthcare provider who is billing Medicare or a state Medicaid program (such as Tenncare in Tennessee), should be concerned about both state and federal laws concerning false claims. In 2019 alone, there have been at least three substantial settlements in the state of Tennessee relating to FCA violations. There have been recent substantial settlements in Arkansas and Kentucky in the last two years.[13]

Vanguard Healthcare, a holding company that owns a chain of subsidiary skilled nursing facilities, was accused by the government of delivering worthless services to five residences and billing for the same. As a result, Vanguard Healthcare agreed to pay more than $18,000,000 to resolve the allegations against it. (See this link for more information).

In February 2019, Tennessee Health Management (THM) agreed to pay $9,764,107.98 to settle allegations that it had violated the FCA. Allegations contained in that federal lawsuit involved the submission of false claims to Tenncare for payment all the way to nursing facility services provided to Tenncare beneficiaries. It is worth noting that when false claims come to light, the offending company or organization should work with the government to immediately cooperate and resolve allegations and future risks. Doing so will minimize the amount of damages they will be forced to pay. THM, in this case, did work with the government to cooperate and resolve the allegations. (See this link for more information).

Wellbound of Memphis, a Memphis dialysis facility, was accused in a federal lawsuit of presenting false claims to Medicare, Tricare, and TennCare. The allegations against Wellbound included improper physician referral requirements in violation of the Anti-Kickback statute. (See this link for more information). In this article, Special Agent Derrick L. Jackson was quoted as saying, "When physicians receive financial incentives in exchange for patient referrals, it distorts medical decision-making and freezes out competition."

As a result of the qui tam (whistleblower) lawsuit brought initially by physician Dr. L. Darryl Quarles, and then joined by the United States government, Wellbound paid $3,246,000 to resolve the claims.

Pharmaceutical giant Walgreens recently agreed to pay a $269,000,000 settlement to the United States over allegations from two separate FCA whistleblower lawsuits. This payment will go to the United States and to multiple state governments in order to settle allegations involving the sale of insulin pens and alleged fraudulent acts related to the Walgreens Prescription Savings Club. Purportedly, Walgreens configured its computer system to prevent pharmacists from dispensing less than a full box of insulin pens, even in instances when dispensing a full box exceeded the dates of supply limit that could be dispensed and reimbursed under federal healthcare. In those instances, when the federal healthcare program denied a claim for the full box, it became Walgreens' practice to report days of supply to conform to the limit but still dispense and bill for the full box. As a result, Walgreens received reimbursements for millions of dollars for insulin pens that were not needed and potentially wasted. Additionally, Walgreens allegedly offered some of its customers a prescription savings club. Under Medicaid regulations, Walgreens should only seek reimbursement at the lowest price points of certain drugs, but instead they submitted claims at a higher, non-prescription savings club price. This resulted in multiple states overpaying Walgreens. (See this link for more information).

Walgreens, like THM and Vanguard, entered into a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services and the Inspector General. A comprehensive CIA is generally three to five years in duration[14] and allows the government site reviews and broad oversight into the offenders' billing practices. This type of agreement is common when settlements are reached.

You might ask – how do these FCA lawsuits come to the attention of the United States government? Is there an auditing system? Generally, private individuals who formerly worked at these corporate entities often bring these types of lawsuits. These private parties are referred to as "qui tam relators". They may have an incentive to bring the wrongful actions to light because they may share in a percentage of the proceeds of any settlement. When the government actually intervenes in the lawsuit, a relator can receive between 15–25 percent of the proceeds of an FCA action. If the government does not intervene, the relator could receive as much as 25–30 percent of the funds received. The government intervenes in fewer than 25 percent of all false claim actions,[15] and if they do decline to intervene, the relator may prosecute the action on behalf of the United States. Candidly, if the Department of Justice declines intervention, the remaining plaintiff generally dismisses the case.[16] In addition, if the relator makes allegations and can prove they were discharged, demoted, suspended, threatened, or harassed because of their furtherance of an action under the FCA, there are additional remedies for that relator. These remedies may include reinstatement, double the amount of back pay, interest on back pay, and compensation for special damages (including litigation costs and reasonable attorney's fees). The FCA incentivizes those individuals to come forward when

they are aware of wrongdoing.

Healthcare FCA claims are on the rise.

Notably, although there is a decrease in the number of total claims brought by the government under the FCA, government-initiated healthcare cases are increasing.[17] The uptick in these cases may be due to the creation of "Medicare Strike Force Teams", which focus specifically on criminal and civil heath care fraud.[18] Further, healthcare-related false claims filings should increase in the next few years, as the government has increased the number of civil enforcement attorneys to initiate claims under the FCA, specifically in healthcare and government contracting.[19]

The FCA is the safeguard intended to protect the health and safety of Medicare patients and can certainly be a tremendous pitfall to any healthcare provider, large or small, who is not dutiful in abiding by the law as it relates to government reimbursements.

There are numerous steps that physicians or a practice group can take to develop a voluntary compliance program. First, groups should designate a compliance officer or contact responsible for monitoring compliance efforts and enforce practice standards throughout the group.[20] Second, physicians should conduct internal monitoring through the performance of periodic audits.[21] Further, practice groups should develop open lines of communication, such as discussions at staff meetings, regarding how to avoid erroneous or fraudulent conduct and update community bulletin boards to inform practice employees of compliance activities.[22] Finally, practice groups should enforce disciplinary standards through well-publicized guidelines that are readily available to all employees.[23] SVMIC is able to assist with compliance and program development. Please visit www.svmic.com for more information.

1. See 31 U.S.C. § 3729 (a)(1)

2. The False Claims Act: A Primer, United States Department of Justice, (April 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

3. See 31 U.S.C. § 3729 (a)(1)(G)

4. The False Claims Act: A Primer, United States Department of Justice, (April 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

5. See 31 USC §§3729; See 31 USC §§3730; See 31 USC §§3731: See 31 USC §§3732; See 31 USC §§3733

6. See 18 U.S.C. § 287; See also A Roadmap for New Physicians, Fraud & Abuse Laws, United States Office of the Inspector General, https://oig.hhs.gov/compliance/physician-education/01laws.asp.

7. The False Claims Act, Centers for Medicare & Medicaid Services, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Fast-Facts/False-Claims.html

8. See 31 U.S.C. § 3729 (b)(1)(B)

9. The False Claims Act: A Primer, United States Department of Justice, (April 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

10. The False Claims Act: A Primer, United States Department of Justice, (April 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

11. The False Claims Act: A Primer, United States Department of Justice, (April 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

12. The False Claims Act: A Primer, United States Department of Justice, (April 22, 2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

13. See *Signature HealthCARE to Pay More Than $30 Million to Resolve False Claims Act Allegations Related to Rehabilitation Therapy, United States Department of Justice*, https://www.justice.gov/opa/pr/signature-healthcare-pay-more-30-million-resolve-false-claims-act-allegations-related (June 8, 2018) (where Signature HealthCARE paid more than $30 million to resolve a false claims act related to rehab therapy); See also *Grenada Lake Medical Center to Pay More Than $1.1 Million to Resolve False Claims Act Allegations Involving Medically Unnecessary Psychotherapy Services, United States Department of Justice*, https://www.justice.gov/opa/pr/grenada-lake-medical-center-pay-more-11-million-resolve-false-claims-act-allegations (August 6, 2018) (where a medical center paid more than $1.1 million to settle claims regarding services that did not qualify for Medicare)

14. See *Corporate Integrity Agreements, United States Office of the Inspector General*, https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp. For a list of current agreements, see *Corporate Integrity Agreement Documents, United States Office of the Inspector General*, https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp

15. *False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits, United States Department of Justice*, https://www.justice.gov/sites/default/files/usaoedpa/legacy/2012/06/13/InternetWhistleblower%20update.pdf

16. *False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits, United States Department of Justice*, https://www.justice.gov/sites/default/files/usaoedpa/legacy/2012/06/13/InternetWhistleblower%20update.pdf

17. *FRAUD STATISTICS – OVERVIEW, United States Department of Justice, December 21, 2018*, https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery

18. *See Megan Jeschke, Amy Fuentes, DOJ Releases 2018 False Claims Act Report and Statistics, Holland & Knight* (Jan. 17, 2019) https://www.hklaw.com/en/insights/publications/2019/01/doj-releases-2018-false-claims-act-report-and-stat

19. *See Megan Jeschke, Amy Fuentes, DOJ Releases 2018 False Claims Act Report and Statistics, Holland & Knight* (Jan. 17, 2019) https://www.hklaw.com/en/insights/publications/2019/01/doj-releases-2018-false-claims-act-report-and-stat

20. Department of Health and Human Services, Office of the Inspector General; OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434-59439 Thru. Oct. 5, 2000. See also *United States Office of the Inspector General, Compliance Guidelines*, https://oig.hhs.gov/compliance/compliance-guidance/index.asp.

21 *Id.*

22 *Id.*

23 *Id.*

Patients Want More Out of the Data You Collect About Them

By Elizabeth Woodcock, MBA, FACMPE, CPC

Patients are seeking to interface the data you collect about them in your practice with their mobile health tracking device – a Fitbit, Apple Watch, or the like. If your practice is fielding these patient requests, you may be questioning your liability related to this information transfer. On April 18, 2019, the Office of the Inspector General released a statement with instructions regarding the liability, while recommending guidance be issued to the patient.

"Under the individual right of access, an individual may request a covered entity to direct their ePHI (electronic protected health information) to a third-party app. In such a circumstance, the covered entity would not be responsible for unauthorized access to the individual's ePHI while in transmission to the app. With respect to such apps, the covered entity may want to consider informing the individual of the potential risks involved the first time that the individual makes the request." [1]

If you consider such a request outlandish, recognize that the Office of the National Coordinator for Healthcare Information Technology (ONC) issued a proposed rule that makes your practice's participation a requirement. In the press release, the ONC states, "The proposed rule helps ensure that patients can electronically access their electronic health information at no cost." This is one of many components of fulfilling the interoperability requirement of the 21st Century Cures Act.

The final rule has not yet been issued. In the interim, the ONC has launched a pilot program called "Data at the Point of Care" (DPC) as part of the federal government's

MyHealthEData initiative. The final rule is expected to be released by the end of 2019.

For more information, see the CMS fact sheet here.

1 https://www.hhs.gov/hipaa/for-professionals/faq/3010/what-liability-does-a-covered-entity-face.html

2020 Proposals for Medicare Released

By Elizabeth Woodcock, MBA, FACMPE, CPC

The federal government recently issued important Medicare proposals for 2020. While you can certainly take a deep dive into the 1,704-page document if time permits, we compiled this article to highlight key proposals that may impact you.

The Quality Payment Program – in which many physicians participate in the Merit-based Incentive Payment System (MIPS) track – is being overhauled. Acknowledging complaints about the challenges associated to the program, the Centers for Medicare and Medicaid Services (CMS) is recommending:

1) Increasing the minimum threshold to 45 points; this would be the magic number you'd need to reach to avoid the nine percent penalty to reimbursement in 2022.
2) Changing the category weight for Quality to 40 percent, pushing the extra weight into the Cost category, which will be 20 percent.
3) Reengineering the program to focus on MIPS Value Pathways, "bundles" of care designed to integrate measures across the four categories; an example is Diabetes Prevention and Treatment.

CMS also submitted the proposed rule for the Medicare Physician Fee Schedule (PFS). The conversion factor for reimbursement is proposed to be $36.09, a paltry increase over this year's $36.04. In addition to this conversion factor update, the Medicare PFS proposal includes:

1) Acceptance of the AMA-proposed evaluation and management (E/M) changes, to include four levels for new patients, the performance of history and exam only as

medically appropriate, and a revision of the times that are issued as guidelines. Further, CMS is accepting the AMA-proposed relative value units for E/M codes, which are higher.
2) Increased payment for Transitional Care Management (TCM) and alterations to coding Chronic Care Management (CCM) services.
3) New telehealth services for opioid use disorders and payment for medication-assisted treatment (MAT) by opioid treatment programs.
4) Flexibility in physician supervision of physician assistants in the absence of state laws.
5) Modification of documentation requirements, so that physicians and advanced practice providers could simply sign and date notes in the medical record recorded by trainees, learners, nurses, or other members of the care team.

These changes are proposed; the final rules for 2020 will be issued by the federal government in November. To read the proposed rule, see this link.
