

The Protecting Access to Medicare Act Jeopardizes the Nation's Community and Regional Independent Clinical Laboratory Infrastructure

**Summary of Key Informant Interviews from Members of
the National Independent Laboratory Association**



906 Olive Street, Suite 1200, St. Louis, MO 63101-1448

Telephone: (314) 241-1445 • Fax: (314) 241-1449 • Email: aab@aab.org/nila@nila-usa.org • Website: www.aab.org/www.nila-usa.org

Press contact: Mark Birenbaum, NILA Administrator

Introduction

Protecting Access to Medicare Act

In April 2014, Congress enacted the Protecting Access to Medicare Act (PAMA) to overhaul the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) for the first time since it was established in 1984. The intent of PAMA was to tie Medicare reimbursement for clinical laboratory services closer to private market rates. Under PAMA, clinical laboratories were required to report private reimbursement and volume data to the Centers for Medicare & Medicaid Services (CMS), which then calculated the weighted median to establish a new reimbursement schedule.

While the intent of PAMA was to establish a market-based system, CMS used a strict definition of an “applicable laboratory,” which resulted in only 0.7% of the laboratory market paid under Medicare Part B represented in the data collection and analysis.¹ The final fee schedule released and implemented on January 1, 2018, did not represent a full market-based payment system for laboratory services as Congress intended in PAMA. The resulting broad and deep cuts to the CLFS impacted many basic laboratory screening tests that are high volume, low cost, and conducted routinely in community and regional independent clinical laboratories to monitor and diagnose common and often chronic health conditions.

Below (Table 1) is a set of common laboratory tests NILA members perform and the total percentage cut to each test under PAMA. The total amount of the cuts will be phased in over six years with 10 percent being cut in 2018. The reimbursement rate listed shows the final payment amount as calculated by CMS from private payor rates based on the data collected from 0.7% of the laboratory market paid under Medicare Part B.

¹ Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>

Table 1: Common laboratory tests conducted in high volume at community and regional independent clinical laboratories and the subsequent cut in reimbursement rates imposed by PAMA

Test Name	Description	Uses	% Cut	Reimbursement Post-PAMA
Complete blood count	Measures vital blood related biodata, including red and white blood cell counts	Critical for patients with leukemia, anemia, autoimmune disorders, cancer and conditions that require regular blood monitoring	35%	\$6.88
Prothrombin time	A blood test that measures how quickly a patient's blood clots	Checks for bleeding problems, monitors blood thinning medication and diagnoses disorders such as leukemia, liver problems and immune disorders	20%	\$4.29
Hemoglobin A1c	Blood tests that measure blood glucose levels	Used to manage and control diabetes	36%	\$8.50
Lipid panel	Blood tests that measure and detect abnormalities in cholesterol and triglyceride levels	Used in screening and treatment for high cholesterol, diabetes, heart disease, kidney disease and obesity	39%	\$11.23
Assay of ferritin	Blood tests used to determine the amount of iron stored in the body	Checks for iron storage disorders such as hemochromatosis, liver disease, rheumatoid arthritis, hyperthyroidism and some types of cancer	35%	\$12.13
Urine bacterial culture	A test used to identify bacteria in the urine that cause infection	Used to diagnose a urinary tract infection, which is a frequent infection in long-term care facilities	35%	\$7.19
Vitamin D	Blood test to determine vitamin D deficiencies	Used to monitor patients at increased risk of vitamin D deficiency, including obesity, osteoporosis, and calcium abnormalities	35%	\$26.37
Thyroid stimulating hormone	Blood test that helps diagnose thyroid disorders	Used to monitor treatment of hyperthyroidism or hypothyroidism	35%	\$14.87
Basic metabolic panel	Blood test that measures sugar level, electrolytes, fluid balance and kidney function	Used to monitor medications that affect kidneys or electrolytes such as high blood pressure medications	31%	\$8.06
Comprehensive metabolic panel	Blood tests that measure glucose levels, electrolyte and fluid balances	Examines liver and kidney function; can diagnose diabetes; monitors high blood pressure or effect of medications	37%	\$9.08

Key Informant Interviews

These significant decreases in reimbursement have extreme consequences for community and regional clinical laboratories, threatening their ability to provide services to Medicare and Medicaid beneficiaries, especially those in small and rural communities, and those who receive home health care or reside in assisted living or skilled nursing facilities (SNFs).

To learn more about the direct impact of the PAMA cuts on independent laboratories, the National Independent Laboratory Association (NILA) conducted eleven key informant interviews with self-selected representatives from community and regional independent clinical laboratories. Interviews were conducted during the first quarter of 2018 immediately after the new CLFS rates were implemented by CMS. Throughout this timeframe, laboratories experienced a minimum of one month of the initial 10 percent cut to the CLFS. Interviews were conducted over the telephone, and questions focused on the impact of PAMA on laboratory operations (Appendix A).

Data Summary

Key Informant Laboratory Demographics

NILA's members are community and regional independent laboratories that are responsible for examining human specimens to provide information for the diagnosis, prevention and treatment of diseases. Many serve specific populations, including inner cities and smaller, rural communities, and provide a unique set of services that are not often provided by large national laboratories. Together, community and regional laboratories create a critical infrastructure to the healthcare industry by providing flexible, fast, accurate laboratory services, especially in many geographic areas not served by the largest publicly traded laboratories.

For the purposes of this analysis, laboratories were categorized into the following groups by the type of laboratory service provided (Figure 1):

- Full service laboratories providing clinical biochemistry, microbiology and anatomical pathology
- Toxicology laboratories providing testing for drugs of abuse, pain management, employee programs and forensics
- Clinical biochemistry laboratories solely providing testing services for clinical biochemistry
- Full service + toxicology laboratories providing the testing menu of a full service laboratory in addition to toxicology laboratory services

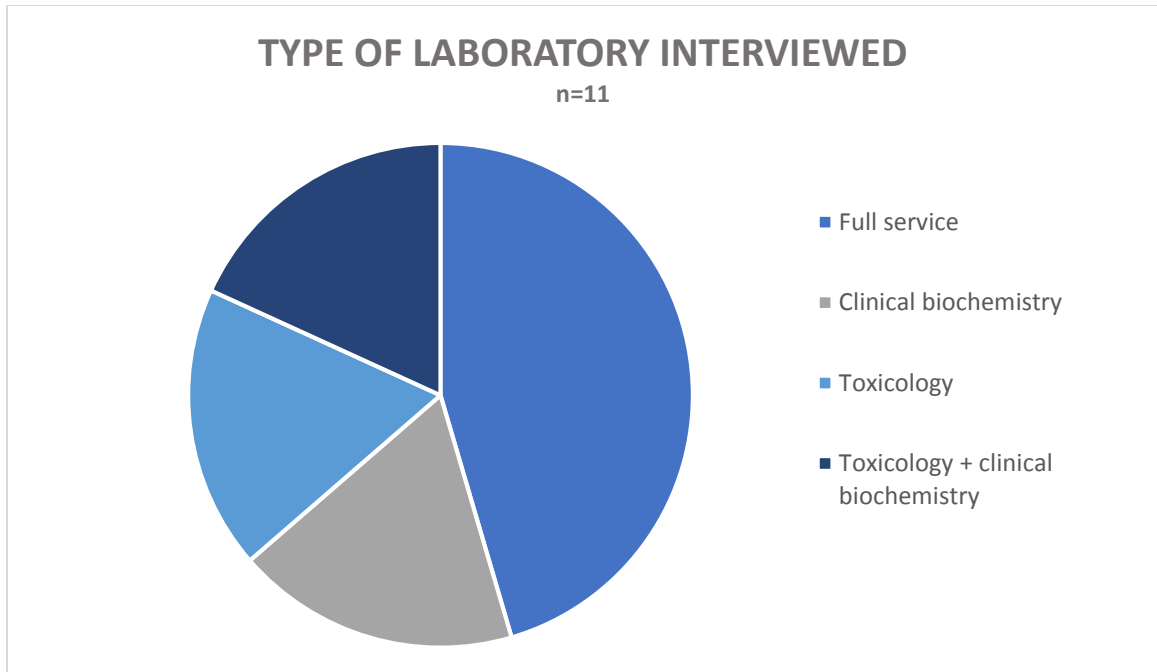


Figure 1: Types of laboratory participating in NILA’s key informant interviews

Four key informant laboratories range in size and serve communities no larger than one state, while seven laboratories provide regional testing services to between 12-25 states. Across all laboratories surveyed, the number of employees range from 32 to 1,000 full-time personnel.

Key informant laboratories were asked to provide a breakdown of their total reimbursement by the following categories (Figure 2):

- Medicare Part A (if applicable)
- Medicare Part B (not including Medicare Advantage Plans)
- Medicare Part C (Medicare Advantage), if applicable
- Medicaid (including Managed Care Plans)
- Private Payors
- Other (co-pays, direct patient billing, worker’s compensation)

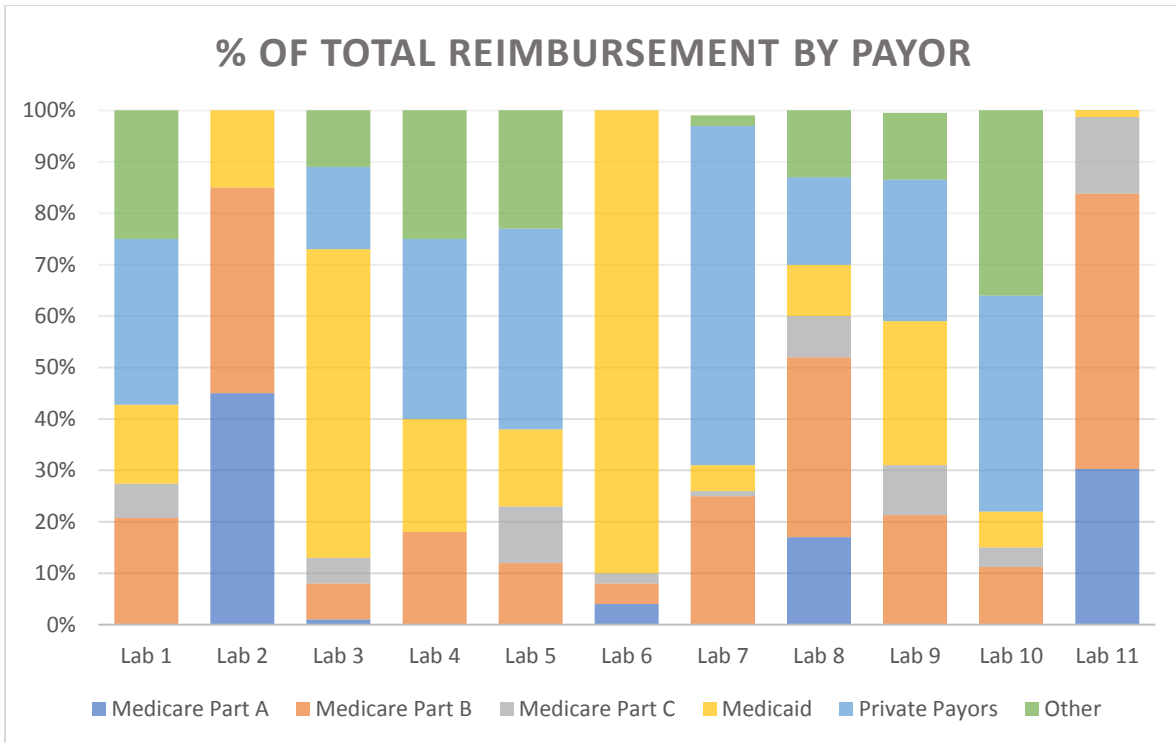


Figure 2: Breakdown of total reimbursement by payor across all key informants

All laboratories reported that, at a minimum, 60% of the laboratory’s business is associated with Medicare’s Part B CLFS (Figure 3), indicating PAMA has broader implications beyond Medicare, reaching into Medicaid and private payor contracts. Four laboratories reported that 100% of their business is impacted by the cuts imposed by PAMA.

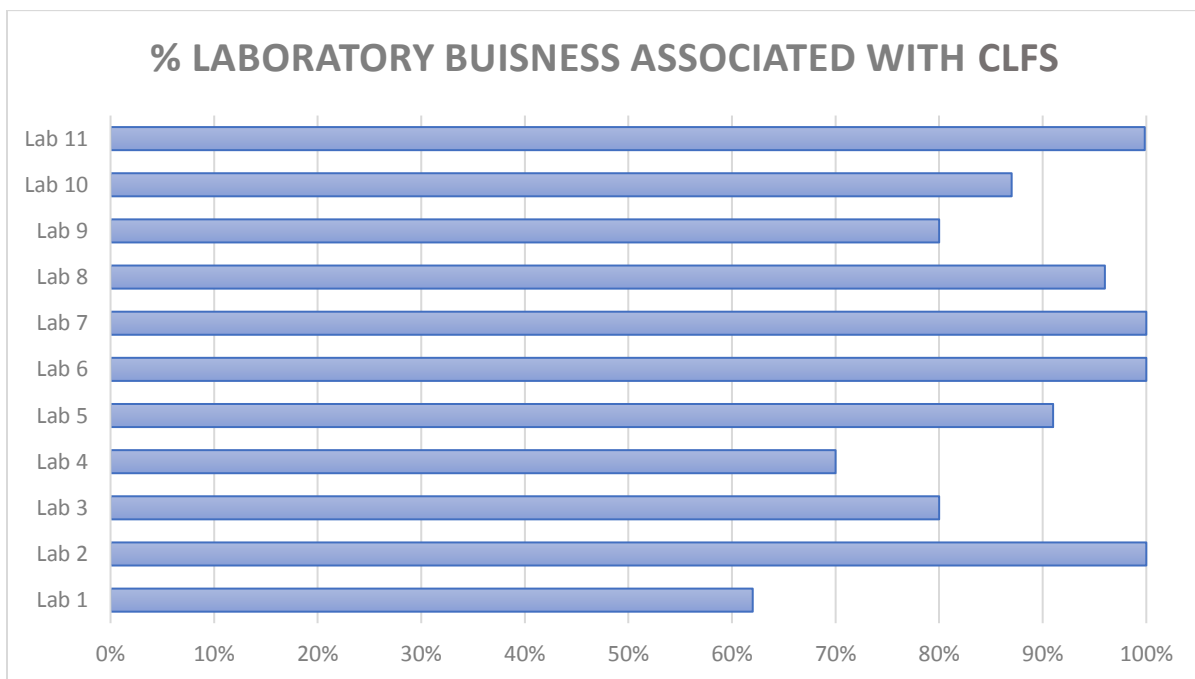


Figure 3: Percent of total laboratory business impacted by changes to the CLFS

Analysis

Adverse Impact of PAMA on Laboratory Operations

All key informants indicate a negative impact on their business and laboratory services as a result of PAMA, and most suggested these cuts were far worse than the steady stream of reductions to the CLFS that laboratories experienced over the past 30 years. The impact includes uncertainty of survival beyond 2018, reductions in workforce, inability to innovate and improve testing capabilities, and eliminating services to rural testing markets. Larger laboratories with diversified services are better poised to adapt to the first year of cuts to the CLFS. Laboratories that only provide clinical biochemistry to long-term care facilities are at risk of not surviving the first year of cuts imposed by PAMA. Only one laboratory expressed confidence in the ability to survive cuts to the CLFS throughout the next three years, but that laboratory indicated that its testing menus and customer service would suffer.

New CLFS Rates Force Changes to Business Practices and Laboratory Services

- ***Change in business models***

The cuts to the CLFS are pressuring laboratories to modify their business plans. Key informants indicate that PAMA has heightened the focus on profitability from current and future clients. With cuts impacting margins, some laboratories will take a closer look at their client lists and determine which physicians' offices or nursing homes might be costlier business partners due to patient population, distance from the laboratory, or other factors. Conducting business with offices that have a majority of Medicare or Medicaid patients, for example, would not be a strategic and sustainable business plan as cuts continue over the next several years. This strategy has already been embodied by one laboratory that has stopped taking on new SNF clients because they know that reimbursement will suffer in the long run.

Laboratories are also diversifying services outside of Medicare in order to mitigate the impact of cuts to the CLFS, such as bringing on toxicology testing. Other laboratories are exploring expanding direct billing to patients.

- ***Limiting services***

The majority of laboratories surveyed have already reduced laboratory testing services in some manner. Unlike large commercial laboratories that primarily serve ambulatory patients that can visit a centralized service center, NILA members, who are community and regional laboratories, are uniquely positioned to provide flexible, personalized services, such as house calls to non-ambulatory patients, expanded hours, and emergency STAT testing. In an effort to adapt to the 2018 PAMA cuts, laboratories have reduced or eliminated house calls to homebound patients, discontinued 24-hour emergency STAT testing, restricted phlebotomy services to SNFs and postponed or stopped research and development efforts to improve testing practices.

- ***Reductions in workforce***

Four laboratories indicate that they have already reduced their workforce in an effort to adapt to PAMA's cuts. One of these laboratories had to terminate 45 full-time employees, which marked the first time in the laboratory's decades long history that its workforce was reduced. Other laboratories have decreased courier and phlebotomy positions as house calls and 24-hour services have been reduced.

Burdens to Laboratory Innovation

PAMA is stifling laboratory innovation and hindering the ability of toxicology laboratories to respond to the opioid epidemic. Toxicology laboratories have long played an integral role in the healthcare continuum by supplying data to healthcare providers to monitor effective pain management and evaluate patients struggling with drug abuse. With the nation amidst an opioid crisis, the toxicology laboratories' role in both detecting opioid misuse and monitoring and evaluating patients being treated with opioids has become more critical than ever. Key informants state that laboratories have been using profit margins to reinvest into faster, more accurate technologies to improve opioid testing practices. With toxicology laboratories feeling pressure from PAMA, and margins becoming increasingly smaller, innovation to address emerging issues, such as the opioid epidemic, will become non-existent, and the laboratory community will fall behind.

Longevity Under Current CLFS Rates is Limited

All laboratories interviewed report some degree of impact from PAMA on their operations. One key informant points out that if any other industry faced a 30% cut, it would be impossible for that industry to survive. Only one laboratory indicated confidence in the ability to survive the initial three years of cuts to the CLFS, but that laboratory noted that reductions in workforce, services and quality of customer service would be negatively impacted. While none of the laboratories are making immediate plans to close operations, one indicated needing to reevaluate after the third quarter of 2018, while other laboratories specified that it would not make sense to stay in business past the second year (2019).

Laboratory Services to Long-term Care Facilities in Critical Jeopardy

Of the eleven laboratories interviewed, nine provide laboratory services to SNFs. Many of the top volume tests that are provided to SNFs have large cuts in reimbursement levels. For example, for comprehensive metabolic panels and lipid panels, which are cut by 37% and 39% respectively. Many key informants state that if PAMA cuts continue beyond 2018, services to SNFs will be dropped in an effort to prevent revenue losses. Of the two laboratories that exclusively provide service to long-term care facilities, one expressed concern about surviving the remainder of 2018, and the other stated that by 2019 the laboratory would close.

Implications

Based on the information gathered from these key informant interviews, PAMA is already negatively impacting the continuity and quality of laboratory services provided by community and regional clinical laboratories and threatens their survival and patient access to laboratory testing throughout the US within the first two years of implementation.

Another consequence not considered by Congress and CMS is the broader implications to laboratory reimbursement beyond payments directly under the Medicare Part B CLFS. The composition of reimbursement for laboratory services is a mix of Medicare, Medicaid, private payors, and direct-to-patient billing. Many state Medicaid agencies base reimbursement for laboratory services on the Medicare CLFS, resulting in direct reductions in reimbursement rates for laboratory services provided under Medicaid. Additionally, key informants indicate that many of their private payor contracts are directly linked to a specific year of the clinical laboratory fee schedule, resulting in reductions in reimbursement from private insurers. This nexus of reimbursement reductions creates devastating consequences to the laboratory industry and underscores PAMA's wide-reaching impact across the network of reimbursement that community and regional clinical laboratories rely on to sustain their operations.

As community and regional clinical laboratories are forced to adapt to a flawed CLFS, the immediate impact of PAMA has necessitated laboratories to reduce their overall flexibility when serving their communities. Reducing and eliminating house calls for non-ambulatory patients has broader implications for the larger health care system because these patients will now have to go to the hospital to have their laboratory tests done. Long-term care facilities will also send more patients to the hospital because community and regional clinical laboratories are no longer providing on call services or 24-hour STAT emergency services.

As PAMA cuts continue past 2018, more community laboratories will go out of business. The implications of NILA members cutting services to the communities they serve as a strategy to survive PAMA are broad and alarming. Most concerning is the void in services to vulnerable populations in rural and underserved communities that will be created as community and regional laboratories go out of business. Community and regional laboratories are uniquely poised to serve the specific needs and provide special attention to these patient populations because of their ability to deliver quick turnaround times on results and provide flexible, on call services. For example, long-term care facilities in rural areas are uniquely served by community and regional independent laboratories who cater to the needs of this vulnerable, non-ambulatory population by providing house calls, emergency STAT testing, and test results within hours. Large national laboratories do not provide coverage in many of these geographic areas and are not poised to do so, since their laboratory facilities are centrally located in populous areas and serve ambulatory patient populations.

PAMA is also broadly restricting access to healthcare to Medicare and Medicaid beneficiaries as a whole. As mentioned in this analysis, laboratories are shifting their business practices to scrutinize the patient

population of potential clients. Some laboratories are choosing to decline or discontinue business with clients that have a large patient population on Medicare or Medicaid because they are not able to sustain their services given the PAMA cuts. Some interviewees also cite broader consolidation in the health care market as an overall concern for their business model. As more independent physician practices are absorbed by larger hospitals and health systems, independent laboratory contracts are often terminated—often resulting in slower turnaround times and less tailored service delivery.

Conclusion

The information gathered from the key informant interviews emphasizes the detrimental and wide-reaching impact PAMA has caused on the services of community and regional independent laboratories. The majority of laboratories interviewed are actively changing business models, dropping testing services, leaving unsustainable healthcare testing markets and preparing to, or already have, reduced their laboratory workforce in order to adapt to the cuts imposed by PAMA. Access to continuous and high-quality laboratory services in rural and underserved communities that have no other option for laboratory services are being compromised. As PAMA cuts continue beyond 2018, the landscape of community and regional clinical laboratories will be diminished, weakened, and potentially become nonexistent for some Medicare and Medicaid populations.

In the long run, if PAMA is not reconsidered, there will be an increased cost to the Medicare program because beneficiaries will either utilize higher cost services (e.g., ambulance transportation to hospitals from SNFs) or will forgo essential clinical laboratory testing that will result in medical complications from lack of detection or monitoring of serious diseases or medical conditions.

The implementation of PAMA did not establish a market-based system, capturing only 0.7% of the total laboratory market paid under Medicare Part B while excluding hospital outreach laboratories that makeup a large segment of the private payor market. This imbalance will result in fewer services, slower turn-around times, less access for Medicare beneficiaries and eventually higher, not lower, costs for the Medicare program.

PAMA's skewed system must be revised to reflect true market rates and must be reconfigured to preserve the nation's vital clinical laboratory infrastructure.

Appendix A: Key Informant Interviews: Impact of PAMA on Independent Laboratories

Purpose: To collect information on the impact of the Protecting Access to Medicare Act (PAMA) cuts to the clinical laboratory fee schedule on independent laboratories. The information gathered from these interviews will be used to describe the impact of PAMA to policy makers on Capitol Hill and staff at the Centers for Medicare and Medicaid Services (CMS) in order to encourage changes to the PAMA statute.

Confidentiality: All information gathered will be anonymized and will not have any identifiers in subsequent reports or public discussion. Interview notes will only be accessible to NILA's Washington, DC representatives, CRD Associates, and Mark Birenbaum, Administrator of NILA.

Format: 60-minute telephone interview at your convenience with Celia Hagan and/or Erin Morton at CRD Associates. Questions will be provided in advance, and it will be helpful to gather the requested information before the scheduled interview to have responses at hand. Interviews will follow the structure of the provided questions, but one of the benefits of conducting a key informant interview is the conversation and dialogue. You may be asked follow up questions to the answers you provide.

Questions:

1. What is your role at the laboratory and how long have you been at your laboratory?
2. How long has your laboratory been in business?
3. What type of laboratory do you operate/what type of testing do you perform?
4. What type of community do you serve? Who relies on your services?
5. Provide a breakdown of their total reimbursement by the following categories (Figure 2):
 - a. Medicare Part A (if applicable)
 - b. Medicare Part B (not including Medicare Advantage Plans)
 - c. Medicare Part C (Medicare Advantage), if applicable
 - d. Medicaid (including Managed Care Plans)
 - e. Private Payors
 - f. Other
6. Of the total reimbursement received, what percent is tied in some way to the Clinical Laboratory Fee Schedule? (Provide a rough estimate if necessary)
7. What are the top 10 tests by volume your laboratory provides?
8. Have you had to/will you need to drop laboratory testing services as a result of PAMA?
9. Have you had to/will you need to lay off employees due to loss in revenue from the cuts?
10. What is the subsequent impact on patients? Are there longer turn around times for test results?
11. How many jobs would be lost if the laboratory closed?
12. Can you survive one year with a 10% cut? Two years?
13. What are the implications beyond the CLFS for your lab (i.e. are your private payor contracts tied to the Medicare fee schedule?)
14. What steps has your lab taken in the past to protect yourself from cuts to the CLFS?
15. Any other impacts you would like to share?