



News Flash - It's Not Too Late to Give and Get the Flu Shot! In the U.S., the peak of flu season typically occurs anywhere from late December through March; however, flu season can last as late as May. Each office visit presents an opportunity for you to talk with your patients about the importance of getting an annual flu shot and a one time pneumococcal vaccination. Protect yourself, your patients, and your family and friends by getting and giving the flu shot. **Don't Get the Flu. Don't Give the Flu. Get Vaccinated!** Remember - Influenza and pneumococcal vaccinations and their administration are covered Part B benefits. Note that influenza and pneumococcal vaccines are NOT Part D covered drugs. You and your staff can learn more about Medicare's coverage of adult immunizations and related provider education resources, by reviewing Special Edition MLN Matters article SE0748 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0748.pdf> on the CMS website.

MLN Matters Number: MM5772

Related Change Request (CR) #: 5772

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Effective Date: July 1, 2008

Related CR Transmittal #: R56DEMO

Implementation Date: July 7, 2008

Implementation of the Medicare Clinical Laboratory Services Competitive Bidding Demonstration

Provider Types Affected

Providers or suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FI), or Medicare Administrative Contractors (A/B MAC)) and/or order laboratory services for Medicare fee-for-service (FFS) beneficiaries under the Medicare Clinical Laboratory Services Competitive Bidding Demonstration project.

What you need to know

CR 5772, from which this article is taken, implements the Centers for Medicare & Medicaid Services (CMS) Medicare Clinical Laboratory Services Competitive Bidding Demonstration in the first Competitive Bidding Area (San Diego-Carlsbad-San Marcos, California metropolitan statistical area, or CBA1); and changes some of the demonstration's requirements that were stated in CR5205, issued August 1, 2006, (see the MLN Matters article at

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<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5205.pdf> on the CMS website) and superceded by CR5359, issued November 1, 2006, (see the MLN Matters article at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5359.pdf> on the CMS website).

Specifically, CR5772 requires that:

- The demonstration covers tests provided to beneficiaries enrolled in the traditional fee-for-service (FFS) Medicare program who reside in the competitive bidding area (CBA1) during the 3-year demonstration period. Required bidders that do not bid, or bid and do not win, may serve as a reference laboratory to laboratories participating in the demonstration. However, they would not be allowed to bill Medicare directly for demonstration tests performed for Medicare FFS beneficiaries residing in the CBA.
- *Laboratories not required to bid.* These laboratories will be paid under the competitively set demonstration fee schedule for the duration of the demonstration.
 - CMS will exempt laboratories that supply less than \$100,000 annually in demonstration tests to Medicare FFS beneficiaries residing in the CBA from submitting bids.
 - CMS will exempt laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD) from submitting bids. (Tests that are paid as part of the ESRD payment bundle are excluded from the demonstration.)
 - CMS will exempt laboratories providing services exclusively to beneficiaries in nursing facilities or receiving home health services from submitting bids.

CR5772 further announces that the demonstration in CBA1 is scheduled to begin on July 1, 2008; and provides Medicare contractors detailed record layouts for the quarterly report and for listing laboratories in the CBA.

CMS will issue a later CR that implements the demonstration in the second CBA (CBA2), which is tentatively scheduled to start on July 1, 2009.

Background

Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to conduct a project to demonstrate the application of competitive acquisition for the payment of most clinical laboratory services that would otherwise be payable under the Medicare Part B fee schedule.

In this project, each of two demonstration sites (competitive bidding areas – CBA1 and CBA2) will run for three years with a staggered start of one year. It will cover certain “demonstration tests”

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furnished under Medicare Part B to any beneficiary enrolled in FFS Medicare who lives in the CBAs.

Competitively bid fees will be set for all tests paid under the Medicare Part B clinical laboratory fee schedule in these demonstration sites, with the exception of Pap smears, colorectal cancer screening tests, and new tests added to the Medicare Part B clinical laboratory fee schedule during the course of the demonstration. In each CBA, the payment basis determined by the bidding will substitute for present payment under the existing clinical laboratory fee schedule.

CBAs will be defined geographically by ZIP codes, and will roughly correspond to a Metropolitan Statistical Area (MSA). Beneficiary residence status will be determined by information in the Medicare system as of the date the claim is processed, and review of a beneficiary's ZIP code of residence must reveal that it is included in the same listed CBA. CMS will provide Medicare contractors with a list of ZIP codes included in each MSA, which they will use to determine whether a beneficiary's residence is included in one of the CBAs.

Two previous Change Requests, (CR) 5205 and 5359 (issued August 1, 2006 and November 1, 2006, respectively), implemented the necessary system requirements to accomplish this project. CR 5772, from which this article is taken, establishes the project implementation dates; changes the requirements for referring and reference laboratory services, Skilled Nursing Facility (SNF) and Home Health services; and provides Medicare contractors a detailed record layout for the quarterly report, for listing laboratories in the CBA with their CB status.

The demonstration in CBA1 is scheduled to begin on July 1, 2008. CMS will issue a later CR that implements the demonstration in the second CBA (CBA2), which is tentatively scheduled to start on July 1, 2009. You should note that multiple winners are expected in each CBA.

Note: Only CLIA-certified laboratories will be allowed to participate in the demonstration.

Laboratory Categories

Under the demonstration, laboratories will be classified as either: 1) "Required bidders" (laboratories that are required to bid in the demonstration because (regardless of where they are located) they provide FFS beneficiaries residing in the CBAs "demonstration tests" that yield \$100,000 or more in annual Medicare Part B (fee-for-service) payments as of calendar year (CY) 2006); or 2) "Non-required bidders" (laboratories whose payments for Medicare Part B (fee-for-service) payments for demonstration tests are below this \$100,000 threshold.

"Non-required bidders" may choose to bid or not bid. Those that do not bid will be considered "passive" laboratories. Such passive laboratories, as well as "non-required bidders" who choose to bid (and win) and "required bidders" who win, (both labeled "winners") will be allowed to provide laboratory services to Medicare beneficiaries in the CBA and will be paid at the competitive bid rate for the demonstration tests paid under the Part B Clinical Laboratory Fee Schedule (CLFS), regardless of where the laboratory firm is located.

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Conversely, “required bidders” and “non-required bidders” who bid and do not win (along with “required bidders” who do not bid) will be labeled “non-winners” under the demonstration. Medicare will not directly pay these “non-winner” laboratories (under either the Part B clinical laboratory fee schedule or the competitively bid price) for demonstration tests that they provide to beneficiaries residing in the CBAs for the duration of the demonstration (regardless of where the laboratory firm is located). Therefore, a passive laboratory that chooses to bid but does not “win” cannot participate in the demonstration in its “passive” status.

There are three types of passive laboratories: 1) “Passive-small business” (those with less than \$100,000 in annual Medicare Part B (fee-for-service) payments for demonstration tests provided to beneficiaries residing in the CBA); 2) “Passive-ESRD” – those that provide clinical laboratory services exclusively to beneficiaries with end stage renal disease (ESRD) residing in the CBAs; and 3) “Passive SNF/Home Health” – those that provide laboratory services exclusively to beneficiaries residing in nursing homes or are receiving home health services.

The “passive-small business” category of passive laboratories is subject to an annual payment ceiling of \$100,000, however this payment ceiling threshold does not apply to the “passive ESRD” or “passive SNF/Home Health” laboratories. Further, you should note that the \$100,000 threshold for “passive” laboratories does not include Medicare payment for tests excluded from the demonstration test list, services for beneficiaries residing in areas outside the CBA, or revenues from sources other than Medicare fee-for-service

You should also note that the \$100,000 threshold does not apply to either the “passive ESRD” or passive SNF/Home Health laboratory categories.

In addition, in order to make it easier for nursing facilities to continue to provide continuity of care, CMS is exempting “passive SNF/Home Health” laboratories from being required bidders. Laboratories providing both Part A and Part B laboratory services to nursing facilities will be able to continue existing business relationships because they will not be at risk of losing Medicare Part A business as a result of the demonstration. They will be paid at the competitively set rate for demonstration tests otherwise paid under the Part B CLFS, and will also continue to receive payment for mileage, phlebotomy, and the existing payment under any schedule other than the Part B CLFS for those tests included in the demonstration.

You should also be aware that during the demonstration period, CMS will require that Medicare contractors monitor (and report to CMS quarterly):

- “Passive-small business” laboratories to ensure that their Medicare Part B annual payments for demonstration tests provided to beneficiaries residing in the demonstration sites do not exceed the dollar threshold (so that they do not unfairly gain market share within the CBA). Passive laboratory firms exceeding their threshold limitations during the demonstration period will be converted to a “non-winner” status, and will be terminated from the demonstration project, and not be paid anything by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration.

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Note: All changes from a “passive” to a “non-winner” will be prospective to the next quarter.

- “Passive-ESRD” laboratories to ensure that payments under Medicare Part B for demonstration tests are provided only to beneficiaries with ESRD residing in the demonstration sites; and
- “Passive SNF/Home Health” laboratories to ensure that payments under Medicare Part B for demonstration tests are provided only to beneficiaries residing in nursing homes or are receiving home health in the demonstration sites.

Project Implementation

The project is being implemented in multiple phases. The first phase (analysis and design) was implemented in January 2007. The second phase (finalization of the requirements, coding development, testing and documentation) was implemented in April 2007.

CR 5772, from which this article is taken, announces that the demonstration in CBA1 is scheduled to begin on July 1, 2008, and that the tentative start date for the demonstration in the second CBA is July 1, 2009.

During the second quarter of calendar year (CY) 2008, CMS will provide Medicare contractors with:

- Information that specifies (along with a few other required fields) the laboratories’ names and Medicare provider numbers, address and zip code, demonstration status (winning, passive (SB, SNF/Home Health, ESRD), or non-winner) and each laboratory’s payment history for services provided to beneficiaries’ living within the first CBA1 as of CY 2006. This information will identify the laboratories eligible to participate in the demonstration (“winning” laboratories), the passive laboratories that are exempt from bidding in the demonstration due to their relatively small size as measured by annual Medicare payments or due to their status as an ESRD or SNF/Home Health laboratory, and those not selected to participate in the demonstration after unsuccessfully bidding (“non-winner” laboratories). The list will specify the name of the laboratory, address, ZIP code, Medicare provider number, and the laboratory’s demonstration status. Any changes to a laboratory’s status in this report will be handled on an ad hoc basis
- A test version of the laboratory competitive bidding demonstration fee schedule file containing the demonstration fee amounts for the preliminary list of services that the demonstration covers. (This test file will be populated only with the data pertaining to CBA1.)
- Modifications to the existing 5-position national ZIP code pricing file for the laboratory competitive bidding demonstration. Also during the second quarter of CY 2008, CMS will provide the final version of the laboratory competitive bidding demonstration fee schedule file containing the Current Procedural Terminology (CPT) codes of the services covered by the demonstration and fees for CBA1.

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To determine the correct laboratory competitive bidding fee schedule amount, contractors will use the July 2008 version of the 5-position national ZIP code pricing file to locate the ZIP code of the beneficiary's residence and map the beneficiary locality designation (i.e., CBA1 or CBA2) to the matching locality on the laboratory competitive bidding demonstration fee schedule file.

Notes:

1) This mapping is for demonstration pricing purposes only, and will not be used to report the laboratory state locality information.

2) For claims within a local carrier's jurisdiction, carriers will continue to report the state locality of the billing laboratory as they do now for clinical laboratory services.

CR 5772 also contains the following details about the demonstration:

- Physician office laboratory (POL) testing and hospital-based laboratories that function as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital are included in the demonstration. A POL enrolled as an independent laboratory or a hospital-based laboratory furnishing laboratory services to non-patients are subject to the demonstration rules. Services provided by a POL and/or a hospital-based laboratory for their own patients are not included in the demonstration and will continue to be paid under the existing CLFS.

Note:

For hospital-based laboratories, only 14X Type of Bills submitted for non-patient laboratory services are covered under this demonstration.

- Hospital inpatient testing is covered by Medicare Part A, it is, therefore, exempt from the demonstration.
- Pap smears and colorectal cancer screening tests are excluded from this demonstration by statute.
- Requirements under the Clinical Laboratory Improvement Amendments (CLIA) program as mandated in section 353 of the Public Health Service Act are applicable.
- Claims for phlebotomy, Healthcare Common Procedure Coding System (HCPCS) code 36415 (Collection of venous blood by venipuncture) must identify the place of service (POS), e.g., Skilled Nursing Facility (POS 31), Home (POS 12), ESRD treatment facility (POS 65), Physician's office (POS 11) or Independent laboratory (POS 81). If the specimen is collected at an independent laboratory draw station, you should use POS 81. For this demonstration, when the specimen is collected at a hospital laboratory or draw station that is acting as an independent laboratory, you should indicate the place of service for CPT code 36415 as POS 81.
- Referring and reference laboratories may be paid under the demonstration with some restrictions:

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- A winning or passive laboratory can refer out and bill for the reference laboratory service and be paid directly by Medicare;
- A reference laboratory that was required to bid in the competitive bidding process but was not a winner under the demonstration can perform reference laboratory services but cannot bill Medicare directly or bill the beneficiary; and
- A reference laboratory that was not required to bid in the competitive bidding process can choose to bill for services that other laboratories refer to them. However, these laboratories are restricted to receiving payment less than \$100,000 a year (for demonstration tests provided to FFS beneficiaries residing in the CBA), and if they exceed the \$100,000 limit, they will be considered a non-winner and Medicare payment will not be allowed.
- **Non-winner laboratories that furnish a demonstration test to a Medicare beneficiary residing in the CBA during the demonstration have no appeal rights when Medicare denies payment for the test, nor may they charge the beneficiary for such a test.** However, non-winners may continue to furnish tests (that are outside the scope of the demonstration) to beneficiaries residing within the CBA, receive Medicare payment for such tests, and may appeal denial decisions for these services.
- Effective for claims with dates of services between July 1, 2008 and June 30, 2011, Medicare contractors will pay competitive bidding demonstration fee schedule amounts for claims that winning and/or passive laboratories submit for demonstration-covered services (including reference laboratory services) provided to beneficiaries residing in the CBA1. Moreover, CMS is aware that the allowed amount under the demonstration could be less than the regular fee schedule allowed amount. Therefore, contractors will add the following message for a demonstration remittance advice:

M114 – This service was processed in accordance with rules and guidelines under the Competitive Bidding Demonstration Project. If you would like more information regarding this project, contact your local contractor.
- Laboratory tests which are exempt from the demonstration (e.g., pap smears, colorectal cancer screening tests), as well as new procedure codes that are added subsequent to the start of the demonstration will be paid in accordance with the existing CLFS. Laboratory tests provided to beneficiaries enrolled in the Medicare Program other than FFS or residing outside the CBA will be paid in accordance with the existing Part B CLFS.
- Effective for claims with dates of services on or after July 1, 2008 through June 30, 2011, carriers will deny, and intermediaries will reject, claims submitted by non-winner laboratories for demonstration-covered services provided to beneficiaries residing in the CBA1, using the following remittance advice reason code and remark codes:

Reason code 96 – Non-covered charge(s).

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Remark Code M114 - This service was processed in accordance with rules and guidelines under the Competitive Bidding Demonstration Project. If you would like more information regarding this project, you may contact your local contractor.

Remark Code M115 (For carriers) – No appeal rights. This item is denied when provided to this patient by a non-contract or non-demonstration supplier.

Remark Code N83 (For intermediaries) - No appeal rights. Adjudicative decision based on the provisions of a demonstration project.

- Effective for claims with dates of services on or after July 1, 2008 through June 30, 2011, carriers will not reject claims with a modifier “90” (Reference (Outside) Laboratory) submitted by a winning or passive laboratory for demonstration-covered services provided to beneficiaries residing in the CBA1. However, they will reject claims from non-winning laboratories for demonstration covered services provided to such beneficiaries, even with modifier “90” present.
- Finally, all of the other business rules provided in CR 5205 and CR 5359 remain applicable, and are not changed by CR 5772.

Additional Information

You can find the official instructions given to your carrier, FI, or A/B MAC in CR 5772 located at <http://www.cms.hhs.gov/Transmittals/downloads/R56DEMO.pdf> on the CMS website.

You might also want to look at MLN Matters article MM5359 (Laboratory Competitive Bidding Demonstration) which you can find at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5359.pdf> on the CMS website. (MM5359 superseded MM5205.)

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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