DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

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TO: Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Early Alert: Incorporating Medical Device-Specific Information on Claim Forms (A-01-16-00510)

The purpose of this memorandum is to alert you to the preliminary results of our ongoing review of the costs Medicare incurred because of recalled or defective medical devices.[1] Our ongoing review shows that the lack of medical device-specific information in the claims data impedes the ability of the Centers for Medicare & Medicaid Services (CMS) to readily identify and effectively track Medicare's total costs related to the replacement of recalled or defective devices.

Current health insurance claim forms include only the procedures performed and a field for reporting device failures and recalls.[2] Therefore, we are unable to determine from the claims data alone specific devices that have been implanted or whether replacement devices were the result of a device recall or a device failure. (CMS would encounter this same impediment.) To determine this, we had to subpoena manufacturers to obtain lists of beneficiaries who received recalled or failed devices and review beneficiaries' medical records. Specifically, we subpoenaed information and reviewed medical records for beneficiaries related to seven devices that had been recalled or that had high failure rates. For these seven devices, we established complex audit procedures and preliminarily identified $1.5 billion in Medicare payments and $140 million in beneficiary copayments and deductibles for services and procedures associated with recalled or failed devices.

[1] *Review of Medicare Expenditures Associated With Defective Medical Devices* (A-01-15-00504).

[2] Although the claim forms include a two-digit field to identify whether a device has failed or has been recalled, our review of claims data showed that hospitals rarely used this field. We will address this issue more fully in our final report.

We believe that CMS should collaborate with the Accredited Standards Committee X12 to include the device identifier (DI) portion of the Unique Device Identifier (UDI) for implantable devices on the next version of the claim forms. The inclusion of the DI could assist in identifying the costs to Medicare for recalled or defective medical devices, help ensure patient safety, and safeguard Medicare trust funds.

BACKGROUND

According to the U.S. Food and Drug Administration (FDA), recalls of medical devices nearly doubled from 2003 through 2012. Independent studies have shown that failed devices of all types have likely cost Medicare billions of dollars during these years because of monitoring, hospitalization, surgeries, imaging, postacute care, physician services, and other costs. Furthermore, beneficiaries adversely affected by defective devices may incur adverse health events and unnecessary costs in the form of deductibles and coinsurance. Although not improper payments, these amounts underscore the significant costs incurred by Medicare and beneficiaries to replace failed or recalled medical devices.

CMS expressed concerns about the impact of additional health care costs and the Medicare expenditures associated with defective medical devices almost a decade ago (72 Fed. Reg. 66222, 66327 (Nov. 27, 2007)). At that time, CMS stated that it would develop a plan to address the extent of these costs.

The Food and Drug Administration Amendments Act of 2007 charged FDA with creating a unique device identification system. The UDI system is intended to better detect devices with adverse events, improve device recalls, and enable more robust postmarket surveillance. There are two parts to the UDI: the DI portion and production identifier (PI) portion(s). The DI identifies the device labeler and the specific version or model of the device. The PI is a variable portion of the UDI that identifies one or more of the following when included on the device label: the device's lot or batch, its serial number, its expiration date, its manufacturing date, or its HCT/P (Human Cell, Tissue or Cellular or Tissue-Based Product) identification code. Currently, claim forms do not include either the DI or the PI of implantable devices.

The Health Insurance Portability and Accountability Act of 1996 generally requires that changes to claim forms be handled through a multistakeholder standards development process. Standards organizations bring together stakeholders to reach consensus on the benefits and costs of these changes. The Department of Health and Human Services (HHS) may not adopt a standard developed by a standards-setting organization unless the organization consults with data content committees. HHS also relies on the recommendations of the National Committee on Vital Health Statistics (NCVHS) and consults with appropriate Federal and State agencies and private organizations.

The Accredited Standards Committee X12, the standards organization responsible for defining and developing the electronic health care claim forms, is proposing revisions to the claim forms. If HHS receives a recommendation from the NCVHS to adopt changes to health care claims, CMS is expected to engage in a related rulemaking process. According to the Accredited Standards Committee X12's recently released time line, the proposed revised claims standards

are expected to be released for comment on December 1, 2016. Unless the Accredited Standards Committee X12 incorporates the DI into this update, medical device-specific information could not be included on the claim forms until the end of the next decade.

We believe that CMS and FDA have recently taken an important step in this direction by co-signing a letter to the Accredited Standards Committee X12 supporting capturing the DI portion of the UDI for implantable devices on the claim forms.[3] According to that letter, collecting the DI on claim forms would allow for evaluation of product performance and identification of safety concerns for devices at the model level, facilitate the collection and analysis of patient data for devices at the model level, help providers and certain payers calculate and compare costs and outcomes on the basis of the device model used, and support program integrity by providing better information to link the patient and implanted device to help track rebates and manufacturers back to the payer or provider.

PRELIMINARY AUDIT RESULTS

To examine the costs Medicare incurred because of recalled or failed medical devices, we initiated a review of the Medicare costs associated with seven cardiac devices from three manufacturers that had been recalled or that had high failure rates. These seven cardiac devices had been implanted into 375,991 Medicare beneficiaries. To conduct this review, we subpoenaed the three device manufacturers to obtain a list of beneficiaries who had received the devices. We used this list to identify 72,710 Medicare beneficiaries who received device replacements. These replaced devices resulted in 8.2 million replacement-related claims totaling $5.1 billion in Medicare payments to providers and an additional $501 million in beneficiary copayments and deductibles. The devices were replaced because of recalls, premature device failures, and necessary upgrades.

Our preliminary results show that there is a significant impediment to readily identifying Medicare's total costs caused by a medical device recall, a device that prematurely failed, or a necessary device upgrade. Specifically, the claim forms list only the services and procedures performed and a two-digit field that providers rarely used for reporting device failures and recalls; the forms do not contain a field for reporting device-specific information. Accordingly, we could not determine from the claims data alone the specific device implanted and whether the device replacement was due to a recall, a premature failure, or a necessary upgrade. Inclusion of the DI portion of the UDI on claim forms would be an important step in the identification of the model and manufacturer of an implanted device. Without the proper use of the two-digit field and any standard device information on the claim forms, we had to establish complex audit procedures and undertake the labor-intensive process of obtaining and reviewing the device recipients' medical records to identify $1.5 billion in Medicare payments to providers and $140 million in beneficiary copayments and deductibles for device replacements and related services and procedures caused by recalls or premature device failures for the seven devices.

[3] CMS and FDA publicly recognized the value of adding DIs to claim forms to improve the data available on device performance in a July 13, 2016, letter to the Chair of the Accredited Standards Committee X12.

The remainder of the $5.1 billion in payments and $501 million in beneficiary copayments and deductibles were associated with device upgrades and replacements resulting from infections.

The complex audit procedures required and the time-consuming process of obtaining and reviewing device recipients' medical records underscore not only the need for providers to indicate whether the device replacement was due to a recall or defective device, but also for including medical device-specific information on claim forms. If the DI is included on claim forms along with the proper two-digit field, we (and CMS) could use hospital claims data to identify beneficiaries who received a recalled or failed medical device model. As described in CMS and FDA's co-signed letter, collecting the DI on claim forms would also result in several benefits, including supporting program integrity. Those benefits could reduce Medicare costs by identifying problem devices more quickly and reduce medical errors by enabling health care professionals and others to more rapidly and precisely identify a device that is potentially contributing to a medical error and obtain important information concerning the characteristics of the device. This in turn could help protect beneficiaries from unnecessary costs in the form of deductibles and coinsurance and improve their chance of receiving the appropriate followup care more quickly.

CONCLUSION

CMS and FDA recently took an important step and co-signed a letter that supported capturing the DI portion of the UDI on the claim forms for implantable devices. Along with the proper use of the two-digit field, we believe that including the DI on claim forms could help identify Medicare's costs related to recalled or failed devices. As described by FDA and CMS, including the DI on claim forms would result in several benefits, which we believe could also help reduce Medicare costs by identifying poorly performing devices, protecting beneficiaries from unnecessary costs, and improving beneficiaries' chance of receiving appropriate followup care more quickly. Including the DI on claim forms could also assist in any related cost-recovery efforts and help prevent fraud and abuse by providing a means to identify unreported manufacturer credits. As the UDI system evolves, we believe that including the PI portion(s) of the UDI on the claim forms could also help identify and track Medicare's aggregate costs related to recalled or defective devices and would provide patient safety benefits by enabling the identification of specific batches and lots of recalled devices.

We believe that this early alert provides important information that policy makers should take into consideration as they contemplate revisions to the claim forms. Therefore, we suggest that CMS collaborate with the Accredited Standards Committee X12 to include the DI on the next version of the claim forms to assist in identifying the costs to Medicare for recalled or defective medical devices, help ensure patient safety, and safeguard Medicare trust funds.

The information in this alert is preliminary, and the audit is continuing. We will issue a draft report at the conclusion of the audit and include CMS's comments and actions taken in response to this early alert. If you have any comments or questions about this memorandum, please do not hesitate to call me, or your staff may contact Brian P. Ritchie, Assistant Inspector General for Audit Services, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov.