G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

July 2016

Inside this issue

www.G2Intelligence.com

Labs Face Nearly Doubled FCA Penalties under DOJ's Interim Final Rule

On June 30 the Department of Justice (DOJ) published an Interim Final Rule in the Federal Register that has significant ramifications for enforcement under the False Claims Act (FCA). Pursuant to the Bipartisan Budget Act of 2015, the DOJ adjusted for inflation the amount of civil monetary penalties that can be imposed for violations of laws enforced by the DOJ.

The new penalties for violations of the FCA were nearly doubled by this adjustment. The current penalty range for FCA violations is a minimum of $5,500 and maximum of $11,000. Under the adjustments, those rates will increase to $10,781 and $21,563, respectively.

Continued on page 9

Theranos Faces More Questions and Challenges And Ramps Up Efforts to Improve Compliance

Both the Centers for Medicare & Medicaid Services (CMS) and some high ranking Democratic Committee members had some bad news for Theranos at the start of this month. The company itself issued a statement announcing "CMS has decided to impose all available sanctions regarding our lab business." Three members of the House Energy and Commerce Committee sent the company a letter expressing concern about compliance problems and asking for a briefing on Theranos' plans to address the issues. Meanwhile, the company took steps to improve its compliance program with new leadership.

Briefing Request from E&C Committee Leaders

Even before CMS announced that the company's latest corrective actions were insufficient, three Democratic Committee leaders sent Theranos a letter seeking more information about "how company policies permitted systematic violations of federal law and how Theranos is working with regulators to address these failures," as well as information about the "steps Theranos is taking to correct flawed test results sent to medical professionals and patients." The letter came from Energy and Commerce Committee Ranking Member Frank Pallone, Jr. (D-NJ), Health Subcommittee Ranking Member Gene Green (D-TX), and Oversight and Investigations Subcommittee Ranking Member Diana DeGette (D-CO).

Continued on page 2

Theranos Faces More Questions and Challenges, *from page 1*

Dated June 30, the letter referred to the CMS November 2015 inspection of Theranos' Newark, Calif. Laboratory and the subsequent letters from CMS on Jan. 25, 2016 and March 18, 2016 detailing failures to comply with Clinical Laboratory Improvement Amendments (CLIA) requirements. The January letter had documented results of the inspection and listed the condition-level and standard-level CLIA violations and the March 18 letter notified Theranos that CMS was considering imposing sanctions. The Committee members also expressed concern about news media reports, in the *Wall Street Journal* in particular, that raised questions about test results involving Warfarin. Additionally, they cited an independent assessment by the Icahn School of Medicine at Mount Sinai which questioned accuracy of Theranos testing, noting that study's inclusion of an example regarding cholesterol testing.

CMS is proposing revocation of the lab's CLIA certificate, effective Sept. 5, 2016.

The leaders requested a briefing addressing the company's efforts to comply with not only the CMS inspection letters but also the FDA 483 inspection reports issued August and September 2015. Specifically, the letter requests the briefing address changes to policies and procedures the company has made, efforts to investigate the "root cause" of compliance issues, how it identified affected patients, and how the company is helping affected providers and patients.

CMS Gives Notice of Impending CLIA Sanctions

CMS issued a letter to Theranos July 7 explaining why multiple submissions made by Theranos in response to CMS' January and March letters still do "not constitute a credible allegation of compliance and acceptable evidence of correction" of the deficiencies found in the 2015 inspection.

For example, CMS found fault with the evidence provided regarding corrective actions taken for patients whose test results were "found to have been affected by the deficient practice." As to quality assessments, CMS said the lab failed to demonstrate what changes were made to ensure there would be no recurrence of the deficiencies. In discussion of proficiency testing, CMS questioned how the lab arrived at its conclusion that no patients have suffered harm.

CMS is proposing revocation of the lab's CLIA certificate, effective Sept. 5, 2016. Loss of CLIA certification brings with it a prohibition against Holmes owning, operating or directing a lab for two years. Other sanctions include:

- Effective July 15, 2016, limitation of the lab's CLIA certificate for hematology services (the effective date is not affected by any appeal filed)
- Effective July 12, 2016, an alternative sanction of $10,000 daily penalty until deficiencies resolved (if appeal is filed, the penalty won't be collected until after the appeal is decided)
- By July 12, 2016, Theranos was required to provide a list of names and addresses of all physicians and clients who used the lab's services since January 2014 (due date applied regardless of any appeal)
- Suspension of Medicare/Medicaid payment eligibility for hematology services effective July 15, 2016
- Cancellation of approval for Medicare/Medicaid payment for all laboratory services effective September 5, 2016 (this takes effect regardless of any appeal filed)

Theranos Response

"We accept full responsibility for the issues at our laboratory in Newark, California, and have already worked to undertake comprehensive remedial actions," Theranos CEO Elizabeth Holmes said in a statement released July 7. "While we are disappointed by CMS' decision, we take these matters very seriously and are committed to fully resolving all outstanding issues with CMS and to demonstrating our dedication to the highest standards of quality and compliance."

> ***"We accept full responsibility for the issues at our laboratory in Newark, California, and have already worked to undertake comprehensive remedial actions"***
>
> **— Elizabeth Holmes, CEO, Theranos**

Theranos got out in front of the news, not only announcing CMS' threatened sanctions in its own statement, but also attaching a copy of the entire CMS July 7 letter, and providing a Q/A addressing several questions concerning the sanctions and their impact on operations. The company said July 8 it is "considering all its options" and didn't indicate whether it would be filing an appeal but vowed to continue on with its mission, promising to work with CMS "non-stop to resolve the issues identified." It addressed the issue of patient safety, stating "Patient safety and quality are our top priorities. As of now, we have not been made aware—by CMS, physicians or patients—of any harm to patient health resulting from our tests."

Theranos' statement also highlighted that the company does more than just lab testing, including research and development of "many technologies that are not dependent on running a clinical laboratory." Promising to continuing building on its mission of accessible and affordable testing, the company explained: "Improving access through innovative technologies is a universal need, with growth opportunities in global and domestic vertical markets."

The company has been active in rehabilitating its compliance image. An "Op-Ed" written by William H. Foege, MD, MPH, a member of the company's Scientific and Medical Advisory Board and the Board of Directors declared there is "another side to the story" and discussed the reason he supports the company in its mission. Foege is a former director of the U.S. Centers for Disease Control and Prevention and former senior medical adviser for the Bill and Melinda Gates Foundation. He indicated he and others were given access to the company's technology, data and validation reports and he believes that "the very foundation of Theranos' inventions— and its hundreds of patents—is credible." To demonstrate this credibility, he notes that the SMAB is assisting the company in preparing for publication of its data in peer-reviewed scientific journals and public presentations.

As we went to press, Theranos announced the appointment of a chief compliance officer, a vice president of regulatory and quality, and a Compliance and Quality Committee. Daniel Guggenheim, a health care lawyer who formerly served as assistant general counsel at McKesson Corp., will handle "day-to-day implementation and oversight of the company's compliance program" as chief compliance officer. Dave Wurtz will oversee regulatory affairs including FDA submissions and approvals and pre- and post-marketing activities. Wurtz performed a similar role at ThermoFisher Scientific as senor director of regulatory, quality and compliance. Finally, the company's board of directors has formed the Compliance and Quality Committee, which will work with both new executives and the board to monitor implementation of the compliance program. "Theranos understands that regulatory compliance is an essential element of any successful and innovative health care company," said Dr. Fabrizio Bonanni, board member and chair of the Compliance

and Quality Committee. "This committee will be integral to fulfilling Theranos' commitment to bringing the highest integrity health information to every person."

Takeaway: Theranos continues to face questions about its technology and compliance with CLIA and FDA requirements as threat of sanctions looms closer. Yet, the company remains resolute that it has sound and credible technology and is taking steps in intensify its compliance efforts.

Lab Is Sentenced as Prosecution of Individuals for Lab Kickbacks Continues

Amidst the guilty pleas and sentencing of dozens of individuals accused of receiving kickbacks for lab referrals, the laboratory company at the center of the case, Biodiagnostic Laboratory Services LLC (BLS) entered a guilty plea the end of June in New Jersey federal court. The company pleaded guilty to one count of conspiracy to violate the Anti-Kickback Statute and the Federal Travel Act and one count of conspiracy to commit money laundering, the Department of Justice (DOJ) announced. U.S. District Judge Stanley R. Chesler then sentenced the company, requiring forfeiture of all its assets (operations have already ceased).

So far, the case has led to 41 guilty pleas including 27 from physicians. Another New Jersey physician entered a guilty plea just days after the lab's sentence was announced. That physician admitted to receiving "consulting fees" in exchange for referrals of patient blood specimens to the lab for testing. The DOJ has claimed the case is "believed to be the largest number of medical professionals ever prosecuted in a bribery case" and it has "recovered more than $12 million through forfeiture." The government alleged millions of dollars in bribes were paid to providers to influence test referrals to the laboratory which yielded more than $100 million for the lab in Medicare and private payor payments. One of the most recent physician sentences involved a 37-month jail sentence to a physician who had pleaded guilty to accepting bribes in violation of the Anti-Kickback Statute. Those bribes were said to include cash payments as well as meals and entertainment such as tickets to professional sporting events, Katy Perry and Justin Bieber concerts, and a Broadway show.

In a separate New Jersey case also involving kickbacks for lab referrals, a physician recently pleaded guilty to conspiracy to accept cash bribes in exchange for referring patients to two lab companies. The government alleged two sales representatives from a marketing and sales company paid a physician thousands of dollars to induce him to refer patient specimens to two of its client laboratories. Those client labs are said to have no knowledge of or involvement in the arrangements. The sales representatives have already previously pleaded guilty to charges of conspiracy to bribe a physician.

These cases provide yet another reminder of the importance of paying close attention to how a lab's services are marketed and what sales and marketing personnel are doing on behalf of the lab to sell its services. Last year, Health Diagnostic Laboratory and Singulex entered into settlement agreements totaling $48.5 million to resolve allegations that physicians were paid processing and handling fees to induce physicians to send specimens to their labs for testing.

Takeaway: The lab at the center of purportedly the largest physician bribery case is finally sentenced as the prosecution of individual physicians for receiving payments for lab referrals continues in that and other cases.

CMS Latest Data Release Offers Labs a Tool to Spot Potential Compliance Red Flags

While implementation of the Protecting Access to Medicare Act of 2014 (PAMA) will have labs collecting private payer payment data to report to the Centers for Medicare & Medicaid Services (CMS), CMS has for the third year in a row reported its own data on what Medicare pays physicians, labs and other providers. Earlier this year, CMS released an updated public data set regarding Medicare payments known as the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (Physician and Other Supplier PUF).

> *"Standardization removes geographic differences in payment rates for individual services, such as those that account for local wages or input prices and makes Medicare payments across geographic areas comparable."*
>
> — CMS

This CMS data release is intended to further the goal of transparency by making public the Medicare charges from and payments to physicians, labs and other providers. According to CMS' press release regarding the data set: "The release of timely, privacy-protected data is especially important as the Medicare increasingly pays providers based on the quality, rather than the quantity, of care they give patients. These initiatives contribute to a wide set of CMS activities focused on achieving better care, smarter spending, and healthier people throughout the health care system."

What's new this year

CMS said it has updated the data set and its supplemental summary tables including the "Medicare Physician and Other Supplier Aggregate Table" (i.e., one record per NPI) and the "Medicare State/National HCPCS Aggregate Tables" to include standardized payment data so users can compare Medicare payment amounts across geographic areas. "Standardization removes geographic differences in payment rates for individual services, such as those that account for local wages or input prices and makes Medicare payments across geographic areas comparable."

Additionally, now researchers don't have to wait for annual extracts under Limited Data Sets (LDS) but can instead request updates to LDS claims files on a quarterly basis.

Details about the data

CMS reports the data set has more than 986,000 health care providers who "collectively received $91 billion in Medicare payments." CMS' website explains: "The Physician and Other Supplier PUF contains information on utilization, payment (allowed amount and Medicare payment), and submitted charges organized by National Provider Identifier (NPI), Healthcare Common Procedure Coding System (HCPCS) code, and place of service. This PUF is based on information from CMS administrative claims data for Medicare beneficiaries enrolled in the fee-for-service program. The data in the Physician and Other Supplier PUF covers calendar years 2012 through 2014 and contains 100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service population."

> *"CMS is committed to the prevention and detection of fraud and abuse in the Medicare program and partners with numerous entities in this endeavor, including federal and state law enforcement agencies, the HHS Office of Inspector General, and the U.S. Department of Justice, among others. If you suspect a potential case of Medicare fraud or abuse, please visit http://stopmedicarefraud.gov for information on how to report it."*
>
> — CMS

Categories of information (columns in the database spreadsheet) include National Provider Identifier, provider name, provider credentials, entity type/gender of provider, provider address, provider type (i.e. clinical laboratory), place of service, HCPCS code and description, number of services provided (the metrics counting the number of services varies by service), number of Medicare beneficiaries receiving the service, number of beneficiaries per day of service (this category removes double counting of beneficiaries receiving multiple services), average Medicare allowable amount, average submitted charge, average Medicare payment amount, average Medicare standardized amount.

Medicare defines the following terms used in the data set as follows:

- Average Medicare Allowed Amount is the amount Medicare pays plus the deductible, coinsurance and any third party responsibility.
- Average Medicare Payment is the amount Medicare pays after that coinsurance and deductible are subtracted.
- Average Medicare Standardized Amount is the average amount Medicare paid after beneficiary deductible and coinsurance amounts are deducted and after the standardization of Medicare payment (i.e., removal of geographic differences in payment as discussed above).

Information and links to the data sets for the past three data releases (released in 2016, 2015, and 2014 addressing data from 2014, 2013, and 2012 respectively) are available on CMS' website at: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicare-provider-charge-data/physician-and-other-supplier.html

Data offers tool for ferreting out potential fraud

Earlier this year, CMS touted its successes using data via its Fraud Prevention System to spot trends and potential fraud hotspots. While the agency didn't cite this public use file as a data set it uses, that emphasis on data highlights the potential compliance uses for the Medicare data publicly available in this data set.

In fact, CMS' questions and answers about the Physician and Other Supplier PUF encourage reporting any suspected fraud found in the data. In answer to the question "What do I do if I think I've identified fraud in the Physician and Other Supplier PUF?" CMS answers: "CMS is committed to the prevention and detection of fraud and abuse in the Medicare program and partners with numerous entities in this endeavor, including federal and state law enforcement agencies, the HHS Office of Inspector General, and the U.S. Department of Justice, among others. If you suspect a potential case of Medicare fraud or abuse, please visit http://stopmedicarefraud.gov

for information on how to report it." Further evidence that HHS fully encourages users to ferret out fraud using this public data set is found in a U.S. Department of Health and Human Services letter to the American Medical Asssociation, which emphasizes the ability of such data to reveal fraud as evidence that the public interest in this information outweighs individual physician/provider privacy interests.

While the value of the data has been questioned—industry stakeholders have argued that the data provides an incomplete picture because it doesn't address quality of or costs to provide services—the government and the media aren't the only ones that can find this data useful.

The data has indeed been used in past years to scout out potential red flags in reimbursement patterns. Mainstream media have used the data to question Medicare revenues and billing practices of specific entities involved in lab testing. *G2 Compliance Advisor* (GCA) noted in prior years the *Wall Street Journal*'s articles citing the Medicare data to question billing for drug testing (See "News-At-A-Glance: Another WSJ Story Implicating Laboratories," *G2 Compliance Advisor*, 11/14, p. 12) and a *Washington Post* article targeting a pain clinic whose physicians included top Medicare recipients of reimbursement for a specific service (See "CMS Data Dump Reveals Pain for Alabama Clinic," *G2 Compliance Advisor*, 5/14, p. 3). Most notably, the Wall Street Journal cited the CMS 2014 Data release in raising questions about Medicare reimbursement to Health Diagnostic Laboratory (HDL), questioning the lab's status as one of the top recipients of Medicare payments for specific tests and services. For example, the article highlighted HDL for receiving 93 percent of all Medicare funds paid for all labs for a specific procedure in 2012 and 64 percent of all Medicare payments for its top nine tests. (See "Wall Street Journal Article Illustrates Increased Compliance Risks for Labs," *G2 Compliance Advisor*, 9/14, p.1) HDL ultimately was the subject of government investigation and settled allegations of kickbacks and medically unnecessary testing for $47 million.

While the value of the data has been questioned—industry stakeholders have argued that the data provides an incomplete picture and doesn't address quality of or costs to provide services—the government and the media aren't the only ones that can find this data useful. Labs looking to gauge their Medicare reimbursement against others in the industry can find value in the data and the interactive features provided to manage and view it. A lab can review its own reimbursement reported in the data set to look for red flags indicating potential compliance issues. For example, if the data shows a lab receives significantly higher Medicare revenue or is performing significantly higher volume for a particular test than other labs, that could be a red flag. Or if review of the data for the past three years shows a significant change concerning any particular test, that too could signal a potential compliance issue warranting a closer look.

How to Use Data

CMS provides the data in two publicly accessible formats: 1) an interactive online data set that users can navigate using filters; and 2) a downloadable "tab delimited file format" that "requires importing into database or statistical software."

In the online data set, CMS has provided search functions, filters and tools to help users make sense of the vast amount of information available in the data set. For example, users can search the data by entering a provider number, specific provider name or by searching for entity names containing a specific word. Data can also be organized using filters to search a specific type of provider in a specific state for a specific HCPCS code.

Visual graphics tools improve understanding by offering a variety of ways to visually display search results. For example, once filters are applied to gather a specific set of information, that data can be visually displayed for comparison with bar graphs, line graphs, pie charts, bubbles and tree maps.

While not perfect or complete, the Medicare data can be one more compliance tool to help lab compliance professionals spot anomalies and trends in a lab's Medicare payments. And at least for Medicare services, a laboratory can compare its charges and volume against others in the industry.

Takeaway: CMS continues to promote transparency by releasing, for the third year in a row, a public accessible data set revealing Medicare charges and payments to labs and other providers.

Transparency Continues to Trump Privacy

The trend is transparency. CMS has overruled stakeholder's concerns about the impact of these data releases on privacy, responding that no beneficiary identifying information is provided. Further, to prevent indirect exposure of Medicare beneficiaries, CMS indicates any aggregated records from 10 or fewer beneficiaries are excluded from the Physician and Other Supplier PUF. HHS specifically addressed privacy concerns in a 2014 letter to the American Medical Association (AMA) explaining "the Department weighed the privacy interests of physicians and the public's interest in shedding light on Government activities and operations and has determined that the public's interest outweighs the privacy interests."

The Department concluded that the data to be released would assist the public's understanding of Medicare fraud, waste, and abuse, as well as reveal payments to physicians for services furnished to Medicare beneficiaries, which are governed by statutory requirements that CMS must follow." HHS cited the *Wall Street Journal's* ability to use Medicare payment data to identify fraud as evidence of the public interest in the information. Therefore, it concluded "release of physician-identifiable payment information will serve a significant public interest by increasing transparency of Medicare payments to physicians, which are governed by statutory requirements, and shed light on Medicare fraud, waste, and abuse."

Additionally, because the data set informs the public about Medicare payments, types of services paid for under Medicare, and Medicare payments to specific physicians, the agency argued it fostered "a more informed debate about the appropriate Medicare payment for particular services." Finally, CMS said this data was in keeping with a shift under the Affordable Care Act toward greater transparency, coordination of care, and sharing of information to increase efficiency, quality, and value of care while lowering costs.

HHS cited the various programs measuring quality of care and providing tools to help the public compare providers, as well as some state laws that require providers publicly reveal charges and payment information as evidence of the "changing nature" of what is publicly shared about physician services and payment. All this transparency means, HHS concluded, that "the physicians' privacy interest in payment data is not the same as it was over 30 years ago or even 5 years ago."

Labs Face Nearly Doubled FCA Penalties under DOJ's Interim Final Rule, *from page 1*

The FCA provides that those who violate the Act can be liable for a penalty between $5,000 and $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act plus three times the amount of damages the Government suffers due to the violation. The court does have the ability to reduce damages to "not less than 2 times the amount of damages" the Government suffers.

The interim final rule is effective Aug. 1, 2016, but written comments can be submitted until Aug. 29, 2016. The new penalty amounts can be imposed only for penalties assessed after the Aug. 1 effective date for violations that occurred after Nov. 2, 2015. Penalties for violations occurring on or before Nov. 2, 2015 are subject to the prior rates.

Takeaway: The cost of noncompliance just increased for labs and all health care providers.

Editor's Note: To learn about how your laboratory can avoid false claims liability, see G2 Intelligence's report, Lab Compliance Essentials 2017: Managing Medicare Fraud & Abuse Liability Risk, released July 2016. This report provides a practical, plain-language guide to protecting labs against false claims, Anti-Kickback Statute and Stark Law violations and discusses the latest enforcement cases involving and affecting lab compliance.

FDA Guidance Addresses NGS Testing, Espousing Flexibility in Oversight

Promoting flexibility and efficiency, the U.S. Food and Drug Administration (FDA) issued two draft guidance documents in early July, addressing oversight of next generation sequencing-based tests and the databases that support clinical claims for these tests.

The FDA explained that "current regulatory approaches are appropriate for conventional diagnostics that measure a limited number of substances associated with a disease or condition," but a more "flexible approach to oversight" is needed for sequencing technologies that "examine millions of DNA variants at a time."

Acknowledging input from genomics experts, providers, patients and other industry stakeholders via public workshops and other efforts, Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health said in a statement that the agency believes the guidance documents "will encourage innovation and advance the goal of precision medicine: to speed the right individualized treatments to patients sooner."

Public Input

The FDA explained that "current regulatory approaches are appropriate for conventional diagnostics that measure a limited number of substances associated with a disease or condition," but a more "flexible approach to oversight" is needed for sequencing technologies that "examine millions of DNA variants at a time."

That need for flexibility was emphasized by participants in a February 2015 FDA workshop addressing potential NGS standards. At that workshop when asked whether standards for NGS tests were feasible and, if so, who should develop them, who should implement them, and how could compliance be verified, panelists recommended the FDA involve multiple stakeholders in crafting any standards and advised that given the rapidly developing nature of the technology, the standards' flexibility was critical. Two more workshops were held later that year in November addressing next-generation sequencing standards and use of databases to establish clinical relevance of genetic

variants. The FDA at the time said it sought "sufficiently flexible assay performance standards that can accommodate innovation, including test modifications, while assuring NGS test safety and effectiveness."

The draft guidance documents just released are intended to provide that flexibility. The FDA explained in its announcement of the documents' release: "When the guidances are finalized, adherence to them will offer appropriate flexible and adaptive regulatory oversight of these tests, while allowing for variations in development and validation and accommodating the rapid evolution of NGS technologies."

The guidance sets forth test design considerations, test performance characteristics, test run quality metrics and general recommendations for performance evaluation studies.

NGS Test Guidance

"Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases"—provides the FDA's proposed recommendations for "designing, developing, and validating NGS-based tests for germline diseases, and also discusses possible use of FDA-recognized standards for regulatory oversight of these tests." The guidance informs test developers how they can get their NGS tests for germline diseases classified as class II devices and potentially exempt from premarket notification. NGS tests have not been classified by the FDA so they would normally fall into Class III device category under existing law. That means the developer would need to submit an application for premarket approval rather than premarket notification under Section 510k.

The guidance is limited to targeted and whole exome sequencing NGS-based tests that diagnose germline diseases or other conditions. It doesn't apply to NGS tests for "stand-alone diagnostic purposes" or for "screening, microbial genome testing, risk prediction, cell-free DNA testing, fetal testing, pre-implantation embryo testing, tumor genome sequencing, RNA sequencing, or use as companion diagnostics," which could have different analytical characteristics not addressed by the guidance. The guidance sets forth test design considerations, test performance characteristics, test run quality metrics and general recommendations for performance evaluation studies.

Genetic Variant Databases Guidance

"Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing(NGS)-Based In Vitro Diagnostics"—details the FDA's thinking on "how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA's regulatory review of NGS-based tests."

One of the FDA's objectives for this guidance is to promote use of publicly accessible databases of genetic variant data to help determine clinical validity of NGS-based tests and thus advance precision medicine. So the guidance sets standards for determining "whether a genetic variant database is a source of valid scientific evidence" that could support the clinical validity of an NGS-based test in a premarket submission. The FDA addresses the quality of the data contributed as well as the privacy and security of information in the databases and transparency as to the sources of data in the databases. As to data quality, the guidance recommends genetic variant databases use consistent nomenclature "that is widely accepted by the genomics community for gene names and/or symbols, genomic coordinates, variants, described clinical and functional char-

acteristics and classifications." The FDA also recommends that metadata accompany the variant data in the databases, demonstrating the number of independent laboratories and names of laboratories reporting variant classifications and the name of the test used to detect the variant and when possible technical characteristics of such tests.

Public comments can be submitted at any time for FDA guidance documents but to have comments considered before these draft guidance documents are finalized, comments must be submitted by October 6, 2016 for each guidance.

The guidance also indicates how publicly accessible databases can apply for FDA recognition and how the FDA will evaluate such databases. The recognition process would be voluntary and similar to the standards recognition process under Section 514 of the Food, Drug and Cosmetic Act for standards assuring safety and effectiveness of medical devices. But, the FDA explains in a footnote it won't be conducted under Section 514. Databases that receive recognition will be reviewed regularly to ensure they continue to meet the requirements of the guidance.

Next Steps

The two draft guidance documents have a 90-day comment period and were published in the July 8 Federal Register. Public comments can be submitted at any time for FDA guidance documents but to have comments considered before these draft guidance documents are finalized, comments must be submitted by Oct. 6, 2016 for each guidance.

The FDA hosted two webinars focusing on the guidance documents on July 27, addressing the technical and regulatory aspects of the guidance documents and the significance of the guidance documents for patients and health care providers. See www.fda.gov/CDRHwebinar for more information about the webinars. Transcripts of the webinars and the slide presentations will be available for review after the webinars.

Takeaway: Workshops and stakeholder input bear fruit with draft FDA guidance on how to get FDA approval for NGS tests and the databases that support their clinical validity.

G2 Compliance Corner

Ensure Compliant Hiring and Firing Strategies

Hiring and firing staff are difficult challenges. While there are many factors to consider in making either decision, compliance should be front of mind in each case. First, there are a host of legal issues that arise when beginning and ending employment relationships, most importantly discrimination risks. All decisions must be made based on non-discriminatory reasons rather than based on factors such as age, gender, race, religion or ethnicity. Make sure your interview questions for applicants don't touch on these issues as well. For example, don't ask an applicant if they have children or plan to have children.

Likewise, when you are terminating an employee consider discrimination issues and ensure the reasons for termination are well documented and are distinct from any discriminatory grounds such as the characteristics just mentioned.

Also, consider the hiring and firing processes also as an opportunity to review the effectiveness of your health care compliance policies and procedures. For example, when orienting new hires to your compliance programs, use that activity to ensure written compliance policies and procedures match what is actually happening in your operations. If you have to terminate an individual for violations of your compliance policies, examine what gaps allowed violations to happen. If a termination is amicable, you might solicit feedback from your departing employee about their perspective on your compliance programs and where improvement might be needed.

In future issues of *G2 Compliance Advisor*, we'll address in more detail specific tips to help you navigate the compliance challenges inherent in hiring and firing staff.

News at a Glance

Gapfill Prices Cut Reimbursement for Molecular Testing. The Centers for Medicare & Medicaid Services (CMS) published interim gapfill prices for new CPT codes for molecular tests introduced earlier this year. Most of the tests wound up having their preliminary prices cut, compared to their prior regionalized prices—in some cases as much as 85 percent. The prices would be placed on the 2017 Clinical Laboratory Fee Schedule if CMS grants final approval later this year, although labs and other parties will have a period to submit comments. The Coalition for 21st Century Medicine, an organization that represents many molecular labs, suggested that the proposed prices were out of sync with the guidelines established by the Protecting Access to Medicare Act of 2014 (PAMA), whose rules were recently finalized by CMS. "The proposed gapfill rates are inconsistent with rates established by commercial payers and the PAMA statute," the Coalition said in a statement. "Additionally, the PAMA statute sets a maximum of 10% reduction in payment for any test code in [2018] using the new market-based rate methodology." In a recent report, William Blair & Co. analyst Amanda Murphy noted that PAMA would likely provide some needed clarity to the issue. "While PAMA has caused angst around potential cuts to CPT codes, the perhaps under-appreciated positive from the legislation is that it will transition pricing power away from CMS and the MACs and provide much needed visibility into pricing," she observed.

Companion Diagnostic Developers Get FDA Guidance. The U.S. Food and Drug Administration (FDA) released draft guidance addressing companion diagnostics: "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product." The FDA indicates the document is intended to guide in vitro diagnostic device (IVD) and therapeutic product sponsors in codeveloping their products and seeking "contemporaneous marketing authorization." The new draft is a follow-up to a 2014 guidance document which defined in vitro diagnostic devices and encouraged earlier development of companion diagnostics. The FDA's announcement of this latest guidance indicates it "provides general principles for addressing issues that may arise when codeveloping a therapeutic product and a corresponding IVD companion diagnostic. It also provides considerations for planning and executing clinical trials and successfully fulfilling FDA regulatory requirements." An Aug. 18 webinar will provide more information about the guidance and answers to questions. Public comments on the guidance should be submitted by Oct. 13, 2016, to be considered before issuance of the final guidance. For more information about the webinar, see www.fda/gov/CDRHwebinar.

Report Indicates Increased Health Care Venture Capital Investment. Health care corporate venture capital (CVC) is increasing across all sectors of the industry in terms of number of deals, dollars invested, and number of active CVC investors, according to a report released last month by Corporate Venture Action Group of the Health Evolution Summit. The report, "The Rising Tide of Strategic Investing: Corporate Adventures in Health Care Venture Capital" resulted from a meeting of the Corporate Venture Action Group, a group of nearly 30 CVCs, including some well-known names like Google Ventures, Merck Global Health Innovation Fund, and UnitedHealth Group Ventures. Simultaneously, Health Evolution Summit conducted a survey of health care CVCs. This report synthesizes findings from both the survey and the group meeting. The report defines CVCs as those that primarily invest in external companies run by unaffiliated entrepreneurs, not investments in internally generated ideas.

 G2 Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315 or Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

Kelly Hardy Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Ron Shinkman and Lori Solomon, Contributing Writers; Randy Cochran, Corporate Licensing Manager; Jim Pearmain, General Manager; Michael Sherman, Marketing Director; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.

