Patient Restraint Allegations and the False Claims Act

By Stacey A. Tovino, J.D.
satovino@central.uh.edu

The Medicare Conditions of Participation for Hospitals (“COPs”) contain patient restraint requirements that apply to hospitals that participate in the Medicare program. Very generally, the civil False Claims Act makes a person or entity liable for knowingly submitting false claims to a federal program or for making or using a false record or statement to have a false claim paid. A recent settlement between Pennsylvania’s Central Montgomery Medical Center (“Central Montgomery”) and the Department of Justice (“DOJ”) shows how allegations of patient restraint violations can implicate the False Claims Act.

The federal patient restraint requirements date back to July 2, 1999, when the Centers for Medicare & Medicaid Services (“CMS”) adopted a final patients’ rights regulation as part of CMS’ ongoing revisions to the COPs. Among other things, the patients’ rights regulation addresses restraints for acute medical and surgical care and restraints for behavior management. In the medical and surgical care context, patients have the right to be free from restraints of any form that are not medically necessary or that are used as a means of coercion, discipline, convenience or retaliation by staff. A hospital is permitted to use a restraint in the medical or surgical context only if: (1) the restraint is needed to improve the patient’s well-being, (2) less restrictive interventions are ineffective, and (3) a physician or other licensed independent practitioner orders the restraint in accordance with state law.

In the behavior management context, patients have the right to be free from seclusion and restraints that are imposed as a means of coercion, discipline, convenience or retaliation. A hospital is permitted to use seclusion or restraint in the behavior management context only if: (1) the situation constitutes a behavioral emergency, (2) the seclusion or restraint is needed to ensure the patient’s physical safety, (3) less restrictive interventions are ineffective, and (4) a physician or other licensed independent practitioner orders the seclusion or restraint in accordance with state law.

On August 6, 2002, a 79-year-old woman with Alzheimer’s disease died at Central Montgomery shortly after Central Montgomery personnel applied a Posey restraint, a vest-like device designed to keep patients from falling or wandering from their beds. Although the county coroner ruled the death an accidental asphyxiation, the incident prompted the federal government to investigate Central Montgomery’s use of physical and chemical restraints.

The U.S. Attorney for the Eastern District of Pennsylvania issued a press release on July 25, 2005, announcing that the DOJ had reached a settlement agreement with Central Montgomery based on allegations that, between February and October 2002, Central Montgomery both (1) ordered and used physical and chemical restraints in violation of the
restraint requirements set forth in the COPs and (2) knowingly billed federal health care programs for the care provided to the inappropriately restrained patients in violation of the False Claims Act. Although it continues to deny both allegations, Central Montgomery agreed to pay the federal government $200,000 and hire an independent consultant to review the hospital’s restraint use policies. According to the settlement agreement, Central Montgomery has drastically reduced its use of physical and chemical restraints and now offers multiple less-restrictive alternatives to restraints.

Although nursing homes have settled similar “quality of care” cases under the False Claims Act, federal prosecutors say that Central Montgomery is the first hospital to do so. However, Central Montgomery officials believe that the DOJ misapplied the False Claims Act because “[the situation] had nothing to do with billing.” The settlement between Central Montgomery and the DOJ thus continues the debate about the appropriateness of using the False Claims Act to remedy violations of federal quality of care requirements.

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1. 42 C.F.R. § 482.13(e) and (f) (2005).
5. Id. § 482.13(f).
6. Restraints include both physical restraints (“any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient’s body that he or she cannot easily remove that restricts freedom of movement or normal access to one’s body”) and drugs used as a restraint (“a medication used to control behavior or to restrict the patient’s freedom of movement and that is not a standard treatment for the patient’s medical or psychiatric condition”). Id. § 482.13(e)(1).
7. Id. § 482.13(e) and (f).
8. Id. § 482.13(e)(2), (3).
9. Seclusion is the “involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.” Id. § 482.13(f)(1).
10. Id. § 482.13(f)(1).
11. Id. § 482.13(f)(2), (3).
15. Id. at 1, 5-6.
16. Id. at 3.
17. Id. at 2-3.
19. Id.