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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

2024 Coding Changes Take Effect January 1

Beginning Jan. 1, 2024, clinical and anatomic pathology laboratories will have dozens of new CPT codes available to them. The codes, developed by the American Medical Association (AMA), are part of the annual CPT update which includes a total of 230 additions, 49 deletions and 70 revisions. Diana Voorhees, principal and CEO of DV & Associates, a coding consulting company in Salt Lake City, describes the new lab coding changes. *See page 2.*

FDA Taking Steps to Oversee Artificial Intelligence in Labs

As artificial intelligence (AI) is increasingly used in healthcare settings, including clinical and anatomic pathology (AP) laboratories, the Food and Drug Administration (FDA) is attempting to fit AI into its regulatory framework while trying to keep pace with innovation. *Laboratory Economics Compliance & Policy Report* recently spoke with Kristen Klesh, a partner with Loeb & Loeb (Washington, D.C.) about the FDA's efforts related to medical products with AI-enabled technology. *Details on page 4.*

FDA Plan to Finalize LDT Rule Could Result in Chaos

If the Food and Drug Administration (FDA) finalizes its proposed rule on lab-developed tests (LDTs) in April as it says it will, the result could be chaos for all diagnostic products, says Allyson Mullen, a director with Hyman Phelps & McNamara (Washington, D.C.). *Continued on page 6.*

CMS Postpones Pricing of Six New Genomic Sequencing Codes

The Centers for Medicare and Medicaid Services (CMS) has postponed final pricing for six new genomic sequencing CPT codes, whose preliminary pricing had raised alarms among industry stakeholders. *More on page 7.*

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2024 Coding Changes Take Effect January 1 (*cont'd from page 1*)

Diana Voorhees, principal and CEO of DV & Associates, describes lab coding changes for 2024.

Molecular Codes

AMA has issued a family of three codes that describe solid organ neoplasms:

81457	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability.
81458	DNA analysis, copy number variants and microsatellite instability.
81459	DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden and rearrangements.

Another family of three codes describes tests done on plasma (also known as liquid biopsy).

81462	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements.
81463	DNA analysis, copy number variants and microsatellite instability.
81464	DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden and rearrangements.

Multianalyte Assays with Algorithmic Analyses

There are a couple of new multianalyte assays with algorithmic analyses (MAAA) tests, including a new enhanced liver fibrosis test from Siemens that will be crosswalked and reimbursed at about $176. By their nature, MAAA procedures are unique to a single laboratory or manufacturer.

81517	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years.

Another new MAAA, SOMAmer© from SomaLogic, will be gap-filled.

0019M	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported at 4-year likelihood of coronary event in high-risk populations.

Chemistry Codes

A new chemistry code will be crosswalked and reimbursed at about $39.

82166	Anti-mullerian hormone (AMH)

Immunology Codes

86041	Acetylcholine receptor (AChR); binding antibody.
86042	Acetylcholine receptor (AChR); blocking antibody.
86043	Acetylcholine receptor (AChR); modulating antibody.
86366	Muscle-specific kinase (MuSK) antibody.

Microbiology Codes

87523	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis D (delta) quantification, including reverse transcription, when performed.
87593	Orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each.

Proprietary Laboratory Analysis

There are 61 new proprietary laboratory analysis (PLA) codes included in AMA's 2024 CPT coding manual, bringing total PLA codes to almost 400. Some of these codes were issued during

2023 quarterly release, which means they were already in use. Several codes are related to oncology testing, including one for the NavDx® test made by Naveris Inc. Several others are related to infectious disease testing, such as for Thermo Fisher's Urogenital Pathogen with Rx Panel. Below are just two of the new PLA codes.

PLA 0356U	Oncology (oropharyngeal) evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence.
PLA 0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine.

Digital Pathology

The AMA has established more than 30 new digital pathology add-on codes, although many of the category III codes are not recognized by insurers, thus are not reimbursed. There are eight codes for cytopathology (88104, 88106, 88108, 88112, 88141, 88160, 88161 and 88162), three codes for FNAs (88172, 88177 and 88173), seven codes for consults (88321, 88323, 88325, 88331, 88332, 88333 and 88334) and two for IF (88346 and 88350).

Diana Voorhees

Addition digital pathology codes include one for archive retrieval (88363), six for FISH (88365, 88354, 88366, 88368, 88369 and 88377), one for blood smear (85097), one for BM smear (85097) and one for EM (88348).

Two examples of add-on codes are listed below:

+0827T	Digitization of glass microscope slides for cytopathology, fluids, washings, or brushing, except cervical or vaginal; smears with interpretation (list separately in addition to code for primary procedure).
+0855T	Digitization of glass microscope slides for bone marrow, smear interpretation (list separately in addition to code for primary procedure).

Description Changes

A number of codes have description changes (i.e., changing "mental retardation" to "intellectual disability"). Some next-generation sequencing codes, such as 81445, 81450 and 81455, have been modified to remove parenthetic comments with the types of genes one would expect to see. An example is below.

81445	~~Targeted genomic sequence analysis panel, s~~ Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes ~~(eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET)~~, interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis.

The following PLA codes also have description changes: 0022U, 0095U, 0269U, 0271U, 0272U, 0274U, 0277U, 0278U, 0308U and 0362U.

The following PLA codes have been deleted: 0012U, 0013U, 0014U, 0053U, 0056U, 0066U, 0097U, 0098U, 0099U, 0100U, 0143U, 0144U, 0145U, 0146U, 0147J, 0148U, 0149U, 0150U, 0151U, 0208U, 0324U, 0325U, 0357U, 0385U and 0397U.

MAAA code 0014M has also been deleted.

Fee Schedule Changes

For the 2024 Physician Fee Schedule, overall payment rates have been reduced by 1.25%. The conversion factor of $32.74 is a decrease of $1.15 (3.7%) from the previous year's conversion factor of $33.89.

The 2024 Clinical Laboratory Fee Schedule updates the data collection and data reporting periods for the Protecting Access to Medicare Act to reflect the one-year additional delay passed by Congress in November. The new data reporting period is Jan. 1 through March 31, 2024. The data collection period for clinical diagnostic laboratory tests (CDLTs) is Jan. 1 through June 30, 2019.

FDA Taking Steps to Oversee Artificial Intelligence in Labs (*cont'd from page 1)*

What is the FDA's primary focus when it comes to AI in clinical and AP labs?

Kristen Klesh

In labs, the FDA is mostly focused on AI in terms of machine learning, such as algorithms. One of the biggest challenges is trying to understand the AI algorithm and ensuring there is proper training to minimize bias that may be built into it. Another challenge from a regulatory perspective is developing metrics for performance estimation for reference standards – what are we cross referencing against to validate the technology to ensure it is meeting performance standards.

What has the FDA done to address AI used in diagnostics?

The FDA has cleared many medical devices that use AI, mostly in areas of radiological health. However, more recently AI has been used in diagnostic settings, such as Paige Prostate [AI software authorized by the agency in September 2021 for use in identifying potential biopsy areas of concern for prostate cancer].

The other area the FDA is working on is trying to adjust their existing regulatory framework to keep up with technology that is constantly evolving. The FDA has developed an accommodation. Instead of a manufacturer submitting a new

Clinical Decision Support Software Guidance

The FDA on Sept. 28, 2022, released its guidance for clinical decision support (CDS) software in which it outlines the criteria by which the FDA will determine whether a commercial CDS software will be regulated as a medical device (similar to a laboratory testing device) or be declared a "non-device" with a lower regulatory burden.

This guidance implements statutory changes made by the 21st Century Cures Act of 2016. According to the FDA, CDC software functions are not devices if the relevant software function meets the following four criteria:

1. The software is not intended to acquire, process or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system.
2. The software is intended for the purpose of displaying, analyzing or printing medical information about a patient or other medical information.
3. The software is intended for the purpose of supporting or providing recommendations to a healthcare professional (HCP) about prevention, diagnosis or treatment of a disease or condition.
4. The software is intended for the purpose of enabling the HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

510k market submission every time an algorithm changes, the FDA has said manufacturers should explain in their submission how they developed the algorithm, how it functions and what the potential is for the algorithm to change over time (see sidebar on Predetermined Change Control Plan for AI-Enabled Devices).

The 21st Century Cures Act carved out the definition of what constitutes a medical device, including so-called clinical decision support software. Generally speaking, if that analysis by the AI is focused on displaying, analyzing, or printing medical information about a patient to support or provide diagnostic recommendations to a physician, but still enables the physician to independently review the basis for the AI recommendations to make an independent diagnosis or treatment recommendations, that software may be carved out of FDA's statutory framework and is not regulated as a medical device. Of course, in such case, the physician will still need to ensure that the software is validated.

Can labs expect to see more in the way of legislative and regulatory oversight in this area?

Yes, there is an FDA work group that is continuing to track what is happening with this technology. [The Digital Health Advisory Committee was formed in October 2023 to advise the agency on issues related to digital health technologies, such as artificial intelligence and machine learning]. We can expect to see additional guidance coming out in the future.

Predetermined Change Control Plan for AI-Enabled Devices

The FDA issued draft guidance in April 2023 to further develop a regulatory approach tailored to artificial intelligence/machine learning (AI/ML)-enabled devices. This guidance would allow manufacturers to predict algorithm changes and implement future modifications without requiring additional marketing submissions.

Under a Predetermined Change Control Plan, manufacturers would be required to submit:

1. A detailed description of the specific planned device modifications.
2. The methodology to develop, validate and implement these modifications in a manner that ensures the continued safety and effectiveness of the devices.
3. An impact assessment to assess the benefits and risks of the planned modifications and risk mitigations.

The draft guidance builds on a framework initially proposed in 2021 and helps clarify the types of modifications that should be included in the Predetermined Change Control Plan. Under this framework, the FDA expects manufacturers to commit to transparency and real-world performance monitoring and to periodically update FDA on changes implemented as part of the approved pre-specifications and algorithm change protocol.

In addition, modifications should be implemented following appropriate, well-defined practices, such as the Good Machine Learning Practice guiding principles jointly developed by the FDA, Health Canada and the United Kingdom's Medicines and Healthcare Products Regulatory Agency.

Additionally, in October 2023 FDA issued a significant proposed rule regarding its intent to increase regulation of laboratory developed tests (LDTs), which have historically been subject to limited FDA oversight. The proposed rule would include a five-stage "phase out" of FDA's enforcement discretion policy and ultimately subject LDTs to the same FDA requirements as other medical devices.

FDA Plan to Finalize LDT Rule Could Result in Chaos (*cont'd from page 1*)

Comments on the FDA's proposed rule (published Oct. 3, 2023) were due Dec. 4, 2023, and the agency posted a notice in the Unified Agenda that it expects to publish a final rule in April 2024. As of Dec. 8, 2023, the agency had received 19,655 comments, noted Mullen in thefdalawblog.com. The FDA is obligated to address major issues when it publishes a final rule, which means it is facing a daunting task between now and April, she says.

Mullen questions whether the FDA will be ready to implement the proposed rule, arguing that the agency's conclusions about its ability to regulate the entire laboratory industry are based on fundamentally flawed assumptions about the number of entities and tests that will be subject to FDA regulation.

FDA Assumptions Inaccurate

The FDA estimates that approximately 12,000 CLIA-certified laboratories are currently certified to perform high-complexity testing in the United States, although the Centers for Medicare and Medicaid Services puts that number at more than 17,000. FDA further assumes that these labs collectively perform roughly 80,000 LDTs, but since the FDA underestimates the number of labs by one-third, the number of LDTs could be well over 100,000, says Mullen.

Allyson Mullen

Even using the lower number, the FDA says it anticipates receiving an astounding number of premarket review submissions for LDTs, including 32,160 510(k) premarket notifications, 4,210 PMAs and panel-track PMA supplements and 4,020 *de novo* applications. The FDA assumes that 80% of LDTs requiring premarket review will be able to identify a "predicate" device and be reviewed under the 510(k) process, an assumption that Mullen says is inaccurate.

"Given that many LDTs are introduced for new indications for which IVDs are not currently available, this assumption is unwarranted," she says. "In other words, FDA's extrapolation from existing IVD submission data ignores some key differences between LDTs and distributed IVDs."

The FDA further assumes that half of LDTs will not need to undergo premarket review because they are exempt, but Mullen says this is unlikely since exemptions apply only to well-established tests. Even assuming the accuracy of FDA's estimates, the agency would require a massive staffing increase at the same time that labs would be looking to hire personnel with the same sort of expertise to be able to navigate the FDA process, she adds.

While the FDA has said it expects to rely heavily on its third-party review program, Mullen says this program has "long been regarded as a flop" and that zero IVDs were cleared through the program between Nov. 1, 2022, and Nov. 1, 2023.

"The bottom line is this: without far better resource planning, this massive regulatory undertaking is going to be a disaster for all stakeholders, including FDA, industry, healthcare systems, providers and, most importantly, patients," says Mullen, who argues that the agency should not finalize the proposed regulation.

"If it does, instead of requiring submissions and then hoping to obtain resources and the necessary congressional authorizations, FDA should have a clear plan for obtaining the required resources," she says. "The failure to do so is likely to result in chaos for all diagnostic products."

CMS Postpones Pricing of Six New Genomic Sequencing Codes

(*cont'd from page 1*)

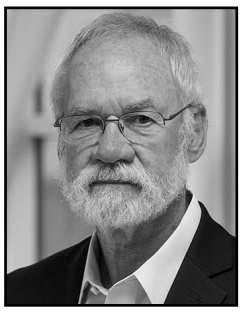
Recommended pricing for the six new codes, which include three for tissue-based testing and three for cell-free DNA testing, ranged from $1,759.60 to $4,375. An advisory panel convened in June agreed with five of the six recommended prices, but the agency on Sept. 27, 2023, initially proposed pricing the six codes at $597 each, crosswalking the codes to existing code 81445. CMS said it did not see "justification in crosswalking to a code that specifies analyzing more than 50 genes."

A number of stakeholders pushed back on the preliminary pricing. In response, the agency in November said it would postpone pricing until next year and in the interim would allow the codes to be gap-filled. Gap-filling allows Medicare administrative contractors (MACs) to determine pricing in their local area initially, with a final price determined the following year.

MACs will create gap-filled amounts for each test code and report them to CMS by April 1. Once these prices are published on the CMS website, there will be a 60-day period for public comments on the new amounts. CMS will then accept reconsideration requests for the gap-filled payments within a 30-day period. After the reconsideration process concludes, the payment amount becomes definitive and CMS will implement local MAC-specific gap-filled amounts based on the median of final gap-filled rates for the test code across all MACs.

Critical that Labs Report Data

For the MAC gap-filled pricing to accurately reflect the value of the testing, it's critical that all laboratories performing these procedures and using these codes report them to their local MACs, says Jan Nowak, MD, PhD, a member of the CAP's Economic Affairs Committee and clinical chief of molecular pathology at Roswell Park Comprehensive Cancer Center in Buffalo, NY.



Jan Nowak, MD, PhD

"Gap-fill pricing only works if a sufficient number of labs provide accurate data to their MACs," says Nowak. "If the number of reporting laboratories is low, and you are going to use the median price, that's a concern."

Nowak suggests that laboratories talk to their local MACs about what data they need to establish accurate pricing for these six GSP codes to ensure the contractors have accurate information.

Proliferation of Genomic Sequencing Codes

As Bruce Quinn, MD, PhD, notes in his blog "Discoveries in Health Policy," there has been a proliferation of genomic sequencing codes in the past two years. Between 2014 and 2022 there were only three CPT codes for genomic sequencing procedures for tumors: 81445 (solid cancers, 5-50 genes), 81450 (heme cancers, 5-50 genes) and 81455 (any cancer, 51+ genes). The first two codes were priced around $600 and the third code was priced at around $3,000.

In 2023, the AMA created an additional code for "RNA only" studies. Now, in 2024, AMA has increased the number of GSP codes to 12.

HHS OIG Pursuing Prison Sentences in Certain Lab Fraud Cases

In fiscal year 2023, the Health and Human Services Office of Inspector General (OIG) initiated 707 criminal actions against healthcare providers, including one against a clinical laboratory owner and operator that resulted in a 27-year prison term, another that resulted in a 15-year prison sentence and a third that led to a 5-year prison sentence.

"There has been an increase in the number and length of prison sentences in cases involving fraud by clinical labs compared to previous years, most notably in circumstances resulting in the denial of access to high quality care and patient harm," says Alissa Fleming, a shareholder with Baker Donelson (Charleston, SC). "Most of the arrangements giving rise to substantial criminal penalties involve schemes where clinical lab owners and operators engaged in conspiracies to deliberately defraud healthcare programs."

Alissa Fleming

On Aug. 18, 2023, Mina Patel was sentenced to 27 years in prison for defrauding Medicare by submitting more than $463 million in genetic and other lab tests that patients did not need and were procured through kickbacks and bribes. According to court documents, Patel, owned of LabSolutions Inc. LLC, conspired with patient brokers, telemedicine companies and call centers to target Medicare beneficiaries with telemarketing calls falsely stating that Medicare covered expensive cancer genetic tests. After the Medicare beneficiaries agreed to take a test, Patel paid kickbacks and bribes to patient brokers to obtain signed doctors' orders authorizing the tests from telemedicine companies.

To conceal the kickbacks and bribes, Patel required patient brokers to sign sham contracts that falsely stated that the brokers were performing legitimate advertising services for LabSolutions when, as Patel well knew, the brokers were deceptively marketing to Medicare beneficiaries and paying kickbacks and bribes to telemedicine companies for genetic testing prescriptions.

From July 2016 through August 2019, LabSolutions submitted more than $463 million in claims to Medicare, including for thousands of medically unnecessary genetic tests, of which Medicare paid more than $187 million. During that time, Patel personally received more than $21 million from Medicare in connection with the fraud.

There has been an increase in the number and length of prison sentences in cases involving fraud by clinical labs compared to previous years, most notably in circumstances resulting in the denial of access to high quality care and patient harm.

Covid-19 Fraud

On June 8, 2023, Billy Joe Taylor was sentenced to 15 years in prison followed by three years of supervised release and ordered to pay almost $30 million in restitution for conspiracy to commit healthcare fraud and money laundering. According to court documents, Taylor and co-conspirators submitted more than $134 million in false and fraudulent claims to Medicare in connection with diagnostic laboratory testing, including medically unnecessary urine drug testing and tests for respiratory illnesses during the Covid-19 pandemic. Taylor and co-conspirators obtained medical information and private personal information for Medicare beneficiaries and then misused that confidential information to repeatedly submit claims to Medicare for diagnostic tests. Taylor and his co-conspirators received more than $38 million from Medicare on those fraudulent claims.

Telehealth Fraud

On June 23, 2023, Michael Stein was sentenced to 60 months in prison and ordered to pay more than $61 million in restitution for involvement in a $73 million conspiracy to defraud Medicare by paying kickbacks to a telemedicine company to arrange for doctors to authorize medically unnecessary genetic testing. The scheme exploited temporary amendments to telehealth restrictions enacted during the Covid-19 pandemic that were intended to ensure access to care for Medicare beneficiaries.

OIG and DOJ are particularly sensitive to arrangements that result in patient harm and testing that provides no clinical benefits to patients and causes increased costs to federal healthcare programs.

According to court documents, Stein, the owner of 1523 Holdings LLC, admitted conspiring with Leonel Palatnik, co-owners of Panda Conservation Group LLC and others to receive kickbacks from Palatnik in exchange for working to arrange for telemedicine providers to authorize genetic testing orders for Panda's laboratories.

Panda's owners and Stein entered into a sham contract for purported information technology and consultation services to disguise the true purpose of these payments. 1523 Holdings exploited temporary amendments to telehealth restrictions enacted during the pandemic by offering telehealth providers access to Medicare beneficiaries for whom they could bill Medicare for consultations. In exchange, these providers agreed to refer beneficiaries to Panda's laboratories for expensive and medically unnecessary genetic testing.

Heightened Criminal Penalties

The heightened criminal penalties demonstrate OIG and DOJ's emphasis on prosecuting bad actors who attempt to take advantage of flexibilities in federal healthcare programs that are designed to increase access to care, says Fleming.

"OIG and DOJ are particularly sensitive to arrangements that result in patient harm and testing that provides no clinical benefits to patients and causes increased costs to federal healthcare programs," she notes.

At-a-Glance: OIG Highlights for Fiscal Year 2023

Statistic	FY 2023 (10/1/22-9/30/23)
Audit Reports Issued	127
Evaluations Issued	42
Expected Audit Recoveries	$283.5 million
Questioned Costs	$1.5 billion
Potential Savings	$47.2 million
New Audit and Evaluation Recommendations	464
Recommendations Implemented by HHS OpDivs	493
Expected Investigative Recoveries	$3.16 billion
Criminal Actions	707
Civil Actions	746
Exclusions	2,112

Source: HHS OIG

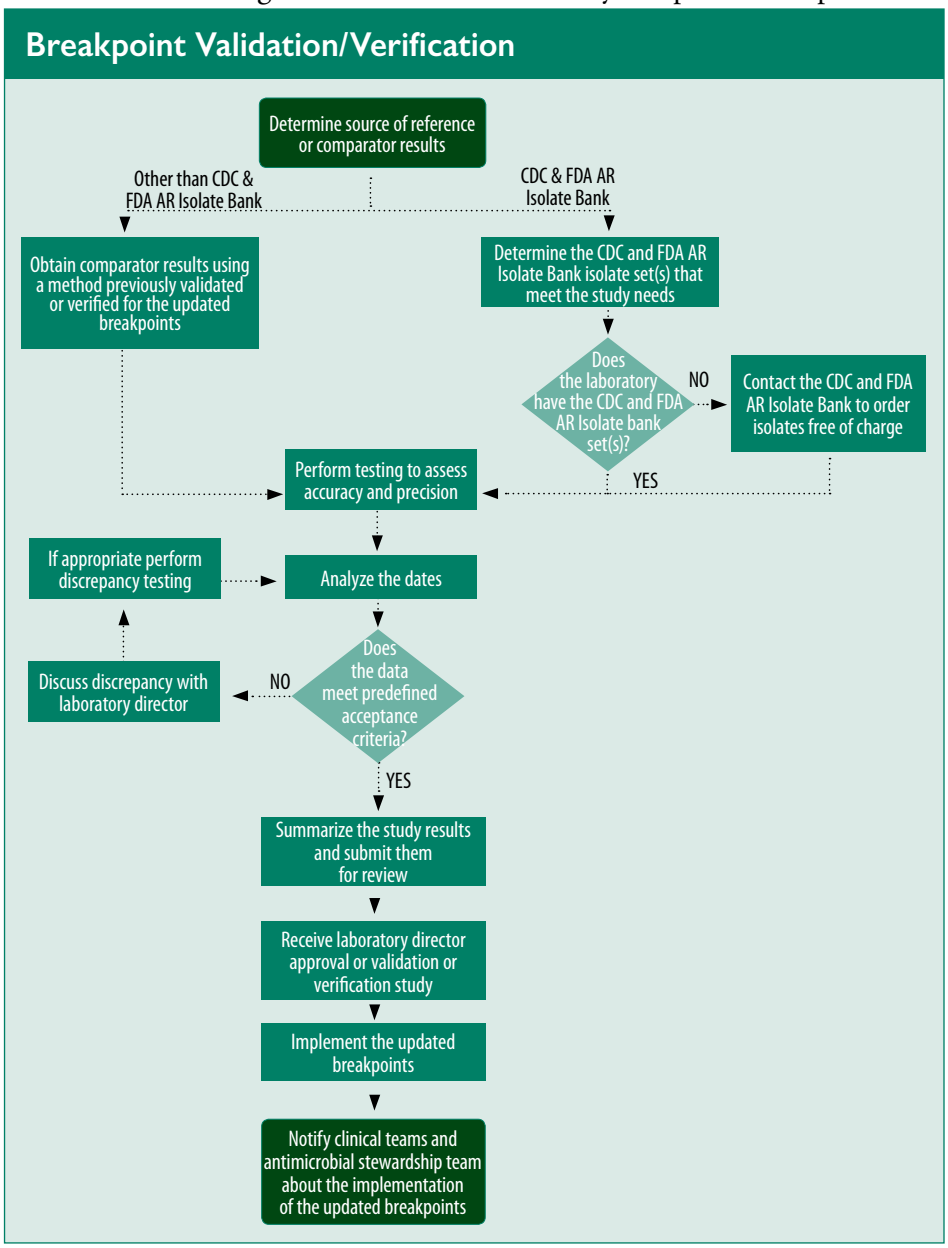
Labs Required to Update AST Breakpoints Beginning January 2024

Effective January 2024, clinical laboratories performing antimicrobial susceptibility testing (AST) will be required to use breakpoints currently recognized by the Clinical Laboratory Standards Institute (CLSI) or the U.S. Food and Drug Administration (FDA).

The CLSI, Association of Public Health Laboratories, American Society for Microbiology, College of American Pathologists and the Centers for Disease Control and Prevention have jointly developed a Breakpoint Implementation Toolkit (BIT) to assist clinical laboratories in updating minimal inhibitory concentration breakpoints. The APHL-ASM CRO Breakpoint Implementation Toolkit published in 2022 contains detailed instructions, as well as worksheets and forms for validating updated carbapenem breakpoints. These instructions can be adapted to verification or validation of other breakpoints when following the 2023 BIT.

The 2023 BIT is broken down into an introduction and seven parts, which include templates for documenting breakpoints in use, a list of all current CLSI breakpoints and corresponding FDA breakpoints and templates for documenting results of a validation study to update breakpoints. The organization suggest that clinical laboratories: 1) Determine which ones they use; 2) Determine which ones are old or out of date (e.g., no longer recognized by CLSI or FDA) and would require updating for continued reporting; 3) Develop a priority list and a plan for updating breakpoints.

Laboratories are encouraged to implement updated CLSI breakpoints as listed in M100, 33rd edition. If CLSI breakpoints are different from FDA breakpoints, a lab can select to use current CLSI or FDA breakpoints. Manufacturers of commercial AST must use FDA breakpoints that are current at the time they submit a test for clearance.



COMPLIANCE 101:

Test Utilization Monitoring

The Health and Human Services Office of Inspector General (OIG) believes that clinical laboratories should take steps to ensure that physicians will make a determination and document the medical necessity of tests billed to the Medicare program (*see the December 2023 Compliance 101*). The OIG says in its Compliance Guidance for Clinical Laboratories that it also believes there are steps laboratories can take to determine whether physicians are being encouraged to order medically unnecessary tests.

"The OIG believes that a laboratory which has reason to believe that its clients are ordering medically unnecessary tests has a duty to determine why that behavior has occurred," write the OIG in the compliance guidance. "More importantly, if the laboratory discovers that it has in some way caused that behavior, we believe the laboratory has the duty to correct the cause."

Analyze Data from Top 30 Tests

Recognizing that there may be other ways to do so, the OIG suggests the following methodology for monitoring test utilization and detecting ordering abuses. It suggests that labs retain and analyze test utilization data from year to year, by CPT or HCPCS code, for the top 30 tests they perform for Medicare beneficiaries. Laboratories could do this by keeping track of the number of tests performed by CPT or HCPCS code or of the number of claims submitted to Medicare for each test. The laboratories would then compute the percentage growth in claims submitted for each of the top 30 tests from one year to the next.

"We believe that if a test's utilization grew more than 10%, the laboratory should undertake a reasonable inquiry to ascertain the cause of such growth," says the OIG. "If the laboratory determines that the increase in test utilization occurred for a benign reason, such as the acquisition of a new laboratory facility, then the laboratory need not take any action. However, if the laboratory determines that the increase in utilization was caused by the use of basic chemistry profiles or some other action on the part of the facility, the laboratory should take any steps that it deems reasonably necessary to address the issue and to ensure that fraud is not being committed."

CodeMap, a consulting company based in Chicago, recommends that labs perform annual utilization monitoring to detect any inappropriate ordering resulting in medically unnecessary testing. The lab should prepare a final written report each year documenting the annual utilization monitoring, its finding and any subsequent action taken by the laboratory.

Clinical laboratory and pathology associations offer additional resources for test utilization monitoring. The College of American Pathologists, for example, gives examples of clinical laboratory utilization committees and how they operate. A study in the American Journal of Clinical Pathology examines various practices used to support appropriate test utilization and determined that three practices in particular were most successful—computerized provider order entry, reflex testing and combining different approaches.

CodeMap's Compliance Policy Manual for Clinical Laboratories, 2023 Edition, is available for purchase at www.codemap.com.

In Brief

Texas Man Pleads Guilty to Covid Test Fraud

A Plano, Texas, man pleaded guilty Nov. 30, 2023, to orchestrating a fraudulent scheme to obtain approximately $1.7 million from Medicare, according to the U.S. Attorney for the Northern District of Texas Leigha Simonton. Damon Heath Roberts, 55, pleaded guilty to one count of conspiracy to solicit or receive kickbacks for referrals to a federal healthcare program. He will be sentenced March 28, 2024, and faces a maximum penalty of five years in federal prison. According to court documents, Roberts, owner of JDS Labs, admitted that he and others, including medical providers and others with access to patient information, began sharing Medicare beneficiary information so that JDS Labs could bill Medicare for over-the-counter Covid-19 tests. Roberts, in exchange for the patient information, would pay a kickback based on the reimbursement from Medicare to the medical providers or other individuals. Roberts submitted nearly $4 million in claims for over-the-counter Covid-19 tests and received about $1.7 million in reimbursement for the claims. In addition, he paid approximately $149,066 in bribes and kickbacks.

CMS Modifies Coverage for Colon Cancer Screening

The Centers for Medicare and Medicaid Services (CMS) has reduced the minimum age for coverage for certain colorectal cancer (CRC) screening tests from 50 years to 45 years (CR 13017). The change applies to the following CPT codes: G0104, G0106, G0120, G0327, G0328 and 82270. Also, CMS says a positive result from a non-invasive stool-based CRC screening test no longer requires that the following colonoscopy be a diagnostic colonoscopy after a Medicare-covered, non-invasive, stool-based CRC screening test returns a positive result (within the context of a complete colorectal cancer screening). CMS also clarified information about modifiers used for screening colonoscopy claims in the context of a complete cancer screening. Effective Nov. 13, 2023, providers must apply the -KX modifier to the claim for the screening colonoscopy to confirm that the clinical requirements of the complete colorectal cancer screening are met. Claims that do not include the -KX modifier will be processed under prior established policies and claims processing instructions for regular screening colonoscopies.

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- Jondavid Klipp, Publisher Laboratory Economics

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