LAByrinth

INDUSTRY, BILLING, AND OPERATIONAL NEWS FOR LABORATORIES

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

A Message from Jim:

Ford had LTDs. Laboratories have LDTs.

The FDA submitted its final rule for regulating laboratory developed testing (LDT) on March 1. To whom was it submitted? The OIRA, aka, the Office of Information and Regulatory Affairs. OIRA (pronounced "oh eye rah" not "oy rah"). It won't take long: the final rule on LDTs could be published as soon as April 1.

Without a doubt, this will be the most impactful new regulatory change for laboratories since PAMA in 2018. Once the final rule is published it will be difficult to overturn. At stake is the question about whether or not the FDA gets to regulate LDTs.

If the FDA gets control, it will almost assuredly result in a lawsuit from laboratory associations about the FDA not having the authority to regulate LDTs.
An ARUP Laboratories survey showed that almost 80% those who responded said they don't have the financial resources to pay FDA's user fees to get their LDTs cleared. What are those fees for 2024? $21,760 per moderate risk submission and $483,560

FDA user fees for 2024 are $21,760 per "moderate risk" 510(k) submissions and $483,560 per "high-risk" premarket authorization submission. 3% of respondents said they could pay. The rest said they didn't know if they could. But even if all of them could, it still remains that 80% of laboratories said they wouldn't be able to afford the FDA's fees.

What'll happen if the final rule is in favor of the FDA? No doubt almost all of the 80%, if not all of them, would remove any or all tests from their rosters.

Time is short. You're encouraged to be in touch with your representatives in DC if you're so inclined to express your opinion on how they should react to the FDA and LDTs. My guess is you don't want laboratories' LDTs to go the way of Ford's LTDs.

Jim O'Neill,

Sales Manager,
Laboratory Services

ADVANCED DATA SYSTEMS RCM

MARCH 2024

United Healthcare (UHC) and Z-Codes

If you're reading this you must know about UCH and the cyberattack on Change Healthcare (CHC). If you happen to not know, click here.

Even with UHC's ongoing issues, it appears their Phase 1 Z-Code requirement will still begin on April 1. That being the case, UHC's commercial plans will require DEX Z-Codes for certain molecular diagnostic test services on facility and professional claims. If not, those claims won't be eligible for reimbursement.

What will Phase 1 Cover?

Z-coding will affect 133 CPT codes as well as 104 proprietary lab analysis (PLA) codes including:

- Adult molecular diagnostic tests relevant to Medicare age population, except inherited cancer testing
- Prenatal carrier screening tests
- Specific services billed under CPT 81479 (Unlisted molecular pathology procedure), including:
  - Genetic disease carrier status for procreative management
  - Pharmacogenomics testing (PGx), including single-gene and multi-gene panels

UHC had stated that Z-code requirements will expand to additional tests later in 2024.

So, assume you'll need to be ready with the required Z-coding for UHC claims on – ***no fooling*** – April 1.

ADSRCM will ensure your UHC claims have Z-coding where needed, assuming they are needed!

CLIA Advisory Committee Meeting: Your Virtual Seat is Available

It's not just "let's get together and meet." The CLIA Advisory Committee is required to meet as per the Federal Advisory Committee Act; the meeting was called for by the CDC.

It will be virtual and is open to the public although the caveat is it's only limited to the number of webcast lines available. Ideally, everyone who wants to participate will be able to attend. The format will allow time for public comment and written comments can be submitted in advance.

It's an all-day event from 10:00 a.m. to 6:00 p.m. on April 10, although meeting times are tentative and subject to change. Confirmed meeting times, agenda items, and meeting materials, including instructions for accessing the live meeting broadcast, will be available on the CLIAC website at https://www.cdc.gov/cliac. Instructions are to check the website on the day (or morning) of the meeting for the web conference link.

Reportedly, the agenda will include agency updates from CDC, CMS, and FDA. Presentations and Advisory Committee discussions will focus on areas such as the applicability of CLIA personnel requirements to pre-analytic testing, the role of artificial intelligence and machine learning in the clinical laboratory, and the use of clinical standards to improve laboratory quality. As mentioned, agenda items are subject to change as priorities dictate.

If reading the Federal Register is your thing, then by all means **click here** and enjoy!

LabFraudAtory Article of the Month

And amazingly, the frauds keep on coming.
This one's an indictment, so no finding or admission of guilt (yet). It involves a federal grand jury in NJ indicting a physician for allegedly submitting over $20.7 million in false Medicare laboratory claims including for expensive cancer genetic tests.

The doctor allegedly received kickbacks from laboratory representatives for approving test orders, including for unnecessary cancer genetic tests that patients didn't request or need as part of their treatment. Also included were Medicare claims for visits that never happened. And to complete his circle, the allegations continue with DME and ordering orthotic braces that were medically unnecessary/ ineligible for reimbursement.

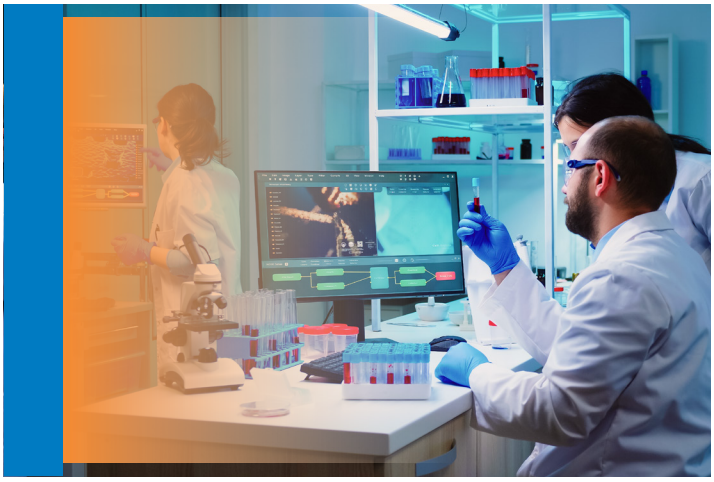
If convicted, the 68 year-old doctor is looking at a maximum of ten years for each of ten counts of conspiracy to commit healthcare fraud, and five years each on an assortment of other charges.

Investigating are the HHS-OIG and FBI.

Click here for the Justice Department's details.

Office of Public Affairs
U.S. Department of Justice

Next Up:
April Newsletter with new articles and items of interest for laboratories of every type and specialty.



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Feedback or comments on our newsletter 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, ADSRCM.

We look forward to being in touch!

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