LAByrinth

Industry, Billing, and Operational News for Laboratories

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



This Month's Message from Jim

Medicare's Good News/Bad News: HbA1c Tests Approved/Final Rule Cuts Pathology 2%-3% for 2024

First, seeing so many clients at our AMP conference display (booth 702) in Salt Lake City, in sessions, and in "out and about" settings was great. Speaking with you about the laboratory landscape is always illuminating, and being able to help you overcome obstacles is rewarding.

Now, the good news/bad news details:

HbA1c testing (83036) is now Medicare-approved for diabetes screening which means easily over \$100 million in revenue for labs. Current Part B coverage includes the fasting plasma glucose test (82947) and the glucose tolerance test.

With the HbA1c test (83036) being approved as part of the 2024 Medicare Physician Fee Schedule Rule, the very significant revenue noted above can be expected by laboratories that perform those tests.

Now, the bad news: the same 2024 fee schedule rule will cut pathology reimbursement rates by 2% - 3% next year. Biblically, it could be "Medicare giveth, and Medicare taketh away."



Jim O'Neill
Sales Manager, Laboratory Services

Specifically on the "taketh away," CPTs 88305, 88307, 88331, and G0416 will decrease by the stated percentages. Blame the adjustment factor of 3.4% (\$32.74) for this. Might there be a last-minute fix? Yes, but if that happens, it would likely be a reduction in the 3.4%, not a complete elimination of it. But anything helps.

We're on top of the laboratory codes noted above, so you don't have to "chapter and verse" them. And that we'll continue to ensure your claims are maximized for the best results possible.

Give me a call to talk more about how we can help you!

LDTs and FDA, Continued

Following up from last month's article about LDTs (laboratory-developed tests) and the FDA, the FDA has now announced that the standard 60-day comment period for its proposed regulation of laboratory-developed test (LDTs) will not be extended past December 4.

This was announced despite groups, including CAP and ACLA, having requested to extend the comment period to 120 days, potentially delaying the rule's implementation while giving Congress more time to pass LDT reform legislation.



Without the extension, the FDA has indicated that a final rule could be published as early as April 1, 2024. The basis of the rule is to help ensure the safety and effectiveness of LDTs.

<u>Click here</u> for all the details and ramifications of the FDA's proposed LTD rules.

Blocking Information Blocking

What's this all about? A patient's medical information isn't supposed to be blocked by those authorized to access it. It's one of the basic tenets of the 21st Century Cures Act, where caregivers across the patient's healthcare continuum can all see what's going on with that patient.

And because a primary tool in this is the EHR, the EHR must be 21st Century Cures Act-certified.

So, "blocking information blocking" is what should happen: information blocking should be blocked. And that's why disincentives have been proposed by HHS if/when the OIG determines that information blocking is taking place:

- ✓ Under the Medicare Promoting Interoperability Program, an eligible hospital or critical access hospital (CAH) would not be a meaningful electronic health record (EHR) user in an applicable EHR reporting period. The impact on eligible hospitals would be the loss of 75 percent of the annual market basket increase; for CAHs, payment would be reduced to 100 percent of reasonable costs instead of 101 percent.
- ✓ Under the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), an eligible clinician or group would not be a meaningful user of certified EHR technology in a performance period and would therefore receive a zero score in the Promoting Interoperability performance category of MIPS, if required to report on that category. The Promoting Interoperability performance category score typically can be a quarter of a clinician or group's total MIPS score in a year.
- ✓ Under the Medicare Shared Savings Program, a healthcare provider that is an Accountable Care Organization (ACO), ACO participant, or ACO provider or supplier would be deemed ineligible to

participate in the program for at least one year. This may result in a healthcare provider being removed from an ACO or prevented from joining an ACO.

These proposed penalties can be fairly severe, but are easily avoidable when using platforms that promote interoperability and which are certified for the Cures Act, as is the MedicsCloud EHR from ADS.

<u>Click here</u> for HHS details on the above.

Late Breaking, Somewhat Good News on a PAMA Update

Both chambers of Congress have passed H.R.6363, titled the "Further Continuing Appropriations and Other Extensions Act, 2024." It's expected to be signed into law at any moment, and may have already been by the time you've read this.

Thumbnail "yay" details are:

- ✓ no PAMA payment reductions to the Clinical Laboratory Fee Schedule for 2024
- ✓ payment reductions of up to 15% for codes that have not reached the first reporting period's weighted median price are delayed until 2025
- ✓ the next PAMA reporting period for applicable laboratories is delayed by one year, meaning the next reporting period will now be January 1, 2025, through March 31, 2025

Presumably, we can *assume* this will happen. CMS is expected to distribute further information in the coming weeks.

Click here for details from congress.gov.



November Laboratory Fraud Story

Amazingly or unfortunately (or both), there's no shortage of laboratory fraud articles; it's been easy to do at least one new story each month in LAByrinth, and November is no exception.

The President of a Silicon Valley is going to federal prison for eight years and was ordered to pay \$24 million in restitution after being convicted in a scheme involving COVID-19 and allergy tests. He was found guilty of multiple charges, including conspiracy, health care fraud, illegal kickbacks, and securities fraud.

Are you ready?

Prosecutors said he defrauded investors by claiming he invented a revolutionary technology to test for virtually any disease using a single drop of blood from a finger stick sample, that he self-proclaimed himself to be the "father of microarray technology," that he was shortlisted for the Nobel Prize, and that his company could be valued at \$4.5 billion. Prosecutors said his financials actually revealed the company was on the verge of bank-ruptcy.

Along the way, prosecutors said he orchestrated an illegal kickback scheme submitting fraudulent claims to Medicare and private insurance companies for unnecessary allergy testing. The company then ran allergy screening tests on every patient for 120 different allergens, regardless of medical necessity.

Prosecutors noted his company billed more per patient to Medicare for blood-based allergy testing than any other laboratory in the country. They also said he launched a deceptive marketing scheme that falsely claimed Dr. Anthony Fauci and other officials mandated testing for COVID-19 and allergies at the same time and required patients receiving his COVID-19 test to be tested for allergies.

More than \$77 million in claims were submitted in claims for COVID-19 and allergy testing, according to prosecutors.

According to the report, prosecutors said this was the first criminal securities fraud case related to the COVID-19 pandemic charged by the Justice Department, and the first criminal COVID-19 health care fraud case brought to trial.

<u>Click here</u> for the details from the US Attorney's office in northern CA.

Thanksgiving Future or Past from Everyone at ADSRCM

In a press release dated 10/3/23, the US Attorney's Southern District (FL) Depending on when you're reading this, (a) best wishes for a happily reflective Thanksgiving, or (b) we hope you had a happily reflective Thanksgiving!



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Next up: December's edition with items and articles of end-of-year interest to laboratorians.

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.

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