White Paper

PAMA Survival 101: Focus on Laboratory Efficiency and Partnerships

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Introduction

PAMA (Protecting Access to Medicare Act) should, at this point, be front and center for laboratories performing outreach testing and billing to the Clinical Laboratory Fee Schedule (CLFS). The Centers for Medicare and Medicaid Services (CMS) has moved forward with the new clinical laboratory fee schedule (CLSF) that reflects a substantial decrease in reimbursement for most general laboratory tests. The new CLSF payment rates implemented in 2018 are based on the calculated weighted median of payments from private insurance payers for the tests most commonly ordered in outreach scenarios.[1,4,6,10] While 1,942 "applicable labs" submitted the payer data, and only 21 hospitals were represented in the group, the resulting payment schedule affects all laboratories claiming reimbursement for outreach testing.[1,6]

The first three years of the phased reimbursement reduction (10% maximum for each year from 2018 to 2020) will give laboratories a good idea of the impact of PAMA on their bottom line. But considering that Medicare has been paying about 35% more on average for the tests most commonly ordered for outreach testing, laboratories can expect to see reimbursement decreasing beyond the first three years and into the second phase of 15% reductions taking place between 2021 and 2023.[4,8,15,16] What will be the total decrease to the bottom line? The total decrease will in fact depend on what CMS uncovers when the second assessment of private-payer versus Medicare payments takes place in the 2019–2020 time frame.

Table 1.
Example of PAMA impact on a lab test with high Medicare vs. private-payer discrepancy.

Test Paid at $40.61 goes to $26.37 NLA		
Year	**Amount of Payment Decrease**	**Payment**
		Test NLA = $40.61
1	10%	$36.55
2	10%	$32.89
3	10%	$29.60
4	15%	$26.37
5	15%	$26.37
6	15%	$26.37
Years 1–6		

NLA: National Limitation Amount

Let's Review Some History

Much has changed since 1984 when the CLFS was first released. Nevertheless, the CLFS has remained the governing document for laboratory test reimbursement. Numerous articles have considered some of the critical factors that the CLFS process should have monitored and addressed in the 33 years since its release:[2,4,5,6,18]

- Appropriate adjustments between cost to perform test and reimbursement, including overhead costs, labor, equipment, reagents, consumables, supplies, and requirements for informatics
- Updates to the fee schedule to compensate for technological changes in existing testing
- Emergence of new markers and technologies (e.g., molecular testing for genomic markers)
- Formal process for updating payment rates
- Annual and systematic adjustments to the payment rates in relation to the Consumer Price Index (CPI)

Let's also consider that private insurers historically look to Medicare as the benchmark from which to establish their payment formularies and lab testing reimbursement. In 2008, the Lewin Group published the "Laboratory Report: A National Status Report," which stated that approximately 67% of private payers, as well as all public payers, based their payment schedules, discounts, and negotiations on the Medicare payment schedule. Private payers averaged 10 to 20% higher payment rates than Medicare, although this has varied based region and type of health coverage.[13,15,16] If no changes were happening to Medicare payments, we could expect that the market would remain status quo, with private insurers paying more than Medicare. But around 2000, payer competition and economic dynamics ultimately drove down private-insurer reimbursement.

Competitive Forces

- Employers aggressively shopped for better rates among the various insurance providers in order to mitigate the ever-escalating cost of employer-provided insurance. Employers wanted to offer their employees multiple options for insurance providers while maintaining a fixed contribution per employee. In order for private insurers to be more competitive, they had to negotiate lower costs with healthcare providers and ancillary service providers (laboratory and imaging).[11,12,13,21]
- Cost sharing became a common strategy for private insurers to save money by passing on the costs of healthcare to consumers participating in a managed care or employer-sponsored healthcare program. This further exacerbated the need for more competitive pricing to meet the needs of the more-educated end user/patient looking to pay less for healthcare costs.[2,12,21]
- The continuous mergers and acquisitions among hospitals and integrated delivery networks has escalated competition among private insurers trying to maintain or secure preferred payer status. Consequently, the providers of ancillary services such as laboratory testing must also pursue more competitive pricing and offerings to maintain preferred provider status. Note the payer variation reflected in Table 2.[11,19]

Table 2.
Average insurer reimbursement rates (2014).

Insurer (A–Z)	Less than Medicare	100% of Medicare	101–105% of Medicare	106–110% of Medicare	Above 110% of Medicare	Don't Know
Aetna	15%	16%	19%	18%	20%	12%
Blue Plans	12%	14%	18%	19%	27%	11%
Cigna	16%	17%	18%	17%	19%	13%
Harvard Pilgrim Health Care	18%	17%	13%	12%	12%	28%
HealthNet	24%	22%	13%	12%	7%	22%
Humana	19%	21%	19%	15%	11%	16%
Kaiser Foundation Health	17%	22%	11%	8%	18%	23%
Medical Mutual of Ohio	20%	19%	16%	10%	10%	26%
Oxford Health Plans	26%	20%	11%	12%	8%	23%
United Healthcare	18%	15%	18%	16%	21%	12%

Source: Insurers Rating Report 2014

The most compelling rationale for the disparity between Medicare and private payer payments is the competition among national and regional reference laboratories to be the preferred provider of laboratory testing for a given private payer. To secure preferred-provider status for laboratory testing, reference laboratories negotiated significantly lower pricing. Consequently, by 2011, the top 25 tests most commonly ordered in outreach testing were reimbursed an average of 23.8% less by private insurers compared to Medicare.[2,3,4,9] More recently, XIFIN, Inc., conducted an analysis showing that private payers reimbursed from 19.6 to 25.6% less than Medicare for 20 of the top 25 tests commonly attributed to outreach testing.1 And since the national reference labs provided the bulk of the private-payer information for the PAMA analysis, the resulting weighted medians already reflect a substantially lower reimbursement amount as compared to reimbursement for hospital laboratories.

We can expect that negotiations between private payers and diagnostic testing providers will continue, hence the concern of many laboratories that the first reduction period of 2018–2020 may be only the beginning of further cycles of reimbursement reduction. Yet the fact remains that, at minimum, 70% of medical decisions begin with a laboratory result. Additionally, population health management requires laboratory testing for care gap assessment, and monitoring of chronic diseases is gaining momentum. So the need for laboratories to continue to provide results for the top 25 tests is increasing, and as an industry, our laboratories must be prepared to function as businesses to survive and thrive in spite of PAMA.

Implementing automation and smart informatics is one of the best ways to improve labor utilization while also expanding the laboratory's efficiency, capabilities, and downstream impact.

Top Three Things a Lab Should be Doing Now

Reimbursement payments have been on the decline for some time. These gradual reductions are driven by managed care, Medicare and Medicaid cost saving measures, and, more recently, the various Centers for Medicare and Medicaid Services (CMS) programs driving the transitions from fee-for-service to fee-for-value (value-based healthcare) tying payment models to quality and performance. Laboratories have responded to these pressures in various ways. At one end of the spectrum, labs have pursued consolidation or managed laboratory strategies, increased volume of send-outs, and /or reduced the number of personnel. At the other end, they have pursued expansion of outpatient and outreach testing, increased their test menus (especially in molecular testing), standardized protocols to ensure proper test utilization, and established strategic partnerships with value-minded vendors.

Item 1: Lower cost through operational efficiency

Jeff Olson, founder and CEO of Nerium International and author of the best-seller "The Slight Edge" (2013), is attributed with saying, "Sometimes you need to slow down to go fast." I've learned how valuable this philosophy can be in making important decisions. I mention this quotation because the expected and immediate reaction to the imminent reduction in reimbursement is "We have to reduce cost now!" But cost reduction needs to be handled in a way that ensures sustainability for the laboratory to function as a business and continue to grow.

Laboratories as providers of healthcare information are also dealing with the impact of the transition from fee-for-service to fee-for-value or value-based healthcare. Fee-for-value requires significant enhancement of processes and focus on quality at each step of the continuum of care.11 The laboratory is integral to this process, especially when we consider the downstream impact of laboratory test results on medical decisions, treatment, and monitoring.

Additionally, the expansion of bundled payments and other quality-based payment models will require laboratories to provide precise and accurate test results to expedite medical decisions and minimize mis-diagnosis and readmissions.[8] In order to deliver on these demands, laboratories must have the right personnel, right instrumentation and assays, and intelligent automation and middleware informatics.

Most laboratories are already strapped for labor resources due to the diminishing supply of well-trained and experienced personnel. Labor, therefore, must be assessed from the perspective of "how do I best utilize and deploy my laboratory personnel and maximize overall efficiency?" Implementing automation and smart informatics is one of the best ways to improve labor utilization and expand the laboratory's efficiency, capabilities, and downstream impact.[7,14,17,20]

Yes, there is an up-front cost associated with automation, whether the lab is upgrading or implementing automation for the first time. But remember: "Sometimes you need to slow down to go fast." While it may seem counterintuitive to invest significant budget with looming reimbursement reductions, the long-term benefits and savings far outweigh the initial costs. Each of the benefits of automation listed above work toward minimizing the impact of PAMA by reducing operational costs, improving the lab's contribution to key fee-for-value quality metrics, expanding the laboratory's capabilities to expand menu and volume, and increasing economies of scale.

Item 2: Lower cost through reagent efficiency and improved test utilization

Another important benefit of smart middleware and informatics is the tremendous amount of data that laboratories can harness relative to efficiency and test utilization. Along with labor, reagents, consumables, and other supplies tend to be an expensive recurring cost. But informatics also presents a great opportunity to analyze the significant waste the laboratory may be unwittingly incurring.

For example, a common practice among many laboratories is to mirror-image test menus across multiple platforms as a precautionary measure in case a system goes down. In such an event, the laboratory can continue to generate results on the mirror-imaged instrument. But look at the data from your middleware or instrument. Once you have the data in hand, ask the following questions:

- Which tests do I have mirror-imaged? Do they constitute my entire chemistry and/or immunoassay menu?
- How many of the mirror-imaged tests are critical STAT tests? (It might make sense to keep such tests on multiple instruments.)
- How many tests are not critical STAT tests, but still reside on multiple platforms?
- How often do I actually get orders for some of the tests that I have mirror-imaged?
- Excluding planned maintenance, how often is the instrument actually offline?
- If the main instrument is offline, how long would it take me to calibrate and QC the second instrument?
- How much reagent, QC, calibrator, and labor am I spending on a daily basis by maintaining the testing menu fully calibrated and with current QC on multiple instruments?
- Is the lab protocol set up to run duplicate or triplicate tests on some assays?
  If so, why? Is it concerned about the quality of the results? Have we reached out to the clinical team of the assay vendor to discuss our concerns? Is there a more robust assay on the market that I should consider?
- Are we leveraging smart informatics and middleware to run diagnostic algorithms and ensure consist test ordering and standardization?

No doubt a number of other questions can be added to this list, offering the laboratory a reality check on how much extra reagent and consumables used wasted on unnecessary testing. Having the right vendor partner can make a huge difference when it comes to performing these types of assessments (and we'll discuss this in the next section), but consider the following example:

> A regional network laboratory within a large health system in the Southwest area of the United States realized over $200,000 in cost savings within the first six months of implementing an efficiency strategy that included reduction of mirror-imaging, analysis of quality control and calibration protocols, and process standardization to drive optimal test utilization.

An important byproduct of the efficiency assessment is knowing exactly how each drop of reagent is being utilized—whether it's for generating a patient result, QC point, calibration curve, or duplicate test. The right middleware from a value-minded vendor partner can help the laboratory achieve efficient use of reagents as well as establish a cost-conscious inventory-management system that eliminates unnecessary inventory and waste and improves labor utilization. If volumes increase or decrease, the laboratory can quickly generate dashboards or reports to guide ordering. Again, in each of these examples, efficiency and knowledge are saving dollars that contribute to fee-for-value metrics, position the laboratory as an active partner in achieving the goals of administration, and help mitigate the impact of lower reimbursement from PAMA.

Item 3: Establish a True Partnership with Your Vendors

Vendors are also going to feel the economic impact of reduction in laboratory testing reimbursement. As laboratories experience declining revenue, they are likely to seek the best pricing as they make purchasing decisions. But best pricing doesn't necessarily equal the best or highest-quality solution for the lab. As mentioned in Item 1, the ability of the laboratory to meet patient and provider needs, sustain operations, and expand services is tied to the quality of the equipment, assays, and informatics, as well as the technical support, service, and consultative capabilities of the vendor.

Laboratories need to challenge vendors on their consultative capabilities, including their knowledge of the market trends affecting healthcare today. For example, the vendor partner should be able to provide comprehensive solutions for implementing ordering protocols and appropriate testing algorithms that standardize the care pathway, and shorten the time to intervention to drive better patient outcomes.

A vendor partner vested in the long-term success of its laboratory customer should offer consultative services and operational assessments that help position the lab as a key contributor in achieving the institution's value-based goals and quality metrics. Additionally, the vendor partner should engage with the laboratory on a continuous basis to implement lean processes, provide ongoing education, and offer solutions that help the laboratory realize return on investment while achieving overall cost savings per episode of care.

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Next Steps

As the first year of PAMA implementation unfolds, each laboratory will gain an understanding of the impact of the reimbursement on their bottom line. Reality will certainly sink in. But if laboratories pro-actively evaluate their operational and reagent efficiency, perform appropriate due diligence of their processes and vendor relationships, and challenge their vendors to offer the value-added services that will help them recognize and monetize their contributions toward institutional goals, they can survive and thrive in spite of PAMA.

It's also important to keep in mind that PAMA is only one factor affecting healthcare reimbursement. Fee-for-value metrics continue to expand and are becoming more complex; thus, achieving full reimbursement continues to challenge providers. The CMS readmission reduction program is adding additional categories, which means that institutions need to have robust processes in place that include laboratory testing to maintain readmissions below the threshold for penalties. More institutions are expanding their population management efforts in order to curtail costs, and the majority of private insurers are also tying reimbursement to value-based metrics.

The next paper in this educational series focuses on the connection between fee-for-value, laboratory test utilization, and PAMA. Subsequent papers will address the other related topics with the overarching goal to educate laboratorians on the critical role laboratory testing plays in the success of these programs and improving patient outcomes and quality of care.

To download a checklist with steps you can take today to prepare for PAMA, visit usa.siemens.com/PAMAchecklist

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Biography

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