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Medicare Demo Threatens Care

Repeal of Competitive Bidding Demonstration Essential

In 2003, Congress directed the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration project on the competitive acquisition of laboratory services reimbursable under the Medicare Part B clinical laboratory fee schedule. 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 Medicare spending, but affect an estimated 60 to 70 percent of medical decisions.

Requested Congressional Action

ASCP urges Congress to repeal the clinical laboratory competitive bidding demonstration project.

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) – will be selected. CMS will use Metropolitan Statistical Areas (MSAs) to define these demonstration sites. 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. Multiple winners are expected in each CBA. The project will cover clinical laboratory tests for all Medicare Part B beneficiaries who live in the demonstration sites, as determined by the zip code of the beneficiary’s residence. A list of potential demonstration sites is provided below.

Last November, CMS announced that the implementation of the demonstration in the first CBA would begin in early 2007. As of May 31, 2007, no date has been announced as to when implementation of the demonstration will begin. The second MSA is scheduled to begin in 2008.

Rules of the Demonstration: 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) will be required to bid in the demonstration. These laboratories will be referred to as “required bidders.” Laboratories that fall under the \$100,000 threshold will not be required to bid. These laboratories are considered “passive” laboratories.

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 are also generally not included in the demonstration. One important exception to this exemption is where the hospital or physician office functions as an independent laboratory performing testing for beneficiaries who are not patients of the hospital OPD or the physician.

Under the demonstration (see table below), *laboratories that bid and are selected* (“win”), including both laboratories that are required to bid and those that are not, will be reimbursed at the laboratory competitive bidding demonstration fee schedule rate for the tests provided to beneficiaries residing in the CBAs. Those *laboratories that bid and are not selected* (“do not win”), including both required and non-required bidders, will not be paid anything by Medicare – neither under the Part B clinical laboratory fee schedule nor under the competitively bid price—for tests provided to beneficiaries residing in the CBA for the duration of the demonstration. Similarly, laboratories that are required to bid but do not will not be reimbursed by Medicare for tests provided to CBA beneficiaries.

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. We are concerned that this demonstration will sacrifice patient quality and access to care in its attempt to reduce Medicare program expenditures. We are also concerned that the President’s fiscal year 2008 budget recommends expanding this program nationwide before the demonstration has even begun.
- **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. 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. As an example, beneficiaries may be forced to travel to a new unfamiliar location to have blood drawn and nursing home beneficiaries could lose ready access to services. Reducing laboratory capacity will also reduce the availability of and access to services for all residents of the community.

- **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 impact an estimated 60 to 70 percent of medical decisions, such an outcome is penny wise and pound foolish.
- **CMS does not clearly define “non-patient” services:** It is unclear whether CMS would include patients who come to the hospital OPD only for the purpose of having laboratory tests performed. Sometimes these patients are registered as outpatients and sometimes they are not. It is also not clear whether patient samples from skilled nursing facilities (SNF) that are collected by hospital staff at the SNF and brought to the hospital for testing would be considered “patient” or “non-patient” services. These kinds of questions are critical to determining whether the hospital meets the \$100,000 threshold. Misunderstanding these important questions could lead to hospitals not submitting a bid when in fact they would be required to do so. This could cause them to lose their ability to be paid by Medicare for these laboratory services through the duration of the demonstration period.

Given the significant impact laboratory testing has on patient diagnosis and therapeutic treatment and its minimal impact on Medicare spending, Congress should proceed carefully to ensure competitively bidding clinical laboratory services does not sacrifice quality or access to care.

Potential Competitive Bidding Demonstration Sites

- Austin-Round Rock, TX
- Birmingham-Hoover, AL
- Buffalo-Niagara Falls, NY
- Cleveland-Elyria-Mentor, OH
- Columbus, OH
- Denver-Aurora, CO
- Jacksonville, FL
- Las Vegas-Paradise, NV
- Milwaukee-Waukesha-West Allis, WI
- Nashville-Davidson--Murfreesboro, TN
- Oklahoma City, OK
- Orlando-Kissimmee, FL
- Phoenix-Mesa-Scottsdale, AZ
- Pittsburgh, PA
- Riverside-San Bernardino-Ontario, CA
- Rochester, NY
- Sacramento--Arden-Arcade--Roseville, CA
- San Antonio, TX
- San Diego-Carlsbad-San Marcos, CA
- San Jose-Sunnyvale-Santa Clara, CA
- Seattle-Tacoma-Bellevue, WA
- Tampa-St. Petersburg-Clearwater, FL