

DOJ Takes New Tack on Hospital Recoupments: Implantable Cardiac Defibrillators

Written by Colin J. Zick, Dean Richlin

September 4, 2012

The U.S. Department of Justice has sent emails to hospitals across the country regarding implantable cardioverter defibrillators, asking the hospitals to self-audit and estimate possible penalties under the False Claims Act. The False Claims Act is a federal statute that prohibits knowingly presenting or causing to be presented a false claim for payment or knowingly using a false statement material to a federal claim. The Act can impose significant monetary damages, including the imposition of treble damages and fines.

DOJ's concern in this case involves whether Medicare patients received implanted defibrillators in violation of CMS rules that address when such devices can be used, and while DOJ acknowledges in the email communication that it will not penalize every device that is not covered by the CMS rulings, its position is generally that submitting a claim for reimbursement for a defibrillator outside of certain circumstances would make the claim false, potentially subjecting the hospital to liability.

The email from DOJ includes that framework, the Department of Justice ICD Investigation Medical Review Guidelines/Resolution Model, in order to resolve claims related to DOJ's Implantable Cardioverter Defibrillator investigation. Under the Resolution Model, DOJ will evaluate each hospital's situation individually and will determine whether a damages multiplier should apply based on, among other things:

- patient harm;
- the hospital's patterns of activity;
- compliance efforts and effectiveness; and
- evidence regarding the hospital's knowledge.

In conducting its investigation into this issue over the past several months and shaping its proposed settlement framework, DOJ stated it consulted with the American Heart Association, the American College of Cardiology, and the Heart Rhythm Society.

This resolution model appears to be part of an emerging trend at DOJ to allow it to deal with nationwide issues that are on a modest financial scale. A similar approach evolved at DOJ regarding inpatient kyphoplasty procedures, as it assumed an investigation from a local U.S. Attorney's Office in which letters have been sent to hospitals across the country requesting documents, audits and repayments, as opposed to detailed hospital-by-hospital investigations.

The DOJ notification has importance not only for those hospitals that have received the notifications but also for other hospitals that perform these procedures.

- First, obviously additional notifications could also be issued in the future. The Department of Justice has not discussed how the hospitals were determined or how many waves of such notifications there might be.
- Secondly, the False Claims Act contains a "reverse" False Claims Act provision under which if a recipient of Medicare funds identifies an overpayment and retains it beyond 60 days of the identification (or the due date of the corresponding cost report), either knowingly concealing it or knowingly and improperly avoiding the repayment, that company is potentially subject to liability under the False Claims Act. Therefore, there may be an obligation under the reverse False Claims Act to conduct an internal investigation in order to determine whether any overpayments need to be re-funded to the government.

Finally, all hospitals that perform these procedures (including those who received notifications and those that did not) need to be aware

of state False Claims Act provisions which exist in more than half of the states, including Massachusetts. Those state statutes are modeled after the federal statute and could be implicated here if hospitals sought any reimbursement under a state or joint state/federal program.

RELATED INDUSTRIES

- [Healthcare](#)

RELATED PRACTICES

- [Business & Commercial Disputes](#)
 - [Federal Government Strategies](#)
 - [Litigation](#)
-

This communication is intended for general information purposes and as a service to clients and friends of Foley Hoag LLP. This communication should not be construed as legal advice or a legal opinion on any specific facts or circumstances, and does not create an attorney-client relationship.

United States Treasury Regulations require us to disclose the following: Any tax advice included in this document was not intended or written to be used, and it cannot be used, for the purpose of avoiding penalties under the Internal Revenue Code.

Attorney advertising. Prior results do not guarantee a similar outcome. © 2017 Foley Hoag LLP. All rights reserved.