Follow-up from Bidder's Conference

Question 1: Will the Centers for Medicare & Medicaid Services (CMS) establish an anti-mark-up rule between laboratories under the terms and conditions of the demonstration?

Answer 1: Mark-up between laboratories may continue under the demonstration.

Question 2: Can referring and reference laboratories share bid prices with each other if the referring and reference laboratories both are submitting bids? Do both referring and reference laboratories have to submit bids individually to be declared winning laboratories under the demonstration?

Answer 2: Each bidding laboratory must provide bid prices for all 303 demonstration test codes. A referring laboratory may request a price list from a laboratory providing its reference testing. Referral and reference laboratory relationships should be identified in Sections C (questions 4 and 5) of the application.

A laboratory firm expecting to receive annual payment less than $100,000 for demonstration tests provided to beneficiaries enrolled in Medicare fee-for-service (FFS) and residing in the competitive bidding area (CBA) is not required to submit a bid, but would be paid under the competitively set fee schedule. Laboratories required to bid that choose not to submit a bid will be considered non-winning laboratories and will not be able to bill Medicare directly for demonstration tests provided to beneficiaries enrolled in Medicare FFS residing in the CBA.

Question 3: Under the demonstration, CMS will exempt laboratories providing services exclusively to beneficiaries in nursing facilities or receiving home health services from being required bidders. Does that exemption from bidding extend to other units associated with a nursing facility such as assisted living and independent living, for example?

Answer 3: 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 competitively set demonstration fee schedule for demonstration tests otherwise paid under the Part B Clinical Laboratory Fee Schedule (CLFS). Laboratories that wish to provide services beyond beneficiaries residing in nursing homes or receiving home health service (such as for assisted living or independent care) in the CBA will be required to bid and win under the demonstration.

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 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 Part B CLFS. Laboratories 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.

Question 4: Are hospital laboratories required to bid under the demonstration if the hospital is a foundation where the parent organization provides the facilities and staff for the clinics (including laboratory services)? What if the laboratory is licensed as an independent laboratory but the medical director(s) of the laboratories are part of a medical group?

Answer 4: Laboratories that are enrolled with a Medicare carrier, intermediary, or A/B MAC and perform Part B clinical laboratory services as an independent laboratory or a hospital laboratory performing "nonpatient" services are subject to the demonstration regardless of their affiliation with other entities. Under the demonstration, a hospital laboratory would continue to submit a "nonpatient" Part B claims either to its fiscal intermediary (using a 14X Type of Bill) or an A/B MAC. An individual who is seen by hospital personnel on a day only for the sole purpose of specimen collection for clinical laboratory testing (whether on hospital premises or off-site) is considered a "nonpatient."

Question 5: Will CMS make information on the number of beneficiaries in the CBA available? What about utilization information?

Answer 5: Various Medicare enrollment tables such as national and state enrollment trends, state enrollment by aged, disabled and all, as well as county level enrollment are available at: http://www.cms.hhs.gov/MedicareEnrpts

Question 6: Will CMS provide total volume per test code for individual laboratories? Will CMS provide information on denied claims?

Answer 6: No. CMS provided the total Medicare payment for demonstration tests provided to beneficiaries enrolled in FFS residing in the CBA to individual laboratories. A letter was sent to individual laboratories either located in the CBA and/or paid more than $25,000 annually for demonstration tests provided to beneficiaries enrolled in FFS residing in the CBA. Market test code volumes and weights for the entire CBA are provided on page 19 of the Bidder's Conference materials.

Question 7: Can a laboratory participate in the demonstration if it enters the CBA market after the demonstration has started without having participated in the bidding process?

Answer 7: A laboratory firm entering the CBA market and expecting to receive annual payment under the demonstration to exceed $100,000 is required to submit a bid during the bidding process as described in the Federal Register Notice (CMS 5045N) published on October 17, 2007. In this example, the laboratory would be considered a non-winning laboratory for the duration of the demonstration.

A laboratory firm entering the CBA market expecting to receive annual payment for demonstration tests that is less than $100,000 is not required to submit a bid, and would be paid under the competitively set fee schedule. In this example, a laboratory would be considered a passive laboratory under the demonstration.

Question 8: What happens if a laboratory acquires another laboratory that is a winning laboratory under the demonstration? What happens if a laboratory acquires another laboratory that is a non-winning laboratory under the demonstration?

Answer 8: The status of the laboratory under the demonstration will be defined by the laboratory firm ownership. In other words, a laboratory firm that is a winner under the demonstration and its acquired laboratory will remain a winning laboratory. A laboratory firm that is declared a non-winning laboratory because it failed to bid or submit a winning bid will remain a non-winning laboratory (including its acquired laboratory) under the demonstration. Should a laboratory firm that chose to be exempt from bidding as a small business acquire a laboratory during the demonstration period, the $100,000 annual payment threshold for demonstration tests provided under the demonstration will apply to the laboratory annual payment combined.

CMS will validate the ownership of a laboratory firm based on the Medicare enrollment information provided on the CMS-855b form.

Question 9: Can a non-winning laboratory draw blood and bill Medicare directly?

Answer 9: If a laboratory is enrolled in Medicare as an independent laboratory and is declared a non-winning laboratory under the demonstration, then the laboratory may not bill Medicare directly for test codes that are paid under the Part B CLFS, including for phlebotomy. Phlebotomy services that are provided by entities other than independent laboratories and paid under fee schedules other than the Part B CLFS are not included in the demonstration.

Question 10: Can a laboratory refuse to provide a laboratory test for a Medicare beneficiary residing in the CBA?

Answer 10: A laboratory that is enrolled as a Medicare supplier cannot legally refuse to provide services to a beneficiary based on payment. (see question & answer 15 for further clarification)

Question 11: What is the proposed timeline?

Answer 11: The Bidder's Conference was held in San Diego on December 5, 2007. Bids are due by February 15, 2008. Winners selected on April 11, 2008. Payments made under the demonstration by July 1, 2008. (Question #28 in Appendix A of the Bidder's Package)

Question 12: How will capacity be determined under the demonstration – and specifically during the bid evaluation process?

Answer 12: Capacity is evaluated to guarantee that the projected demand for demonstration test codes will be met under the demonstration. The projected demand for demonstration test codes will be determined from historical baseline utilization data for demonstration test codes trended forward by a factor reflecting the anticipated increase in utilization of demonstration test codes during the demonstration period. Both baseline utilization and the trend factor will be estimated from historical Medicare claims and enrollment data for the San Diego MSA.

Capacity will be determined using information provided by applicants, along with Medicare administrative claims data. Each applicant is required to report current annual test volume and maximum annual test capacity, which will be used to help determine each applicant's capacity.

In addition to the information that applicants provide, CMS will use Medicare paid claims to examine the historical volumes actually supplied to the San Diego MSA Medicare fee-for-service market by applicants. Historical volumes supplied to the National Medicare fee-for-service population will also be used. The Medicare claims data and the CLIA database will serve as additional sources of information, and as a validation of the capacities reported by applicants.

The multi-dimensional selection process is based on the competitive prices submitted and quality of care and access to care. There are several dimensions to access to care, including capacity, geographic coverage, financial strength and stability, subcontracting and referral relationships, special populations and providers, expansion plans, and multiple winners. The process allows for capacity to be greater than the projected demand so, should a laboratory discontinue participation in the demonstration, beneficiary access to quality laboratory services would not be impacted. In addition, the application allows a laboratory to indicate whether or not there is interest in or capacity to expand service to additional geographic areas under the demonstration.

(Note: Laboratories participating in the demonstration must be a Medicare enrolled supplier.)

Question 13: Are all the carriers and fiscal intermediaries (FIs) involved in the project? Or will laboratories participating in the demonstration submit claims through only a carrier or FI in South California?

Answer 13: Under the demonstration, laboratories (other than non-winning laboratories) should continue to submit claims as usual to the Medicare carrier, fiscal intermediary (FI), or Part A/B Medicare Administrative Contractor (MAC) routinely used.

Medicare will pay one single competitively-set price for each test code included in the demonstration and otherwise paid under the Part B Clinical Laboratory Fee Schedule for services provided to FFS beneficiaries residing in the San Diego-Carlsbad-San Marcos demonstration area (regardless of where the laboratory firm is located). The residence of beneficiaries and the status of the laboratory under the demonstration (e.g., winning, non-winning) will be determined by information in the Medicare system. Non-winning laboratories will not be able to bill Medicare directly. A laboratory may not bill a Medicare beneficiary for any medically necessary covered laboratory test.

Question 14: Will CMS post the questions submitted to the public mailbox and project telephone line?

Answer 14: We have been using the project listserv to share questions and answers. We then compile those questions and answers, and update the document on the project webpage.

Question 15: Can a laboratory refuse to provide a laboratory test for a Medicare beneficiary residing in the demonstration area? What if a beneficiary goes to a laboratory that is a non-winning laboratory under the demonstration?

Answer 15: There are mechanisms under the demonstration for a non-winning laboratory to receive payment for services included in the demonstration that are provided to Medicare FFS beneficiaries residing in the demonstration area. A non-winning laboratory can continue to collect or receive specimens serving as a reference laboratory under the demonstration, and bill Medicare through a referring laboratory for services it provides in the demonstration area.

A laboratory that is enrolled as a Medicare supplier cannot legally refuse to provide services to a beneficiary based on payment. In other words, a participating Medicare supplier (also known as a supplier who accepts assignment) has agreed that it will accept Medicare payment as payment in full. (See Medicare Claims Processing Manual, 30.3.3.) Since assignment is mandatory for clinical laboratories, these laboratories could not refuse – as a general matter – to treat all Medicare beneficiaries in a service area because the laboratory fee schedule in that area (whether competitively set or not) does not provide high enough payment. (see question & answer 10).

Thus, for example, a laboratory acting as a passive laboratory could not refuse to treat all FFS beneficiaries in the demonstration area due to an unwillingness to accept the competitively set fee schedule. That said, this would not prohibit a non-winning laboratory from failing to provide services to the beneficiary or sending their specimen elsewhere, if a physician inadvertently refers a beneficiary to a non-winning laboratory and there is no agreement between the non-winning laboratory and a winning or passive laboratory to bill Medicare directly.

A directory of laboratories that Medicare FFS beneficiaries (or their specimens) can be sent to under demonstration will be shared with persons authorized to order clinical

laboratory tests and to beneficiaries themselves. CMS and our contractors will provide educational materials and reach out to health care providers, so that the likelihood of a beneficiary or their specimen going to a non-winning laboratory will be minimal. In addition, there is a toll-free help line (1-866-613-3948) established for beneficiaries, physicians, or laboratories to call for information about the demonstration. CMS will also post the directory on the demonstration website, and provide demonstration fact sheets for beneficiaries, beneficiary advocate groups, physicians, and laboratories.

If, for some reason, the person ordering the laboratory test(s) refers the beneficiary to a non-winning laboratory, and the non-winning laboratory direct-bills the Medicare program, the fiscal intermediary or carrier will send a notice to both the physician and the laboratory advising them that the laboratory in question is a non-winning laboratory and providing the physician with a list of laboratories participating in the demonstration. Since a laboratory test cannot be performed without an order from an authorized person, this education of health care providers will prove vital in ensuring that beneficiaries are not misdirected to non-winning laboratories.

Last updated March 7, 2008