

Fair Market Value in the Healthcare Regulatory Landscape

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Introduction

Federal and state governments have enacted complex laws and regulations to regulate the affairs of businesses. Where regulators once required individuals and businesses who inadvertently violated regulations to implement corrective measures, it's now commonplace for them to deploy the full range of potential sanctions against wrongdoers, including administrative, civil, and criminal measures.¹ The healthcare laws and regulations that physicians, hospitals, and other healthcare providers must obey when providing services to patients in this country have become so intrusive and sometimes counterintuitive that what seems to be a good business opportunity to the uninitiated often will be problematic.² Consequently, it's not unusual for

1. Adapted from Michael E. Clark, *Government Enforcement Risk Areas Facing In-House and Outside Business Counsel*, materials from the ABA Section of Business Law program "Keeping the Government Outside the Boardroom," ABA Annual Meeting (Aug. 9, 2002).

2. One federal court observed that the healthcare laws, "are among the most completely impenetrable texts within human experience" and that, while they are "dense reading of the most tortuous

healthcare clients to be informed that what makes good business sense may run afoul of these laws. This book offers a valuable tool designed to help minimize these risks.

So how did the healthcare industry get so complex and dangerous? For one thing, Congress and regulators have reacted to perceived program vulnerabilities by, respectively, enacting statutes and promulgating regulations to address these issues. Because of the money involved, healthcare providers can be expected to take advantage of available pathways that allow them to maximize their reimbursement for services they provide. In addition, most healthcare service consumers don't understand or fully appreciate the true costs being spent on healthcare services because they are cushioned from that shock by the prevalence of insurance coverage. Simply put, most healthcare consumers only focus on their insurance copayments and applicable deductibles.

The various coding and nomenclature regimens for identifying the places, types, and complexity of services provided add further complexity to the healthcare payment and reimbursement systems. Moreover, in response to perceived program vulnerabilities in the Medicare and Medicaid³ programs, the Center for Medicare and Medicaid

kind, [] Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase." *Rehabilitation Association of Virginia, Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994) (Ervin, C.J.).

3. President Johnson signed the legislation into law that established the Medicare and Medicaid programs on July 30, 1965. See CMS, "Medicare & Medicaid 50th Anniversary," at <https://www.cms.gov/Outreach-and-Education/Look-Up-Topics/50th-Anniversary/Medicare-and-Medicaid-50th-Anniversary.html>. Medicare is an aged-based program that provides health insurance for U.S. citizens 65 years of age or older (except that some people who suffer from certain disabilities, such as end-stage renal disease, are not subject to the age restrictions), while Medicaid is a jointly administered and needs-based federal and state program that helps to pay for the medical costs incurred by some people with limited income and resources. While Medicaid may cover services that Medicare does not (such as long-term care and personal care services), states have different rules about Medicaid eligibility. See "What is the difference between Medicare and Medicaid?" U.S. Dep't of Health & Human Services (June 2015), available at <http://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html>.

Services (CMS),⁴ the agency within the U.S. Department of Health and Human Services (HHS) that oversees the Medicare program, continues to revise the requirements for payment and reimbursement to physicians and other participating providers. More recently, CMS has hired specialized fraud contractors that use data analytics to identify patterns that indicate possible wrongdoing.

Finally, Congress and state governments have enacted (and continue to add to) a patchwork quilt of statutes, rules, and regulations—collectively known as the “fraud and abuse laws”—that are designed to prevent fraud and to punish wrongdoers. Federal and state regulators also have, in turn, promulgated increasingly intrusive rules and regulations to deter and punish wrongdoers.

While the fraud and abuse laws are discussed in greater depth, *infra*, the key *federal* statutes worth noting here are the civil False Claims Act (FCA),⁵ the Anti-Kickback Statute (AKS),⁶ and the Ethics in Patient Referrals Act of 1989,⁷ more commonly known as the Stark law (after former U.S. Rep. Fortney “Pete” Stark, (D-CA)).⁸ Many states have enacted analogous measures (some of which are even *broader* than their federal counterparts), to address Medicaid fraud and, in some instances, private payor fraud.⁹ The common goal in these statutes is

4. CMS was formerly known as the Health Care Financing Administration (HCFA).

5. The False Claims Act is codified, as amended, at 31 U.S.C. §§ 3729 et seq.

6. The federal Anti-Kickback Statute is codified, as amended, at 42 U.S.C. § 1320a-7b. “Since 1972, [it] . . . has prohibited the offering, solicitation, or receipt of kickbacks, bribes, or rebates in exchange for referrals of patients for items or services for which payment may be made under Medicare or a state health care program, which includes Medicaid state plans as well as programs receiving funds under Titles V, XX, and XXI of the Social Security Act.” Robert Wanerman, et al., “Avoiding Fraud and Abuse Penalties and Sanctions,” Cha. 6, p. 354, *PHARMACEUTICAL LAW: REGULATION OF RESEARCH, DEVELOPMENT, AND MARKETING* (Michael E. Clark, ed., BNA 2007).

7. The Stark law is codified, as amended, at 42 U.S.C. 1395nn.

8. *See generally*, “Pete Stark, Health Policy Warrior, Leaves a Long Legacy,” Morning Edition, National Public Radio (Jan. 2, 2013) (describing Stark’s accomplishments during 40 years in Congress), *available at* <http://www.npr.org/sections/health-shots/2013/01/02/168133216/pete-stark-health-policy-warrior-leaves-a-long-legacy>.

9. For example, the State of Texas enacted an anti-solicitation statute that broadly applies to ALL payors, which is codified as amended at TEX. OCC. CODE §§ 102.001, 102.003, and 102.011.