WHITE PAPER

Laboratory Testing Reimbursement: Rescue Me!

Perspectives on Surviving PAMA

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Declining laboratory testing reimbursement is nothing new and has been gradually happening for a number of years. However, reimbursement for laboratory testing stands to undergo an unprecedented decrease starting in 2018 as a result of PAMA (Protecting Access to Medicare Act). With PAMA comes the implementation of the new Medicare payments 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 the controversial "applicable labs" are the ones required to submit payer data, the resulting payment schedule will affect every laboratory 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 is currently paying an average of 24% more for the tests most commonly ordered for outreach, laboratories can expect to see reimbursement for some of those tests decreasing past the first three years and into the second phase of reductions (15% per year) taking place between 2021 and 2023.[4,8,15,16] You might be asking "what will be the total decrease to the bottom line?" That depends on what CMS uncovers when the second assessment of private payer payments versus Medicare payments takes place from 2019 to 2020. In the meantime, laboratories need a rescue plan to ensure they can survive and thrive amidst the declining reimbursement.

TABLE 1

EXAMPLE OF PAMA IMPACT ON LAB TEST WITH HIGH MEDICARE VS. PRIVATE PAYER DISCREPANCY

Assumption: Test with $20 NLA is priced at $8.50

YEAR	AMOUNT OF PAYMENT DECREASE	PAYMENT
1	10%	Test NLA = $20.00
2	10%	$18.00
3	10%	$16.20
4	15%	$14.58
5	15%	$12.39
6	15%	$10.53
Years 1-6	55% reduction in payment	$8.95

NLA = National Limitation Amount

LET'S REVIEW SOME HISTORY

We can all agree that quite a bit has changed since 1984 when the Clinical Laboratory Fee Schedule (CLFS) was first released. Nevertheless, the CLFS has remained the governing document for laboratory testing reimbursement. Some of the critical factors that the CLFS process should have monitored and addressed in the 33 years since its release include the following: [2,4,5,6,18]

- Appropriate adjustments between cost to perform test and reimbursement. This includes overhead costs, labor, equipment, reagents, consumables, supplies, and requirements for informatics.
- Updates for the fee schedule to compensate for technological changes to existing testing.
- Emergence of new markers and technologies (i.e. 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 looked at Medicare as the benchmark from which to establish their payment formularies and lab testing reimbursement. The Lewin Group published the "Laboratory Report: A National Status Report" (2008) stating that approximately 67% of private payers, as well as all public payers based their payments, discounts, and negotiations on the Medicare payment schedule. Private payers averaged 10 to 20% higher payment rates than Medicare, although this is still very much dependent on region and type of health coverage.[13,15,16] If no changes were happening to Medicare payments, one could expect private insurers continuing to pay more than Medicare. But around 2000 interesting dynamics ultimately drove down private insurer reimbursement. And the common denominator of these dynamics was competition.

- Employers aggressively shopped around 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 insurance provider options while maintaining a fixed contribution per employee. Private insurers negotiated lower payments with healthcare providers and ancillary service providers (laboratory and imaging) to stay competitive and in the running.[11,12,13,21]
- Cost sharing became a common strategy for private payers to save money by passing the costs of healthcare onto the 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 merger of hospitals and integrated delivery networks (IDNs) continued to escalate competition among private payers as they struggled to secure their preferred payer status across the newly formed entities. Subsequently, the providers of laboratory and imaging ancillary services associated with the private payers also had to pursue more competitive pricing (Note payer variation reflected in Table 2).[1,19]
- Competition among national and regional reference laboratories to secure preferred provider contracts with private payers drove these labs to negotiate significantly lower pricing. Consequently, by 2011 the top 25 tests most commonly ordered for outreach testing through reference labs were reimbursed an average of 23.8% less by private insurers as compared to Medicare.[2,3,4,9] More recently, XIFIN, Inc. conducted a study showing that private payers reimbursed somewhere between 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 are providing the bulk of the private payer information for PAMA to establish the new payment schedule, we can anticipate that the resulting averages will reflect a substantially lower figure as compared to reimbursement for hospital laboratories.

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%	12%	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%
UnitedHealthcare	18%	15%	18%	16%	21%	12%

Source: Insurer's Rating Report 2014

We can expect continued negotiations between private payers and diagnostic testing providers; hence the concern for many hospital laboratories that the first reduction period of 2018-2020 may only be the beginning of further cycles of reimbursement reduction. Yet it's recognized that more than 70% of medical decisions begin with or are influenced by laboratory results. Population health management initiatives also rely on laboratory testing for care gap assessment and monitoring of chronic disease; therefore, the demand for and utility of laboratory testing continues to increase. But for laboratories to continue to provide testing, they must be prepared as a business to survive and thrive in spite of PAMA.

TOP THREE THINGS A LAB SHOULD BE DOING NOW

As previously stated, reimbursement reduction has been gradually happening for some time. Drivers of reimbursement reduction include managed care programs, bundled payments, Diagnostic Related Groups (DRGs), and more recently the incentive programs driving the transitions from fee for service (FFS) to fee for value (FFV) (value-based purchasing), along with the payment models tied to quality and performance. Many laboratories have responded to these pressures in various ways. At one end of the spectrum, lab administrators pursued consolidation or outsourced their laboratory services. Others increased send-outs and reduced personnel. And at the other end of the spectrum, we see lab administrators increasing outpatient and outreach testing, expanding test menu especially in molecular diagnostics, standardizing protocols to ensure proper test utilization, and establishing 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 the quote, "Sometimes you need to slow down to go fast." I mention this quote because an expected reaction to the eminent reduction in reimbursement is "We have to reduce cost now!" But cost reduction, especially through reduction of laboratory personnel in a resource-strapped industry, should be handled thoughtfully to ensure sustainability for the laboratory, availability of services for the patients and physicians, and continued opportunities for growth.

Laboratories as providers of healthcare care information are also dealing with the impact of the transition of value-based purchasing or FFV from FFS. FFV requires significant enhancement

of processes and delivery of 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 test results on screening, diagnosis, treatment, and monitoring. Additionally, the expansion of bundled payments such as the upcoming cardiac bundle requires that labs provide test results to expedite medical decisions and minimize misdiagnosis and readmissions.[8] In order to deliver on these demands, laboratories need to 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, needs to 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 while also expanding the laboratory's efficiency, capabilities and down-stream impact.[7,14,17,20]

The many benefits of laboratory automation and smart middleware informatics include:

- Elimination of unnecessary and labor-intensive steps (which opens up the capability for menu and volume expansion).
- Reduction of potential for human errors.
- Automation of sample handling and storage.
- Advantages of auto verification, QC rules library and diagnostic algorithms.
- Predictable turnaround times to ensure consistency of downstream decisions, actions and care.
- Improvements in quality of care, patient outcomes and cost tied to specific value based metrics such as Medicare Spend Per Beneficiary (MSPB), readmission reduction, decreased ER wait times, and patient satisfaction.

Yes, there is an up-front cost associated with automation — whether the lab is upgrading automation or implementing automation for the first time. But remember, "Sometimes you need to slow down to go fast." While it may seem counter-intuitive to invest significant budget with looming reimbursement reductions, the long-term benefits and savings far outweigh the initial costs. Each of the above listed benefits of automation work towards minimizing the impact of PAMA by reducing operational costs, improving the lab's contribution towards 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

Next to labor, reagents, consumables and other supplies (RCOs) tend to be an expensive, recurring cost. However, another important benefit of smart middleware and informatics is the ability to harness extensive data relative to the laboratory's efficiency and test utilization to identify waste the laboratory may have but not even realize.

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 pulled from your middleware or your instrument. Once you have the data in hand, ask the following questions:

- Which tests do I have mirror imaged? For example, is it my entire chemistry and/or immunoassay menu?
  - How many of the tests I have mirror-imaged are critical stat tests? (Might make sense to keep it on multiple instruments)
  - How many tests are not critical stat tests, but I still have on multiple platforms?
  - How often do I actually get orders for some of the tests that I have mirror image?
- Excluding planned maintenance, how often do I encounter a situation where the instrument is actually off line?
- If the main instrument is off line, how long would it take me to calibrate and QC non-critical assays on the second instrument?
- How much reagent, QC, calibrator and labor am I spending monthly in maintaining the testing menu on multiple instruments fully calibrated and with current QC?
- Is the lab protocol set up to run duplicate or triplicate tests on some assays? If so, why? Is it concern around the quality of the result? Have we reached out to the vendor's clinical team to discuss our concerns? Is there a more robust assay in the market I should consider?
- Is my middleware programmed to release greater than 85% of my lab tests utilizing autoverification?
- Are we "over-troubleshooting" our assays and instruments with excessive calibrations and QC runs instead of addressing the root cause?

- Are we running extra calibrations and QC because of individual technologist preferences, because "it's always been done this way," or because the technologist feels more confident with their processes and results?
- 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 may surface during this assessment to provide a comprehensive reality check of the excess reagents and consumables spent 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:

- Six hospitals from a large integrated delivery network (IDN) across the southwestern/western region of the United States realized yearly savings of $232,543 by implementing a reagent efficiency strategy that included reducing or eliminating mirror imaging, employing analysis around unnecessary QC and calibration, and standardizing testing protocols to ensure optimal test utilization.

Exactly how each drop of reagent is being utilized — whether it's for generating a patient result, QC point, calibration curve, or duplicate test — is an important by-product of the information generated through this assessment. Having the right middleware from a value-minded vendor partner can help the laboratory achieve reagent efficiency utilization, as well as establish a cost-conscious inventory management system that eliminates unnecessary inventory and waste while improving 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 FFV 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 laboratory administrators experience declining revenue, their purchasing decisions may be made based on lowest price. But lowest price 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 their 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, shorten the time to intervention, and contribute directly to the goals of the Triple Aim by improving patient outcomes and the patient experince at a lower cost.

Important questions laboratories should be asking of their vendors include:

- Will you regularly provide our staff with practical education on the role laboratories play in key Medicare programs such as readmission reduction, population management and value-based purchasing?
- Will you assist us in developing a strategy to position the laboratory as a contributor and partner in achieving the institution's quality metric goals?
- Do you contractually guarantee the performance or metrics we expect to achieve with your solution?
- Will you help us implement testing algorithms that improve test utilization and drive targeted medical decisions?
- Do you offer instrument-specific tools that assess the exact efficiency of the instrument?
  - If so, do you offer these consultative services on a periodic basis to help us improve our operational efficiency?

A vendor partner vested in the long-term success of the laboratory customer should be offering the above mentioned value-add services. Additionally, the vendor partner should engage with the customer on a continuous basis to implement lean processes, provide ongoing education and offer solutions that help the laboratory realize return on investment (ROI) through the contribution and achievement of quality goals, improvement on patient outcomes and overall cost savings per episode of care.

NEXT STEPS

As the second half of 2017 approaches, we should begin to see some information on how the lab's average reimbursement from private payer compares to Medicare's CLFS, and laboratory administrators may be able to estimate the impact the new payment policy might have on their bottom line. If lab administrators proactively evaluate their operational and reagent efficiency, perform appropriate due diligence on their processes and vendor relationships, and challenge their vendors to offer the value-add services that help them recognize and monetize their contributions toward institutional goals, they have successfully executed a rescue plan to position their lab to survive and thrive in spite of PAMA.

It's important to also keep in mind that PAMA is only one factor affecting healthcare reimbursement. FFV metrics continue to expand and are becoming more complex; thus, achieving full reimbursement for healthcare services continues to challenge providers. Medicare's readmission reduction program is adding additional categories which means that hospitals needs to have robust processes in place that include laboratory testing in order to maintain readmissions below the penalty threshold. More institutions are expanding their population management efforts to proactively curtail healthcare costs, and the expansion of bundled payments to include cardiac conditions paves the way of other complex disease conditions to follow suit.

The next paper in this educational series will focus on how laboratories can contribute towards the value-based or FFV goals. Subsequent papers will cover the other topics mentioned above with the overarching goal to educate laboratorians on the critical role laboratory testing plays in the success of these incentive programs and in achieving the goals of the Triple Aim — lowering healthcare cost, improving patient outcomes and enhancing the quality of care.

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References

1. Arnold & Porter and Xifin. (June 2016). Applicable laboratories: Is your lab required to report? Retrieved from http://www.apks.com/en/perspectives/events/2016/06/pama-applicable-laboratories
2. Burns, J. (September 2016). Why lab prices declined 32% during 3-year study. Employer's use of reference pricing got patients to choose lower-priced labs over high-priced labs. The Dark Intelligence Group. Retrieved from http://www.darkintelligencegroup.com/the-dark-report/laboratory-billing/why-lab-prices-declined-32-during-3-year-study/
3. Burns, J. (November 2016). Expert explains why payer errors skew labs' PAMA price data. Labs warned that payers' information is full of errors. The Dark Intelligence Group. Retrieved from http://www.darkintelligencegroup.com/the-dark-report/laboratory-billing/expert-explains-why-payer-errors-skew-labs-pama-price-data/
4. Dark Daily. (2016). CMS Issues PAMA Final Rule That Aims to Cut Medicare's Clinical Laboratory Test Price Schedule Sharply Beginning in 2018. Retrieved from http://www.darkdaily.com/cms-issues-pama-final-rule-that-aims-to-cut-medicares-clinical-laboratory-test-price-schedule-sharply-beginning-in-2018#axzz4GbdgVj79
5. CMS (Centers for Medicare & Medicaid Services). (2011). Medicare Claims Processing Manual, Chapter 16—Laboratory Services (Rev. 2136, 1-21-11). Retrieved from http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads//clm104c16.pdf
6. CMS (Centers for Medicare & Medicaid Services). (2016). PAMA Regulation. Retrieved from https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html
7. Covilma L. & Gammie., A. (February 2015). The LEAN lab: Automation, workflow, efficiency. MLO. Retrieved from http://www.mlo-online.com/the-lean-lab-automation-workflow-and-efficiency.php
8. Furtell, K. (April 2016). PAMA and bundled payments force labs to feel a reimbursement shift. MLO. Retrieved from http://www.mlo-online.com/pama-and-bundled-payments-force-labs-to-feel-a-reimbursement-shift
9. Hammelman, E. (2012). Commercial vs. Medicare Pricing for Clinical Lab Tests in 2012. Retrieved from http://www.acla.com/wp-content/uploads/2014/03/Hammelman.pdf
10. hc1.com. (2016). The Laboratory Executive's Guide to Surviving PAMA. Retrieved from https://www.hc1.com/resources/whitepapers/
11. Holly, Mike. (2013). How government regulations made healthcare so expensive. Retrieved from https://mises.org/blog/how-government-regulations-made-healthcare-so-expensive
12. INC.com (2013). Health maintenance organizations and preferred provider organizations. Retrieved from https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjmr5Xt5ezQAhUhi1QKHaIJCEgQFggaMAA&url=http%3A%2F%2Fwww.inc.com%2Fencyclopedia%2Fhealth-maintenance-organizations-and-preferred-provider.html&usg=AFQjCNHBRiD37LvUx1XLcfN1n1pKW3Rdwg&bvm=bv.141320020,d.eWE
13. Kane, L. and Peckham, C. (2014). Insurer Ratings Report 2014. Retrieved from http://www.medscape.com/features/slideshow/public/insurerratingsreport2014#32
14. Laposata, M. (2003). Reducing Medical Errors by Providing Expert Advice in the Selection and Interpretation of Laboratory Tests. Quality Institute Conference. Retrieved from http://wwwn.cdc.gov/mlp/QIConference/Presentations/Laposata-CDC%20errors%20talk%20final.pdf
15. Lewin Group. (May 2008). Laboratory Medicine: A National Status Report. Retrieved from https://wwwn.cdc.gov/futurelabmedicine/pdfs/2007%20status%20report%20laboratory_medicine_-_a_national_status_report_from_the_lewin_group_updated_2008-9.pdf
16. Regenstein, M. and Andres, E. (2012). Results from the National Survey of Independent and Community Clinical Laboratories. Department of Health Policy at George Washington University School of Public Health and Health Services
17. Roy, C. L., Poon, E.G., Karson A.S., et al. (2005). Patient safety concerns arising from test results that return after hospital discharge. Ann Intern Med, 143:121.
18. Rudolf, P.M., Gustafson, T.A., Madsen, J.B., and Cassidy, A. (2015). Medicare proposes new payment system for clinical lab tests, but leaves many of labs' questions unanswered. Arnold & Porter Advisory. Retrieved from http://www.apks.com/en/perspectives/publications/2015/10/medicare-proposes-new-payment-system-for-clinica__
19. Schechter, A. and Cooper, Z. (2016). The true price of reduced competition in Healthcare: Hospital monopolies drastically drive up prices. ProMarket. Retrieved from https://promarket.org/the-true-price-of-reduced-competition-in-health-care-hospital-monopolies-drastically-drive-up-prices/
20. Terry, M. (2015). Buyer's guide for clinical laboratory automation. Achieving high production lab automation and lean workflow: What lab managers should know before issuing the RFP. Dark Daily. Retrieved from http://www.darkdaily.com/white-papers/free-special-edition-white-paper-buyers-guide-for-clinical-laboratory-automation-615#axzz4VHWSJQho
21. U.S. Department of Labor. (July 1996). A Look at Employers' Costs of Providing Health Benefits." Prepared by the Office of the Chief Economist. Retrieved from https://www.dol.gov/oasam/programs/history/reich/reports/costs.htm