COSMOS
Navigate the Compliance Universe

Compliance Today - October 2022

Sophie Lee (sophie.lee@fticonsulting.com) is Director at FTI Consulting in Atlanta, GA.

Compliance challenges posed by no-cost and warranty credit devices

By Sophie Lee

Compliance officers face daily challenges in understanding new regulations and guidelines, and monitoring and mitigating the risks associated with established rules and policies. One such challenge involves the requirements to report the no-cost and warranty credit for medical devices. This topic has been a focus of the Office of Inspector General (OIG) and appears to be receiving attention from nongovernmental payers as well.

CMS billing requirements

According to the Centers for Medicare & Medicaid Services (CMS) Medicare Claims Processing Manual:

> *Effective January 1, 2014, when a hospital furnishes without cost an initial placement of a medical device as part of a clinical trial or a free sample medical device or when a hospital furnishes without cost a new replacement device or with a credit of 50 percent or more of the cost of a new replacement from a manufacturer, due to warranty, recall, or field action, the hospital must report the amount of the device credit in the amount portion for value code 'FD' (Credit Received from the Manufacturer for a Medical Device). Also, effective January 1, 2014, hospitals must report one of the following condition codes when the value code 'FD' is present on the claim:*
>
> - *49 Product Replacement within Product Lifecycle—Replacement of a product earlier than the anticipated lifecycle.*
> - *50 Product Replacement for Known Recall of a Product—Manufacturer or FDA has identified the product for recall and therefore replacement.*
> - *53 Initial placement of a medical device provided as part of a clinical trial or free sample—Code is for outpatient claims that have received a device credit upon initial medical device placement in a clinical trial or a free sample.*[1]

The Medicare payment is reduced by the amount of the device credit for specified procedure codes reported with value code FD.

OIG concerns regarding overpayment

OIG has conducted several audits related to reporting manufacturer credits associated with recalled or

prematurely failed cardiac medical devices. Federal regulations and guidance specify how hospitals must report the replacement of a beneficiary's implanted device if a hospital receives a full or partial credit from the manufacturer for a medical device covered under warranty or replaced because of a defect or recall. OIG found that some hospitals likely did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed cardiac medical devices. These hospitals did not adjust the claims with proper condition and value codes to reduce payments as required. One such audit report issued in March 2018 (A-05-16-00059) estimated potential overpayments of $4.4 million across 296 claims or approximately $14,865 per claim.[2] A similar audit report issued in November 2020 (A-01-18-00502) estimated $33 million in potential overpayments related to the 911 hospitals reviewed.[3]

CMS issues letters to hospitals to require a self-assessment to investigate, identify, report, and return cardiac medical device-related overpayments.

Many Medicare Advantage (MA) plans have also conducted medical record reviews and denied payments related to recall or warranty credit medical device-related procedures. The plans seek to recoup or reduce the payment made for the affected cases through these audits. Medicare pays these plans a fixed amount per enrollee to provide benefits covered by Medicare, so any reduction in provider reimbursement raises plan profits. Therefore, there are strong incentives for MA plans to perform audits to recoup potential overpayments.