

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

**Answer:** 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.)