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INSIDE *NIR*



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## Aetna Cuts Pathology Reimbursement To 70% of Medicare

Pathologists contracted with Aetna will see their reimbursement for pathology services drop to about 70 percent of Medicare rates effective Sept. 1, 2014.

In letters sent to health care professionals, the payer said it was updating its Aetna Market Fee Schedule based on industry standards and other sources, such as the resource-based relative value scale posted on the Web site of the Centers for Medicare and Medicaid Services. While the letters were initially sent to providers in Ohio, sources say they expect the new fee schedule to be rolled out nationwide.

"I fully believe this will be a national policy," says Michelle Miller, vice president of Vachette Pathology, a revenue management company based in Blissfield, Mich.

Currently, pathologists who are out-of-network with Aetna in Ohio are receiving 80 percent to 100 percent of billed charges, so the new fee schedule will represent a significant cut for providers, she explains.

*Continued on p.2*

## TRICARE Plans Demo on LDTs, but Critics Say It Already Has Authority to Cover Tests

Plans by TRICARE to expand coverage of laboratory-developed tests (LDTs) under a new demonstration program have received mixed reaction from lab groups, which say that the program already had authority to cover LDTs.

TRICARE, which provides medical services for military families and retirees, announced June 18 that a new demonstration program would allow it to review tests not approved by the Food and Drug Administration (FDA) to determine if they are safe and effective for use. This demonstration, called the Defense Health Agency [DHA] Evaluation of Non-United States Food and Drug Administration Approved Laboratory Developed Tests Demonstration Project, also includes coverage for prenatal and preconception cystic fibrosis, with certain limitations.

TRICARE also said that beneficiaries who have paid for LDTs now included in the demonstration since Jan. 1, 2013, are eligible for retroactive reimbursement.

According to the announcement, TRICARE generally covers only "medications and medical devices like LDTs reviewed and approved

*Continued on p. 7*

**Aetna Cuts Pathology Reimbursement to 70% of Medicare,** *from p. 1*

For example, one client of Vachette's had been receiving about $120 in reimbursement for CPT 88305. Under the new fee schedule, that client will now receive payment of $28.14 for the professional component (PC) of the test. In Ohio, Medicare pays $37.52 for the PC, with a global payment of $67.34.

| NEW AETNA RATES V. MEDICARE, 2014 | | | | |
|---|---|---|---|---|
| CPT CODE | MODIFIER | DESCRIPTION | AETNA (9/1/14) | MEDICARE 2014 NATIONAL PAYMENT |
| 88300 | | Surgical Path Gross | $10.44 | $14.69 |
| 88300 | 26 | | $3.44 | $4.66 |
| 88300 | TC | | $7.99 | $10.03 |
| 88305 | | Tissue Exam by Pathologist | $50.51 | $70.57 |
| 88305 | 26 | | $28.14 | $38.33 |
| 88305 | TC | | $22.37 | $32.24 |
| 88307 | | Tissue Exam by Pathologist | $203.18 | $288.37 |
| 88307 | 26 | | $61.77 | $84.18 |
| 88307 | TC | | $141.40 | $204.19 |
| *Sources: Aetna and CMS* | | | | |

# FDA to Review 23andMe 510(k) for Rare Syndrome

The Food and Drug Administration (FDA) has agreed to review a submission by 23andMe for a health report focused on Bloom syndrome, a rare condition.

Google Inc.-backed 23andMe Inc. recently submitted to the FDA a revised 510(k) application for its direct-to-consumer genetic testing service focusing on Bloom syndrome, the Silicon Valley-based company said.

In a June 20 blog post, 23andMe Chief Legal and Regulatory Officer Kathy Hibbs called the submission "an important step in our work with the FDA in the coming months."

"Once cleared, it will help 23andMe, and the FDA, establish the parameters for future submissions. More importantly, for our customers, it marks a baseline on the accuracy and validity of the information we report back to them," Hibbs said.

In November 2013, the FDA told 23andMe to immediately stop marketing its Saliva Collection Kit and Personal Genome Service to consumers until the company received federal marketing approval for the product. At the time, the FDA said "serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported."

For a fee, 23andMe, which is based in Mountain View, Calif., provided more than 200 personalized health and trait reports as well as genetic ancestry information.

The FDA said it rejected 23andMe's 2012 510(k) clearance applications after the company failed to provide requested information.

"We are pleased to be moving forward with the FDA and committed to our company mission of empowering individuals with their genetic information," Hibbs said.

***Takeaway: 23andMe is slowly taking steps to get FDA approval to use its genetic testing service to identify a rare health disorder.***

  

# Medicare Seeks Input on More Than 100 New Lab Test Codes

The Centers for Medicare and Medicaid Services (CMS) in July will consider pricing recommendations on more than 100 new clinical laboratory codes that will be priced on the 2015 Clinical Laboratory Fee Schedule. More than 60 of the new codes are related to drug testing.

The meeting will be held July 14 at CMS headquarters in Baltimore. Attendees may register for the meeting online at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/*. Proposed pricing for the new codes should be published in September, with final pricing released in November.

| NEW TEST CODES | |
|---|---|
| ***PRESUMPTIVE DRUG CLASS SCREENING*** | |
| **803XX** | Drug screen, any number of drug classes from Drug Class List A; any number of non-TLC devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation including instrumented-assisted when performed (e.g., dipsticks, cups, cards, cartridges), per date of service |
| **803XX** | Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (e.g., discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service |
| **803XX** | Drug screen, presumptive, single drug class from Drug Class List B, by immunoassay (e.g., ELISA) or non-TLC chromatography without mass spectrometry (e.g., GC, HPLC), each procedure |
| **803XX** | Drug screen, any number of drug classes, presumptive, single or multiple drug class method; thin layer chromatography procedure(s) (TLC) (e.g., acid, neutral, alkaloid plate), per date of service |
| **803XX** | Drug screen, any number of drug classes, presumptive, single or multiple drug class method; not otherwise specified presumptive procedure (e.g., TOF, MALDI, LDTD, DESI, DART), each procedure |
| ***DEFINITIVE DRUG TESTING*** | |
| **803XX** | Alcohols |
| **803XX** | Alcohol biomarkers; 1 or 2 |
| **803XX** | Alcohol biomarkers; 3 or more |
| **803XX** | Alkaloids, not otherwise specified |
| **803XX** | Amphetamines; 1 or 2 |
| **803XX** | Amphetamines; 3 or 4 |
| **803XX** | Amphetamines; 5 or more |
| **803XX** | Anabolic steroids; 1 or 2 |
| **803XX** | Anabolic steroids; 3 or more |
| **803XX** | Analgesics, non-opioid; 1 or 2 drugs |
| **803XX** | Analgesics, non-opioid; 3-5 |
| **803XX** | Analgesics, non-opioid; 6 or more |
| **803XX** | Antidepressants, serotonergic class; 1 or 2 drugs |
| **803XX** | Antidepressants, serotonergic class; 3 |
| **803XX** | Antidepressants, serotonergic class; 6 or more |
| **803XX** | Antidepressants, tricyclic and other cyclicals; 1 or 2 drugs |
| **803XX** | Antidepressants, tricyclic and other cyclicals; 3-5 |
| **803XX** | Antidepressants, tricyclic and other cyclicals; 6 or more |
| **803XX** | Antidepressants, not otherwise specified |
| **803XX** | Antiepileptics, not otherwise specified; 1-3 drugs |
| **803XX** | Antiepileptics, not otherwise specified; 4-6 |
| **803XX** | Antiepileptics, not otherwise specified; 7 or more |
| **803XX** | Antipsychotics, not otherwise specified; 1-3 drugs |

  

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| ***DEFINITIVE DRUG TESTING (CONT.)*** | |
| **803XX** | Antipsychotics, not otherwise specified; 4-6 |
| **803XX** | Antipsychotics, not otherwise specified; 7 or more |
| **803XX** | Barbiturates |
| **803XX** | Benzodiazepines; 1-12 |
| **803XX** | Benzodiazepines; 13 or more |
| **803XX** | Buprenorphine |
| **803XX** | Cannabinoids, natural |
| **803XX** | Cannabinoids, synthetic; 1-3 |
| **803XX** | Cannabinoids, synthetic; 4-6 |
| **803XX** | Cannabinoids, synthetic; 7 or more |
| **803XX** | Cocaine |
| **803XX** | Fentanyl |
| **803XX** | Gabapentin, non-blood |
| **803XX** | Heroin metabolite |
| **803XX** | Ketamine and norketamine |
| **803XX** | Methadone |
| **803XX** | Methylenedioxyamphetamines (MDA, MDEA, MDMA) |
| **803XX** | Methylphenidate |
| **803XX** | Opiates, 1 or more |
| **803XX** | Opioids and opiate analogs; 1 or 2 |
| **803XX** | Opioids and opiate analogs; 3 or 4 |
| **803XX** | Opioids and opiate analogs; 5 or more |
| **803XX** | Oxycodone |
| **803XX** | Pregabalin |
| **803XX** | Propoxyphene |
| **803XX** | Sedative hypnotics (non-benzodiazepines) |
| **803XX** | Skeletal muscle relaxants; 1 or 2 |
| **803XX** | Skeletal muscle relaxants; 3 or more |
| **803XX** | Stimulants, synthetic |
| **803XX** | Tapentadol |
| **803XX** | Tramadol |
| **803XX** | Stereoisomer (enantiomer) analysis, single drug class |
| **803XX** | Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3 |
| **803XX** | Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6 |
| **803XX** | Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more |
| ***THERAPEUTIC DRUG ASSAYS*** | |
| **801XX** | Digoxin; free |
| **801XX** | Valproic acid (dipropylacetic acid); free |
| ***TIER 1 MOLECULAR PATHOLOGY PROCEDURES*** | |
| **812XX** | FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (e.g., D835, I836) |

  

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| ***TIER 1 MOLECULAR PATHOLOGY PROCEDURES*** | |
| **812XX** | MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis |
| **813XX** | PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate-specific antigen]) ratio (e.g., prostate cancer) |
| ***GENOMIC SEQUENCING PROCEDURES (GSPS) AND OTHER MOLECULAR MULTIANALYTE ASSAYS*** | |
| **814XX** | Aortic dysfunction or dilation (e.g., Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK |
| **814XX** | Aortic dysfunction or dilation (e.g., Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); duplication/deletion analysis, panel must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1 |
| **814XX** | Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis |
| **814XX** | Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (e.g., parents, siblings) (List separately in addition to code for primary procedure) (*Use 81416 in conjunction with 81415*) |
| **814XX** | Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (e.g., updated knowledge or unrelated condition/syndrome) |
| **814XX** | Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21 |
| **814XX** | Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis |
| **814XX** | Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure) (*Use 81426 in conjunction with 81425*) |
| **814XX** | Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g., updated knowledge or unrelated condition/syndrome) |
| **814XX** | Hearing loss (e.g., nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, and WFS1 |
| **814XX** | Hearing loss (e.g., nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes |
| **814XX** | Hereditary colon cancer syndromes (e.g., Lynch syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2 |
| **814XX** | Hereditary colon cancer syndromes (e.g., Lynch syndrome, familial adenomatosis polyposis); duplication/deletion gene analysis panel, must include analysis of at least 8 genes, including APC, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, and MUTYH |
| **814XX** | Nuclear encoded mitochondrial genes (e.g., neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP |
| **814XX** | Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (e.g., ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed |
| **814XX** | Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA and RNA analysis when performed, 5-50 genes (e.g., BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed |
| **814XX** | Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed |

  

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| ***GENOMIC SEQUENCING PROCEDURES (GSPS) AND OTHER MOLECULAR MULTIANALYTE ASSAYS (CONT.)*** | |
| **814XX** | Whole mitochondrial genome (e.g., Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERRF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection |
| **814XX** | Whole mitochondrial genome large deletion analysis panel (e.g., Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed |
| **814XX** | X-linked intellectual disability (XLID) (e.g., syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2 |
| **814XX** | X-linked intellectual disability (XLID) (e.g., syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2 |
| ***MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES*** | |
| **XXXXM** | Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier |
| **XXXXM** | Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a namogram of tumor disease index |
| **XXXXM** | Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score |
| **815XX** | Oncology (breast), mRNA, gene expression profiling by real-time PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score |
| ***CHEMISTRY*** | |
| **830XX** | Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1) |
| ***MICROBIOLOGY*** | |
| **875XX** | Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets |
| **875XX** | Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets |
| **875XX** | Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets |
| **876XX** | Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (e.g., 6, 11, 42, 43, 44) |
| **876XX** | Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) |
| **876XX** | Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed |
| **878XX** | Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies |
| ***REPRODUCTIVE MEDICINE PROCEDURES*** | |
| **89XXX** | Cryopreservation, mature oocyte(s) |
| ***G CODES*** | |
| **GXXXX** | Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3). |
| *Source:* www.cms.gov/ClinicalLabFeeSched/. *Click on "Laboratory Public Meetings" to access the download. Numbering of new codes will be finalized at a later date. CPT codes copyright American Medical Association.* | |

  

**TRICARE Plans Demo on LDTs,** *from p. 1*

by the [FDA]. The demonstration allows the Defense Department to performs its own evaluation of an [LDT], establish a list of these tests deemed safe and effective, and establish a process to add new tests to that list. TRICARE will maintain and publish a list of approved tests and will continually update it as new tests are reviewed and approved for coverage. The regional contractor must preapprove use of the test for it to be covered."

The American Clinical Laboratory Association (ACLA) said that while it greatly appreciates DHA's effort to further review certain laboratory tests, it reiterates its view that current regulations already allow for TRICARE coverage of LDTs. In fact, TRICARE, like Medicare, Medicaid, and commercial insurers, has a long history of covering LDTs, which play a critical role in the diagnosis and treatment of disease, said Alan Mertz, ACLA president.

"While ACLA maintains current regulations allow for TRICARE coverage of laboratory-developed tests, if a demonstration project facilitates the restoration of coverage for molecular pathology tests for all TRICARE beneficiaries, then it is important to move forward in this process."

*"In many cases, laboratories have continued to provide testing services to TRICARE patients and are awaiting payment. In other cases, TRICARE beneficiaries have been forced to absorb one hundred percent of the costs for testing, or seek assistance from patient advocacy organizations. This is unacceptable."*
*—Sharon Terry, President and CEO, The Genetic Alliance*

In January 2013, TRICARE stopped reimbursing clinical laboratories for more than 100 molecular pathology tests when care was obtained from the civilian provider network. Testing services for TRICARE beneficiaries receiving health care at a military treatment facility were not affected. Among services affected were tests for cystic fibrosis, Fragile X syndrome, and other tests considered to be standard of care in the diagnosis and treatment of leukemia and lung and other cancers.

TRICARE's abrupt change in coverage led to an outpouring of concern from members of Congress, military organizations, medical societies, patient and disease groups, and laboratories, all of whom have urged the DHA to restore TRICARE coverage for these critical tests.

In addition to the demonstration project, S. 2410, the Carl Levin National Defense Authorization Act for Fiscal 2015, includes a provision to clarify DHA's authority to cover LDTs. ACLA has endorsed that provision and believes its enactment remains necessary despite announcement of the demonstration project by DHA.

The same day that TRICARE announced the demonstration, the Genetic Alliance sent a letter to Congress calling for DHA to restore coverage for the LDTs that have been denied. The letter, signed by a number of consumer and medical organizations, notes that FDA has a longstanding "enforcement discretion" policy with respect to LDTs, under which FDA has "clearly and repeatedly said that it does not require premarket review or clearance for LDTs to be lawfully marketed. There are thousands of LDTs currently legally marketed, which neither have, nor are required to have, FDA clearance or approval."

Despite acknowledging the important role of LDTs in health care delivery costs, the DHA has denied coverage of these tests for over a year, said the alliance. "In many cases, laboratories have continued to provide testing services to TRICARE patients and are awaiting payment," wrote Sharon Terry, president and CEO. "In other cases, TRICARE beneficiaries have been forced to absorb one hundred percent of the costs for testing, or seek assistance from patient advocacy organizations. This is unacceptable."

***Takeaway: While it appears that TRICARE may be open to covering lab-developed tests provided to beneficiaries, critics say the program never should have stopped covering them.*** G2

  

# LDT Guidance Unlikely to Be Released Anytime Soon

Draft guidance from the Food and Drug Administration (FDA) of lab-developed tests appears to be stuck at the Office of Management and Budget and likely will not be released any time soon, according to a consultant who specializes in FDA regulation of medical diagnostics and tests.

Speaking at G2 Intelligence's MDx *NEXT* conference in Baltimore June 12, Mya Thomae said she believes it's unlikely that the draft guidance will ever be released, citing intense opposition by clinical laboratories. While manufacturers of in vitro diagnostic tests have called on FDA to "level the playing field" for IVDs and LDTs, Thomae said she does not believe there is the political will to push the document through. Even if it were to be issued, the FDA does not have the resources to regulate additional laboratory tests. Thomae is president and CEO of Myraqa Inc., a regulatory consulting firm in Redwood Shores, Calif.

Regulation of LDTs by the FDA would present a whole new set of challenges for the industry as clinical utility is defined differently by the FDA than by the marketplace, explained Thomae. Most assays are used in the Clinical Laboratory Improvement Amendments (CLIA) environment long before making it to the FDA, if they ever do. The agency sometimes wants more clinical utility studies even when markers are in disease guidelines, she noted.

"CLIA enforcement discretion appears to be here to stay for the foreseeable future," said Thomae.

Ultimately, money may well dictate regulatory direction, said Thomae. "If reimbursement organizations require FDA clearance or approval of assays, then companies will obtain FDA clearance or approval," she predicted. "If reimbursement organizations continue to remain ambivalent to FDA clearance or approval, then change is unlikely."

The FDA has tried to place some restrictions on lab-developed tests through guidance documents issued Nov. 25, 2013, on research-use only (RUO) and investigational-use only (IUO) in vitro diagnostic products. The final guidance did omit the most controversial language included in the draft, which would have recommended that manufacturers of RUO- or IUO-labeled IVDs halt sales to lab customers they discover are using the products in clinical diagnosis.

Instead, the final guidance focuses on manufacturer statements and actions that would provide evidence of a clinical intended use for an RUO- or IUO-labeled IVD, including not only promotional labeling and advertising but also the "solicitation of business from clinical laboratories" by a manufacturer's sales people who "make routine calls to clinical laboratories that do not perform research or clinical studies." The guidance also encourages use of a "certification program" under which users certify that they will not use RUO or IUO products in a "manner inconsistent with the labeling."

***Takeaway:** While the FDA wants to regulate lab-developed tests, extensive opposition by lab groups is helping keep LDT guidance from being finalized. Even so, the FDA is using other guidance documents as a way to restrict development of LDTs.*



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