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Medicare Demo Threatens Care

Repeal of Competitive Bidding Demonstration Essential

Requested Congressional Action

- Repeal the clinical laboratory competitive bidding demonstration project.
- Cosponsor S. 2099 (the Preserving Access to Laboratory Services Act of 2007) or HR 3453 (the Community Clinical Laboratory Fairness in Competition Act of 2007).

ASCP's Concern

The American Society for Clinical Pathology (ASCP) is concerned that competitive bidding laboratory services will negatively affect patient care and have long-term negative impacts on laboratory services and access to care. Laboratory services account for less than two percent of overall Medicare spending, but affect an estimated 60 to 70 percent of medical decisions. Further constraints on these high-value medical services may adversely affect the Medicare program and its beneficiaries.

Background

Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the CMS to conduct a demonstration project on the use of competitive acquisition for payment of clinical laboratory services that would otherwise be payable under the Medicare Part B clinical laboratory fee schedule. The purpose of the demonstration is to determine whether competitive bidding can be used to provide quality Part B clinical laboratory services at a price below current Medicare reimbursement rates.

Structure and Timing: Two demonstration sites – referred to as “competitive bidding areas” (CBAs) – are to be selected. The first demonstration site, in San Diego, CA, was announced in late 2007. The second site may be announced sometime later this year. At each site, the demonstration will run for 3 years, with the second demonstration site beginning operations one year after the first site. In each CBA, payment rates for laboratory services determined through the competitive bidding process will be substituted for payment rates under the existing clinical laboratory fee schedule.

Participating Laboratories: Laboratories with \$100,000 or more in annual Medicare Part B (fee-for-service) payments in 2005 for clinical laboratory tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory is located) are required to bid in the demonstration. Laboratories that fall under the \$100,000 threshold will not be required to bid.

Hospital inpatient testing is exempt from the demonstration because it is covered under Medicare Part A. Hospital outpatient department (OPD) testing and physician office laboratory testing may be included in the demonstration.

ASCP's Concerns with Competitive Bidding

ASCP is concerned about this demonstration project for many reasons:

- **Laboratory services are not a commodity:** Clinical laboratories provide highly complex medical services to Medicare beneficiaries. Laboratory testing involves collecting specimens from patients, transporting specimens within hours to the laboratory, using highly trained personnel to perform tests, and reporting most results the next day to physicians. All these features would be put at risk with competitive bidding.
- **Competitive bidding will reduce the number of labs serving the community:** Losing bidders will no longer be able to provide laboratory services to Medicare beneficiaries and may be forced to close their doors altogether. Reducing laboratory capacity will also reduce the availability of and access to services for all residents of the community. This will negatively impact the continuity of patient care and result in a reduction in widespread and ready access to laboratory services that Medicare beneficiaries currently enjoy.
- **No room for further reduction:** The payment rates derived from this demonstration project could eventually be used to replace the existing clinical laboratory fee schedule. Hospitals are already being underpaid for laboratory services under the current payment system. Laboratory payments have decreased by about 50 percent in real, inflation-adjusted terms between 1984 and 2006. The reduction in real terms will continue to accumulate through 2008 under current law. Further cuts could dramatically affect access to laboratory services in the nation.
- **Questionable goal:** Competitive bidding, by its very nature, places emphasis on obtaining the best price. Given that laboratory services account for only 1.6% of Medicare spending, but guide an estimated 60 to 70 percent of medical decisions, excessive constraints on such high value medical services may adversely affect the Medicare program and its beneficiaries.

Status of the Demonstration

In late January 2008, a lawsuit was brought by a group of clinical laboratories serving patients in the San Diego area. On April 8, 2008, Judge Thomas Whelan of the U.S. District Court of Southern California issued a preliminary injunction, ordering CMS to suspend its implementation of the clinical laboratory competitive bidding demonstration project.

In reaching its decision, the court found that the demonstration project would cause “irreparable injury” to patients and laboratories in the San Diego area. Though the judge indicated the plaintiffs had shown a likelihood of success on a number of the arguments raised in the case, it is unclear whether plaintiffs will ultimately succeed. Consequently, ASCP continues to urge Congress to protect Medicare beneficiary access to quality care by repealing the demonstration.