

## Healthcare Fraud Prevention Partnership Issues a Review of Clinical Laboratory Services

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### 1. Overview

The Healthcare Fraud Prevention Partnership (“HFPP”) recently published its second white paper, entitled “Examining Clinical Laboratory Services,” which provides a comprehensive overview of practices that raise fraud and abuse concerns involving clinical laboratory services and providers.<sup>1</sup> The purpose of the white paper is to supply foundational information on health care fraud and abuse issues facing the laboratory testing industry, and to further set the stage for additional discussions and interventions to address these issues. As background, the white paper describes a “broad consensus” among its partners on the need to do more to combat potential fraud and abuse in laboratory billing.

HFPP is a voluntary partnership sponsored by the Centers for Medicare & Medicaid Services (“CMS”) with close to 100 members, including federal and state government agencies, law enforcement, private health insurance plans, employer organizations, and health care anti-fraud associations.<sup>2</sup> According to the CMS website, HFPP aims “to foster a proactive approach to detecting and preventing health care fraud through data and information sharing.”<sup>3</sup> Accordingly, while the *OIG Work Plan* has long focused on issues involving clinical laboratories,<sup>4</sup> this white paper is no doubt a harbinger for even more government enforcement in the diagnostic laboratory space. Laboratory compliance

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<sup>1</sup> Healthcare Fraud Prevention Partnership, *Examining Clinical Laboratory Services: A Review by the Healthcare Fraud Prevention Partnership* (May 2018), available at <https://hfpp.cms.gov/Hfpp-White-Papers/HFPP-Clinical-Lab-Services-White-Paper.pdf>.

<sup>2</sup> CMS, *Healthcare Fraud Prevention Partnership: Current Partners* (2017), available at <https://hfpp.cms.gov/about/current-partners.html>

<sup>3</sup> CMS, *Healthcare Fraud Prevention Partnership: About the Partnership* (2017), available at <https://hfpp.cms.gov/about/index.html>.

<sup>4</sup> Office of Inspector Gen., Dep’t of Health and Human Servs., *OIG Work Plan: Fiscal Year 2017*, available at <https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/hhs%20oig%20work%20plan%202017.pdf>.

activities should focus on ensuring that laboratories have appropriate and compliant practices in these areas, the rationales for which are thoroughly documented.

### **2. Systemic Challenges**

In the white paper, HFPP addresses certain traits endemic to clinical laboratory testing that potentially enable fraud and abuse by making it harder to detect. First, HFPP identifies that the number of variability of laboratories makes it easier for bad actors to take advantage of laboratory/provider relationships. Second, HFPP further recognizes that due to the high-volume, low-dollar nature of laboratory testing, it is more likely for individual instances, or even patterns, of improper billing to fly under the radar. Lastly, the continuing advancement and complexity of these tests makes it all the more difficult for payors to understand and effectively police laboratory billing.

### **3. Focus on Three Fraud and Abuse Schemes**

The white paper identifies three categories of potentially fraudulent or abusive practices reported by the HFPP partners: abuse of billing standards, improper laboratory relationships, and medically unnecessary testing.

#### *a. Abuse of Billing Standards*

The two abusive billing practices identified in the white paper are the improper use of the 91-modifier and the unbundling of laboratory panels. Modifier 91 is a Current Procedural Terminology (“CPT”) code modifier that allows a clinical laboratory to report the same test performed more than once on the same patient, on the same day. The concern addressed in the white paper is that the use of the 91-modifier is permissible only in certain narrow circumstances where a follow-up test is required. The 91-modifier is not meant to be used when a test is repeated to confirm the initial results, nor should it be used to bill for additional tests that were not actually performed or for tests that were performed on another day or in another location.

Certain clinical laboratory tests that are commonly ordered together and/or analyzed simultaneously on a single patient specimen are bundled together into what are called “panels” for billing purposes, so that a single reimbursement rate can be set for the panel as a whole. Reimbursement for the panel from the federal health care programs is typically lower than what the total reimbursement would have been if each test within the panel was billed individually. “Unbundling” occurs when a clinical laboratory bills each individual test separately, rather than using the panel, in order to maximize reimbursement. According to the white paper, fraud may occur when laboratories may purposefully limit the tests that they can perform in order to circumvent the panel and justify only billing for individual tests, which ultimately leads to a higher reimbursement rate.

*b. Improper Laboratory Relationships*

The white paper identifies several examples of improper referral, billing, or ownership arrangements that implicate federal and state fraud and abuse laws. For example, it describes a type of “pass-through billing” scheme whereby a physician pays a clinical laboratory to perform a test, and then the provider files the claim, allowing the physician to make a profit if the reimbursement from the payor is more than what the physician paid to the clinical laboratory. Even more egregious, these pass-through billing schemes can result in the same test being billed twice, once by the physician and once by the clinical laboratory. According to the white paper, pass-through billing is especially prevalent in rural areas, as rural health care providers are eligible for higher reimbursement rates, provided to them as an incentive for practicing in such underserved areas.

The white paper was released in the wake of significant clinical laboratory investigations, including the Health Diagnostics Laboratory Inc. (“HDL”),<sup>5</sup> Millennium Health,<sup>6</sup> and Biodiagnostic Laboratory Services LLC (“BLS”)<sup>7</sup> cases. Shortly after the release of the HFPP white paper, the U.S. Department of Justice (“DOJ”) in a press release<sup>8</sup> announced a \$114 million judgment against three individuals, including the former chief executive officer of HDL, for submitting more than 35,000 fraudulent claims to Medicare and TRICARE for reimbursement.<sup>9</sup> The fraudulent claims were generated by the individuals due to an illegal arrangement whereby the individuals would pay physicians between \$10 and \$17, disguised as processing and handling fees, for each patient referred to either HDL or another clinical laboratory, a violation of the federal Anti-Kickback Statute. The press release also included a statement from Acting Assistant Director of the FBI Criminal Investigative Division Chris Hacker that “[t]he FBI will continue to aggressively investigate allegations of criminal misconduct between companies and individuals who engage in kickback schemes at the expense of the U.S. government.”

*c. Medically Unnecessary Testing*

Within the medically unnecessary testing category, the white paper identifies several “high concern” schemes, including the use of excessively large panels; standing or reoccurring orders for laboratory tests that do not meet the Medicare requirements for

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<sup>5</sup> U.S. Dep’t of Justice, *United States Obtains \$114 Million Judgment Against Three Individuals for Paying Kickbacks for Laboratory Referrals and Causing Claims for Medically Unnecessary Tests* (May 29, 2018), available at <https://www.justice.gov/opa/pr/united-states-obtains-114-million-judgment-against-three-individuals-paying-kickbacks> (hereinafter “Press Release”).

<sup>6</sup> U.S. Dep’t of Justice, *Millennium Health Agrees to Pay \$256 Million to Resolve Allegations of Unnecessary Drug and Genetic Testing and Illegal Remuneration to Physicians* (Oct. 19, 2015), available at <https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic>.

<sup>7</sup> U.S. Dep’t of Justice, *Five Former Salesmen for Morris County Clinical Lab Sentenced for Bribing Doctors In \$100 Million Test Referral Scheme* (May 17, 2018), available at <https://www.justice.gov/usao-nj/pr/five-former-salesmen-morris-county-clinical-lab-sentenced-bribing-doctors-100-million>. Author Melissa Jampol was an Assistant U.S. Attorney involved in the multi-year investigation into BLS.

<sup>8</sup> See Press Release, *supra* note 5.

<sup>9</sup> *Id.*

permissible standing orders; excessive or improper urine drug testing, particularly by sober living facilities and pain clinics; and excessive or improper genetic testing. DOJ and other government entities charged with investigating health care fraud and abuse continue to be highly focused on areas of laboratory billing that are susceptible to these types of schemes, and are actively working to investigate and engage in enforcement activities aimed at ferreting out any related fraudulent schemes. The report cites a DOJ settlement with Millennium Health that includes a \$237 million recovery to resolve False Claims Act claims by Medicare, Medicaid, and other federal health care programs in which the government alleged that Millennium Health caused physicians to order excessive numbers of urine drug tests in part through the promotion of “custom profiles” that created a system of standing orders in violation of federal health care payment rules. By creating and promoting these profiles, Millennium Health allegedly circumvented the need for the physician to conduct an individualized assessment of each patient’s needs, which would result in a failure to meet the federal health care program reimbursement standards for medical necessity.

#### 4. Conclusion

This white paper is identified as a “starting point” for HFPP to identify issues specific to clinical laboratories and to educate payors about such issues, as part of its long-term dedication to combatting fraud and abuse. Next, no doubt, will be legislative and administrative proposals to limit the opportunity for fraud and abuse. Such proposals often impact legitimate activity as well. It is clear that the trend of increased government scrutiny of the clinical laboratory industry will continue with even greater vigor. Now, more than ever, strong clinical laboratory compliance programs are important to the successful prevention and defense of government investigations.

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*This Client Alert was authored by **Arthur J. Fried, Melissa L. Jampol, and Alison M. Wolf**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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