MEDICARE CLINICAL LABORATORY SERVICES COMPETITIVE BIDDING DEMONSTRATION PROJECT

FREQUENTLY ASKED QUESTIONS

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General Demonstration Questions

1. What is a demonstration project?

The Centers for Medicare and Medicaid Services (CMS) conducts and sponsors a number of innovative demonstration projects to test and measure the effect of potential program changes. Our demonstrations study the likely impact of new methods of service delivery, coverage of new types of service, and new payment approaches on beneficiaries, providers, health plans, States, and the Medicare Trust Funds.

2. Are demonstration projects evaluated?

Yes. Evaluation projects validate our research and demonstration findings and help CMS monitor the effectiveness of Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). An evaluation of this demonstration project will be conducted by an independent research organization under contract with CMS.

Legislative Authority

3. What is the purpose of the project?

Section 302 (b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 mandates a demonstration project using competitive bidding for clinical laboratory services. The purpose of the demonstration is to determine whether competitive bidding can be used to provide quality laboratory services at prices below current Medicare payment rates.

4. What are the legislative requirements?

Section 302 (b) mandates that CMS conduct a demonstration that applies competitive acquisition to clinical laboratory services that would otherwise be paid under the Medicare Part B (FFS) clinical laboratory fee schedule. The MMA excludes Pap smears and colorectal cancer screening tests; excludes "face-to-face encounters" and includes requirements under the Clinical Laboratory Improvement Amendments (CLIA) program. The MMA requires that CMS deliver a Report to Congress.

5. What does "face-to-face encounter" mean?

The intent of Congress was to exclude testing performed by physician office laboratories or by hospital laboratories for their own patients. Therefore, the authorizing legislation excludes laboratory tests paid under Medicare Part A or inpatient prospective payment system and testing provided to patients by a physicians office laboratory (POL). A laboratory's drawing station for non-patient specimen collection would not qualify for the MMA exclusion.

Under section 942 of the MMA, Congress used "face-to-face" for the purpose of collecting insurance information to determine the Medicare Secondary Payer (MSP) status, for which a laboratory's specimen collection site would qualify.

Under the demonstration, the face-to-face exclusion is defined as laboratory testing provided for POL patients, hospital inpatients, and hospital outpatients.

6. What is the purpose of applying the requirements of the Clinical Laboratory Improvement Amendments (CLIA) program to the demonstration?

Section 302(b) of the MMA mandates that CLIA program requirements are applied to the demonstration project. Section 353 of the Public Health Service Act provides legislative authority for CLIA. The objective of the CLIA program is to ensure quality laboratory testing. All clinical laboratories must be properly certified to operate a clinical laboratory in the United States, and enrolled as providers to receive Medicare or Medicaid payments. http://www.cms.hhs.gov/CLIA/

7. What is meant by multiple winners?

Section 302(b) of the MMA does not mandate any predetermined number of winning laboratories. The number of winning laboratories will be based on multidimensional criteria, such as quality, financial stability, demonstration test code bid price, capacity and geographic coverage in effort to ensure beneficiary access to high quality laboratory services.

8. What is meant by budget savings?

Section 302(b) of the MMA requires the total amounts to be paid to contractors in a competitive acquisition area during the demonstration are expected to be less than the total amounts that would otherwise be paid under the Part B Clinical Laboratory Fee Schedule.

9. What is in the Report to Congress?

The CMS submitted a preliminary Report to Congress on April 19, 2006, (as required by the MMA) summarizing the proposed design for the demonstration. The Report specifically addresses quality of care issues and beneficiary access to quality laboratory services, which will be a significant focus of both the selection criteria for the demonstration and its evaluation.

The Report describes the proposed criteria for the selection of sites, including the use of Metropolitan Statistical Areas (MSAs) to define the demonstration areas (consistent with how sites were defined under the DME demonstrations).

The Report is available to the public on the demonstration project website at: (http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=

dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage).

Demonstration Test Codes

10. What test codes are included in the demonstration?

The demonstration will include clinical laboratory services paid under the clinical laboratory fee schedule for all Medicare Part B FFS beneficiaries who live in the demonstration area. The demonstration will set fees in the demonstration area for test codes paid under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) with both high volume and high payments nationally, with the exception of Pap smears and colorectal cancer screening tests, and new test codes added to the CLFS during the demonstration. A complete list of the test codes included in the demonstration is available as part of the bidding application (Section D) and in Table 1 of the Bidder's Package.

The approximately 300 tests codes on which laboratories must bid represent approximately 99 percent of the Medicare Part B CLFS based on both volume and payment nationally (in 2006).

11. What tests are excluded from the demonstration?

Pap smears and colorectal cancer screening tests, and new test codes added to the Medicare Part B CLFS during the demonstration are excluded.

Laboratory tests performed by physician office laboratories or by hospital laboratories for their own patients are also excluded.

Clinical laboratory services will continue to be paid under the existing clinical laboratory fee schedule for all Medicare Part B FFS beneficiaries who live outside the demonstration area. The project does not include Medicare payment for tests that are not included in the demonstration test code list, tests that are part of the ESRD payment bundle, or revenues from payers other than Medicare.

12. How does the demonstration affect Medicare coverage decisions?

Medicare coverage decisions are not affected by the demonstration. The MMA mandates a demonstration that applies competitive bidding to clinical laboratory services that would otherwise be paid under the Medicare Part B (FFS) clinical laboratory fee schedule (CLFS). The demonstration replaces the existing CLFS with a "demonstration fee schedule" that is competitively set for payment to participating laboratories providing laboratory services to beneficiaries residing within the CBA for the duration of the 3 year demonstration project. Therefore, all CMS coverage decision procedures and policies remain intact.

Structure of the Demonstration

13. Which laboratories are required to bid?

Required bidders are defined as those organizations that expect to supply at least $100,000 annually in demonstration test codes to Medicare beneficiaries residing in the CBA during any year of the demonstration. Required bidders that bid and win will be paid under one competitively set demonstration fee schedule for services provided to beneficiaries residing in the CBA for the duration of the demonstration. See Questions 10 and 11 for tests included in/excluded from the demonstration.

14. Which laboratories are not required to bid?

The CMS will exempt small laboratories (those with less than $100,000 in annual Part B FFS demonstration tests in the competitive bidding area) from being required bidders. Those laboratories will be allowed to provide laboratory services to Medicare beneficiaries in the bidding area and will be paid under the demonstration fee schedule.

The CMS will exempt laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD) from being required bidders. Laboratories providing services exclusively to ESRD beneficiaries will not be required to bid, and will be paid at the demonstration fee schedule for demonstration test codes otherwise paid under the Medicare Part B CLFS. Tests that are paid as part of the ESRD payment bundle are excluded from the demonstration.

Also laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services in the CBA will not be required to bid, and will be paid at the demonstration fee schedule for demonstration test codes otherwise paid under the Medicare Part B CLFS.

15. Why is the demonstration dependent on where a Medicare (FFS) beneficiary resides?

The nature of the laboratory industry makes it possible to be located anywhere in the country and still be able to provide laboratory services to providers and/or patients in one particular CBA.

16. Are ESRD tests excluded from the demonstration? What is the basis for exempting these tests?

ESRD tests paid as part of the bundle payment are excluded from the demonstration. The MMA does not exempt ESRD clinical laboratory testing paid under the Medicare Part B FFS Clinical Laboratory Fee Schedule for ESRD beneficiaries from the demonstration.

However, laboratories providing testing exclusively to ESRD beneficiaries residing in the CBA will have the option to not bid and receive payment at the demonstration fee schedule amount. Under this provision, payment for demonstration test codes that are currently paid under the Medicare Part B CLFS will be paid under the demonstration fee schedule for ESRD beneficiaries residing in the CBA. These laboratories may choose to participate in the bidding process, however; in that case, all rules would then apply and they would have to win to receive payment under Medicare Part B for demonstration tests provided to ESRD beneficiaries residing in the CBA.

17. What is the basis for exempting laboratories providing services exclusively to beneficiaries residing in nursing home or receiving home health services from being required bidders?

In developing the demonstration design, CMS focused on protecting access to quality laboratory services for all Medicare beneficiaries, including vulnerable populations. CMS is exempting laboratories providing services exclusively to nursing facilities from being required bidders, thereby making it easier for nursing facilities to continue to provide continuity of care. In addition, laboratories providing both Medicare Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships. Laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration and would be paid at the competitively set rate for demonstration tests otherwise paid under the Medicare Part B CLFS. Laboratories will also continue to receive payment for mileage, phlebotomy, and the existing payment under any schedule other than the Medicare Part B CLFS for those tests included in the demonstration.

18. Each demonstration site will last three years. Does this mean that the bid prices submitted by the competing laboratories must be good for the entire three-year period?

Yes.

19. What does staggered start mean?

The second demonstration site will be implemented a year after the implementation of the first demonstration site.

20. Does CMS plan to build in some controls or design features to monitor and prevent bidders from exploiting their market positions?

The CMS will be reviewing bids for elements of gaming and anti-trust. In addition, the demonstration will be monitored for the entire duration of the project, especially regarding quality, access, and unfair business practices.

21. What was the basis for selecting the $100,000 threshold for mandatory participation?

The CMS carefully considered the number of laboratories that would be required to bid if the threshold for bidding was set at $50,000, $100,000, or $200,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries in various metropolitan statistical areas (MSAs) of the United States. On the basis of this analysis, we determined that if all laboratory firms with more than $100,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries enrolled in FFS in an MSA were required to bid, we could expect bids from between 10 and 13 laboratory firms in each of the geographic areas under consideration.

22. Are there predetermined numbers of bidders or winners?

No.

23. What are the incentives for "passive" laboratories to participate?

If all laboratories were allowed to participate regardless of whether or not they have submitted winning bids, no laboratory would have an incentive to bid efficiently. In addition, if only the very largest laboratories were required to bid, the competitively set fee schedule would be driven by only those large (often nationally operated) laboratories. Therefore, we have attempted to design the demonstration so as to ensure healthy competition among the largest possible number of laboratory firms, while affording smaller firms the opportunity to continue providing services in the defined competitive bidding area (CBA).

Some small businesses may view the demonstration as an opportunity to gain in market share. We are allowing non-required bidders to make the business decision to bid, or not bid and receive the fees (with restrictions) that are competitively set under the demonstration.

Demonstration Site(s)

24. How were the sites selected?

The fundamental criteria for the demonstration sites proposed allow for potential Medicare program savings from the demonstration, are administratively feasible, are representative of the laboratory market, and will yield demonstration results that can be generalized to other MSA.

We selected an MSA that is located within a single State because MSAs that cross state boundaries increase administrative costs when two carriers and two fiscal intermediaries are responsible for administering claims for the MSAs.

The recommended MSAs have a moderately large Medicare population, with neither very low nor very high Medicare-managed care penetration.

Bidding

25. How will laboratories know what zip codes to bid on? Can labs submit bids based on specific zip codes?

The demonstration area is approximately equal to a metropolitan statistical area (MSA). In effort to easily and clearly identify the demonstration area, CMS will provide a list of the zip codes that make up the MSA. The specific list of zip codes that make up the MSA is referred to as the competitive bidding area (CBA).

The CMS will select multiple laboratories based on the competitive prices submitted and non-price criteria such as: quality, capacity, financial stability, and geographic coverage information provided in the application. The multi-dimensional selection process also allows for enough capacity that should a laboratory discontinue participation in the demonstration, beneficiary access to quality laboratory services would not be impacted. Laboratories participating in the demonstration must be CLIA certified and a Medicare enrolled supplier.

Geographic coverage is one element of the application. The application asks laboratories to identify the geographic areas they currently serve within the CBA. For example, a laboratory may indicate the entire CBA, county or counties within the CBA, or specific zip codes. The application also allows a laboratory to indicate whether or not there is interest in or capacity to expand service to additional areas under the demonstration.

The bid price submitted for each demonstration test HCPCS code is the bid price for the entire CBA. Bid prices from winning laboratories will be used to set the one and only demonstration fee schedule for the CBA.

26. Will collusion and/or anticompetitive behavior be monitored?

Bidding behavior will be subject to anti-trust laws and regulations prohibiting collusion or anticompetitive behavior (under the jurisdiction of the Federal Trade Commission and the Department of Justice).

27. What is the process for bidding?

The CBA and the date of a Bidder's Conference were announced in a Federal Register Notice and CMS press release disseminated using various CMS listservs (see question 47). The final Bidder's Package is available to the public. The "Bidder's Conference" is planned for potential bidders to learn about the rules and ask questions about the bidding process.

There will be a single bidding competition covering all demonstration test codes. Bidders will be required to complete the bid table provided in the application (Section D) -- submitting a bid price for each Health Care Procedure Coding System (HCPCS) code in the demonstration test menu. Bidding laboratories will be asked to identify demonstration test codes that they do not perform, and will be asked to explain their plans for responding to requests for demonstration test codes that they do not perform in house (e.g., subcontracting and referrals). As part of their bid, laboratories will provide information on ownership, location of affiliated laboratories and drawing stations, CLIA certification, and quality.

28. What is the proposed timeline?

- Bidder's Conference will be held in San Diego-Carlsbad-San Marcos metropolitan area on December 5, 2007.
- Bids due by February 15, 2008.
- Winners selected on April 11, 2008.
- Payments made under the demonstration by July 1, 2008.

29. Will the bidding package be available to the public?

Project materials are available to the public on the demonstration project website at:

(http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage).

30. Will the completed applications be made public? Will the bids be made public? Are applications that were submitted accessible to the public through the Freedom of Information Act (FOIA)?

No. All applicant information will be protected and can not be obtained through the FOIA process. Applications will not be made public. Any information or data about the demonstration project released by CMS or its contractors will be in aggregate and non-identifiable.

31. What is the definition of "gaming?"

Gaming is defined as unrealistic bidding in an attempt to gain an advantage in the bidding evaluation. An example of gaming is "low-balling." Each bid--both on a composite basis and by individual HCPCS code-defined test—will be compared to standards such as the average bid, the median bid, the distribution of bids, and the current Medicare Part B CLFS. Extreme, outlying, and unrealistic bid prices will be identified and subject to further scrutiny. A bidder who is determined to be gaming may be disqualified.

32. Can a laboratory that does not perform all tests in-house continue to send out those tests?

Specimens can be referred to any CLIA certified laboratory for testing. However, under the demonstration, only winning and passive laboratories may directly bill Medicare. The "70/30 rule" which requires laboratories to perform in-house at least 70 percent of what is billed to Medicare, and refer or send out no more than 30 percent of what is billed to Medicare continues to apply under the demonstration.

33. What happens if a laboratory typically uses a reference laboratory that is a non-winning laboratory under the demonstration?

A non-winning laboratory may not directly bill Medicare under the demonstration. Reference laboratories that do not bill Medicare directly may continue to perform demonstration tests under arrangement with a winning or passive laboratory for FFS beneficiaries residing in the CBA.

In addition, the existing "70/30 rule" that requires 70 percent of testing billed to Medicare by a laboratory must be performed by that laboratory is applicable.

The demonstration does not impact laboratories providing and billing for services to beneficiaries in Medicare Advantage plans, to Medicare beneficiaries residing outside the CBA, and to non-Medicare patients.

34. What happens if a required bidder does not bid or does not win?

A required bidder must bid and win to directly bill Medicare for demonstration test codess provided to a beneficiary enrolled in FFS and residing in the CBA. A required bidder that chooses not to bid or does not win may perform demonstration tests for a beneficiary enrolled in FFS and residing in the CBA, however only a winning or passive laboratory may bill Medicare directly for those services.

35. What is the bid process given the following scenario: A bidder that performs in-house the top 100 demonstration test codes by volume, and refers out the other demonstration test codes to be performed by reference lab(s)?

The approximately 300 tests codes on which laboratories must bid represents almost all of the Medicare Part B CLFS based on volume and revenue nationally. Each bid will be evaluated on the composite of prices for the full list of demonstration test codes. In evaluating the bid, bid prices for each HCPCS and ATP code will be weighted by their market volumes (provided for you in Section D, question 4, Column C of the application form). A bidder must provide bid price for all demonstration test codes, including prices for tests that it refers out.

36. What is the bid process given the following scenario: A laboratory performs one single demonstration test code in-house.

Bidders must provide a bid price for each demonstration test code. A required bidder that chooses not to bid or does not win may perform demonstration tests for a beneficiary enrolled in FFS and residing in the CBA, however only a winning or passive laboratory may directly bill Medicare for those services. A laboratory with a limited test menu may bid, but can also consider being a subcontractor/reference laboratory for other laboratories that are bidding. Small laboratories that are exempt from being required bidders may continue to perform and bill Medicare for demonstration tests for beneficiaries enrolled in FFS and residing in the CBA and will be paid under the competitively set demonstration fee schedule (subject to an annual cap on revenues for demonstration test codes).

37. What is the bid process given the following scenario: The bidder performs all demonstration test codes in-house.

Bidders must provide a bid price for each demonstration test code listed in the Bid Table.

38. What is the bid process given the following scenario: A laboratory organization submits its own bid under the demonstration and is also named as a reference laboratory on another organization's application.

This is allowed under the demonstration. A laboratory may be both a bidder and a reference laboratory for another bidder.

39. What is the bid process given the following scenario: One laboratory organization submits two applications with different reference labs/subcontractors for each bid.

This is not allowed under the demonstration. Each organization may submit only one application.

40. What is the bid process given the following scenario: Two laboratories are affiliated and under common ownership. Each submits a bid under the demonstration.

This is not allowed under the demonstration. Laboratories that are under common ownership or control must submit a single application.

41. What is the bid process given the following scenario: A laboratory submits a bid and also applies for passive laboratory status.

This is not allowed under the demonstration. The application requires a laboratory to identify itself as one of the following: a required bidder submitting a bid, a

required bidder not submitting a bid, a non-required bidder submitting a bid, or a non-required bidder not submitting a bid

42. What is the bid process given the following scenario: A laboratory designating passive status under the demonstration is included as a reference laboratory on another laboratory's application?

This is allowed under the demonstration. A laboratory identifying itself as qualifying for passive status may choose not to bid and may be included as a reference laboratory on another laboratory's application.

43. What is the bid process given the following scenario: A laboratory is bid as a reference laboratory on multiple applications?

This is allowed under the demonstration. A laboratory may be bid as a reference laboratory on multiple applications.

Application Evaluation Process

44. Who is responsible for reviewing and evaluating the bidding application form?

A panel of technical staff from CMS, RTI and Palmetto GBA will make up a Bid Evaluation Panel responsible for reviewing each of the eligible bids. BEP members will have expertise in CMS program, policy or operations specifically relating to clinical laboratory issues, CLIA, Medicare, competitive bidding and acquisition, health care economics and CMS claims payment systems.

BEP members are legally held to CMS privacy, confidentiality, and ethics rules, and will sign an additional agreement that specifically addresses the confidentiality of all information provided on all applications submitted, and to protect the applications overall.

45. What is the basic process for evaluating the applications?

In Stage One, the BEP will identify applicants who are eligible bidders. Ineligible applicants will be notified by CMS and will have an opportunity to appeal the decision (within 7 days of notification from CMS).

In Stage Two, a composite bid price for each eligible bidder will be calculated. The composite bid is a single price that is calculated for each bidder by RTI and is the average of a bidder's prices for each demonstration test code weighted by each test code's weight.

Stage Three will determine the financially competitive range of composite bid prices for the demonstration and the eligible bidders who are in the financially competitive range. The financially competitive range will be based on the bidder's

composite bid prices, their laboratory test capacity, and the projected demand for demonstration test codes in the competitive bid area. A composite bid is considered financially competitive if it is equal to or less than the cutoff price.

In Stage Four, the BEP will recommend to CMS the winning applicants determined to offer the best value for the Medicare program based on price and non-price criteria.

In Stage Five, bidders recommended by the BEP to CMS will be offered a contract defining the terms and agreements – a legally binding agreement required for participation in the demonstration project.

46. How will CMS ensure that beneficiaries will have access to laboratory services?

To ensure access for beneficiaries and providers, the BEP will select multiple winners. It will analyze geographic coverage of the CBA by laboratories that fall into the financially competitive range, the availability of the demonstration test codes, and the ability to provide or arrange for needed services in the CBA. Under the demonstration, although non-winning laboratories will not be allowed to bill Medicare directly for demonstration test codes, they will be allowed to subcontract with participating laboratories to perform demonstration test codes, which will further safeguard access. Also, laboratories serving exclusively ESRD beneficiaries or beneficiaries who are residents of nursing homes or receiving home health services may continue to provide such services without bidding.

Access will also be measured as part of the evaluation of the demonstration.

Winning Laboratories

47. What kinds of terms and conditions will winning laboratories be expected to agree to?

Laboratories will be required to meet the requirements described in the Bidder's Package, but the terms and conditions are not yet final. The final terms and conditions will be agreed to prior to contract award and implementation, as with other demonstration projects.

The terms and conditions for participation in the demonstration will include acceptance of competitively set fees for demonstration test codes, as well as performance measurement in addition to compliance with CLIA standards. In order to protect beneficiaries, bidders will not be allowed to select beneficiaries who require less service.

48. What happens when a bidder has been declared a winner of the bidding competition, however its bid includes a reference laboratory that is a non-winner?

Any CLIA certified laboratory can act as a subcontractor/reference laboratory to winning and passive laboratories under the demonstration, including non-winning laboratories. Thus, a non-winning laboratory can be a reference laboratory for a winning laboratory under the demonstration. However, only winning and passive laboratories will be able to bill Medicare directly. Non-winning laboratories will not be able to directly bill Medicare for demonstration test codes provided to beneficiaries enrolled in FFS and residing in the CBA.

There will be only one round of bidding under the demonstration. Winning bidders under the demonstration and the demonstration test fee schedule will be determined from the original bid submissions. All demonstration test codes will be paid at the single demonstration fee schedule during the demonstration period.

49. What happens when a bidder has been declared a winner of the bidding competition, but this laboratory was also included as a reference laboratory for a non-winning bidder?

Winning or non-winning status under the demonstration is not conferred on reference or subcontracting laboratories on an application. Winning or non-winning status is determined only for applicants. Therefore, if a laboratory organization that is a winner is named as a reference laboratory or subcontractor on a non-winning application, that laboratory will have winning status under the demonstration.

50. What happens when a bidder has passive laboratory status under the demonstration, but this laboratory was also included as a reference laboratory for a non-winning applicant?

A laboratory with passive laboratory status under the demonstration may participate as a reference laboratory on bid applications. The applicant is the entity that will be declared a winner or non-winner under the demonstration. Winning or non-winning status under the demonstration is not conferred on reference or subcontracting laboratories on an application. Winning or non-winning status is determined only for applicants. Therefore, if a laboratory organization that has passive laboratory status under the demonstration is named as a reference laboratory or subcontractor on a non-winning bid, that laboratory will have passive laboratory status under the demonstration.

51. What happens when a laboratory is declared a non-winner for its application and is included as a reference laboratory on another winning application?

A winning or passive laboratory can send out to or contract with any CLIA certified laboratory serving the CBA (including non-winning laboratories). A winning or passive laboratory may directly bill Medicare for demonstration test codes provided to beneficiaries enrolled in FFS and residing in the CBA, however

a non-winning laboratory may not directly bill Medicare for demonstration test codes provided to beneficiaries enrolled in FFS and residing in the CBA.

52. How will providers, physicians and beneficiaries know which laboratories are winning laboratories participating in the demonstration?

The CMS will provide a directory of participating laboratories that will be made available through mailings, websites, listservs, carriers and fiscal intermediaries. The directory will also provide contact information for assistance.

53. Is it permissible under the demonstration to refer specimens to any winning/passive laboratory? Does that include laboratories located inside or outside the CBA?

Yes. Multiple winning laboratories will be selected based on price and non-price criteria (such as quality, capacity, and geographic coverage). All winning laboratories will be CLIA certified and enrolled in Medicare. All laboratories will be paid the same price for each test code, however non-winning laboratories are not permitted to bill Medicare directly. Laboratories, physicians and beneficiaries will have the choice of selecting from any of the participating laboratories regardless of location.

Non-winning Laboratories

54. Can non-winning laboratories provide services to Medicare beneficiaries?

Under the demonstration, a laboratory must be either a winning laboratory or passive laboratory to bill Medicare directly for services to beneficiaries residing in the CBA. A non-winning laboratory cannot bill Medicare directly but can act as a subcontractor/reference laboratory to winning and passive laboratories under the demonstration. Non-winning laboratories can continue to receive payment directly from Medicare for testing provided to beneficiaries residing outside the CBA and who are therefore not subject to the demonstration.

55. Can laboratories bill patients for laboratory services?

Under Medicare, a laboratory may not bill a beneficiary for covered laboratory tests.

56. Can a laboratory refer tests for a beneficiary residing in the CBA to a non-winning laboratory?

Yes. A non-winning laboratory can act as a subcontractor/reference laboratory for winning and passive laboratories. However, the non-winning laboratory cannot bill Medicare directly for services to a beneficiary residing in the CBA.

Passive Laboratories

57. What is a "passive" laboratory?

A passive laboratory is a laboratory that is not required to bid in order to participate in the demonstration. Small business laboratories, laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD), and laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services are exempt from being required bidders.

Under the demonstration, a small business laboratory is defined as one that bills for less than or equal to $100,000 in annual Medicare payment for beneficiaries residing in the CBA. Under the demonstration, laboratories meeting that definition have the option of not bidding and participating in the demonstration but being held to an annual limit or cap of $100,000 in annual Medicare payment for beneficiaries residing in the CBA.

Under the demonstration, an ESRD laboratory is defined as one that provides services exclusively to beneficiaries receiving Medicare benefits based on their diagnosis of ESRD who reside in the CBA. Under the demonstration, laboratories meeting this definition have the option of not bidding and participating in the demonstration but being limited to providing services to only ESRD beneficiaries.

Under the demonstration, laboratories providing services exclusively to nursing facilities are exempt from being required bidders, thereby making it easier for nursing facilities to continue to provide continuity of care. In addition, laboratories providing both Medicare Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships. Laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration and would be paid at the competitively set rate for demonstration test codes otherwise paid under the Medicare Part B CLFS. Laboratories will also continue to receive payment for mileage, phlebotomy, and the existing payment under any schedule other than the Medicare Part B CLFS for those tests included in the demonstration.

58. What are the other options for laboratories that meet the definition for "passive?"

A laboratory that is not required to bid under the demonstration rules has the option to participate in the bidding process. However, all bidding rules would apply. Any laboratory that bids and does not win in the bidding competition is classified as a non-winner under the demonstration.

59. What happens if a passive laboratory exceeds its limitation?

The CMS will monitor passive laboratories to ensure caps or limits are not exceeded. Any passive laboratory exceeding the revenue or population restriction will not be allowed to continue participation in the demonstration for the remainder of the demonstration period.

60. Does a laboratory that provides services to a skilled nursing home (SNF) qualify as an exempt or passive laboratory?

Laboratories providing services exclusively to nursing facilities are exempt from being required bidders. In addition, laboratories providing both Medicare Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships. Laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration and would be paid at the competitively set rate for demonstration test codes otherwise paid under the Medicare Part B CLFS. Laboratories will also continue to receive payment for mileage and phlebotomy services.

The demonstration covers clinical laboratory services paid under Medicare Part B Clinical Laboratory Fee Schedule (CLFS). Laboratory services provided to beneficiaries that do not reside in the SNF and paid under Medicare Part A are exempt from the demonstration. Laboratory services provided to beneficiaries that reside in a SNF are covered by Medicare Part B and therefore included in the demonstration project. A laboratory that provides Medicare Part B laboratory services to SNF residents may qualify as a passive laboratory if it meets the requirements identified in question 57.

Beneficiary Outreach and Provider Education

61. How will beneficiaries know which laboratory or specimen collection station to go to? How will physicians and referring laboratories know which laboratory to send specimens/patients to?

A directory of participating laboratories will be distributed both in hard copy (within the CBA) and electronically. The demonstration project hotline will also have that information available.

62. Where can beneficiaries, physicians, or laboratories call to get information about the demonstration?

There is a toll free help line established 1-866-613-9348 and a project website at Information about the Medicare Clinical Laboratory Services Competitive Bidding Demonstration project can be found at:

http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage

63. Where can beneficiaries, physicians, or laboratories call if there is a concern about the quality a laboratory?

Complaints about a participating laboratory can be directed to the project hotline **1-866-613-9348** the CMS Regional Office or State agency, or the project e-mail box.

- http://www.cms.hhs.gov/RegionalOffices/
- http://www.cms.hhs.gov/ContactCMS/
- Lab_Bid_Demo@cms.hhs.gov

Any additional questions from laboratories regarding the demonstration project may be addressed to: **lab-demo@rti.org.**