

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



REVISED product from the Medicare Learning Network®

- [Inpatient Psychiatric Facility Prospective Payment System](#), Fact sheet, ICN 00839

MLN Matters® Number: MM8961

Related Change Request (CR) #: CR 8961

Related CR Release Date: January 30, 2015

Effective Date: For claims received on or after July 1, 2015

Related CR Transmittal #: R3181CP

Implementation Date: July 6, 2015

Implementation of New National Uniform Billing Committee (NUBC) Condition Code "53" - "Initial placement of a medical device provided as part of a clinical trial or a free sample"

Provider Types Affected

This MLN Matters® Article is for hospitals submitting outpatient claims to Medicare Administrative Contractors (MAC) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 8961 implements Condition Code "53" (Initial placement of a medical device provided as part of a clinical trial or a free sample) for reporting on the outpatient hospital claim. Make sure your billing staffs are aware of the new Condition Code of 53.

Background

Current system edits require a condition code to be billed for outpatient claims when the provider bills value code "FD" (Credit Received from the Manufacturer for a Replaced Medical Device), indicating that they have received a credit on the device.

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A new Medicare outpatient payment policy was implemented on January 1, 2014, requiring reporting of value code FD for medical devices furnished without cost to the hospital or when the hospital receives a full or partial credit for the device. (See the Federal Register December 10, 2013, pages 75005-75008, IV. OPPTS Payment for Devices, B. Adjustment to OPPTS Payment for No Cost/Full Credit and Partial Credit Devices at <https://www.federalregister.gov/articles/2013/12/10/2013-28737/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical> on the Internet.)

Under this policy, outpatient hospitals are required to report the amount of the credit in the amount portion for value code “FD” (Credit Received from the Manufacturer for a Medical Device) when the hospital receives a credit for a device listed in Table 31 of Federal Register December 10, 2013 that is 50 percent or greater than the cost of the device.

Currently, hospitals must use either condition code 49 (Product Replacement within Product Lifecycle) or 50 (Product Replacement for Known Recall of a Product) along with value code FD. These two condition codes describe only replacement devices. They do not describe a reduced cost for initially implanted (non-replacement) devices, which are commonly supplied to Medicare beneficiaries, especially in the context of medical device clinical trials. Therefore, a new condition code is needed to describe initially implanted medical devices that are not replacement devices.

Effective January 1, 2014 (and for claims received on or after July 1, 2015), an additional new condition code "53" was created for institutional provider use. This new code is used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due a clinical trial or a free sample.

Please note that you are no longer required to append the “FB” or “FC” modifier when receiving a device at no cost or with a full or partial credit. Additionally, the Centers for Medicare & Medicaid Services (CMS) limits the Outpatient Prospective Payment System (OPPS) payment deduction for device-intensive Average Production Costs (APCs) to the total amount of the device offset when the “FD” value code appears on a claim.

When a hospital furnishes a device for which it incurs no cost, (these cases include, but are not limited to, devices replaced under warranty, due to recall, or due to defect in a previous device; devices provided in a clinical trial; or devices provided as a sample) the hospital charge for a device furnished to the hospital at no cost should equal \$0.00. However, some hospital billing systems require a charge be reported for separately billable codes in order for the claim to be submitted for payment, even items for which the hospital incurs no cost.

Hospitals paid under the OPPTS that implant a device furnished at no cost to the hospital shall report a charge of zero for the device, or, if the hospital’s billing system requires that a charge be entered, the hospital shall submit a token charge (e.g. \$1.00) on the line with the device code.

CMS recognizes that showing a charge for a device that has been furnished without cost is not optimal, but showing a token charge in this circumstance will allow claims for reasonable and necessary services to be adjudicated.

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Additional Information

The official instruction, CR 8961 issued to your MAC regarding this change is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3181CP.pdf> on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Net-work-MLN/MLNMattersArticles/index.html> under - How Does It Work.

Seasonal Flu Vaccinations - For information on coverage and billing of the influenza vaccine and its administration, please refer to [MLN Matters® Article #MM8890](#), “Influenza Vaccine Payment Allowances - Annual Update for 2014-2015 Season” and [MLN Matters® Article #SE1431](#), “2014-2015 Influenza (Flu) Resources for Health Care Professionals.”

Also, check out the following resources from the Centers for Disease Control and Prevention (CDC): [Influenza \(Flu\)](#) web page for the latest information on flu including the CDC 2014-2015 recommendations for the prevention and control of influenza, antiviral information, CDC flu mobile app, Q&As, toolkit for long term care employers, and other free resources. Review the CDC’s [Antiviral Drugs](#) website for information about how antiviral medications can be used to prevent or treat influenza when influenza activity is present in your community, and view the updated “Influenza Antiviral Medications: Summary for Clinicians.” A CDC Health Update reminding clinicians about the importance of flu antiviral medications was distributed via the CDC Health Alert Network on January 9, 2015, and is available at <http://emergency.cdc.gov/HAN/han00375.asp> on the Internet.

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