May, 2024

LAByrinth

Industry, Billing, and Operational News for Laboratories

- Presented by ADSRCM and our MedicsRCM Services for Laboratories to Drive Revenue, Productivity, Staffing, and Workflow -

Message from Jim:

Jim O'Neill
Sales Manager, Laboratory Services

It was great meeting so many laboratorians at the Executive War College (EWC) conference in New Orleans.

Reflecting on the insights gained, it's evident that the laboratory industry is undergoing transformative changes.

Feeding off that energy, we're fired up and ready to help propel laboratories towards greater profitability and efficiency with our cutting-edge, outsourced RCM & Billing Services, or with the MedicsPremier system for laboratories that prefer to use an in-house platform.

I hope you enjoy the rest of the read as we look forward to staying in touch!

The LDT Discussion Continues

The ADLM (formerly AACC) has submitted testimony to Congress opposing the FDA's position on the proposed laboratory-developed testing (LDT) rule. The VALID Act would give the FDA legal authority to oversee LTDs.

The testimony's essence is that LDTs are already tightly enough overseen by CMS (CLIA) without needing even more micromanagement by the FDA. This could severely impact the development of LDTs, ultimately to the detriment of those who'd benefit the most: patients.

Click here for the ADLM release and details on their Congressional testimony. If you're so inclined, you should contact your representatives in DC to express your opinion.

23ANDME, 23AND*YOU*

23ANDME recently announced that unauthorized access to millions of its customers' personal information may have started five months earlier than previously reported.

The consumer genetics company uses customers' DNA to provide them with family histories and origins and to identify family members who may have been unknown to those customers. The company also provides health information based on customers' DNA.

The data breach consisted of customers' names, DOBs, familial information, and customers' self-reported locations.

Info on the breach can be found by visiting www.23andme.com.

Clinical Laboratory Directors: A New Role Play

If you have a Doctorate in Clinical Laboratory Sciences (DCLS), CMS says you can now be the director of a high-complexity laboratory. However, CMS' final rule on this has prompted questions from laboratory associations, including the Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) and the American Society for Microbiology (ASM).

Both ADLM and ASM expressed hesitating opinions in that this wasn't delved into enough, and how the decision to allow it was made without being formally endorsed by the Clinical Laboratory Improvement Advisory Committee (CLIAC), which typically advises on such policies.

For that reason, ADLM and ASM have asked CMS to hold a public forum conducted by CLIAC to address questions about qualifications for high-complexity laboratory directors. Both laboratory organizations suggested that forum attendees include the CMS certifying boards, accrediting organizations, other relevant professional societies, and even the three universities that office DCLS degrees.

Click here for details from CMS.

Medicare Meeting on Clinical Diagnostic Laboratory Tests

Speaking of CMS public forums, CMS has announced a meeting notice for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel). It's scheduled for Thursday, July 25, 2024, from 10:00 a.m. to 4:00 p.m., Eastern Daylight Time (E.D.T.), and Friday, July 26, 2024, from 10:00 a.m. to 4:00 p.m., E.D.T.

The discussion aims to advise the Secretary of the Department of Health and Human Services and the Centers for Medicare & Medicaid Services Administrator on issues related to clinical diagnostic laboratory tests.

The Panel is also expected to participate virtually in the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting for Calendar Year (CY) 2025 on Tuesday, June 25, 2024, to gather information and ask questions to presenters.

The teleconference dial-in instructions and session details will be available on the CMS website approximately two weeks before the meeting at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

Click here for Federal Register details.

Laboratory Fraud Article of the Month

Amazingly, the labfraudatory stories keep on coming. Each one seems harder to believe than the one before it, and this one is no different.

How can a simple over-the-counter COVID-19 testing kit catalyze a $30 million Medicare fraud scheme? When a bad actor laboratory bills Medicare for enough of them when they were ineligible for reimbursement in the first place. Genetic testing kits were also involved.

Here's how this one went: the FL laboratory owner and his co-conspirators purchased Medicare Beneficiary ID numbers unlawfully, and then used those numbers to bill Medicare for the over-the-counter test kits to the tune of $30 million in fraudulent claims, of which Medicare reimbursed $15 million.

Indeed, those involved must've wondered, "How will we ever be caught?" Well, the FBI and HHS-OIG were the investigating agencies; he pleaded guilty and faces five years when sentenced on June 20.

Click here for the DOJ's details on the case.

<<<<< >>>>>

Next up:
June with new articles and items of interest for laboratories of every type and specialty.

Contact us at 844-599-6881 or email rcminfo@adsc.com for more about our outsourced MedicsRCM services for your laboratory and our guarantee to increase your revenue in 90 days, or about the MedicsPremier platform implemented on your server or our cloud if an in-laboratory system is preferred.

Feedback or comments on our newsletters/content are greatly appreciated. Please opine by emailing marc.klar@adsc.com or by calling me at 973-931-7516. I would love to hear from you!
-Marc E. Klar, Vice President, Marketing, ADS RCM.

Advanced Data Systems RCM
The ADS Building, 15 Prospect Street, Paramus, NJ 07652
844-599-6881 • rcminfo@adsc.com • www.adsc.com