July, 2022

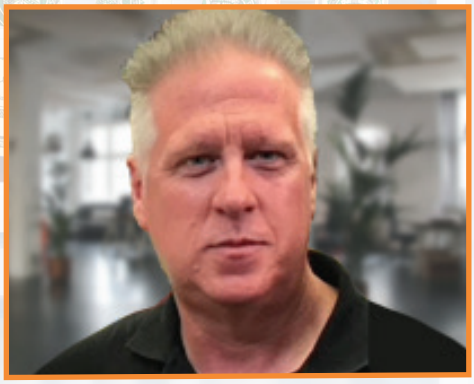
# LAByrinth

## Laboratory Billing, Revenue Cycle Management, and Industry Happenings

**July brings articles on diagnostic breath testing for COVID-19, SALSA, 2023 ICD-10, Monkeypox, and more.**

## This Month's Message from Jim:

The consensus of the laboratories I work with, and through a recent NILA presentation, collections have decreased approximately 5% - 6% thus far in 2022 vs. 2021 due to the large number of **patients moving to Advantage Programs**.



**Jim O'Neill**
*Sales Manager, Laboratory Services*

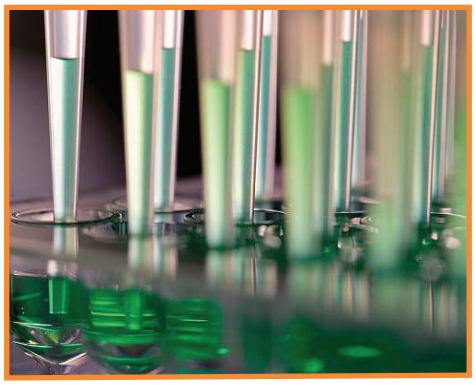
Pain points noted include:

1. Advantage programs have **increased 12%** since 2020
2. More Medicare and Medicaid patients are **moving away** from traditional plans
3. Laboratories are getting **old Insurance information from referring physicians instead of the correct,** updated Advantage coverage
4. **Patients are getting confused** with their new Advantage plans once they start using the coverage
5. **Patient statement revenue has recently decreased** for most laboratories on the call, some thinking inflation was involved

The good news is **ADS RCM is adept at laboratory claims and billing for Advantage programs**. Our **eligibility verification** will detect coverage in advance of tests being performed, and our **insurance discovery** option can be used to **capture the correct coverage** if necessary. Patient responsibility amounts are displayable in advance helping ensure balances are successfully paid, and that doing so through our **mobile online payment** utility helps to complete the circle.

All in all, you'll be in great hands with ADS RCM on Advantage plans, and really, any plans!

# CMS Coverage Transparency: the Final Rule is Final



CMS' Transparency in Coverage final rule took effect July 1. It requires payers nationwide to publish the cost of nearly every healthcare service they've negotiated with providers, including for **laboratory services**.

- ✓ Originally set to take effect Jan. 1, CMS delayed it for six months over concerns with the time and effort it would take payers to come into compliance with the new policy.
- ✓ The rule requires payers to disclose **in-network** provider rates for covered items and services, **out-of-network** allowed amounts and billed charges for all covered items and services, and **negotiated rates and historical net prices** for covered prescription drugs administered by providers.
- ✓ Prices **must be posted** in **machine-readable files** containing the following sets of costs for items and services:
  - **In-network rate file:** rates for all covered items and services between the payer and in-network providers.
  - **Allowed amount file:** allowed amounts for and billed charges from out-of-network providers.
- ✓ Payers not in compliance could face **fines of up to $100 per day for each violation** and for **each individual affected** by the violation.

So, all of your payers should have their rates published by the time you read this. Click *here* or copy/paste *https://www.cms.gov/healthplan-price-transparency for details and additional information*.

# FDA's Authorized Diagnostic Breath and Genotyping Tests for SARS-CoV-2

A SARS-CoV-2 diagnostic test that **analyzes breath samples**, as well as a **genotyping test** authorized for the identification and differentiation of SARS-CoV-2 Phylogenetic Assignment of Named Global Outbreak (PANGO) lineages, have been granted emergency use authorization (EUA) by the U.S. Food and Drug Administration (FDA).

The EUAs were issued for each individual test with **certain conditions of authorization** required of the manufacturer, and the **types of location required** for use of the test:

- ✓ Authorized for use on April 14, 2022, the InspectIR COVID-19 Breathalyzer can be used to test **exhaled breath** from individuals **18 years** and older **with or without symptoms** or other **epidemiological reasons** to suspect COVID-19.

  Use of the InspectIR COVID-19 Breathalyzer is restricted to qualified, trained personnel working under the **direction of a medical professional** who's licensed or permitted by state law to order tests. Additionally, it is only permitted to be used in settings where patient **specimens are collected and analyzed**.

- ✓ On June 10, 2022, the FDA granted EUA status to the Labcorp VirSeq SARS-CoV-2 NGS Test, a sequencing test on the PacBio Sequel II sequencing system, designed for the **identification and differentiation** of SARS-CoV-2 PANGO lineages from SARS-CoV-2-positive samples discovered using the Labcorp COVID-19 RT-PCR Test or Labcorp SARS-CoV-2 & Influenza A/B Assay. *Click* or copy/paste *https://www.fda.gov/medical-devices/coronavirus-diease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2* for details.

## A Hot Topic for Laboratories: SALSA (the Saving Access to Lab Services Act)

Great news for community and regional independent laboratories comes in the form of SALSA which **protects them from Draconian reimbursement cuts** in 2023 and beyond, thanks to action taken by a bipartisan group of legislators working together on this issue.

Specifically, Senators Sherrod Brown (D-OH) and Richard Burr (R-NC) and Representatives Gus Bilirakis (R-FL), Richard Hudson (R-NC), Bill Pascrell (D-NJ), Scott Peters (D-CA), and Kurt Schrader (D-OR) introduced SALSA as a way to fix what was flawed data reporting and rate setting methodologies arising from the Protecting Access to Medicare Act (PAMA) of 2014.

SALSA is asking to (1) amend title XVIII of the Social Security Act to **improve the accuracy of market-based Medicare payment** for clinical diagnostic laboratory services, and (2) **to reduce administrative burdens** in the collection of data, and for other purposes.

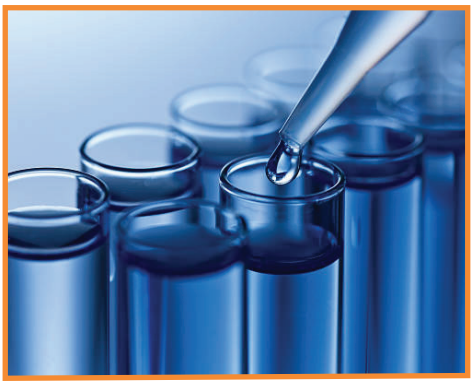
A few modifications SALSA addresses include changing the use of statistical sampling for widely available clinical diagnostic laboratory tests from January 1, 2023 to beginning on or after January 1, 2026. Also, in lieu of requiring the reporting of applicable information from each applicable laboratory, "the Secretary shall require the collection and reporting of applicable information from a statistically valid sample of applicable laboratories for each such widely available clinical diagnostic laboratory test."

To meet this requirement, it is recommended the Secretary develop a methodology for a statistically valid sample for each applicable HCPCS code for a widely available clinical diagnostic laboratory test. This methodology would provide a sample that allows for the payment amount for such a test to be **representative of rates paid by private payers to applicable laboratories receiving payment including independent laboratories, hospital laboratories, and physician office laboratories that furnish** the widely available clinical diagnostic laboratory test.

The definition of "widely available clinical diagnostic laboratory tests" would be a payment rate of **under $1,000 per test** and performing **more than 100 tests** in the first 6 months of the calendar year preceding the data collection period. SALSA is also recommending a reporting period frequency of **every 4 years** rather than every 3 years.

Additionally, SALSA is requesting the **exclusion of manual remittances**. This is defined as an applicable laboratory for which **less than 10%** of the laboratory's total paid claims during a data collection period are paid by private payers by means other than an electronic standard transaction. Please click KEL22338 (nila-usa.org) or copy and paste it to see the entire SALSA text.

## VALID Act Concerns: ASM Advocates for Specific Amendments



On the heels of an article in the June, 2022 edition of LAByrinth, the American Society for Microbiology (ASM) has expressed concerns to the Senate's Health, Education, Labor, and Pensions (HELP) Committee about the recent Verifying Accurate Leading-Edge IVCT Development (VALID) Act released as part of a legislative package on May 17, 2022.

This if passed, this legislation **could have a major impact** on clinical microbiology laboratories. ASM has been working independently with other laboratory associations and organizations to express **strong opposition to provisions in the bill**, which is part of the FDA's Landmark Advancements Act (FDASLA).

VALID would create a new category of in-vitro clinical tests (**IVCTs**) that includes test kits and laboratory-developed tests (**LDTs**), and it would give the FDA the authority to review and approve these tests before they go on the market. ASM released a statement to Congress on May 22, 2022, urging the HELP Committee to address its concerns before advancing the bill as part of the FDASLA.

An excerpted statement from ASM to the HELP committee noted, "We urge you to amend the draft legislation to **alleviate the financial, regulatory and administrative burdens** found within the VALID Act that would, among other aspects of the bill, **be detrimental to infectious disease diagnostic testing and laboratory capacity throughout the nation.**"

The VALID Act would require laboratories to **register all LDTs within a year**. ASM noted this additional requirement would place a **severe strain on laboratories** that **don't have the resources or capacity to respond to such demands** for both grandfathered and new tests.

ASM suggested a longer, **three-year schedule** to enable laboratories enough time to complete LDT registration for complying with these new criteria. ASM also recommended using an **electronic, internet-based test menu** to condense data making the process even more effective. Click *https://asm.org/Articles/Policy/2022/-May-2022/VALID-Act* or copy and paste to see the actual ASM article.

## 2023 ICD-10-CM Files Now Available

2023's ICD-10-CM files in the link below contain information on code updates for FY 2023. They're to be used **both for discharges and patient encounters** occurring from October 1, 2022 through September 30, 2023.

Note: **ADS RCM** and our MedicsRCM service has clients covered on these codes.
*https://www.cms.gov/medicare/icd-10/2023-icd-10-cm*

## Monkeypox Vaccine Strategy

The Administration announced the first phase of its national monkeypox vaccine strategy, a critical part of its monkeypox outbreak response, according to a news release. The vaccine strategy will help immediately address the spread of the virus by providing vaccines across the country to individuals at high risk. This phase of the strategy aims to rapidly deploy vaccines in the most affected communities and mitigate the spread of the disease.

Making Testing Easier: The new national monkeypox vaccine strategy builds on the Administration's efforts to make testing more widely available and easier to access. On day one of this outbreak, providers had access to a high-quality, FDA-cleared test to detect monkeypox. Last week, CDC began shipping tests to five commercial laboratory companies, including some of the nation's largest reference laboratories, to further increase monkeypox testing capacity and access in every community. This action will dramatically improve convenience for patients and healthcare providers across the nation.

In the coming weeks, HHS expects to receive an additional 240,000 vaccines, which will be made available to a broader population of individuals at risk. HHS will hold another 60,000 vaccines in reserve.

As additional doses are received from the manufacturer, HHS will make them available to jurisdictions to expand availability to the vaccine for individuals with elevated risk. HHS is increasing the availability of doses by leveraging its long-standing partnership with the manufacturer of JYNNEOS to expand vaccine supply and by accelerating completion and shipment of doses to the United States. HHS expects more than 750,000 doses to be made available over the summer. An additional 500,000 doses will undergo completion, inspection, and release throughout the fall, totaling 1.6 million doses available this year.

Click *here* or copy and paste: *FACT SHEET: Biden-Harris Administration's Monkeypox Outbreak Response | The White House* for full details.

## NIH scientists discover norovirus and other "stomach viruses" spread through saliva

Researchers have known for some time that enteric viruses, such as noroviruses and rotaviruses, can spread by eating food or drinking liquids contaminated with fecal matter containing these viruses.

A class of viruses known to cause severe diarrheal diseases – including the one famous for widespread outbreaks on cruise ships – can grow in the salivary glands and spread through their saliva, scientists at the National Institutes of Health have discovered, according to a news release.

The transmission of these so-called enteric viruses through saliva suggests that coughing, talking, sneezing, sharing food and utensils, and even kissing all have the potential for spreading the viruses.

The findings, which appear in the journal Nature, could lead to better ways to prevent, diagnose, and treat diseases caused by these viruses, potentially saving lives. The study was led by the National Heart, Lung, and Blood Institute (NHLBI), part of NIH.

"This is completely new territory because these viruses were thought to only grow in the intestines," said senior author Nihal Altan-Bonnet, PhD, Chief of the Laboratory of Host-Pathogen Dynamics at the NHLBI. "Salivary transmission of enteric viruses is another layer of transmission we didn't know about. It is an entirely new way of thinking about how these viruses can transmit, how they can be diagnosed, and, most importantly, how their spread might be mitigated."

Click *here* or copy and paste for the complete article: *NIH scientists discover norovirus and other "stomach viruses" can spread through saliva | National Institutes of Health (NIH)*

# Noridian News

The following will be of interest if you work with Noridian, but it's suggested that everyone glance through this since MACs generally pick up on each other, in a manner of speaking.

Medicare Jurisdiction E Part B Updates, Subscribed Interests

- ✓ MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease LCD Title (L36180)- 11 - Effective June 30, 2022

  This Local Coverage Determination (LCD) has been revised under contractor numbers: 01112 (NCA), 01182 (SCA), 01212 (AS, GU, HI, and NMI), and 01312 (NV).

- ✓ MolDX: DecisionDx-UM (Uveal Melanoma) LCD (L37070) - R6 - Effective June 30, 2022

  This Local Coverage Determination (LCD) has been revised under contractor numbers: 01112 (NCA), 01182 (SCA), 01212 (AS, GU, HI, and NMI), and 01312 (NV).

- ✓ MDS FISH LCD (L37620) - R5 - Effective June 30, 2022

  This Local Coverage Determination (LCD) has been revised under contractor numbers: 01112 (NCA), 01182 (SCA), 01212 (AS, GU, HI, and NMI), and 01312 (NV).

- ✓ The following Local Coverage Determination (LCD), associated Billing and Coding Articles (LCA) and Response to Comments have been retired under contract numbers: 01112 (NCA), 01182 (SCA), 01212 (AS, GU, HI, and NMI), and 01312 (NV).

- ✓ Billing and Coding: MolDX: DecisionDx-UM (Uveal Melanoma) (A57621) R3 - Effective June 30, 2022

Recent Announcements Published to "Latest Updates"

- ✓ Noridian Medicare Portal - Removing Voice Call Option for MFA - July 1, 2022

  Effective July 1, 2022, Noridian Medicare Portal users will no longer have the option to have a voice phone call to receive the Multi-Factor Authentication (MFA) passcode when logging in. The email and text option will continue to be available.

- ✓ RARC, CARC, MREP and PC Print Update CR12774

  CR 12774 tells you about the latest update of the Remittance Advice Remark Code (RARC) and Claims Adjustment Reason Code (CARC) code sets.

- ✓ Changes to the Laboratory NCD Edit Software for October 2022 CR12803

  CR 12803 tells you about changes to the Laboratory National Coverage Determination (NCD) Edit Module for October 2022.

- ✓ MLN Connects - June 30, 2022

CMS has made available the latest edition of the MLN Connects.

- ✓ Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2 - Revised CR12723

  CR 12723 tells you that CMS updated the Medicare coverage for pneumococcal vaccinations to align with the Advisory Committee on Immunization Practices (ACIP) recommendations.

- ✓ Claims Processing Instructions for the New Hepatitis B Vaccine Code 90759 CR12686

  CR 12686 provides instructions to update the Common Working File (CWF) and the Fiscal Intermediary Shared System (FISS) to include the new Hepatitis B vaccine code. ICD-10 and Other Coding Revisions to NCDs - July 2021 - Revised CR12124

  CR 12124 tells you about updates of International Classification of Diseases, 10th Revision (ICD- 10) conversions and other coding updates specific to National Coverage Determinations (NCDs).

- ✓ Internet Only Manual Update to Publication 100-04, Chapter 16, Sections 70.5, 70.8, and 70.9 to Remove References to the CLIA Files CR12766

  CR 12766 revises the claims processing manual, publication 100-04, chapter 16, sections 70.5, 70.8, and 70.9.

noridian
Healthcare Solutions

## Did You Know?

Did you know that Targeted Probe and Educate (TPE) is resuming? Visit the Noridian Medicare Website for more information and upcoming webinars. Additional information can be found on the CMS website at Targeted Probe and Educate | CMS

Visit *medweb@noridian.com* for more information and links to their complete updates.

## Laboratory Revenue Revue

We've presented food for thought on some recent top issues involving laboratories.

But **getting paid** can't be overlooked; if you're not generating the revenue needed for your laboratory to survive, you could say **nothing else matters**.


Yet, simply "getting paid" in itself **isn't even enough**. You'll want to be paid **as thoroughly and as much as possible** both from your **insurance payers and patients**. First, an extraordinary return is realized when your laboratory's claims are (1) at **maximum value per payer** with (2) a **nearly 100% success rate** on first attempt submissions. Completing the circle is when the bulk of your **patient A/R** is paid within 45 days.

And then, you'll want that incoming maximized revenue to resonate even more through **in-house staff consolidations** and a reduction, if not

a complete **elimination of current technology costs**.

If you're thinking, "this pie-in-the-sky premise all sounds great but how can it be done?" look to **MedicsRCM**.

Off the bat MedicsRCM has such a **remarkable record for increasing laboratory clients' revenue by 10% - 20%**, we'll actually **guarantee** to increase yours in **90 days** over whatever system or service you're currently using.

Laboratory claims are submitted with a nearly 100% first attempt success rate, again optimized for maximum reimbursement without over-coding. Our Denial Preventer® avoids a majority of denials proactively; others are edited and resubmitted within 72 hours. And we have dynamic tools for ensuring patients pay their balances on time.

Our +300 person outsourced workforce alleviates clients' staffing issues, helping to consolidate those costs as well. And the system we use, MedicsPremier from ADS, is available at no additional cost eliminating any support or hosting fees you might be paying now.

MedicsRCM is a transparent, on-demand service enabling you to view all of your data at any time. Clients are encouraged to do so, to the extent they want, including an ability to compile and generate their own reports, analytics, KPIs, and dashboards with exportability to Excel. The MedicsRCM team routinely compiles reports and reviews them as well with clients.

We can interface with virtually any LIS, LIMS, EHR, HIS, and G/L system.

When factoring revenue increases, staffing consolidations, and zero technology costs, we almost always become a no cost service to clients!

You're encouraged to call **844-599-6881** or email rcminfo@adsc.com to see how we can help your laboratory be more profitable, and operate at peak efficiency.

## November AMP Conference, Phoenix AZ

If you're attending, visit us at **booth 1003**. That'll be another great way to connect!

**Advanced Data Systems RCM**

The ADS Building, 15 Prospect Street, Paramus, NJ 07652

844-599-6881 • rcminfo@adsc.com • www.adsc.com