LABORATORY ECONOMICS Volume 1, No. 8, October 2023

Kimberly Scott, Editor, kscott@laboratoryeconomics.com

COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

Some MACs Changing Coding on STI Testing in Conflict with AMA Guidelines

Some Medicare Administrative Contractors (MACs) appear to be changing CPT codes that clinical laboratories submit for infectious disease testing so that the labs are reimbursed for only one code instead of for multiple codes. According to William Dettwyler, founder and president of Codus Medicus, a lab coding consultant based in Salem, Ore., certain payers are changing codes for sexually transmitted infection testing and paying a lower amount. *Continued on page 2.*

MolDX to Cover Molecular Biomarker Testing for RA Targeted Therapy Selection

Medicare's Molecular Diagnostic Services Program (MolDX), on Aug. 25, 2023, announced a new local coverage determination (LCD) for molecular biomarker testing to guide targeted therapy selection in rheumatoid arthritis (RA). MolDX also announced three draft LCDs for prostate GEP tests, lung nodules and thyroid nodules. The rheumatoid arthritis LCD (DL39424) is significant because it marks a partial reversal of MolDX's previous non-coverage policy and now provides limited coverage based on new evidence received during the comment period. *More on page 4.*

Labor Department Sues United Subsidiary Over Denied Drug Screening Claims

A lawsuit filed by the Department of Labor (DOL) against UnitedHealth Group subsidiary UMR over incorrectly denied emergency room and urinary drug screening claims should serve as a warning that failure to review medical necessity of claims can land a payer in hot water. *Details on page 7.*

Everlywell Lawsuits Over Food Sensitivity Tests Dismissed

Two separate class-action lawsuits filed against Everlywell Inc. (Austin, TX) have been dismissed. Both lawsuits alleged that Everlywell's food sensitivity tests are "worthless," given that they cannot identify adverse food sensitivities as advertised. *Continued on page 9.*

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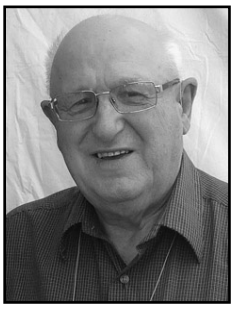
SOME MACS CHANGING CODING ON STI TESTING IN CONFLICT WITH AMA GUIDELINES (*con't from page 1*)

"It has come to my attention that certain payers have decided to utilize the CPT codes in ways that do not agree with the terminology defined in the AMA CPT coding rules," says Dettwyler. "It appears some payers have bastardized the coding system to suit their own reduced payment allowance for laboratory services."

At issue is a conflict between guidance contained in the National Correct Coding Initiative (NCCI) Policy Manual, which is used by MACs as a general reference tool, and the American Medical Association's (AMA) CPT Codebook, which says laboratory procedures should be coded at the highest level of specificity. Introductory language to the 2021 NCCI Policy Manual states: "If a laboratory procedure produces multiple reportable results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service."



William Dettwyler

The Association for Diagnostics & Laboratory Medicine (formerly the American Association for Clinical Chemistry) in a 2021 letter to Carole Blackford, director of CMS's Hospital & Ambulatory Policy Group, pointed out the conflict, saying, "The NCCI introductory language provides guidance to report a procedure with a single miscellaneous or unlisted CPT code that provides no information on what was actually tested. This coding guidance is overbroad and unclear . . . . [and] violates AMA CPT guidance."

ADLM further notes that the CCI guidance actually creates more work for MACs. "If laboratories were to follow the instructions in the [CCI] Manuals, MACs would have to adjudicate a vast number of claims with miscellaneous and unlisted codes," it says in its letter. "On top of this plain administrative burden, MACs will have to request and process a tremendous amount of additional documentation to determine which tests were performed and contend with a far greater number of appeals for mistakenly denied claims."

STI Payer Policy

Some MACs have begun following the CCI guidance rather than the AMA CPT instructions. In late 2021, for example, Anthem Blue Cross Blue Shield announced a policy for STI testing effective Dec. 1, 2021. The policy is in effect in a number of states, including but not limited to, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio and Wisconsin. The policy appears to have been adopted by some other insurers as well, including AmeriGroup Medicare Advantage and BCBS of Minnesota.

Anthem said it considers CPT codes 87491, 87591 and 87661 to be part of a laboratory panel grouping unless provider, state or federal contracts and/or requirements indicate otherwise. "When the plan receives a claim with two or more single test laboratory procedures codes reported, the plan will bundle those two or more single tests into the comprehensive laboratory procedure code 87801 . . . . Regardless of the number of units billed, reimbursement will be based on a single unit of the CPT code 87801." Modifiers will not override this new policy, Anthem adds.

Thus, if a provider is trying to determine what type of STI a patient has and they order tests for three different infectious agents (Chlamydia trachomatis, Neisseria gonorrhoeae and Trichomonas vaginalis), the lab will bill only 87801 instead of the three more specific codes and will receive a single payment of $70.20 rather than three separate payments of $35.09 ($105.27).

What's more, 87801 (infectious agent detection by nucleic acid (DNA or RNA), multiple organisms) reports out a single result, says Dettwyler, arguing that this creates a problem for the ordering physician who is seeking multiple tests to determine what type of STI a patient has but only gets a single result.

"There are only two types of reports for code 87801, positive or negative," says Dettwyler. "If the practitioner gets the report as positive, the first thing they will ask is, which of the three tests was positive? The lab would say one or more was positive, but 87801 does not give information on each specific test."

This policy ties the hands of practitioners, who are receiving a result for a test they did not order, adds Dettwyler, noting that practitioners will need to understand when their patients have an insurance policy that dictates what lab procedures they are allowed to order and bill. In this case, it is the payer who is practicing medicine, not the practitioner, he argues.

"CPT 87801 is not a code that would even be approved by a laboratorian," says Dettwyler. "It is of little value even to a medical practitioner, as it is only designed to be of value if all the agents involved are not present, hence its negative value. In the case where there is a positive result, any reliable practitioner would repeat the testing and ask for each agent to be separately reported."

Laboratories are not primarily used to reporting of negative results, as most testing is related to a precise number. In microbiology, testing is typically done to identify the causative organisms, not report to the practitioner what organisms the patient does not have.

"Labs need to actively confront this payer takeover and work with practitioners to ensure that the practice of medicine is not taken over by the payers and the insurance industry," says Dettwyler.

Labs Must Make Choice

Jerry Tavolino, chief information officer for CodeMap, a consulting firm based in Chicago, says he had hoped the discrepancy between the NCCI and AMA would be cleared up by now, but the NCCI program "went into pause this summer when CMS was delayed in the process of awarding the NCCI contract to a new contractor."

CodeMap says this conflict places labs in a difficult situation where they must choose which guidance to follow—the NCCI manual or long-standing AMA guidance included in the CPT manual and supporting materials.

"Either approach may present potential compliance issues that should be discussed with laboratory management and legal/compliance departments," says CodeMap in guidance to clients. "Seeking written guidance from both federally funded and private payers may offer further assistance."

Comparison of Medicare Part B Rates & Denials

Code	Description	2023 Rate	Submitted Claims 2022	Denied Claims 2022	Denial Rate 2022
87491	Chlamydia trachomatis, amplified probe technique	$35.09	362,468	134,288	37%
87591	Neisseria gonorrhoeae, amplified probe technique	$35.09	358,620	134,249	37%
87661	Trichomonas vaginalis, amplified probe technique	$35.09	235,883	55,643	24%
87801	Detection of multiple organisms; amplified probe technique	$70.20	698,273	166,784	24%

Source: CodeMap

MolDX to Cover Molecular Biomarker Testing for RA Targeted Therapy Selection (*con't from page 1*)

Beginning Oct. 15, 2023, MolDX will provide coverage of molecular biomarker tests to guide targeted therapy selection in RA in limited cases. Currently, PrismRA, made by Scipher Medicine (Waltham, MA) is the only commercially available molecular signature response classifier (MSRC) test that predicts the inadequate response to all tumor necrosis factor inhibitor (TNFis) therapies in RA.

An estimated 1.3 million adults in the United States live with RA. RA treatment response is defined in terms of disease activity or remission scores. Commonly used are the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) response criteria. ACR improvement scores of ACR20, ACR50 and ACR70 represent the percent improvement in a standard set of indices. A 50% response (ACR50) is needed for most patients to reach low disease activity.

Up to 90% of patients with RA are treated with TNFi therapies as first-line biologic or targeted synthetic disease-modifying anti-rheumatic drugs (DMARD), according to Scipher. Only about one-third of those patients reach ACR50 at six months with a biologic or targeted synthetic therapy (b/tsDMARD) after failing treatment with methotrexate. The PrismRA test result shows whether TNFi therapy is more or less likely to work for treatment.

The MolDX final LCD lists 12 criteria for coverage, including that the patient has a history of failure, contraindication or intolerance to at least one first-line therapy for the treatment of RA and the patient has not initiated a biologic or targeted synthetic therapy for RA or has initiated targeted synthetic therapy and is being considered for an alternate class of targeted therapies as a result of failure or intolerance to the initial targeted therapy.

MolDX explains the rationale behind the change in policy in a response to comments article (A59519). While the program acknowledges the need for testing to help physicians and patients avoid a trial-and-error-based approach to care, it notes there are limitations of currently available clinical and laboratory tools to support this effort.

Previously, molecular biomarker tests had not adequately demonstrated they could reliably identify responder and non-responders to a class of therapies given that the overall prevalence of non-response to TNF inhibitors, a mainstay of therapy, is so high in this population (about 60% to 70%). However, newer data has been published and was provided during the comment period, which led to the modified policy.

"We agree that despite the many limitations of predictive biomarker tests, a review of the evidence supports their limited use given their demonstrated validity and utility," writes MolDX. "Specifically, when a non-response (NR) signature is obtained by the molecular signature response classifier (MSRC), nearly 90% of those patients will prove to not clinically respond to TNFi therapies using multiple validated disease response criteria, including the ACR50 and CDAI. For these patients, a change in management would ultimately serve to avoid time on an unnecessary therapy and shorten the time to an appropriate therapy."

MolDX highlights some important points about the evidence regarding these tests to date:

1. They have only demonstrated their utility in a subset of the RA population (only half of the TNFi non-responders).

2. They are only informative about one particular class of therapies (TNFis).
3. The use of this testing does not guarantee improved disease activity and/or remission outcomes because many of these patients will also not initially respond to the alternate therapies.
4. It is not appropriate that patients continue classes of therapy that they have already failed due to payer preference and/or lack of consideration of national guidelines (that support switching over cycling).

Since the clinical utility of predictive testing is largely dependent on consensus-based management recommendations, the coverage decision is subject to revision pending changes in the literature and consensus guidelines, notes MolDX in the LCD. New tests that become available with significantly improved performance may render older tests no longer compliant with this policy, it adds.

For these RA tests, laboratories should use CPT 81599 (unlisted multianalyte assay with algorithmic analysis), says the accompanying billing article (A59529).

Abdulrahman Saadalla, MB, BCh

The new LCD is good news for RA patients and will help physicians avoid a trial-and-error-based approach to care, believes Abdulrahman Saadalla, MB, BCh., Medical Director at ARUP Laboratories (Salt Lake City) and assistant professor in the Department of Pathology at the University of Utah.

"Coverage for this test is a milestone and a breakthrough in the management of rheumatoid arthritis patients," he says. "The test is a clear example of precision medicine. It incorporates patient-specific gene expression data and clinical features to predict non-responsiveness to TNF inhibitors. Such a test can hopefully help physicians and patients save time, costs and, ultimately, achieve better outcomes."

Advanced Prostate Draft LCD

In DL39636, MolDX proposes a coverage policy for gene expression profile tests that assess risk or predict therapeutic response in men who have an established diagnosis of castration resistant or metastatic prostate cancer. Such testing is considered reasonable and necessary to help guide treatment decisions in men with prostate cancer and a life expectancy such that they are candidates for prostate cancer treatment, according to the most recent nationally recognized guidelines at the time of testing based on Food and Drug Administration (FDA) labelling.

The scope of the policy includes gene expression profile tests regardless of methodology, notes MolDX. It is exclusive of targeted and comprehensive genomic profiles (CGP) by next-generation sequencing (NGS) and single biomarker expression analyses.

The draft lists specific coverage criteria including but not limited to: the patient is a candidate for more than one management option; the test has shown that it predicts response to a specific therapy among accepted therapy options; and the patient has not received pelvic radiation or androgen deprivation therapy (ADT) prior to the biopsy or prostate resection specimen on which the test will be performed (with an exception).

The draft LCD notes that National Comprehensive Cancer Network (NCCN) guidelines recommend the Decipher Prostate (Veracyte) genomic risk classifier, a gene expression profile test, to inform adjuvant treatment if adverse features are found post-radical prostatectomy (RP) and to risk stratify patients with PSA resistance/recurrence after RP. More recently, the Decipher GC,

PAM50 classifier and other gene expression profile tests have been used to prognosticate and predict response to therapy in advanced and metastatic prostate cancers, notes the LCD. However, MolDX notes that the mention of specific tests in this policy as part of the literature review does not automatically imply coverage. Rather, the LCD creates a foundation for coverage of tests that meet the specific criteria detailed in the LCD.

The associated billing article DA59462 recommends 81479 (unlisted molecular pathology procedure) as a potentially covered code.

Lung Nodules Draft LCD

DL39654 outlines limited coverage of molecular biomarkers for risk stratification of indeterminate pulmonary nodules following bronchoscopy. Coverage criteria includes, but is not limited to:

1. The beneficiary has undergone bronchoscopy for an indeterminate pulmonary nodule and the procedure has failed to provide a specific histopathological diagnosis such that further diagnostic procedures are considered necessary to pursue a diagnosis and test results will be used to meaningfully inform patient management within the framework of nationally recognized consensus guidelines.
2. The beneficiary does not have a personal history of cancer, a current diagnosis of cancer and an overall low or high risk for pulmonary malignancy such that test results would not meaningfully alter patient management and significantly improve patient outcomes.

Next-generation sequencing (NGS) performed to identify genetic variants in samples classified as malignant is not within the scope of this policy but may fall under other established policies, notes MolDX. Billing article DA59476 lists 81479 as a possible billing code.

Thyroid Draft LCD

DL39646 proposes limited coverage of molecular testing for risk stratification of thyroid nodules. MolDX proposes to cover molecular diagnostic tests for use in a beneficiary with an indeterminate or suspicious thyroid nodule when the patient has not been tested with the same or similar assay for the same clinical indication and has an indeterminate thyroid nodule as defined by Bethesda categories III-IV or has a Bethesda category V nodule for which molecular testing may aid in further stratifying the type of malignancy (this is a partial list of coverage criteria).

"Given the cost and risks associated with thyroid surgery, the clinical decision making that goes into the extent of surgery, additional follow up management and published guidelines, this contractor finds that molecular tests that aid in medical decision-making for thyroid nodules of Bethesda Categories III-V are reasonable and necessary," says the draft LCD.

The request for coverage came from Paul Gerard, MD, Medical Director of Managed Care and Government Accounts for Veracyte, manufacturer of Afirma MTC. Gerard notes that Veracyte previously submitted a coverage request specifically for Afirma MTC, but given MolDX's interest in foundational over product-specific LCDs, Veracyte is requesting more broad coverage of thyroid nodule classifiers.

Billing article DA59470 lists potentially covered codes 81479 (unlisted molecular pathology procedure), as well as 81546 (Veracyte GSC Genomic Sequencing Classifier).

LABOR DEPARTMENT SUES UNITED SUBSIDIARY (*cont'd from page 1*)

UMR is UnitedHealthcare's third-party administrator that provides benefits services to at least 2,136 self-funded employer health plans serving more than 5 million participants, says the complaint, filed July 31 in a Wisconsin federal court. UMR is based in Wausau, WI.

An investigation by the DOL's Employee Benefits Security Administration alleges UMR's procedures for adjudicating emergency room claims relied solely on diagnosis codes and did not comply with the "prudent layperson" standard in the Affordable Care Act (ACA) and the Employee Retirement Income Security Act (ERISA). The investigation also found that UMR denied nearly all urinary drug screening claims without reviewing the claims for medical necessity.

Under UnitedHealthcare's current policy on drug testing (2023R6005B), the payer will allow one drug test within the presumptive drug class and one drug test within the definitive drug class per date of services by the same or different provider.

According to the complaint, UMR's procedures for adjudicating UDS claims resulted in it denying all urine drug screening (UDS) claims in violation of ERISA's prudence provisions. UMR was required to apply a standard of "medical necessity" to determine whether a UDS claim was medically necessary. DOL alleges that UMR violated ERISA by denying UDS claims because it applied no standards and simply denied all claims.

Payers continue to scrutinize urine drug testing claims for excessive utilization.

For a limited time from Aug. 26, 2018, to present, UMR did allow some UDS claims to be paid if the drug screen was done in an emergency setting. But beginning Oct. 11, 2019, UMR changed its practice again by switching the denial code for UDS claims from 914 (lack of medical necessity) to 515 (a denial requesting more medical records from the provider). UMR's explanation of benefits for denied UDS claims also failed to comply with the requirements of the ACA and the DOL's claims procedures regulations, says the complaint.

For ERISA-covered, self-funded employee welfare benefit plans, UMR used a "True Emergency" policy for approximately 371 of the plans and adjudicated ER claims by using one of two diagnosis code lists: "True ER" (T10 coding) or "Sudden and Severe" (T11 coding). UMR had exclusive control over the T10 and T11 lists, says the complaint, noting that the plans have no role in how UMR uses those lists when adjudicating ER claims.

UMR adjudicates ER claims for most of the diagnosis code list plan by first comparing the diagnosis codes identified by the providers to the applicable T10 or T11 list. If an ER claim is submitted and does not have at least one diagnosis code on the applicable T10 or T11 list, UMR denies the claim, the complaint alleges. If at least one diagnosis code is on the list, UMR adjudicates the claim as payable.

"UMR considers no additional information and conducts no further analysis or review of the claim before initial denial," says the complaint. "When UMR denies a claim because it does not have at least one diagnosis code that is on the applicable T10 or T11 list, UMR sends the affected claimant an Explanation of Benefits (EOB) that has very limited information."

'Prudent Layperson" Standard

DOL says that since at least 2011, the prudent layperson standard has been the required level of

review for ERISA plans covering hospital emergency services. The definition of "prudent layperson" comes from the ACA's definition of "emergency medical condition," which defines it as "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition . . . placing the health of the individual . . . in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part."

In addition, DOL's claims procedures regulation requires, among other things, that ERISA plans have reasonable claims procedures for the filing of claims, notification of benefit determinations and appeal of adverse benefit determinations. It also requires that when participants receive adverse benefit determinations, participants must be provided with specific reasons for the determination, the specific plan provisions on which the determination is based and a description of any additional material or information necessary for the claimant to "perfect" the claim.

'Prayer for Relief'

According to the complaint, UMR simply denied all UDS claims from August 2015 to Aug. 25, 2018. From Aug. 26, 2018, to present, UMR denied all UDS claims that were not from either an emergency room or urgent care center. UMR made the change to its UDS-denial policy in August 2018 because UMR determined that 98% of UDS claims in an emergency room setting were overturned on appeal.

In its complaint, the DOL lays out its "prayer for relief" and requests that the court take the following actions:

- Require UMR to reform its procedures for receiving, processing and adjudicating ER claims and UDS claims to comply with ERISA;
- Require UMR to readjudicate all ER claims and UDS claims that were denied or partially denied from Jan. 1, 2015, to present, in compliance with ERISA;
- Enjoin UMR from committing future violations of ERISA.

Downside of Automation

Clarisa Blattner

While not familiar with UMR's claims review procedures, Clarisa Blattner, senior director, revenue and payor optimization, XiFin (San Diego), says some payers are becoming too reliant on automated claims reviews, which can pose a compliance risk.

"What we've noticed is the insurance companies are using artificial intelligence (AI) to calculate what they are denying without looking into a patient's medical necessity," she says. "If payers are denying claims, it needs to be based on some kind of medical policy so providers know what is considered medically necessary. Claims should be decided on a case-by-case basis."

Though automation can help speed the claims review process, there needs to be a process for outliers to be manually reviewed, says Blattner, noting that no review should be 100% automated.

[For more on payers' use of AI in claims review, see Blattner's recent blog posting on XiFin's website: https://www.xifin.com/resource/blog-post/medicare-advantage-plans-use-of-ai-drives-rising-denials/.]

EVERLYWELL LAWSUITS DISMISSED (*cont'd from page 1*)

The first lawsuit, *Spiro et al. v. Everly Well Inc.* (23-cv-04539), filed June 8 in U.S. District Court for the Central District of California, was voluntarily dismissed by the plaintiffs on July 31, after they concluded that the case was no longer worth pursuing.

The plaintiffs had alleged that Everlywell falsely represented that its tests can identify food sensitivities by measuring IgG antibody levels, when IgG antibodies cannot detect food sensitivities. Filed on behalf of plaintiffs Benjamin Spiro, Leah Spiro and Stephanie Rebecca Andrecs, the lawsuit alleged that Everlywell "misleads consumers into chasing false positives, making unnecessary dietary alterations and paying a premium for a product that does not work. In addition, consumers unknowingly surrender their personal information to Everlywell under the guise of procuring valuable health insights, thereby raising significant privacy concerns and potential misuse of this sensitive data."

According to the allegations, the worldwide scientific community "universally" agrees that the product is incapable of providing medically accepted health information about a user's "sensitivity" or "reactivity" to certain foods. Both the American Academy of Allergy, Asthma & Immunology (AAAAI) and the Canadian Society of Allergy and Clinical Immunology have condemned IgG testing.

According to the AAAAI, the scientific studies that are provided to support the use of this test are often out of date, in non-reputable journals and many have not even used the IgG test in question. "The presence of IgG is likely a normal response of the immune system to exposure to food," says the academy. "In fact, higher levels of IgG to food may simply be associated with tolerance to those foods."

Could Be Harmful

The complaint had alleged that Everlywell's food sensitivity tests may actually prove harmful to consumers' health in that it could provide them with "phony diagnoses and misinformation" advising them to incorporate allergens into their diet.

What's more, consumers are not told until after they've purchased their kits that they cannot receive their test results until they agree to allow the defendants to retain, use and sell their private data, including medical information extracted from the blood test samples, the complaint said.

Court Dismisses Second Lawsuit

A second lawsuit, Joyce Toth v. Everlywell Inc. (23-cv-11043), filed June 8 in U.S. District Court for the District of Massachusetts, was dismissed by the court on August 2. This lawsuit had also alleged that Everlywell's food sensitivity tests do not identify adverse food sensitivities as advertised.

Everlywell Background

Everlywell was founded by its CEO Julia Cheek, age 39, in 2015. Cheek and Everlywell were featured on Shark Tank in November 2017. Investor Lori Greiner offered Cheek $1 million as a line of credit (with an interest rate of 8%) in exchange for 5% equity stake. Cheek accepted the offer without countering.

In addition to selling lab tests direct to consumers, Everlywell owns PWNHealth, which provides telehealth services, and Home Access Health Corp., which sells self-collected fingerstick blood test kits.

Everlywell has raised a total of more than $250 million to date. Outside investors include BlackRock and Highland Capital Partners

Lab Owner Sentenced to Prison in Kickback Case

The owner of a clinical laboratory in Louisiana has been sentenced to 36 months in federal prison for conspiring to pay and receive healthcare kickbacks, resulting in more than $40 million being fraudulently billed to Medicare and Louisiana Medicaid. Terry Wilks Jr., 41, of Greenwell Springs, LA, has also been ordered to pay more than $5 million in restitution and to forfeit almost half a million dollars.

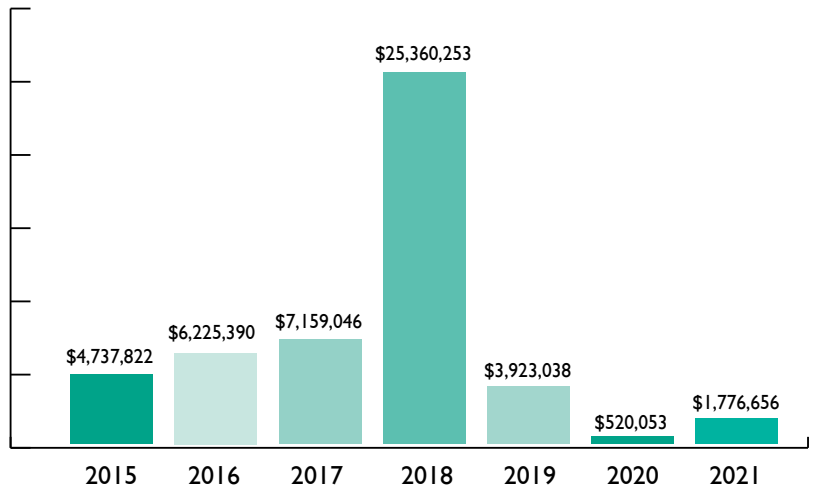
Laboratory sales representative Leslie McHugh, 38, of Palmetto, FL, was previously sentenced to 12 months and one day in federal prison for her involvement in the scheme. Both Wilks and McHugh are also sentenced to two years of supervised release following imprisonment, according to the U.S. Attorney's Office for the Middle District of Louisiana.

Wilks was an owner and CEO of Acadian Diagnostic Laboratories, LLC, a clinical laboratory based in Baton Rouge, LA, while McHugh worked as a sales representative, according to court documents. In late 2016, McHugh was excluded from participation in the Medicare program. However, despite her exclusion, she continued to refer doctors' orders and specimens for testing by Acadian, in exchange for kickbacks paid by Wilks. These referrals caused the submission of claims by Acadian to Medicare and TRICARE.

During the period that McHugh was excluded, Wilks made cash and wire payments, totaling more than $69,000, to McHugh in exchange for referrals. As a result of those referrals, Acadian submitted more than $500,000 in claims to Medicare and TRICARE and was reimbursed more than $127,000. In addition to paying McHugh kickbacks, Wilks also admitted paying another sales representative of Acadian more than $2.3 million in kickbacks for his referrals to the lab from January 2016 through December 2018, which resulted in more than $40 million billed to Medicare and Louisiana Medicaid. Acadian received $39 million in Medicare Part B payments from 2016-2018.

In September 2019, a grand jury indicted Wilks and McHugh on seven counts of healthcare fraud and conspiracy. Both struck deals with prosecutors and pleaded guilty April 6 to paying and receiving illegal kickbacks.

Total Medicare Part B Payments to Acadian Diagnostic Labs



Source: CMS

The case was investigated by the Health and Human Services Office of Inspector General's Medicaid Fraud Control United, the FBI and DCIS, and was brought as part of the Medicare Fraud Strike Force. Trial attorneys Samantha E. Stagias and Justin M. Woodard of the Fraud Section and Assistance U.S. Attorney Kristen L. Craig of the Middle District of Louisiana prosecuted the case.

COMPLIANCE 101:

Investigating, Reporting and Correcting Identified Problems

Laboratory compliance programs should require that when the chief compliance officer or others involved in the management of a laboratory learn of potential violations or misconduct, that they promptly investigate the matter to determine whether a material violation has in fact occurred, says the Health and Human Services Office of Inspector General (HHS OIG) in its laboratory compliance program guidance.

Depending on the nature of the allegations, the investigation will probably include interviews and review of relevant documents, such as submitted test claims, test requisition forms and laboratory test reports. Some laboratories may wish to engage outside auditors or counsel to assist them with the investigation.

If the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, the employee(s) probably should be removed from his or her work activity until the investigation is completed. In addition, the laboratory should take steps to prevent the destruction of documents or other evidence relevant to the investigation.

Reporting

If after appropriate investigative inquiry, management has reasonable grounds to believe that the misconduct violates criminal law or constitutes a material violation of regulations governing federally funded healthcare programs, then the laboratory should report the existence of the misconduct to the OIG as soon as possible. The OIG recommends that the lab give notice of the misconduct within 60 days after receipt of the credible evidence. Such prompt reporting will demonstrate the laboratory's good faith and willingness to work with the government to correct and remedy the problem, says the OIG.

When reporting the misconduct, the laboratory should give the OIG any evidence the laboratory has related to the misconduct, including evidence disclosed to the laboratory from another source. The laboratory should then continue to investigate the reported violation, and once the investigation is complete, the lab should notify the OIG and the Department of Justice of the outcome of the investigation. If it determines that criminal activity may have occurred, the appropriate state or federal authorities should be notified immediately. The laboratory should also take appropriate corrective action, including prompt restitution of any damages to the government and the imposition of appropriate disciplinary action.

Corrective Action

If the investigation reveals that misconduct did occur, corrective actions should be initiated immediately. For example, if the investigation finds that the laboratory has received overpayments, the lab should make prompt restitution of such sums to the appropriate federally funded healthcare program. Failure to repay the overpayment immediately could be interpreted as an intentional attempt to hide the overpayment from the government, says the OIG. For that reason, lab compliance programs and written policies and procedures should emphasize that monies to which the laboratory had no legal entitlement in the first place may not be legally retained and must be returned immediately.

In addition to making prompt restitution and taking corrective action, the laboratory should take whatever disciplinary action is necessary to cure the problems identified by the investigation and prevent it from happening again.

In Brief

CMS Withdraws Problematic Drug Testing Edits

The Centers for Medicare & Medicaid Services (CMS) is withdrawing edits that would have disallowed payments for definitive drug tests (G0480, G0481 and G0483) when performed on the same day as the presumptive drug test (80305, 80306 and 80307). LECPR wrote about these edits in the September issue (*Navigating New CMS Billing Edits for Drug Testing, p. 1*). The withdrawal takes effect Oct. 1, 2023, but will be retroactive to July 1, 2023. Medicare Administrative Contractors (MACs) are instructed to adjust those claims with dates of service between July 1, 2023, and Oct. 1, 2023, to allow payment as appropriate under existing payment and coverage policies, says CMS in an announcement. Alternatively, a lab may choose to use the MAC appeal process if it does not want to wait for the automatic adjustment to occur, or it can wait to submit its claims until CMS implements the change.

CAP Seeks Changes to LCD on Genetic Testing for Oncology

The College of American Pathologists (CAP) and 44 other healthcare organizations have asked Medicare Administrative Contractors First Coast and Novitas to revise a proposed local coverage determination (LCD) framework (DL39367) that outsources review to three third-party databases to govern policy coverage. If finalized as drafted, the LCD, "Genetic Testing for Oncology," would cause Medicare beneficiaries with cancer to lose access to clinically appropriate genetic testing, the CAP says in a Sept. 8, 2023, letter to the MACs. The Centers for Medicare and Medicaid Services (CMS) has made it clear that a Medicare contractor must make its own review of the scientific evidence used to support a local coverage determination, argues the CAP, which is asking the MACs to remove any reference to third-party databases from their final LCDs. The CAP is also recommending that First Coast and Novitas allow for additional genetic testing for hereditary cancer syndromes, which are considered germline testing, as science advances and additional tests become available that help contribute to the management of patient care.

Jondavid Klipp, Publisher Kimberly Scott, Editor Jennifer Kaufman, Chief Copy Editor