IMPLANTABLE CARDIAC DEFIBRILLATORS CONTINUE TO BE SCRUTINIZED BY DOJ

The U.S. Department of Justice (DOJ) has shown interest in potential fraud linked to hospitals billing Medicare for implantable cardioverter defibrillators (ICD). Last year, the DOJ issued civil investigative demands on a number of hospitals, investigating whether ICDs were furnished to patients whose conditions did not satisfy the coverage indications published by CMS in a National Coverage Determination (NCD). The DOJ has since broadened its inquiry to hospitals nationwide. We expect the government’s concerns only to pick up steam as a recent publication in the Journal of the American Medical Association (JAMA) adds fuel to the fire.

In the JAMA article, the researchers’ review -- which focused on initial primary prevention ICD implants that occurred between January 1, 2006, and June 30, 2009 -- found that 22.5 percent of patients did not meet evidence-based guidelines for the devices. Patients were classified as receiving a non-evidence-based ICD implant if they met certain criteria; for example, they had a myocardial infarction within 40 days before ICD implantation, the patient had coronary artery bypass graft surgery within three months before ICD implantation or if the patient had newly diagnosed heart failure at the time of ICD implantation.

Despite these findings, the researchers are careful to point out some of the ICD implants may have been clinically appropriate, stating, "the ultimate judgment regarding care of a particular patient must be made by the physician and the patient in light of all the circumstances presented by that patient. There are circumstances in which deviations from these guidelines are appropriate."

The American College of Cardiology (ACC) and Heart Rhythm Society (HRS) issued a statement in response to the “important study” and reiterated the importance of research and measurement tools designed to improve patient care. The statement also emphasized that "the vast majority of implanting physicians are prescribing ICDs with the confidence that they are providing the best care for their patients." ACC and HRS echo the JAMA authors in clarifying that there are clinical situations in which the guidelines do not address unique patient circumstances.

For more information, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390, or Ameena N. Ashfaq, aashfaq@bakerlaw.com or 713.646.1329.

OIG UNVEILS MOST WANTED HEALTHCARE FUGITIVES LIST

Today the U.S. Department of Health and Human Services Office of Inspector General (OIG) introduced its Most Wanted Fugitives List in an effort to shine a spotlight on individuals sought by authorities on charges of healthcare fraud and abuse. This list -- the first list of its kind published by the OIG -- encourages the public to assist in apprehending the OIG’s most wanted fugitives.
The Most Wanted Fugitives List features photos and profiles of each fugitive and offers an online tip form and the OIG hotline number for reporting information. The current ten most wanted fugitives allegedly have cost taxpayers more than $124 million in fraud.

In the press release announcing the launch of the website, Inspector General Daniel R. Levinson stated "[w]ith our Most Wanted Fugitives List, OIG is asking the public's help in tracking down fugitives. The public has a stake in the fight against fraud, waste, and abuse."

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**CMS Implements Fraud Prevention Measures**

On February 2, 2011, the Centers for Medicare and Medicaid Services (CMS) issued a final rule implementing the new Patient Protection and Affordable Care Act (PPACA) "proactive fraud prevention" measures for Medicare, Medicaid and the Children's Health Insurance Program (CHIP), including new provider screening and enforcement tools such as suspending payments in cases of suspected fraud.

The final rule establishes requirements for suspending payments to providers and suppliers based on "credible allegations of fraud" in Medicare and Medicaid. Although the definition of "credible allegation of fraud" includes allegations from any source, including, among others, civil false claims cases and fraud hotlines, CMS believes the statutorily required consultation between CMS and the OIG prior to implementing a payment suspension will provide ample opportunity for the credibility of an allegation to be assessed and for a preliminary investigation into the allegation of fraud to occur sufficient to meet a reasonable evidentiary standard. CMS reiterated that "this authority will be exercised judiciously by CMS, in consultation with the OIG, and that only in the most egregious cases will payment suspensions last longer than the previously established timeframes for payment suspensions."

Under the final rule, CMS also will apply three levels of screening tools: (1) "limited risk" providers, including, but not limited to, physicians, nonphysician practitioners and medical groups or clinics, will have enrollment requirements, license and database verifications; (2) "moderate risk" providers/suppliers, including comprehensive outpatient rehabilitation facilities, independent diagnostic testing facilities and currently enrolled home health agencies, will have the above verifications plus unscheduled site visits; and (3) "high risk" providers/suppliers, including prospective durable medical equipment, prosthetics, orthotics and supplies suppliers and home health agencies, will have verifications, unscheduled site visits, criminal background checks and fingerprinting. States may rely on the results of the Medicare screening process for providers and suppliers that also are enrolled in Medicaid or CHIP.

The new screening procedures are applicable to newly enrolling providers and suppliers, including eligible professionals and those providers and suppliers currently enrolled in Medicare, Medicaid and CHIP who revalidate their enrollment information beginning on March 25, 2011. These new procedures are applicable to currently enrolled Medicare, Medicaid and CHIP providers, suppliers and eligible professionals beginning on March 23, 2012. Based on comments provided to the proposed rule published September 23, 2010, CMS eliminates the distinction between (1) publicly traded and nonpublicly traded companies and (2) government-owned and non-government-owned ambulance companies for purposes of the screening levels. CMS declined to apply the provisions of the final rule to managed care plans and organizations because there are a large number of other regulatory provisions that form the framework for oversight of managed care plans, and CMS did not wish to duplicate these requirements. To pay for this increased screening, a $500 fee will be imposed on most providers/suppliers enrolling in Medicare, Medicaid and CHIP for the first time, as well as currently enrolled entities revalidating their status. CMS is
only accepting comments on limited areas, including methods that can be used to ensure the privacy and confidentiality of
the records generated pursuant to adopting the criminal history records checks and the effectiveness of such checks.

The final rule also establishes the authority for imposing a temporary moratorium on Medicare, Medicaid and CHIP
enrollment on providers and suppliers when necessary "to help prevent or fight fraud, waste, and abuse without impeding
beneficiaries’ access to care." Any temporary enrollment moratorium will be announced in a notice in the Federal Register
that will include the rationale for the imposition of the moratorium, the particular provider or supplier type or the
establishment of new practice locations of a particular type in a particular geographic area.

The final rule also indicates that CMS is in the process of developing a new Notice of Proposed Rule Making incorporating
the compliance plan provisions and comments that will be published at a later date. For more information regarding recent
fraud enforcement measures, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390, or Summer D.
Swallow, sswallow@bakerlaw.com or 713.646.1306

MEDICAL NECESSITY OF STENTS UNDER CONTINUED SCRUTINY

On January 26, 2011, Maryland’s new health secretary briefed lawmakers that the state was contemplating legislative
avenues to better regulate the use of cardiac stents in patients. The announcement came in light of an ongoing
investigation into allegations that a local cardiologist may have implanted hundreds of potentially medically unnecessary
stents from 2007 through mid-2009, costing the Medicare program approximately $3.8 million. This same physician also
was linked in a recent U.S. Senate Finance Committee report to stent manufacturer Abbott Laboratories, which paid him
for consulting work.

Maryland lawmakers are considering modeling legislation off Vermont or Massachusetts laws prohibiting gifts between
drug and medical device companies and physicians. These laws require public disclosure of payments device
manufacturers make to healthcare providers and limit the items sales representatives can offer physicians, including
restrictions on trinkets, trips and most meals. Other options Maryland is considering include legislation providing for
information-sharing among state agencies or creating an accreditation process for cardiology centers that perform stent
procedures.

In releasing the Senate report, Senator Max Baucus (D-Mont.) stated "Doctors should not be performing invasive medical
procedures patients don't need, and taxpayers certainly shouldn't be paying for these wasteful and improper implantations.
... Even more disconcerting is that this could be a sign of a larger national trend of wasteful medical device use, which is
why we included aggressive new tools in the new health care law to fight fraud, waste and abuse." From year 2004 to
2009, Medicare paid an estimated $25.7 billion for cardiac stent procedures.

This potential movement in state law and the recent release of the Senate report indicates a continued national and state
level focus on the medical necessity of cardiac stent placements.

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CMS REITERATES GUIDANCE ON INPATIENT ADMISSION DETERMINATIONS

CMS recently issued guidance regarding inpatient admission decisions in response to concerns raised by hospitals
concerning how Recovery Audit Contractors (RACs), Medicare Administrative Contractors, fiscal intermediaries and
Comprehensive Error Rate Testing Contractors are utilizing screening criteria to analyze medical documentation and
make medical necessity determinations on inpatient hospital claims. However, the CMS special edition Medlearn Matters
issuance fails to provide further clarification on the use of screening processes; rather, it instructs hospitals to review
current standards as published in manuals.

CMS refers hospitals to the Medicare Program Integrity Manual and reiterates that CMS requires contractor review staff to
use a screening tool as part of their medical review process of inpatient hospital claims. While there are several
commercially available screening tools Medicare contractors may use -- such as Milliman, Interqual and other proprietary
systems -- CMS does not endorse any particular brand. CMS repeats that contractors are not required to automatically
pay a claim even if screening indicates the admission was appropriate and, conversely, contractors are not required to
automatically deny claims that do not meet the screening tool guidelines. The guidance emphasizes the following
language: "In all cases, in addition to screening instruments, the reviewer shall apply his/her own clinical
judgment to make a medical review determination based on the documentation in the medical record."
CMS also references the Medicare Benefit Policy Manual (MBPM) and reiterates what constitutes an appropriate inpatient admission: a person who has been admitted to a hospital for bed occupancy to receive inpatient hospital services. The guidance restates the MBPM instructions that a physician is responsible for deciding whether the patient should be admitted as an inpatient.

Inpatient admission determination is an area that is being scrutinized in government investigations, such as the kyphoplasty investigations. We also have seen inpatient admission decisions being questioned by Medicare contractors (e.g., RACs). Accordingly, hospitals should review such guidance and continue to institute measures to document compliance. Such documentation is a valuable tool when produced in response to medical reviews and in support of appeals.

For more information, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390, or Ameena N. Ashfaq, aashfaq@bakerlaw.com or 713.646.1329.

EVENTS CALENDAR

February 18

Houston partner Susan Feigin Harris will speak on "Shifting Political Winds: The Impact on the Healthcare Industry" at the February meeting of the Healthcare Financial Management Association in Houston, Texas.

Houston partner Scott McBride will speak on "Healthcare Enforcement and Compliance" at the February meeting of the Healthcare Financial Management Association in Houston, Texas.

February 24

Houston partner Susan Feigin Harris will speak on "The Affordable Care Act: We Had the Audacity. . . Now What?" at the 12th Annual Conference on Emerging Issues in Healthcare Law sponsored by the American Bar Association in New Orleans, Louisiana.