

Preparing Your Lab for PAMA

As you are likely aware, the Centers for Medicare & Medicaid Services (CMS) are changing the way lab reimbursements are determined as a result of the Protecting Access to Medicare Act of 2014 (PAMA). New Medicare payment rates will be

market-based, determined by median private payer reimbursements as reported by applicable labs. Even if you are not an applicable lab that must report your payer reimbursements, you need to have a complete understanding of your laboratory costs and potential PAMA repercussions in order to prepare your lab for the changes ahead. Figure 1 outlines the three main differences between the current clinical laboratory fee schedule (CLFS) and the post-PAMA lab fee schedule.1

The list below are steps applicable labs must take to report their private payer data.²

- 1. Lab registers for a CMS ID and password
- 2. Lab logs into CLFS module via the CMS portal

Current (Implemented in 1984)

Payment rates are based on lab charges in 1984-1985, adjusted annually for inflation

Fifty-seven local fee schedules

Same pricing schedule for all categories of lab testing

(To be implemented in 2018)

Payment rates for tests will be based on private payer rates, updated every three years

Single national fee schedule

Adds a new category of lab tests—advanced diagnostic laboratory tests (ADLTs)—with a different pricing schedule

Figure 1: Comparison of current CLFS vs. future CLFS after PAMA changes.

PAMA Timeline

We are already into the first reporting period for PAMA, which is January 2017 through the end of March 2017. A draft of the new fee schedule is promised for September 2017, with the final (after a comment period) expected in November 2017.

inside this issue...

Orchard's POCT Solution	4
The Importance of an LIS Maintenance Plan	5
Where in the World is Orchy?	5
Rules Scheduler & New Rules Action	6
Spotlight On: Amanda Malek	9
Featured ORC Question	.10
Advantages of a Remote Backup	.10
2017 Event Calendar	.12

The new pricing becomes effective January 1, 2018.

One criticism of the PAMA data collection methodology is that only 5% of labs (12,547) in the United States are considered applicable.

This 5% represents 69% of Medicare payments (see Figure 2).¹The concern is that this sampling of payer reimbursements from larger labs will skew the new pricing.³

3. Lab reports private payer

data, manually or via

and accuracy of data

Expected PAMA Impact

certifies the completeness

Excel upload 4. Lab CEO or CFO

For the first three years of PAMA (2018-2020), the price change can be no more than 10%. For the following three years (2021-2023), the reduction can be up to 15%. In other words, over the next six years, reductions can be as much as 75%. CMS has reported that it expects PAMA-driven reductions to total \$3.9 billion over the next 10 years, with 2018 cuts estimated at \$400 million across the board.²

Small & Mid-size Labs Will Feel the Pressure

PAMA's reimbursement cuts are considered by industry experts to have potentially devastating effects, particularly for small- to

See "Preparing Your Lab for PAMA" on page 2.

Preparing Your Lab for PAMA

Continued from page 1.

mid-size community and regional labs, physician's office labs, and rural and community hospitals.³ The National Independent Laboratory Association (NILA) reports that some of its community variances between states with a national limitation amount (NLA) or maximum payment. Some states have reimbursement rates that are lower than the NLA. Traditionally, Medicare pays

lab members have a large Medicare population (up to 60%) with profit margins of only 3% to 4%. So, you can immediately ascertain that labs with a 3% to 4% profit margin that face a 10% cut for 60% of their patient testing will no longer be profitable, and future reductions will only make the situation more grim. Small and rural hospital labs that depend heavily on income from outreach testing for Medicare patients may also feel the PAMA cuts more deeply.³

New Nationwide Prices: What Does This Mean for Labs?

When the new fee schedule comes out, there will be one nationwide fee schedule; in the past, there have been price

Labs That We Estimate Will Report Private Payer Data Represented More Than Two-Thirds of Medicare Payments in 2015



the lower of either the NLA or the local fee rate. This means that if you are in a state with rates lower than the NLA, you may see an increase in rates for some tests after the PAMA fee schedule goes into effect. The expectation is that for 38 states, at least one of the top 25 lab tests will see an increase in fee rate, and for some states, 22 of the 25 tests will see an increase.¹ Prudent lab managers should compare their state reimbursements with the NLA to understand the implications of a nationwide fee schedule.¹

To illustrate this, let's say that in your state, the 2015 Medicare reimbursement was \$58 for a specific lab test with an NLA of \$98. After

Figure 2: Applicable labs will use the CMS portal to upload their private payer reimbursements and volumes.

Kim Futrell

Meg Stanage

PAMA, depending on private payer median, the fee can increase or decrease by up to 10% of the NLA. In this case, a 10% decrease (from \$98) would be \$88.20; therefore, the rate in this example could increase in your state from \$58 to \$88.20. In theory, the median private payer price could be higher than the Medicare rate for certain tests, making the new PAMA pricing an increase for certain tests in some states.¹ Additionally, the practice of bundling tests into panels for payment will be eliminated and the new rates will apply to each individual test based on the individual median private payer rates for those tests.¹

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What about ADLTs?

PAMA creates a new category of lab tests—advanced diagnostic laboratory tests (ADLTs) (see Figure 3). Tests that meet the ADLT criteria will have separate pricing that requires reporting of payer reimbursements annually.

To Fine or Not to Fine

The penalties for non-compliance are a bit unclear. PAMA clearly states that the U.S. Secretary of Health and Human Services can fine laboratories up to \$10,000 per day for each failure to report or each misrepresentation/ omission of data. However, in the same document, CMS states that it does not intend to verify whether labs report or not, and for labs who do report their data, CMS does not intend to verify accuracy of the data. This is another concern regarding the validity of the PAMA price-setting methodology.

What is an ADLT?

To be considered an advanced diagnostic laboratory test (ADLT), a test must be performed by a single lab and either:

- Be approved by the FDA, or
- Be a test that:
 - Evaluates a patient's DNA, RNA, or proteins
 - Provides new clinical diagnostic information that cannot be obtained from any other test(s)
 - Uses a unique algorithm that predicts the chance of a patient developing a condition or responding to a treatment

Figure 3: Definition of an ADLT.

Be Prepared—Make Sure You Understand How PAMA Will Affect Your Lab

In order to face legislative changes such as PAMA, laboratorians must refocus their efforts and find new ways to demonstrate their value. Orchard Software is here to keep you informed and to provide valuable resources to help with this transition. The good news is that while the lab is not the problem in rising healthcare costs, it can be part of the solution. Providers cannot take care of patients without the lab, so the lab will not go away as a tool in healthcare—the lab actually becomes more valuable. Labs remain essential no matter what happens to reimbursements. However, it will be the most forward-thinking labs and those labs willing to embrace change that will be the most successful. Make sure you have a firm understanding of your lab costs so that you can compare your internal costs to the NLA and to the new PAMA fee schedule and align your organizational business strategy with a full awareness of PAMA's impact on your lab.

Notes

 Murrin, S. (2016, September). Medicare payments for clinical diagnostic laboratory tests in 2015: Year 2 of baseline data. Department of Health and Human Services-Office of Inspector General. Retrieved from https://oig.hhs.gov/oei/ reports/oei-09-16-00040.pdf

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Orchard's POCT Management & Integration Solution: Orchard Trellis



The Positive Impact of POCT on Operational Efficiency & Patient Care

Point-of-care technologies are quickly becoming part of the healthcare landscape transformation. In the right situations, when implemented properly and thoughtfully, point-of-care testing (POCT) can have a positive impact on operational efficiency and patient care. Additionally, having POCT test results captured in the EHR will allow for quicker diagnosis and treatment, automated billing, and inclusion of POCT data in valuable medical analytics. Orchard Software is here to help manage your organization's POC testing with Orchard[®] Trellis[™].

Instrument & Host Integration for Fast Result Delivery

With Trellis, POCT results are integrated into the EHR, promoting fast access and making results available for population health management. Orchard understands the complexities and challenges associated with POCT and offers a configurable solution to meet your specific POCT scenario, including working with your existing EHR, managing bedside testing, or managing near-patient testing in a clinic setting.

Simplification of POCT Administration & Management

Trellis simplifies the integration, administration, and management of point-of-care testing. It has flexible deployment options to address the complexities and diversity of POC testing and eases the workload for POC coordinators by providing remote access to manage POCT in multiple locations. With Trellis, administrators can manage devices, operator training and competency assessments, QC review, and more. In addition, Orchard's POCT solutions offer order entry, quality control, and result evaluation rules functionality, plus Levey-Jennings QC graphs and linearity reports.

Top Value Drivers of Trellis

- Manage POCT across diverse testing networks
- Simple personnel and certification management
- · Comprehensive instrument and host interfacing
- Order entry, quality control, and result evaluation rules functionality
- Quality control and linearity for POCT
- Comprehensive POCT reports and delivery
- Cost savings and improved patient care

Trellis is your solution for point-of-care testing of all shapes and sizes. For more information, please contact your Orchard Software Account Manager.



Trellis has flexible deployment options to address the complexities and diversity of POCT by providing remote access to manage POCT in multiple locations.

The Importance of an LIS Maintenance Plan for Future Success

As the healthcare terrain changes, what are your plans to ensure the future success of the laboratory and solidify the lab's value within your organization? In a "do more with less" world, are you maximizing the potential of your existing laboratory information system? As an Orchard Software client, you have the foundation in place to meet and overcome these challenges. The evolution of our software functionality directly relates to creating efficiencies and supporting the role of the laboratory as a diagnostic information hub. Taking full advantage of the software's tools is a vital way to increase the value of the laboratory within your organization.

Multiple Support Options Available

Orchard provides a variety of training and professional service options to assist in your continued LIS education. Of these, our most popular offerings include the Gold and Platinum support levels. In addition to our standard support offerings, Gold support offers a seat in Orchard's P.A.C.E.[®] accredited Advanced User Training Class for you or a member of your staff. Hotel accommodations, meals, and airfare for the training class are included with your Gold support package. During class week, you will receive hands-on experience using many of the database management and maintenance tools, and you will learn the newest features of the most current Orchard® Harvest[™] LIS version (v11) or Orchard® Copia® version (v7). This is also a valuable opportunity to network with other laboratorians in a shared-interest setting.

Premier-level Support: Platinum

Platinum is our premier level of service and support. It goes one step further by including a training seat plus one week of professional service time by an Orchard System Engineer. This time can be used for a variety of purposes, including evaluating the system and providing workflow and system refinement, additional system training at your facility, or assistance with building browsers. Whether your goal is system refinement, improved test utilization, adding a System Administrator, or <insert your personal LIS objectives here>, give your Orchard Software Account Manager a call at (800) 856-1948. They will be glad to discuss a solution best suited to your specific needs.



Where in the World is Orchy?

The last time we saw Orchard Software's famous mascot, Orchy, he was taking in the beautiful sights of the Pitons in St. Lucia. Orchy hiked through the rain forest, watched cascading waterfalls, and took in breathtaking views from the mountaintops. Not all of Orchy's time in St. Lucia was spent hiking the rain forest; sand has been found around Orchy's desk. Our friend found a beautiful beach where he let the sun take his winter blues away. (We don't blame him one bit.)

Congratulations, Karen!

Karen Eastin, LIS Manager of Blount Memorial Hospital Laboratory, correctly guessed Orchy's location of St. Lucia and the Pitons, winning the drawing for the Orchy prize package.

Orchy Learns a Legend

On Orchy's current adventure, he is learning the tale of Sang Nila Utama, a Malay prince who sailed across the seas to discover new lands. According to legend, while the prince was on an adventure, a sea creature appeared that had the head of a lion



On Orchy's current adventure, he is learning the legend of Sang Nila Utama.

and the tail of a fish. This inspired the prince to name his new island settlement "Lion City." Although the sea creature is just legend, Orchy learned that the city's half-lion half-fish guardian captures the essence and roots of this former fishing village. The lion head represents the name of the city and the fish tail embodies the hardworking people.

If you think you know where Orchy is located, please send your answer to **news@orchardsoft.com** by April 21st, 2017, in order to be eligible to win an Orchard prize package.

Rules Scheduler & New Result Evaluation Rules Action (Create Micro Report)

In Orchard® Harvest™ LIS 10.0.160405, two features were added that allow you to result and report out negative microbiology cultures automatically. One is Rules Scheduler, which allows you to set up result evaluation rules that run on a schedule versus each time a test is resulted. The other is "Create Micro Report," a result evaluation rule action that can add either a preliminary or final report to a culture. The driving force behind adding this feature was the desire to result and report negative blood cultures automatically, without user interaction.

Rules Scheduler Added to Table Setup Options

In Table Setup, there is now a "Rules Scheduler" button. Click this to open a table where you can create schedules

for result evaluation rules. For a result evaluation rule to be eligible for use by the Rules Scheduler, you must first select the "Run only on auto-run schedule" checkbox found at the top of the Rules – Result Evaluation table's edit rule window.

Once the checkbox has been selected, the rule will be visible in the Rules Scheduler table. When a result evaluation rule has this checkbox selected, the ability to use the "Associated Order Choices" tab is disabled, as this function will be performed in the Rules Scheduler table entry configuration. If an existing result evaluation rule is edited and the "Run only on auto-run schedule" checkbox is selected, all currently associated order choices in the Rules - Result Evaluation table are ignored.

Use Rules Scheduler to Schedule Result Evaluation Rules

After the appropriate result evaluation rules are set up, you can go to the Rules Scheduler table and create a schedule. Different schedules can be set up for different result evaluation rules. Each rule schedule will have a name and an assigned workstation to auto-run the schedule. Any workstation(s) assigned to auto-run a rules schedule must be turned on and running Harvest LIS for the schedule to process.

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To add a result evaluation rule to the Rules Scheduler table, select the "Run only on auto-run schedule" checkbox.

Click the "Edit Schedule" button to define the schedule. Available options are separated by tabs: Hourly, Daily, Weekly, Monthly, and Yearly. These are the same scheduling options available elsewhere in Harvest LIS and should accommodate any time frequency needs. Note that the lowest interval a schedule can run is every five minutes. Be aware of the time schedule and how it could affect time-sensitive checks.

Select Rules & Order Choices to Add to Scheduler

After the schedule has been set up on the Rules Scheduler table, you need to select which rules the schedule will run. Click the "Rules" button. Note that the only rules visible in this window are the ones that have the "Run only on auto-run schedule" checkbox selected. Finally, the associated order choices need to be defined. Click the "Order Choices" button and make the proper selections. Once the schedule is saved, it will be active and start checking the selected rules and order choices in the given interval. Rules set up to run on an auto-run schedule will only be evaluated during the auto-run process and will not be checked during normal rule evaluation processes, such as updating the results on a test. Note that when creating a new auto-run schedule, you should first run it in a test environment, as some actions still open dialog boxes that pause the auto-run process.

Add Reports to Micro Orders via Create Micro Report

The "Create Micro Report" action, added to result evaluation rules, allows you to add final and preliminary reports to micro orders. If an order does not meet the requirements to have a final report added, the report will be added as a preliminary report. This is an important point because if a rule is set up to be able to retrigger and this action cannot add the final report, it will continue to add a new preliminary report each time it triggers. This action is capable of running on auto-run rules.

Example for Negative Blood Cultures

By combining the use of these two new functions, your system can be configured to automatically result and report out negative blood cultures. The following example will result and report negative blood cultures at 24 hours, 48 hours, 72 hours, 96 hours, and 5 days.

Each rule is configured to trigger when the Current Date/Time is greater than the Collection Date/Time plus

X (where X is 24 hours, 48 hours, 72 hours, 96 hours, and 5 days). In the example, these rules have also been configured to change the order choice status of the blood culture to help track it through the workflow. Observe that a separate condition is included for the aerobic and the anaerobic bottles versus combining the conditions. This causes the conditions to be evaluated on an "AND" basis versus "OR" had they been combined. Also, notice that the 24-hours rule both adds the micro test "Result" and sets its value while the remaining rules simply set the value. Lastly, the 5-days rule is set to allow retriggering in case the culture is ineligible for a final report; instead, a preliminary report will be added every 24 hours until the culture is finalized.

Important Note: The "Result" test cannot be the test that is set as the "Default Isolate" for Microbiology. If the "Default Isolate" test is used, when the 24-hours rule runs, a dialog box will appear asking if you wish to assign an isolate number. This will prevent the rule process from continuing until the question is addressed.

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Using these two functions, in the example, negative blood cultures will auto-report at 24 hours, 48 hours, 72 hours, 96 hours, and 5 days.

Rules Scheduler

Continued from page 7.

Now that the result evaluation rules are configured, the Rules Scheduler table must be set up. In the example, the scheduler will run all five associated result evaluation rules every five minutes on blood culture samples. Those meeting the result evaluation rule criteria will be resulted as "No growth at X hours," will change order choice status, and will report out automatically. The following screenshots show the schedule setup, rule association, and order choice association:

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2: Rule association

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3: Order choice association

Contact Orchard Software Technical Support at (800) 571-5835 or support@orchardsoft.com for more information and/or assistance with setting up these or other rules on a schedule.

Spotlight On: Amanda Malek, Associate Director of Project Management



A manda has been with Orchard Software for three years. Prior to her current role as Associate Director of Project Management, Amanda worked as a System Engineer with a focus on microbiology, traveling around the country to work on large hospital installations.

Amanda's Background

Before starting at Orchard, Amanda worked for the Molecular Laboratory at Indiana University Health and also for Mid America Clinical Laboratories at St. Vincent Indianapolis Hospital. She is a graduate of Purdue University, where she earned a Bachelor of Science in Medical Laboratory Sciences. Amanda is currently enrolled at Indiana Wesleyan University, where she is working toward her MBA in Healthcare Administration.

For Fun

Amanda loves to travel, especially to the beach. Although very busy with school and work, she is planning on completing her first triathlon this summer! Her husband also works for Orchard as a System Engineer. The rest of their family resides in Wisconsin, where Amanda and her husband both grew up. Go Packers!

Featured ORC Question

Sign in to the ORC today and join the conversation!

Is it possible to create a browser filter for the order choice and results browser that lets me filter out everything not run on a specific day of the week over a period of time? (orc.orchardsoft.com/questions/56851507)

We just implemented that feature in Orchard[®] Harvest[™] LIS 11.161222. Here is a description of the new feature:

Added the ability to create browser and other filter conditions based on day of the week. When selecting a date column to filter on, valid comparison values now include Sunday, Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, Weekday, and Weekend. These comparisons may only be used with "Is equal to" and "Is not equal to" comparison options. These filter conditions will compare the day of the week for each date value and include the row if it equals (or does not equal, if selected) the specified day. Weekday will match on any date that falls on Monday through Friday, and Weekend will match on any date that falls on Saturday or Sunday.

Also added a new question mark icon next to the comparison field that will display an alert explaining the date comparison options when a date comparison is selected, or a more general explanation of the #Prompt# feature when any other type of comparison is selected.

The Questions area of the Orchard Resource Center (ORC) provides a forum for timely and detailed answers to your inquiries regarding Orchard's product line.

Navigate to orc.orchardsoft.com/questions to sign into the main Questions page, where you can browse existing questions or topics, and submit new questions. Searching for questions is as simple as typing the question or subject into the search bar of the main ORC page.

Questions are evaluated not just by Orchard staff, but also Orchard clients and other experts!

orc.orchardsoft.com/questions

Advantages of a Remote Backup

Remote Backup is a configuration that allows labs to run daily backups without disrupting laboratory workflow. This setup utilizes two servers with similar specifications running the same build of Orchard® Harvest™ LIS; one acting as the primary server to which clients connect, and one acting as the remote server where backups are stored. Because no backup is carried out on the primary server, the database remains permanently available to read/write. Servers may be either physical or virtual, but both must be the same type.

Eliminate Downtime While Adding a Redundant Server

In addition to eliminating lab downtime for backups, this configuration has the advantage of being able to use the remote server as the primary if the primary server fails for any reason or if there is an event such as a power outage or network disruption. Although failures are rare, the larger a database becomes, the more important it is to be able to recover quickly if needed. Note that this method is only available to labs using Harvest LIS v11 and later.

For more information, please call Orchard Software Technical Support at (800) 571-5835.

Harvest the power of Orchard's white paper series to help you demonstrate the value your laboratory provides.



The changes taking place in healthcare necessitate careful decisions about health information technology partners. As part of our ongoing efforts to support the laboratory community, Orchard Software offers an informative white paper series chock-full of the latest lab-related information you need to stay successful.

A "Must Read" for Laboratorians & Healthcare Leaders

If you are interested in learning about the laboratory's role in the changing healthcare environment, download Orchard's informative white papers at www.orchardsoft.com/whitepapers.

- The Value of the Lab in the New Healthcare Model
- The Value of Data in the New Healthcare Model
- Structured Data: Essential in Healthcare Analytics & Interoperability
- Effective Test Utilization: A Laboratory's First Step in Contributing to the New Healthcare Model
- Laboratory Informatics: Supporting the Future Needs of Healthcare
- Laboratory Point-of-Care Testing: A Future Outlook
- Laboratory Data Integration Driving Meaningful Medical Analytics
- Tulare County Public Health Lab's Lean Journey
- Molecular Informatics: Shaping Change in the Lab
- Point-of-Care Testing: The Great Boom Ahead
- Extending the Laboratory's Reach to Meet Healthcare's New Paradigm
- Total Cost of Ownership for a Laboratory Information System
- A Personal Journey: Understanding the Value of Medical Analytics

Call Orchard at (800) 856-1948 to learn more about our various lab information systems and how they can assist you in demonstrating your lab's value.

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2017 Orchard Software Event Calendar

Date	Trade Show/Event	Location
3/22 - 3/25/2017	AMGA	Grapevine, TX
3/26 - 3/29/2017	CLMA	Nashville, TN
4/5 - 4/8/2017	Symposium for Clinical Laboratories/COLA	Las Vegas, NV
5/4 - 5/5/2017	Clinical Laboratory Collaborative Conference (CLCC)	Northglenn, CO
6/11 - 6/14/2017	APHL Annual Meeting	Providence, RI
7/30 - 8/3/2017	AACC Clinical Lab Expo	San Diego, CA
8/8 - 8/10/2017	Allscripts Client Experience (ACE) Meeting	Chicago, IL
9/6 - 9/8/2017	ASCP	Chicago, IL
10/8 - 10/11/2017	CAP17-The Pathologists' Meeting	National Harbor, MD