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Maryland Health System Settles FCA Case Over Physician Supervision of Radiation Therapy

By Nina Youngstrom

In a case about the immediate availability of a supervising physician, University of Maryland Shore Regional Health agreed to pay \$296,870 to settle false claims allegations over radiation therapy and diagnostic services that were provided without direct physician supervision, the U.S. Attorney's Office for the District of Maryland said May 17.^[1]

Easton-based Shore Regional Health is part of University of Maryland Medical System. The False Claims Act (FCA) lawsuit against Shore was set in motion by a whistleblower, John Phillip Sawyer, who was employed from 2007 through June 2018 as lead physicist and radiation safety officer at Shore.

According to the FCA settlement, DOJ alleged Shore billed Medicare for radiation therapy and diagnostic services provided at the Cancer Center at Shore Regional Health from Jan. 16, 2014, through July 5, 2018, without the requisite physician supervision.^[2] At the time, Medicare covered radiation therapy and diagnostic services provided in outpatient settings under a physician's direct supervision, which means the physician is immediately available to render assistance and direction throughout the performance of the procedure, although the physician doesn't have to be in the same room, the settlement explained. DOJ alleged that Shore's cancer center only had one physician, John Mastandrea, M.D., available to supervise radiation therapy and diagnostic services during that period. On many occasions, Mastandrea allegedly "was performing uninterrupted radiation oncology services at a separate location, the Shore Health Medical Pavilion at Easton, while unsupervised radiation therapy and diagnostic services were being performed at the Cancer Center. Shore submitted claims to the Medicare Program for these unsupervised radiation therapy and diagnostic services performed at the Cancer Center," the settlement said.

While DOJ's investigation of Shore focused on the direct physician supervision requirement for certain radiation therapy treatments that required immediate availability during the procedure, CMS in January 2020 relaxed the supervision requirement for radiation therapy, a spokesperson for University of Maryland Shore Regional Health told RMC. CMS shifted from direct to general supervision, "which does not require the physician to be immediately available," said the spokesperson, Michael Schwartzberg.

The settlement is for a modest sum of money and "doesn't signal the government is interested in aggressively pursuing direct supervision cases," said attorney Brian Feldman, with Harter Secrest & Emery LLP. The carefully constructed language in the settlement is "reminding the world they do not require the doctor to be present in the room when the procedure is performed to meet direct supervision" requirements. The government doesn't say "we will claim a violation every time you weren't present," Feldman noted. DOJ also seems to be saying the physician must be uninterrupted at a separate location to cross the FCA threshold, he explained.

Doctor Was Allegedly Busy With Farm Animals

The whistleblower, however, elaborated on the alleged supervision failures in his third amended complaint.^[3]

Sawyer alleged that Mastandrea, a radiation oncologist, often wasn't at Shore when radiation oncology procedures were performed during business hours every day, especially Fridays, Saturdays, and Sundays. From 2012 until February 2018, he often left early to go home and take care of farm animals and other animals "instead of directly supervising the performance of dangerous procedures involving radiation therapies," the complaint alleged.

In December 2017, Shore was made aware of alleged noncompliance with Medicare billing requirements. "Defendant Shore's corporate compliance department was warned by individual employee(s) about Defendant Mastandrea's noncompliance with Medicare and Medicaid regulations, his frequent early departures, particularly on Fridays and Saturdays, and his unavailability while patients were undergoing medical procedures," the complaint alleged. "As a result, beginning in February 2018, Defendant Shore's corporate compliance department ultimately ordered Defendant Mastandrea to stay at Defendant Shore's outpatient center at all times while patients were receiving the medical procedures referenced in paragraph 46"—brachytherapy, radiosurgery, intensity modulated radiation therapy, stereotactic body radiation therapy, stereotactic radiosurgery, image guided radiation treatment, and daily treatments and simulations.

Mastandrea was not a party to the settlement. Shore Regional Health didn't admit liability in the settlement, and in a statement, University of Maryland Shore Regional Health said it "takes the responsibility of caring for our communities very seriously. The organization acted in good faith in interpreting the Centers for Medicare & Medicaid Services physician supervision guidelines in place at the time, and found that no patient harm resulted from this practice."

Contact Feldman at bfeldman@hseilaw.com.

1 Department of Justice, U.S. Attorney's Office for the District of Maryland, "University Of Maryland Shore Regional Health Agrees to Pay \$296,870 to Settle Federal False Claims Act Allegations of Billing for Unsupervised Radiation Therapy and Diagnostic Services," news release, May 17, 2022, <https://bit.ly/3a87tuH>.

2 Settlement, United States ex rel. John Phillip Sawyer v. Shore Health System and John Mastandrea, 18-cv-02228-JKB (D. Md, May 6, 2022), <https://bit.ly/3GHRjV9>.

3 Complaint, United States ex rel. John Phillip Sawyer v. Shore Health System and John Mastandrea, 18-cv-02228-JKB (D. Md, July 20, 2018), <https://bit.ly/3ma7Zek>.

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