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Worthless Services: What They Are, Why They Matter, and How to Monitor in Your Organization

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Organizational expenses are typically in the jurisdiction of management or finance teams, while patient safety events are usually addressed by the risk management department or by internal peer review processes. But when should cost-cutting measures or adverse events be forwarded to the compliance or legal departments as well? Recent Department of Justice (DOJ) enforcement actions suggest that quality issues are not reserved for risk management or the Joint Commission. Systemic issues should be evaluated by Compliance and Legal to determine whether False Claims Act (FCA) concerns are also present. From a physician's perspective, this is an important reminder: physicians often have malpractice risk at top of mind, but many physicians may not be aware of the worthless services doctrine or that they can face FCA liability that would overlap with malpractice liability.

The "worthless services" doctrine holds that a provider submits a factually false claim in violation of the FCA by providing services that are "so substandard as to be tantamount to no service at all." FCA enforcement related to substandard care and worthless services has been consistent and costly over the past several years.

On February 22, 2023, Cornerstone Healthcare Group Holding Inc. and CHG Hospital Medical Center LLC. dba Cornerstone Hospital Medical Center, located in Texas, agreed to pay $21.6 million dollars to resolve improper billing claims. Cornerstone Medical Center was located in Houston and operated as a long term care hospital. The original complaint referenced among other things, unlicensed, unauthorized students rendering medical procedures; the submission of claims for payment for services certain treating physicians allegedly rendered when those physicians were actually out of the country and could not have performed the services; and finally, the investigation concluded that Cornerstone Medical Center billed for services not supported by the patients' diagnosis or medical records, and billed for services that were either not rendered or were so inadequate they were worthless (in some cases, resulting in harm to patients).

On February 27, 2023, the DOJ and the New York Attorney General reached a $7 million settlement involving alleged false claims submitted by a New York nursing home. As alleged by the government, the operators of the nursing facility understaffed the nursing home, which resulted in medication errors and avoidable injuries including resident falls and pressure ulcers. The government also alleged that the facility did not consistently maintain hot water in the facility, maintain an adequate linen inventory, or dispose of solid waste. The government contended that each claim for reimbursement submitted for these "worthless" services constituted a false claim under the FCA.

Similarly, on March 31, 2023 the U.S. District Court for the Eastern District of Pennsylvania denied a motion to dismiss filed by three nursing homes in an FCA lawsuit brought by the DOJ under a worthless services theory

based on alleged substandard care provided to residents. See U.S. v. American Health Foundation Inc., Case No. 2:22-cv-02344, 2023 WL 2743563 (E.D. Pa. Mar. 31, 2023). In American Health Foundation, the DOJ alleged that American Health Foundation, Inc. (AHF) and related entities provided non-existent or grossly substandard services to Medicare and Medicaid beneficiaries (the Beneficiaries). Additionally, AHF allegedly failed to maintain adequate staffing levels and repeatedly failed to follow infection control protocols. Among other things, the complaint alleges that: (1) certain health care providers were not following proper hand hygiene while caring for Beneficiaries; (2) certain Beneficiaries developed pressure ulcers and remained untreated; (3) numerous Beneficiaries suffered from repeated falls at the health care facility; and (4) unnecessary medications were provided to the Beneficiaries. At the same time, AHF failed to provide proper psychiatric medicine, allegedly resulting in a patient's suicide.

In 2021, SavaSeniorCare, LLC and related entities agreed to pay over $11.2 million to resolve FCA allegations whereby Sava billed federal programs for grossly substandard services. In 2019, Vanguard Healthcare, LLC, various affiliated companies, and certain providers agreed to pay $18.6 million to resolve state and federal FCA allegations, including the failure to properly administer prescribed medications, provide standard infection control and wound care, and meet basic nutrition and hygiene requirements, amongst others.

These actions are not just limited to long term care. In 2018, an ophthalmologist and his practice, Metropolitan Retina Associates, Inc., agreed to pay $2.064 million to resolve claims that they billed Medicare and Medicaid for substandard diagnostic tests that were of such poor quality as to be effectively worthless and for ophthalmic ultrasounds that were either not performed or lacked any supporting documentation. Finally, in 2017, DOJ announced a staggering $53.6 million settlement with Genesis Healthcare, Inc., to resolve allegations that it billed federal payers for grossly substandard and worthless services ineligible for payment.

These matters underscore DOJ's commitment to view quality of care cases as potential FCA cases. According to DOJ, every claim to a federally funded health care program certifies that the services provided meet the standard of care. Therefore, services that fail to meet a certain standard of care are considered false. Stated differently, the government expects to purchase services of a certain quality, and when it is of the opinion that it did not receive that quality, a potential FCA claim exists.

With that said, it remains to be seen how far the courts will go in permitting qui tam plaintiffs to assert that the quality of care failed to meet the standard of care. This would promote federalization of medical malpractice, which courts have historically be reluctant to do in similar contexts.

Theories of FCA Liability for Substandard Care

DOJ brings FCA claims for payment of substandard care under two theories of liability: the "worthless services theory," and an "implied certification theory." With respect to the worthless services theory, DOJ alleges instances in which services are literally not provided, or the services are so substandard as to be tantamount to no service at all. For a provider, the DOJ must do more than offer evidence that the provider's services are worth some amount less than the services paid for. That is, a "diminished value" of services theory does not satisfy this standard—services that are "worth less" are not "worthless."

With respect to the "implied certification" theory, DOJ believes an FCA violation exists when a claim is filed for reimbursement despite the provider's failure to treat beneficiaries with an appropriate level of care or in a safe and secure environment. Under this theory, DOJ alleges (1) a provider's substandard care violated a statutory, regulatory, or contractual requirement; and (2) had the government known of that violation, it would not have paid the provider's claims for that care.

Monitoring Compliance Concerns Related to Quality

At a time when the government is reliably and consistently pursuing FCA cases under a worthless services theory, this trend is also coinciding with a growth in non-traditional health care corporate operation of health care providers. Large nursing home operators, private equity companies, and even health system consolidation are all resulting in a trend towards increased efficiency and lower costs. This may be overt cost-cutting like decreased staffing or less obvious cost-cutting such as limited oversight of physicians and nurses. These cost controls must not affect quality, and it would be prudent for Compliance and Legal to have a place at the table when implementing such controls. Sometimes lower costs in the short term can cost much more in the long term.

An adequate compliance program is also essential. Compliance programs should be updated to include audits or other investigations designed to review the quality of services being provided. This may include a review of staffing ratios, inventory review, and similar audits that track the requirements of state licensure, Joint Commission, or other accreditation bodies. Compliance programs should also be designed to monitor any serious cost-cutting measures to ensure that such measures will not affect quality of care. All complaints about poor quality, particularly recurring complaints about the same person or issue, must be taken seriously and investigated as a compliance matter. Quality complaints should not just be shifted to risk management. Instead, because such complaints are a risk and compliance issue, compliance programs should also be updated to include risk management, where necessary, to carry out a strong investigation.

Smaller physician practices must take heed as well—individual and small group practices historically have lagged in development of effective compliance programs and may not regularly be auditing medical records for quality of care. However, these may be just the practices that are assisting with staffing of high-risk providers such as nursing homes. Therefore, practices and organizations of all sizes should consider implementation of compliance programs that include a quality of care review.

It is also important to note that in the Cornerstone settlement, the "worthless services" question dovetailed with a more common billing question. That is, the patient medical records did not support medical necessity, nor did they support that the codes billed were actually rendered. In many cases, such issues are addressed as over-billing (for example, a 99215 for high level evaluation and management was billed when only a 99212 was appropriate when looking at the patient's needs and the documentation of the services actually performed in the record). As a result, standard coding audits remain important. Physicians who bill codes that are too high for what the physician documents in the medical record may not just be over-billing such that a repayment of the difference in amounts is all that is required. Compliance and Legal must consider also whether there was intentionality to the physician's actions, not just inadequate documentation, and whether a self-disclosure would be more appropriate than a simple repayment to the government.

Finally, if it is determined that "worthless services" have been billed for, Compliance and Legal should take proper steps to ensure that all amounts billed are repaid to the government. Legal should be consulted to evaluate whether repayment or self-disclosure should be considered.

In summary, the direction all quality improvement programs must take is a non-punitive approach that encourages open dialogue and opportunities for improvement. For example, quality standards should be included in physician contracts detailing the organization's expectations. Having an infrastructure that incorporates quality measures and tracks quality metrics is important as well. Providers and health care organizations that focus on health care quality and develop comprehensive quality improvement and patient safety programs in conjunction with an effective compliance program will benefit, as will their patients. It is the physician's responsibility to ensure that services provided meet the standard before filing a claim for federal reimbursement.

