Notification to CMS of an FDA Cleared or Approved Clinical Diagnostic Laboratory Test (CDLT) under the Medicare Clinical Laboratory Fee Schedule (CLFS)

Instructions

This form is to be used by laboratories or manufacturers to notify the Centers for Medicare & Medicaid Services (CMS) about CDLTs that are cleared or approved by the U.S. Food and Drug Administration (FDA), that are not advanced diagnostic laboratory tests (ADLTs).

In notifying CMS of FDA clearance or approval for a CDLT (that is not an ADLT), a laboratory or manufacturer, that is, **the notifying entity**, is required to provide current coding information for the test, the status of any application to the American Medical Association (AMA) for a unique level I Healthcare Common Procedure Coding System (HCPCS) code for the test, and/or a request for CMS to assign a level II HCPCS code that is unique to the test. If the FDA cleared or approved test does not already have a unique level I HCPCS code and if an application for a level I HCPCS code for the test has not been submitted to the AMA, or if an application is not in the process of being submitted to the AMA, an application for a level II HCPCS code for the FDA cleared or approved test must accompany this notification form.

Do **not** use this form to notify CMS of an FDA cleared or approved CDLT that has been granted ADLT status by CMS or that is under consideration for ADLT status. Single laboratories requesting ADLT status for a test under "Criterion B" of the ADLT definition, that is, a test cleared or approved by the FDA, must use the CMS application for ADLT status, which is available from the CMS website via the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

Background Information

On June 23, 2016, CMS published the CLFS final rule, "**Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule**" (CMS-1621-F; 81 *Fed. Reg.* 41036 through 41101). The final rule implements section 1834A of the Social Security Act (the Act), which requires extensive revisions to the Medicare payment, coding, and coverage for CDLTs.

Section 1834A(e) of the Act requires CMS to ensure that a unique HCPCS code is assigned for a laboratory test that is cleared or approved by the FDA. A "unique" HCPCS code is one that describes only a single test. It is possible that one HCPCS code may be used to describe more than one existing CDLT that is cleared or approved by the FDA. For instance, one version of the test could be FDA cleared or approved while other versions of the test may not be FDA cleared or approved. In this circumstance, the same HCPCS code would be used for both the FDA cleared or approved version of the test and the non-FDA cleared or approved versions of the test. Thus, the current HCPCS code would not be unique in describing only the FDA cleared or approved version of the test.

To that end, the American Medical Association (AMA) will create level I HCPCS codes (that is, *Current Procedural Terminology* (CPT®)[1] codes) or CMS will create level II HCPCS codes to identify laboratory tests that are cleared or approved by the FDA if the FDA cleared/approved test has not already been assigned a unique HCPCS code.

To ensure compliance with these provisions, the notifying entity must notify CMS of any FDA cleared or approved CDLT (that is not an ADLT). Any laboratory which furnishes, designs, offers or sells a CDLT that has been cleared or approved by the FDA, or any manufacturer that designs an FDA cleared or approved CDLT, may submit this notification form to CMS and serve as the notifying entity. That is, the notifying entity must use this form to notify CMS about *any* CDLT that has been cleared or approved by the FDA—whether it has already been assigned a unique HCPCS code or has not yet been assigned a unique HCPCS code.

This notification of an FDA cleared or approved CDLT may be submitted to CMS at any time during the year. CMS will use the notification to ensure that each FDA cleared or approved CDLT is assigned a unique HCPCS code describing only a single test, if such test has not already been assigned a unique HCPCS code. When submitting a notification of an FDA cleared or approved CDLT (that's not an ADLT), the notifying entity must inform CMS whether the test already has been assigned a unique HCPCS code. If the test is not currently assigned a unique HCPCS code, the notifying entity must inform CMS if a completed application for a unique level I HCPCS code for the test was submitted to the AMA (or whether an application is in the process of being submitting to the AMA).

If the notifying entity is in the process of submitting an application for a level I HCPCS code to the AMA, it must submit a revised notification form to CMS after a completed application has been submitted to the AMA. In submitting a revised notification form, the notifying entity must provide the date a completed application for a unique level I HCPCS code for the FDA cleared or approved test was submitted to the AMA. Once CMS is informed that a completed level I HCPCS code application has been submitted, CMS will contact the AMA to ensure that a unique laboratory test code, which describes only a single test, is assigned to the FDA cleared or approved CDLT.

If the FDA cleared or approved CDLT has not already been assigned a unique level I HCPCS code, and the notifying entity has not submitted a completed application for a level I HCPCS code to the AMA or is <u>not</u> in the process of preparing an application for a unique level I HCPCS code, it must submit to CMS, along with this notification form, a request for CMS to assign a unique level II HCPCS code for the FDA cleared or approved test. CMS will review the request and assign a unique level II HCPCS code for the FDA cleared or approved test on a quarterly basis.

The application for a level II HCPCS code for FDA cleared or approved tests is available from the CMS website via the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html

[1]*Current Procedure Terminology* (CPT®) copyright 2016 American Medical Association. All Rights Reserved.

Send Completed Notifications to:

Notifications of an FDA cleared or approved CDLT and follow-up notifications that a completed level I HCPCS code application has been submitted to the AMA (if the notifying entity is currently in the process of preparing a level I HCPCS coding request) may be submitted to CMS in hard copy and or electronic format to the addresses below. If submitting electronically, scan and send the signed notification form and any additional relevant attachments as a single file in PDF format. The notification form must include a physical signature. Digital signatures and digital initials will not be accepted.

Hard Copy:

Centers for Medicare & Medicaid Services
CM/HAPG/Division of Ambulatory Services
7500 Security Boulevard
Baltimore, Maryland 21244
Mail Stop: C4-01-26
Attention: CLFS Team

Electronic: CLFSFormSubmission@cms.hhs.gov

Questions regarding this form may be sent to: CLFS_Inquiries@cms.hhs.gov.

Test Name and Notifying Entity Information

Name of FDA Cleared or Approved Test: _____

Name of Notifying Entity: _____

Address: _____
Number and Street

_____ _____ _____
City/ Town State Zip code

1. Please check the box below if the statement is true.

☐ • The test is cleared or approved by the FDA.

2. Provide below, and/or attach to this application, information that shows the test is cleared or approved by the FDA. This information must include the FDA premarket approval or premarket notification (i.e., 510[k]) number for the test:

   • FDA premarket approval or notification number: _____

   • Date of FDA clearance or approval: _____/_____/_____
   MM/ DD/ YYYY

   • Name and branch of the FDA reviewer:_____
   name and branch

3. Please provide information about the existing code(s) and descriptor(s) currently used to bill for the FDA cleared or approved test. If the FDA cleared or approved test is currently described by an existing level I HCPCS code (CPT code) or level II HCPCS code, or some other code or identifier that is being used by the laboratory to bill for the test, include the following information, as applicable, in **the table below**:

   • The specific HCPCS code (as defined in 42 C.F.R. § 414.502), the Not Otherwise Classified (NOC) code, or the unlisted CPT code;
   • The MolDX Z-Code Identifier;
   • The code or other descriptors used to describe the test.

Existing HCPCS Code or Other Existing Unique Identifier Used to Bill for the Test*	Descriptor*

** In the event that multiple payors are currently paying for the test, this notification must include all existing HCPCS codes or other unique identifier(s) used for billing the test and corresponding code descriptors. Note that if the existing code(s) and descriptor(s) currently used to bill for the FDA cleared or approved test are not a unique HCPCS code, that is, a HCPCS code describing only a single test, item 4 must be completed below.*

4. Item 4 asks for information that is required for a laboratory test cleared or approved by the FDA that does **not currently** have a unique HCPCS code, that is, a HCPCS code describing only a single test. If the FDA cleared or approved CDLT has already been assigned a unique HCPCS code, item 4 should be omitted. Note that a MolDX Z-Code Identifier, even if it describes a single FDA cleared or approved test, is not classified as a "HCPCS" code.

   If the FDA cleared or approved test is **not currently** assigned a unique HCPCS code (that is, a HCPCS code describing only a single test):

   - Provide the date (month, day, year) a completed application for a unique level I HCPCS code for the FDA cleared or approved test was submitted to the AMA:

     _____/_____/_____
     MM/ DD/ YYYY

   or,

- If you have not submitted a level I HCPCS code application for the FDA cleared or approved test to the AMA but you are in the process of preparing an application, provide an estimated submission date (month, day, year):

_____/_____/_____
MM/ DD/ YYYY

or,

- If you have not submitted a level I HCPCS code application for the test to the AMA and are not in the process of preparing an application, submit to CMS, along with this notification, a request for CMS to assign a unique level II HCPCS code for the FDA cleared or approved test. The level II HCPCS laboratory test code request form can be downloaded from the *CLFS PAMA Regulations* web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

5. Penalties for Falsifying Information on this Notification

18 U.S.C. § 1001 authorizes criminal penalties against an individual who, in any matter within the jurisdiction of any department or agency of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious, or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. Individual offenders are subject to fines of up to $250,000 and imprisonment for up to five years. Offenders that are organizations are subject to fines of up to $500,000 (18 U.S.C. § 3571). Section 3571(d) also authorizes fines of up to twice the gross gain derived by the offender if it is greater than the amount specifically authorized by the sentencing statute.

6. Certification Statement

The authorized official, as described in paragraph 7, MUST sign and date the section below.

I, the undersigned, certify to the following:

- I have read and understand the Penalties for Falsifying Information, as printed in this notification. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this notification or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this notification form, may be punished by criminal, civil, or administrative penalties including, but not limited to revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.

- The information provided on this notification is true, correct and complete. If I become aware that any information in this notification is not true, correct, or complete, I agree to notify CMS of this fact immediately.

7. Authorized Official Information and Signature for the Notifying Entity

An authorized official is an appointed official of the notifying entity (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to make changes or updates to the organization and communicate information to CMS regarding Medicare program requirements.

My signature legally binds the notifying entity to the Certification Statement. By my signature, I certify under penalty of perjury that the information contained herein is true, accurate and complete.

Name: _____

Title/Position: _____

Signature: _____ Date: _____

8. Contact Person

The contact person is an individual who can be reached to answer questions regarding the information furnished in this notification.

Name: _____

Title/Position: _____

Telephone Number: _____
Include Area Code and Extension (if Applicable)

Email Address: _____