



Membership Matters

ASCLS Recruitment Series
Part IV: Legislative Update





Legislative Issues facing ASCLS and the Profession





Current Issues

- Competitive Bidding
- Laboratory Fee Schedule
- Workforce Shortage and the Allied Health Reinvestment Act
- State Licensure
- What Can You Do?





Competitive Bidding Defined

- A method for setting the price of health care services through a bidding process in order to establish payment rates based on the lowest price submitted by providers. Medicare would require that its beneficiaries' lab work be outsourced to the “winning bid” sites.





Competitive Bidding

Congress and the Centers for Medicare and Medicaid Services (CMS) have considered competitive bidding for procurement of Medicare laboratory testing services as one possible measure to reduce cuts to the Medicare program.





Competitive Bidding

- In 1985, the Secretary of Health and Human Services issued a request for proposals to establish demonstration projects for the provision of clinical laboratory services for Medicare beneficiaries on a competitive bidding basis.
- The Budget Reconciliation Act of 1985 prohibited any such projects.





Competitive Bidding

- The Balanced Budget Act of 1997 lifted the prohibition and permitted CMS/HCFA to develop demo projects on competitive bidding.
- Up to 5 demos were mandated, one being laboratory services for Medicare Part B.
- This marks the first time a lab demo made it into law.





Competitive Bidding

- October 2007--San Diego-Carlsbad-San Marcos MSA selected as first demo site
- February 2008--Bids were submitted
- April 11, 2008--Winning labs would be notified
- July 1, 2008--Demonstration would be initiated
- Fall 2008--Second demo site to be selected





Competitive Bidding

- FY 2009 budget calls for a competitive bidding PROGRAM prior to the completion of the demo, and a 5% decrease in reimbursement for these services.





Competitive Bidding

- Covers 330 most commonly ordered tests.
- All beneficiaries permanently living in designated ZIP code.
- Excludes ESRD bundled tests.
- Beneficiaries who travel outside the area will be able to obtain testing, but the lab will be reimbursed at the demonstration fee schedule rate.





Competitive Bidding

- Criteria for Demo sites
 - Single state with 1-4 million total population
 - Medicare population 100,000-400,000
 - Medicare managed care population 5-50%





Competitive Bidding

- Definition of non-patient varies depending on issue.
- Bid package says non-patient has specimen drawn by hospital personnel but not registered as an in- or outpatient.
- Medicare manuals have multiple definitions:
 - Patient whose specimen is drawn and sent to hospital for analysis
 - Patient who is neither in- or outpatient; has specimen submitted for analysis but is not present





Competitive Bidding

- Patient having blood drawn in hospital collection site is considered outpatient for Medicare Secondary Payer (MSP), but is considered non-patient for competitive bidding.





Competitive Bidding

- Participation determined by whether participants live in ZIP codes included in MSA.
- If a lab's volume increases, and the \$100,000 ceiling is exceeded by \$25,000 or more, that lab cannot continue to do testing covered in the demonstration.
- If subcontractor loses as a prime bidder, lab can provide testing as a subcontractor but cannot bill Medicare directly.





Competitive Bidding

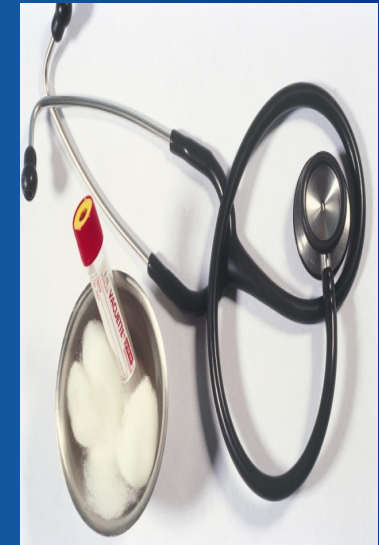
- Winning bidders must agree to demonstration terms and conditions
 - Includes a requirement to serve all beneficiaries in an included ZIP code.
 - Labs will not be able to pick only those patients they want to serve.
 - Significant for nursing homes in that large national labs characteristically do not serve nursing home patients; large labs will have to develop new relationships to serve nursing homes.





Competitive Bidding

- Will CMS terminate demonstration if patient care suffers?
- What provisions have been made for national disasters?
- Restrict Physician choice
 - No connection to electronic medical record
 - Physicians required to use even more laboratories for their patients





Lawsuit Against Demonstration

- 3 San Diego area laboratories, Sharp HealthCare; Scripps Health; and Internist Laboratory of Oceanside, filed suit against U.S. Department of Health and Human Services (HHS) on January 29, 2008.
- Plaintiffs assert:
 - HHS failed to follow required rulemaking process, adequate input not obtained from all stakeholders
 - Inadequate protection for small business
 - Demo will cause irreparable harm to Medicare beneficiaries and labs
 - Requested temporary injunction to stop project





Lawsuit Against Demonstration

- Court denied injunction February 14, 2008.
- Labs sought another injunction to block project and asked CMS to return bids submitted in February unopened.
- At hearing on April 8, 2008, the court granted a preliminary injunction (PI).





Lawsuit Against Demonstration

- According to PI, CMS was not to:
 - Proceed with implementation of the demonstration project in San Diego
 - Announce the winning bidders on April 11, 2008
 - Disclose information on any bids submitted
 - The injunction will stay in place until there is a full trial on the merits of the case.





Competitive Bidding Repeal ?

- Congressional Repeal
 - Attempted to add legislation to Medicare bill at end of 2007, but Congress extended provisions until their next session.
 - On June 24, 2008, the House passed the Medicare bill H.R. 6331 approving a repeal of the demonstration project.
 - On July 9, 2008, the Senate passed Medicare legislation by virtue of a cloture vote 69 to 30.
 - If this bill becomes law, it would repeal the demonstration project for clinical laboratory services.





Fee Schedule

- Fear is that bids submitted in the San Diego competitive bidding process could be used to reset the fee schedule.
- Currently using the same fee schedule established in 1984.
- Original agreement was that co-payment would be dropped if fee schedule was instituted.
- In 1984 the fee schedule was set at 115% of the median fee, now at 74%.





Fee Schedule

- Balanced Budget Act of 1997 eliminated the CPI increase for lab tests from 1998 through 2002.
- Subsequent freezes to the fee schedule have been applied since that date.
- The current freeze will expire December 31, 2008.
- Legislation is ready to be introduced in July proposing a restructuring of the fee schedule.





Workforce Shortage

- In the period from 2000-2010, a total of 120,000 positions in CLS will be needed.
- This includes 80,000 new jobs and filling 40,000 vacancies.
- Of the 12,000 openings per year, academic institutions are producing only 4,200 graduates per year.
- Much of the workforce is near retirement.





Allied Health Reinvestment Act

- Many schools are unable to reach capacity.
- Programs across the country are closing.
- Work schedules in health care are less attractive than in other fields.
- Job Stress!!!
- Increased demand for testing--aging population, new testing methods, bioterrorism threat.





State Licensure

- Currently 12 states and Puerto Rico require licensure to perform complex clinical laboratory testing.
- Another 8 states are currently or previously considering licensure of laboratory personnel.
- ASCLS supports individual state licensure efforts.





What Can You Do?

- Join ASCLS
 - Even if you can't be an "active" member, your dues money will help to fund legislative and other efforts on the national level.
 - You can request to be notified of legislative updates and often get the opportunity to participate in "grassroots" movements such as contacting your Senators and Representatives.

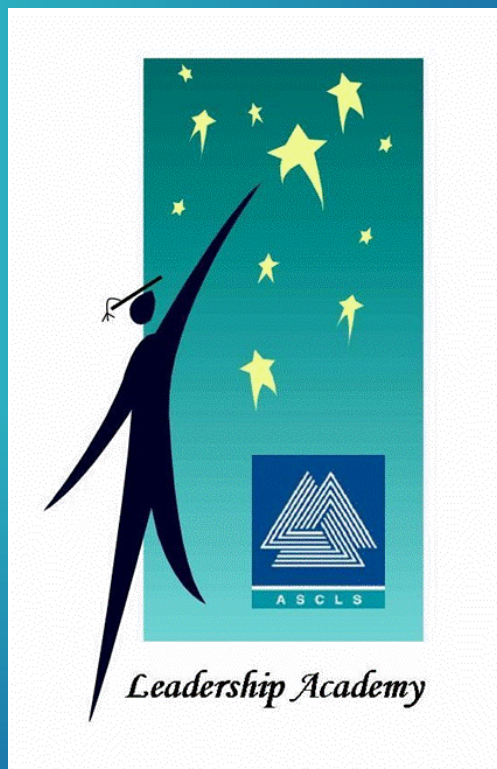




What Can You Do?

- Keep Informed
 - <http://www.ascls.org/currentevents/index.asp>
 - Read online articles and updates
- Contact your Senator's and Representatives:
 - House of Representatives:
http://www.house.gov/house/MemberWWW_by_State.shtml#ms
 - Senate:
http://www.senate.gov/general/contact_information/senators_cfm.cfm
- Educate fellow laboratorians -- Spread the word!





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