July, 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:

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The CDC has revised its website for your reading and perusaling (I made up that word) pleasure.

Spurred on by the pandemic, the CDC's "Moving Forward" effort let to numerous initiatives to enhance the speed and clarity of the agency's communications. Newly streamlined, the website results from extensive user testing and feedback, all to help ensure that vital health information is more accessible and easier to find for providers, laboratorians, clinicians, and patients.

To that end, improved content is now labeled by audience, and is designed to produce a better user experience overall. The CDC said website content was streamlined by over 65% to make it easier for users to find the information they need and for patients to make informed decisions about their health.

The streamlined content itself has been simplified to meet user needs better.

You'll now see feedback from over 3,000 users during a March beta preview, during which the public was invited to provide input before the launch. Throughout 2024, expect the CDC to continue improving and optimizing its web content.

Visit www.CDC.gov and see what you think! Click here for their press release.

I hope you enjoy the rest of the read!

HHS and the Proposed HTI-2 Rule

A new HHS-proposed rule has been put out for public comment. Luckily, it has an easy to remember name: the Health Data, Technology, and Interoperability Patient Engagement, Information Sharing, and Public Health Interoperability rule, acronymed to the HTI-2 Rule.

HTI-2 has two sets of new health IT certification criteria: one for public health and the second for health IT for payers to be certified under the ONC Health IT Certification Program. Both would improve public health response and advance value-based care delivery, with an eye toward application programming interfaces (APIs), facilitating interoperability between healthcare providers and public health organizations or payers.

There's a lot more to HTI-2, the full details of which can be seen by visiting healthit.gov/proposedrule. You can also click here to see the HHS release.

Revised CLIA Final Rule

QSO-24-15-CLIA is a memo released on July 8 to State Survey Agency Directors. Here are the exciting bullets:

- ✓ Publication of Final Rule: CMS-3355-F was published on July 11, 2022. This final rule implements revised regulations to update those the Centers for Medicare & Medicaid Services (CMS) identified as unnecessary, obsolete, or excessively burdensome on laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

- ✓ Effective Date: The regulations §§ 493.2 and 493.801 through 493.959 are effective two years after publication in the Federal Register [July 11, 2024]; amendments to 42 CFR §§ 493.20 and 493.25 related to laboratories performing tests of moderate complexity and high complexity testing that also perform waived testing and proficiency testing enrollment will be effective 30 days after the publication date of this final rule and are effective August 10, 2022.

  This revision updates the table found on page 4 of this memo to correctly list two analytes, Cancer antigen (CA) 125 and Carcinoembryonic antigen (CEA), under Endocrinology (§§ 493.933).

- ✓ This revision also corrects the reported units for CEA from "ng/dL" to "ng/mL." The units were previously revised in the Federal Register, and this memo reflects the revision on page 9.

Click here for the full details.

Labfraudatory Story of the Month

The results of these genetic tests—which were supposed to detect genetic mutations that could indicate an elevated risk of cancer, cardiovascular disease, Parkinson's disease, and other serious illnesses—were not used in the patients' treatment.

Thirty-six defendants were charged in the $1.1 billion Medicare fraud scheme.

Click here for the DOJ's details and a rundown of a number of other "great ideas" that didn't turn out as planned.

SCOTUS Overturns the Chevron Deference

While the Chevron deference has nothing to do with chess or a gas station (although it came about 40 years ago by way of an action that involved Chevron Oil), it has everything to do with how federal agencies were given a lot of latitude to interpret laws and decide best as to how those laws would be applied.

With the Supreme Court recently overturning the Chevron deference (or doctrine) principle, courts cannot now defer to an agency's (such as CMS) interpretation of one of its own statutes when there's ambiguity. Instead, a court must exercise independent judgment in interpreting a statute.

What does Chevron's overturning mean specifically for healthcare? The decision could have significant implications for federal agencies such as HHS, CMS, and the FDA.

The overturning means that courts are now mandated to exercise their own independent judgment in interpreting ambiguous or silent statutes. These agencies issue guidance every year and oversee highly technical and scientific areas of the law. Consequently, there will likely be an increase in legal challenges against their regulations as they are issued.

- ✓ An example specifically for laboratories is that the FDA's new rule on laboratory-developed tests (LDTs) could be positively affected since, by eliminating Chevron, courts would have more leeway in deciding conflicts of statutory interpretation. In contrast, before, courts were required to defer to a federal agency's (in this case, the FDA's) reading of an ambiguous law or regulation.

  As such, the overturning of Chevron could boost the ACLA's lawsuit challenging the FDA's authority to regulate laboratory-developed tests (LDTs).

On the larger healthcare landscape, Chevron's ending could result in higher - even significantly higher - Medicare payments for providers.

Click here for the Regulatory Focus article and details.

There *is* Denying Laboratory Denial

Hearkening back to February's Executive War College, a major discussion topic included laboratory claim denials.

Denials happen when coding is incorrect, claims have errors and/or omissions, prior authorizations were needed, multiple claims for a patient should've been bundled into a single master claim, and particular payers don't reimburse for specific tests.

Seemingly, creating denials is a major focus for payers, almost to the point where it appears they're in business as much to deny claims as to pay them.

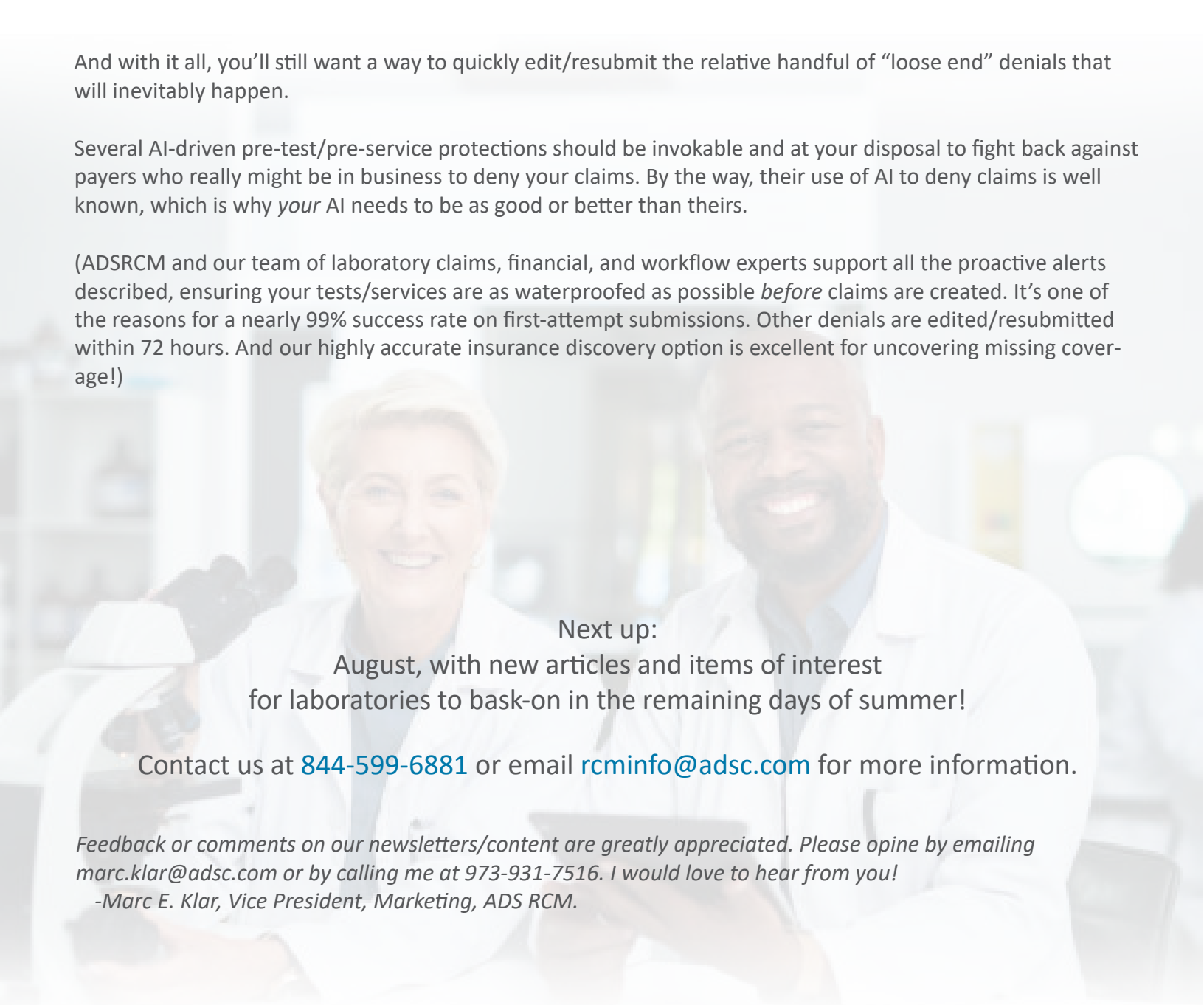
To combat that, laboratories need a way to proactively detect denials with alerts on claims likely to be denied by those payers, then an ability to edit them so they won't be denied.

But before destined-to-be-denied claims are even created, you'll want to be alerted to out-of-network situations, unverified eligibilities, and believe this or not: whether self-pay/no insurance patients actually *do* have coverage!

And with it all, you'll still want a way to quickly edit/resubmit the relative handful of "loose end" denials that will inevitably happen.

Several AI-driven pre-test/pre-service protections should be invokable and at your disposal to fight back against payers who really might be in business to deny your claims. By the way, their use of AI to deny claims is well known, which is why *your* AI needs to be as good or better than theirs.

(ADSRCM and our team of laboratory claims, financial, and workflow experts support all the proactive alerts described, ensuring your tests/services are as waterproofed as possible *before* claims are created. It's one of the reasons for a nearly 99% success rate on first-attempt submissions. Other denials are edited/resubmitted within 72 hours. And our highly accurate insurance discovery option is excellent for uncovering missing coverage!)



Next up:
August, with new articles and items of interest
for laboratories to bask-on in the remaining days of summer!

Contact us at 844-599-6881 or email rcminfo@adsc.com for more information.

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!
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