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FEATURE

Uncle Sam Becomes a Doctor

Government Challenges to Medical Necessity

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On July 1, 2013, Sacred Heart Hospital in Chicago abruptly closed its doors just weeks after the FBI announced criminal charges against two hospital executives for fraudulently billing for unnecessary medical services, such as tracheotomies. The decision to close immediately and without notice followed Medicare's related decision to suspend payments for services for 180 days. Due to the investigation and payment suspension, physicians stopped admitting patients to the hospital, leaving only about six of 119 hospital beds filled. Although dramatic, this situation exemplifies the shifting balance between what a physician may deem medically necessary and what the government will deem to be a proper claim for reimbursement.

In an effort to reduce the costs of health care, President Obama issued Executive Order 13520 on November 20, 2009, with the stated goal that "every effort must be made by the Federal Government to confirm that the right provider receives the right reimbursement for the right reason at the right time." Similarly, the Deficit Reduction Act calls for saving $340 billion in Medicare and Medicaid spending by 2021. Such mandates have eroded the longstanding reluctance to second-guess medical decision-making by encouraging Federal agencies to investigate decisions about medical necessity. This article examines how the government challenges what is medically necessary for a patient and how to protect against such challenges.

Types of "medical necessity" investigations

A provider would seem to have nothing to worry about when certifying to Medicare or Medicaid that a service is "medically indicated and necessary for the health of the patient" as long as that service is actually provided as billed. That is because health care fraud enforcement tends to focus on easily proven matters like claims submitted for services to fictitious patients or claims for services not rendered. A more difficult type of fraud enforcement challenges "up coding," in which services are billed at a higher level than they were provided. For instance, a basic office consultation that is billed as if it were a more complicated one. These kinds of enforcement actions have produced huge restitution and monetary penalties, as well as jail for those purposely abusing the public-payer reimbursement system. The success of fraud enforcement in these areas has emboldened investigators to move into the even more difficult area of medical necessity.

Medical necessity cases fall into three basic categories:

- **Medically unnecessary claims:** provider rendered services that are not needed by the patient (e.g., motorized wheel chairs and stents)
- **Medically excessive claims:** provider rendered services that may be needed by the patient but are delivered excessively, in a quantity that is not in accord with standards of care (e.g., pediatric dental work and pain management)
- **Failure of care claims:** provider rendered services that fail to supply necessary services and/or supply inadequate/worthless services (e.g., nursing homes and home health care)

Because medical necessity cases require agents, prosecutors and judges to assess the quality of care provided to patients, these cases "obligate federal courts to step outside their primary area of competence and apply a qualitative standard measuring the efficacy of those procedures." *United States ex. rel. Mikes v. Strauss*, 274 F.3d 687 (2d Cir. 2001). Often, the medical necessity criteria is the lowest standard of care available. Medicare operates under the longstanding expectation found in Section 1862(a)(1)(A) that "no payment shall be made for items or services that are not reasonable or necessary." Accordingly, medical necessity of care may be challenged if, in the eyes of the government, the care prescribed (a) fails to meet the reimbursement criteria established by Medicare/Medicaid, (b) is not the lowest level of care proven to impact the diagnosed condition, (c) is not provided in the most cost efficient manner possible, (d) is provided for convenience of the patient, (e) is for beneficial rather than essential care, and/or (f) is deemed to be experimental.

Conducting the Investigation

Data mining is one of the most effective tools now being used in these investigations. By using powerful computers to crunch large amounts of data already contained in the reimbursement history of patients, investigators can find a provider, known as an "outlier," who treats patients very differently than his/her peers. The government is particularly interested in outliers who bill

for expensive services or bill more frequently because, of course, these services drain the most money from healthcare programs.

Once an outlier has been identified, a specific audit or investigation is initiated in order to determine whether services were properly provided. A relatively new approach increasingly employed by government auditors is to send attestation statements to be completed by the provider before the audit begins. The statements ask very pointed questions about the compliance program and internal auditing results, and require a signature from the individual(s) completing the form. These certifications add to the evidence of wrongful intent by the provider if it is determined that the billing was improper.

Agents then collect documentation from the medical files of patients identified by data mining. The collection can occur in various ways. On one extreme is a request that the provider voluntarily produce documentation; on the other is seizure of the documentation by execution of a search warrant. By far the most common way to gather records is by service of one of the various kinds of subpoenas available to the government. Use of a civil investigative demand (CID) or an administrative subpoena is routine in health care fraud investigations because the information obtained can be shared easily between civil and criminal investigators, unlike when a grand jury subpoena is issued.

Once collected, the documentation from the medical files is evaluated by academic and practicing physicians to determine how the treatment provided by the outlier compares to standards of care or preferred practices from the Centers for Medicare and Medicaid Services, the American Medical Association and other medical associations or clinical journals. The government also examines how patients are treated by other providers, and what subsequent providers report about the patient's prior care and/or condition. The government determines the outlier's membership and participation in medical societies and identifies the professional publications and billing manuals received by the outlier. The government also can obtain records from continuing medical education classes attended by the outlier and from medical malpractice cases in which the outlier is deposed.

The government will interview nurses, office staff and patients in its attempt to evaluate the treatment provided by the outlier. These interviews generally begin informally, with agents meeting at the homes of those being interviewed. If the investigation reveals potential fraud, the interviews can become formal, including depositions or even testimony before a grand jury.

The Consequences

The consequences of an investigation can be devastating to both the provider and the facility. Depending upon whether the evidence shows that a hospital was on notice of a doctor's medically unnecessary claims, the government may decline to proceed against the hospital under principles of the Holder memorandum, which sets the DOJ guidelines for indicting organizations. Alternatively, if the government determines the hospital knew or should have known about the issue through its compliance program (including its own peer review and data mining), the government may initiate a criminal prosecution or a False Claims Act (FCA) action. Although subtleties of the act are beyond the scope of this article, potential liability under the FCA is huge: any person who knowingly (broadly defined to include reckless disregard of truth) submits a false claim to the government is liable for a civil penalty of not less than $5,000 and not more than $10,000 for ***each*** false claim plus **three** times the amount of the damages sustained by the government. In addition to spurring government investigators, the FCA also incentivizes employees to report claims by establishing that a qui tam plaintiff (i.e., whistleblower) receives 15 to 30 percent of the funds recovered from a defendant.

How to Protect Yourself

The key ingredients to an effective compliance program in heavily regulated, government pay industries such as health care are: (a) careful, informed listening, (b) detailed data and chart analysis, and (c) proactive compliance. Risk-based compliance is not sufficient — the current environment in the health care industry requires strict compliance with all requirements. Providers cannot afford to ignore or explain away complaints from any source, whether patients, nurses or staff. The complaint evaluation process must be separated from medical decision-making and institutional financial pressures in order to look beyond mere billing errors. Compliance must evaluate the underlying substance of the medical care delivered in comparison to accepted national data such as National and Local Coverage Determinations (NCD/LCD) from the Centers for Medicare & Medicaid Services. Chart and peer review must be incorporated into the compliance process. Compliance officers must have unfettered access to the Board, and be provided with the tools to assess the medical necessity decisions on a patient-by-patient and institution-wide basis.

Detailed documentation of the care provided remains critical to the compliance process; no longer just to prove *that* care was provided, but now also to explain *why* this particular level of care was necessary. Providers must continually be educated about the evolving standard of care applicable to their practice, perhaps by a case manager who oversees high-risk services and evaluates regularly whether to modify policies because of changes to NCD/LCD requirements. Providers must be informed that medical necessity is not a matter of individual doctor preference. Instead, the government will increasingly judge medical decision-making by examining the cold, hard record against external standards of care.

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