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The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*

David R. Hoffman**

Introduction

Quality of care. What does it mean in the nursing home context, where frail and vulnerable older adults reside, and where costs are reimbursed on a per diem basis by various government programs in a managed-care environment? What is the role of the government in ensuring that appropriate care is provided?

The protection of our older adults residing in nursing homes is one of the most important functions of government, whether federal, state, or local. While recognizing that the nursing home industry is one of the most regulated, enforcement of those regulations, by whatever means, is paramount to ensuring appropriate care.

One federal statute that may be used as an enforcement mechanism to ensure proper care is the False Claims Act. Under the False Claims Act, the federal government may bring a claim against any person for making a false or fraudulent claim for payment or approval to an officer or employee of the United States government. Penalties under the False Claims Act are significant. Anyone found liable under the Act must pay the United States government a civil penalty of not less than \$5000 and not more than \$10,000, plus up to three times the amount of

^{*} The opinions expressed herein do not represent the official policy of the United States Department of Justice and are solely those of the author. He represented the United States in *United States v. GMS Management-Tucker, Inc.* This articles shares some insight into how the case unfolded and where future prosecutions may be headed.

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^{1. 31} U.S.C. § 3729-3733 (1995).

^{2.} Id. at § 3729(a)(1).

damages that the government sustains because of the act of that person.³

In the context of health care delivery, the False Claims Act may be used when health care providers or facilities bill the government, under Medicaid or Medicare, for services that were either inadequate or simply undelivered. Such was the case in United States v. GMS Management-Tucker, Inc.4 This case involved claims by the government that nursing home residents' nutritional needs and wounds were not properly treated, and the billing of Medicare and Medicaid programs for these services amounted to filing false claims. Specifically, the United States Attorney for the Eastern District of Pennsylvania brought a civil action in February 1996 under the False Claims Act, against Tucker House II, Inc. and GMS Management-Tucker, Inc., alleging that these two defendants billed and collected, as part of a scheme to defraud the United States of America, for services rendered to residents of Tucker House Nursing Home when, in fact, the elderly residents did not receive the adequate care for which the United States was billed. The case was settled by two consent orders pursuant to which the owner of the nursing home and the management company paid penalties of \$25,000 and \$575,000, respectively, to recompense for past billing. More importantly—certainly in terms of quality of care regulation—the nursing home owner and the management company each entered into separate consent orders requiring them to improve their provision of nutritional and wound care services.

This case exemplifies the role of statutes such as the False Claims Act in ensuring quality of care in long-term care facilities. In order to convey the full import of the case, part I of this article will first examine the particular federal and state requirements pertaining to the delivery of health care services in long-term care facilities that were applicable to the defendants in this case. Next, part II will look at the facts particular to this case, which appropriately led to the filing of the complaint, and part III will describe the settlement provisions, which should act to significantly improve the quality of health care delivered in the defendants' long-term care facilities. Part IV concludes that the False Claims Act was an effective tool against quality of care abuses in the long-term care facilities of the defendants and that it should continue to be used as such for all long-term care facilities.

^{3.} Id. § 3729(a).

^{4.} No. 96-1271 (E.D. Pa. Feb. 21, 1996).

ties to protect nursing home residents throughout the United States.

I. Federal and State Requirements for the Delivery of Health Care Services to Tucker House Nursing Home Residents

Tucker House Nursing Home is a long-term care (nursing) facility licensed under federal and state law and is certified to participate in the Medicare and Medicaid programs. Consequently, there are a number of federal and state requirements regarding the delivery of health care services in a long-term care facility—all of them reflecting, in part, quality of care concerns—that applied to the defendants in *United States v. GMS Management-Tucker, Inc.* The first of these comes from the Nursing Home Reform Act⁵ (hereinafter "the Act").

The Act mandates that nursing facilities comply with federal requirements relating to the provision of services.⁶ Specifically, in terms of the quality of life for residents of nursing facilities, the Act states: "A nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." Additionally, the Act mandates that a nursing facility "provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care which describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met"

A duty is placed on the nursing facility to fulfill the residents' care plans by providing, or arranging for the provision of, inter

(1) is primarily engaged in providing to residents—

Id. at § 1396r(a).

^{5.} Pub. L. No. 100-203, 101 Stat. 1330 (1989) (codified at 42 U.S.C. § 1396r (1995)). A nursing facility is defined in the Act as an institution that

⁽A) skilled nursing care and related services for residents who require medical or nursing care,

⁽B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons, or

⁽C) on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities, and is not primarily for the care and treatment of mental diseases

^{6.} Id. at § 1396r(b).

^{7.} Id. at § 1396r(b)(1)(A).

^{8.} Id. at § 1396r(b)(2)(A).

alia, nursing and related services and medically related social services that attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident; pharmaceutical services; and dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident.⁹

The Social Security Act mandates that skilled nursing facilities that participate in the Medicare program and nursing facilities that participate in the Medical Assistance Program, also known as Medicaid, meet certain specific requirements in order to qualify for such participation.¹⁰ These regulations "serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid."¹¹ The Act mandates that the state shall certify, in accordance with surveys it must conduct, the compliance of nursing facilities (other than facilities of the state).¹²

Federal regulations, when addressing quality of care concerns, mandate that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." The regulations specifically address the area of nutrition and those individuals who are tube fed. 15

Tucker House Nursing Home is also subject to certain state regulation in its delivery of health care services as a long-term

^{9.} Id. at § 1396r(b)(4)(A)(i-iv).

^{10. 42} C.F.R. § 483.1-.75 (1996).

^{11.} Id. at § 483.1(a)(3)(b).

^{12. 42} U.S.C. § 1396r(g)(1)(A).

^{13. 42} C.F.R. § 483.25.

^{14. &}quot;Based on a resident's comprehensive assessment, the facility must ensure that a resident (1) [m]aintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and (2) [r]eceives a therapeutic diet when there is a nutritional problem." 42 C.F.R. § 483.25(i).

^{15.} Based upon a resident's comprehensive assessment,

the facility must ensure that-

⁽¹⁾ A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

⁽²⁾ A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

Id. at § 483.25(g).

health care facility. By state regulation, Pennsylvania facilities are required to meet the daily nutritional needs of patients.¹⁶ Additionally, if consultant dietary services are used, the consultant's visits must be at appropriate times and of sufficient duration and frequency to assure the consultant provides continuing liaison with medical and nursing staff, provides advice to the administrator, and participates in the development and revision of dietary policies and procedures.¹⁷

Pennsylvania's long-term care facilities are also required to provide nursing services that meet the needs of residents.¹⁸ It is incumbent upon the director of nursing services to assure that "preventive measures, treatments, medications, diet and other health services prescribed are properly carried out and recorded."19 Moreover, a nursing facility is required to retain a medical director who is responsible for the "coordination of the medical care in the facility to ensure the adequacy and appropriateness of the medical services provided to patients."20

Finally, a nursing home administrator is charged with the general administration of the facility whether or not these functions are shared with one or more other individuals.21 According to regulations promulgated by the State Board of Examiners of Nursing Home Administrators,²² a nursing home administrator is responsible for, among other things: (a) evaluating the quality of resident care and efficiency of services,23 (b) maintaining compliance with governmental regulations,²⁴ and (c) developing policies that govern the continuing care and related medical and other services provided by the facility and that reflect the facility's philosophy to provide a high level of resident care in a healthy, safe, and comfortable environment.²⁵

Beyond these state requirements, which apply to all long-term care facilities, are requirements specific to Tucker House via a

^{16. 28} PA. CODE § 211.6(a) (1996).

^{17.} Id. at § 211.6(m) (1996).

^{18.} Id. at § 211.12(a) (1996). 19. Id. at § 211.12(e)(9) (1996).

^{20.} Id. at § 211.2(k) (1996).

^{21. 63} Pa. Cons. Stat. Ann. § 1102(2) (West 1996).

^{22. 49} PA. CODE § 39.91 (1996). These were enacted to "establish and maintain a high standard of integrity and dignity in the profession and to protect the public against unprofessional conduct on the part of nursing home administrators." Id. at § 39.91.

^{23.} *Id.* at § 39.91(1)(ii).

^{24.} Id. at § 39.91(1)(vi).

^{25.} *Id.* at § 39.91(1)(i).

provider agreement with the state. In Pennsylvania, the Department of Public Welfare administers the Medical Assistance Program, and as a prerequisite to enrollment as a provider in the Medical Assistance Program, Tucker House had to enter into a provider agreement and agree to the following terms:

- (1) That the submission by, or on behalf of, the Facility defined as [Tucker House] of any claim, either by hard copy or electronic means, shall be certification that the services or items from which payment is claimed actually were provided to the person identified as a medical assistance resident by the person or entity identified as the Facility on the dates indicated.
- (5) That the Facility's participation in the Medical Assistance Program is subject to the laws and regulations effective as to the period of participation, including all of those that may be effective after the date of the agreement and that the Facility has the responsibility to know the law with respect to participation in the Medical Assistance Program.²⁶

These statutes, regulations, and agreements form the foundation for the care provided to residents of Tucker House, as monitored by the state and federal governments.

II. FACTS LEADING TO THE FILING OF THE COMPLAINT

On March 2, 1994, an older adult was transported from Tucker House to Hahnemann University Hospital in Philadelphia. At the time of admission, he had approximately twenty-six decubitus ulcers or pressure ulcers, most at the stage IV level.²⁷ One of the decubitus ulcers extended into the shoulder joint and was measured at twelve-by-twelve centimeters, while another was the size of a grapefruit on his hip. All of the twenty-six pressure ulcers were necrotic and malodorous. The elderly gentleman also had a gangrenous left leg, and all five toes on his right foot were in a necrotic state and in the process of falling off. Finally, he was dehydrated, malnourished, se-

^{26.} Provider Agreement between the Pennsylvania Department of Public Welfare and Tucker House (on file with the author).

^{27.} Pressure ulcers, or bedsores, are inflamed ulcers on the skin over a bony part of the body, resulting from prolonged pressure on the part. Stage IV ulcers are considered the most severe. At this stage, a deep crater-like ulcer has formed, and the full thickness of the skin and the underlying tissues are destroyed. Such ulcers can be life threatening, given the danger of serious infection. The Signet Mosby Medical Encyclopedia 87 (Walter D. Glanze & Kenneth N. Anderson eds., rev. ed. 1996). Most pressure ulcers can be prevented through a variety of techniques.

verely anemic, and his eyes were infected. In treating him, the hospital staff was able to communicate with him through the blinking of his eyes, and he advised the staff that he was in a great deal of pain. He was not, as asserted by counsel for Tucker House, diabetic.

Hospital staff, upset with the condition of this man, properly contacted the local long-term care ombudsman program, which in turn contacted law enforcement officials. Tucker House was inspected by Pennsylvania Department of Health surveyors, who identified numerous quality of care deficiencies. Several state surveyors then commenced an extended survey, noting additional serious deficiencies. The surveyors ordered Tucker House personnel to immediately arrange for the transfer of several residents from Tucker House to local hospitals for treatment.

This gentleman and two other residents of Tucker House served as the basis for the government proceeding against the defendants, based upon the lack of adequate care provided to them while at Tucker House. These two additional victims also suffered from malnutrition and exhibited severe skin breakdown as evidenced by multiple decubitus ulcers.

Any defense made to inadequate care—particularly that the victims were old or that they would have died anyway—is incomprehensible. Similarly astounding is the assertion that it is unfair to prosecute a nonprofit, community board of trustees that is also, in fact, the licensee that benefited from the reimbursements made by the government for care that was provided. This amazement derives from the fact that we are dealing with frail and vulnerable older people—individuals who are, in some instances, totally reliant on the staff of the facility to accomplish even the most basic of activities, such as eating and drinking. Certainly these individuals are sick, but the case at bar involved those who had no underlying reason for not being able to eat, gain weight, and heal their bodies except for the ineptitude of the staff, coupled with the goal of maximizing profits. Therefore, the licensee and the management company were both appropriate defendants. Ultimately, the Tucker House board of directors installed new management in an effort to provide the proper care to the frail elderly residing in Tucker House Nursing Home.

III. THE SETTLEMENT

On March 6, 1996, the Honorable Jan DuBois, United States District Court Judge for the Eastern District of Pennsylvania, entered two agreed-upon consent orders between the United States and the two defendants, Tucker House II, Inc. and GMS Management-Tucker, Inc., the parent of Geriatric and Medical Companies, Inc. ("Geri-Med"). Under the terms of the consent order, the owner of the nursing home paid penalties of \$25,000, and the management company paid penalties of \$575,000.

Beyond these monetary penalties are the separate consent orders requiring each defendant to improve the manner in which nutritional and wound care services are provided. These consent orders transcend simply remedying the treatment of the three victims by including all nineteen facilities owned by Geri-Med (covering 4000 residents) and providing a state-of-the-art nutrition and wound-care monitoring program.

The consent order entered into by Geri-Med, which was acquired and is now owned by Genesis Health Ventures, contains the following requirements:

- Implementation of a corporate compliance program that ensures appropriate response to weight loss and addresses the nutritional needs of all residents in the nineteen facilities;
- Provision of wound care in accordance with the Agency for Health Care Policy and Research ("AHCPR") Guidelines;
- Training of staff responsible for providing care to the residents on nutrition policies and procedures, wound care, and corporate compliance programs; and
- Monthly reporting of nutritionally at-risk or compromised residents to the United States Attorney's Office upon request.

The Geri-Med consent order also provides for the review and analysis of nutrition and wound care provided at seven facilities by the University of Pennsylvania's Institute on Aging, which will report all findings to the United States Attorney's Office. The Institute on Aging will analyze the nutritional services and wound care management at the various Geri-Med nursing homes, and will evaluate and refine a nutritional risk assessment tool to identify those residents who are at risk of clinical complications from nutritional decline. The United States and Geri-Med agreed that innovative approaches and experimentation are needed to improve the nutritional health of nursing home residents, and they have attempted to facilitate such approaches,

including the strengthening of an interdisciplinary response to nutrition issues.

The consent order entered into by Tucker House Nursing Home requires the following:

- Implementation of a nutritional monitoring and quality assessment program;
- Provision of wound care in accordance with the AHCPR guidelines;
- Training of all Tucker House nursing home staff on the nutrition and wound care requirements; and
- Monitoring by the United States Attorney's Office of compliance with the consent order and reporting to the government of all nutritionally compromised or at-risk residents for a period of at least one year.

These provisions are specifically targeted to improve the quality of health care services delivered by the defendants' long-term health care facilities and providers. Thus, they demonstrate the success in using the False Claims Act as an enforcement mechanism in regulating quality of care.

IV. THE USE OF THE FALSE CLAIMS ACT

Should the False Claims Act ("FCA")²⁸ be used in cases involving the rendering of inadequate care? The answer is a resounding yes.

The notion that quality of care cases cannot be pursued under the FCA is simply incorrect. In the recent case of *United States* ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc.,²⁹ the district court, in denying the defendant's motion to dismiss, found that quality of care issues are proper for FCA actions:

[False Claims Act] cases cited by the government involving contractors who furnished inferior goods are inapposite, but they provide a useful analogy. It may be easier for a maker of widgets to determine whether its product meets contract specifications than for a hospital to determine whether its services meet "professionally recognized standards for health care." In the Court's view, however, a problem of measurement should not pose a bar to pursuing an FCA claim against a provider of substandard health care services under appropriate circumstances.

^{28. 31} U.S.C. §§ 3729-3733 (1995).

^{29. 945} F. Supp. 1485 (W.D. Okla. 1996).

In this case, the second amended complaint alleges that [the defendant] charged the government for in-patient care of children and adolescents "who were subjected to unreasonable risks of physical and mental harm, including sexual perpetration" and "the risk of harm was sufficiently unreasonable, and the risks of harm known by [the defendant] were sufficiently blatant, that it was improper for [the defendant] to admit government insured patients into such an environment and to bill the Government Payors for the care of these patients." . . . The Court declines to hold that these allegations, if proved, cannot form the basis of an FCA claim. 30

The court also rejected the argument that since a facility is licensed and regulated by the government under a comprehensive regulatory scheme, an FCA action could not be pursued.³¹ Quality of care issues can and will be addressed through the use of the FCA.

Conclusion

The use of the False Claims Act has led to a comprehensive change in how care is to be provided to over 4000 residents at nineteen different facilities. The provision of adequate nutrition and wound care to these residents is not a facility-specific concern; rather, it has been elevated to a corporate compliance level. If long-term care facilities exhibit gross negligence in the provision of care to our elderly, and we, the taxpayers, are paying for this care through the Medicare and Medicaid programs, simply stated, there is the potential for False Claims Act liability. This type of action, coupled with appropriate criminal sanctions against those who mistreat nursing home residents, will go a long way in ensuring that adequate care is rendered. The use of the False Claims Act is another weapon available to the government to combat inappropriate behavior, and it will be pointed at those who choose profits over good care, neglect over concern, and greed over compassion when caring for nursing home residents.

^{30.} Id. at 1488-89.

^{31.} Ia