

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**QUESTIONABLE BILLING FOR
MEDICARE PART B CLINICAL
LABORATORY SERVICES**



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EXECUTIVE SUMMARY: QUESTIONABLE BILLING FOR MEDICARE PART B CLINICAL LABORATORY SERVICES OEI-03-11-00730

WHY WE DID THIS STUDY

Medicare is the largest payer of clinical laboratory (lab) services in the nation. From 2005 to 2010, Part B Medicare enrollment increased by 10 percent, while spending for lab services increased by 29 percent. In 2010, Medicare payments for all Part B lab services totaled \$8.2 billion. We conducted this study to identify questionable billing patterns among Medicare lab services.

HOW WE DID THIS STUDY

We based this study on an analysis of Part B claims for lab services with dates of service in 2010. Labs submit claims for each lab service provided for Medicare beneficiaries. Each claim contains information about the lab provider, the ordering physician, the beneficiary, and the lab service. We developed 13 measures to describe labs' billing patterns and to identify labs with questionable billing patterns. We calculated and analyzed the distribution of the measures for each lab. We then calculated a statistical threshold for the 13 measures and determined whether a lab's billing was unusually high for each measure. Additionally, we calculated the total number of claims and total allowed amount associated with certain measures of questionable billing.

WHAT WE FOUND

In 2010, over 1,000 labs exceeded the thresholds (i.e., had unusually high billing) for 5 or more measures of questionable billing for Medicare lab services. For example, a lab might have an unusually high percentage of claims with ineligible and/or invalid ordering-physician numbers, or an unusually high allowed amount per ordering physician. Almost half of the labs that exceeded the thresholds for five or more measures of questionable billing—compared to 13 percent of all labs—were located in California and Florida, areas known to be vulnerable to Medicare fraud. Some labs that exceeded the thresholds for fewer than five measures also exhibited billing that may warrant further review. Medicare allowed \$1.5 billion across all labs for claims associated with questionable billing.

WHAT WE RECOMMEND

There may be some labs that have legitimate reasons for exceeding certain thresholds. However, collectively, these findings call for stronger oversight of labs and identify specific issues with Medicare payments for lab services that need to be addressed to more effectively safeguard Medicare. Therefore, we recommend that the Centers for Medicare & Medicaid Services (CMS) (1) review the labs identified as having questionable billing and take appropriate action, (2) review existing program integrity strategies to determine whether these strategies are effectively identifying program vulnerabilities associated with lab services, and (3) ensure that existing edits prevent claims with invalid and ineligible ordering-physician numbers from being paid. CMS concurred with all recommendations.

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OBJECTIVE

To identify questionable billing for Part B clinical laboratory (lab) services in 2010.

BACKGROUND

Clinical lab services include a range of chemical and other types of examinations of specimens taken from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition.¹ Some of the most common lab services are complete blood counts, lipid panels (tests for cholesterol screening), and urinalyses. More than half of Medicare beneficiaries receive some type of lab service, other than pathology, over the course of a year.² Part B lab services may be performed by independent labs, physician office labs, hospital labs (for outpatient services), or labs located in other institutions.

Lab services are covered under Medicare Part B when they are ordered by a physician or qualified nonphysician practitioner who is treating the patient.^{3,4} Lab services ordered by anyone other than the treating physician are not considered reasonable or necessary.⁵

Medicare Payment for Lab Services

Medicare is the largest payer of clinical lab services in the Nation.⁶ From 2005 to 2010, Medicare enrollment in Part B increased by 10 percent, while spending for Part B lab services increased by 29 percent.^{7,8} In 2010,

¹ Centers for Medicare & Medicaid Services (CMS), *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 80.1.

² Direct Research, LLC., *Trends in Medicare Carrier-Paid Laboratory Testing Services*, February 2006, p. 33.

³ For the purposes of this report, we refer to physicians and nonphysician practitioners as “physicians.”

⁴ 42 CFR § 410.32(a).

⁵ *Ibid.*

⁶ Medicare Payment Advisory Commission (MedPAC), *Clinical Laboratory Services Payment System*, October 2011, p. 1.

⁷ CMS, *Medicare Enrollment: National Trends 1966–2010*. Accessed at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareEnrpts/downloads/HISMI2010.pdf> on October 18, 2013.

⁸ CMS, *Data Compendium* (2011 Edition), Table II.3 (“Medicare Benefit Payments by Type of Benefit, Fiscal Years 2008–2010”). Accessed at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/DataCompendium/2011_Data_Compendium.html on October 18, 2013, and CMS, *Data Compendium* (2008 Edition), Table II.3 (“Medicare Benefit Payments by Type of Benefit, Fiscal Years 2006–2007”). Accessed at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/DataCompendium/16_2008DataCompendium.html on October 18, 2013.

Medicare payments for all Part B lab services totaled \$8.2 billion. Since 1997, the payment rates for lab services have increased three times. In 2003, payment rates increased by 1.1 percent; in 2009, by 4.5 percent; and in 2012, by 0.65 percent.⁹

Medicare Billing Codes for Lab Services

Medicare sets payment rates for over 1,100 Healthcare Common Procedure Coding System (HCPCS) codes used to bill for lab services.¹⁰ The HCPCS is a uniform coding system consisting of descriptive terms and identifying codes for reporting medical services, procedures, products, and supplies. HCPCS codes can define a single test or a panel (a group of tests that are commonly performed together).

Each HCPCS code is assigned a Berenson-Eggers Type of Service (BETOS) code. The BETOS coding system was developed primarily to analyze the growth in Medicare expenditures. BETOS codes cover all HCPCS codes, and a HCPCS code is assigned to only one BETOS code. BETOS codes T1A through T1H (T1 codes) are used for clinical lab services. Most HCPCS codes with a T1 code fall under HCPCS codes 80000 through 89999, which are pathology and lab services codes.

Related Office of Inspector General Work

In 2000, the Office of Inspector General (OIG) issued a report identifying a number of common Medicare fraud schemes involving clinical lab services.¹¹ These schemes include billing for services not performed, not ordered, or not needed; unbundling lab tests; upcoding; duplicate billing of lab tests; and falsifying diagnoses.¹² All of these fraudulent billing practices were identified during Project LabScam, a nationwide law enforcement project that focused on the billing practices of all major independent labs in the country—specifically, independent clinical diagnostic laboratories. The project resulted in settlements against several laboratories, including Laboratory Corporation of America Holdings, SmithKline Beecham, MetPath/MetWest, Damon, Roche, and Allied. The report also stated that there were indications that problems similar to those uncovered through Project LabScam were occurring with smaller laboratories and certain providers.

⁹ MedPAC, *Clinical Laboratory Services Payment System*, October 2011, p. 2.

¹⁰ *Ibid.*, p.1.

¹¹ OIG, *Medicare Payments for Clinical Laboratory Services: Vulnerabilities and Controls*, OEI-05-00-00070, January 2000.

¹² Unbundling is the practice of inappropriately reporting each component of a service or procedure instead of reporting the single comprehensive code. Upcoding is the practice of billing at a higher level than warranted.

A 2002 OIG study investigated whether Medicare was paying for lab services ordered by physicians with invalid or inactive unique physician identification numbers (UPINs).^{13, 14} OIG found that in 2000, Medicare paid \$7.4 million for clinical lab service claims with invalid ordering UPINs and \$15.3 million for lab service claims with inactive ordering UPINs.

A 2013 OIG study found that in 2011, Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab tests. Medicare could have saved \$910 million in 2011 if it had paid the lowest payment rate among insurers for these 20 tests. OIG recommended that CMS seek legislation that would allow CMS to establish lower payment rates for lab services. OIG also recommended that CMS consider seeking legislation to institute copayments and deductibles for lab services.¹⁵

In addition, OIG has issued multiple reports related to questionable billing patterns by other Medicare providers. Some of the most recent such reports have reviewed questionable billing by community mental health centers, home health agencies, retail pharmacies, and prescribers of Part D drugs.¹⁶

METHODOLOGY

We extracted Medicare claims for lab services from CMS's calendar year (CY) 2010 National Claims History Physician/Supplier Part B claims file. To identify lab services, we extracted claims with T1B through T1H BETOS codes, which identify clinical lab tests as the type of service received.

Exclusions. We excluded the following from our analysis:

- claims for labs that had less than \$1,000 in total Medicare allowances,
- claim lines with an allowed amount of \$0, and

¹³ CMS discontinued assigning UPINs in June 2007 and began using the National Provider Identifier (NPI) as the primary and secondary provider identifier in May 2008.

¹⁴ OIG, *Clinical Laboratory Claims with Invalid or Inactive Physician Numbers*, OEI-03-01-00670, October 2002.

¹⁵ OIG, *Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings*, OEI-07-11-00010, June 2013.

¹⁶ OIG, *Questionable Billing by Community Mental Health Centers*, OEI-04-11-00100, August 2012; OIG, *Inappropriate and Questionable Billing by Medicare Home Health Agencies*, OEI-04-11-00240, August 2012; OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012; OIG, *Prescribers With Questionable Patterns in Medicare Part D*, OEI-02-09-00603, June 2013.

- claims without an NPI in either the field for the ordering physician or the field for the performing provider.
- claims with a placeholder NPI in either the field for the ordering physician or the field for the performing provider.¹⁷

Table 1 provides the total number of claims that were excluded from the analysis as well as the total allowed amount for these excluded claims.

Table 1: Total Number of Claims and Total Allowed Amount Excluded From Analysis

	Number of Claims	Allowed Amount
Before Exclusions	160,954,331	\$7,289,295,095
After Exclusions	145,613,262	\$7,258,915,889
Total Exclusions	15,341,069	\$30,379,206

Source: OIG analysis of claims for 2010 Part B clinical lab services.

Our final data set contained 145.6 million lab claims, which were submitted by 94,609 labs for 23 million beneficiaries. In total, Medicare allowed \$7.3 billion to these providers for lab services rendered in 2010.

Grouping Lab Providers. Because large, nationwide, independent laboratories may have greater billing volume and may have different billing patterns compared to smaller, nonindependent labs, we separated claims data into two groups: independent labs (ILs) and nonindependent labs (non-ILs).¹⁸ An example of a non-IL would be a lab in a physician’s office. We analyzed these two groups separately.

Using data from the Provider Enrollment, Chain, and Ownership System (PECOS), we identified the specialty reported by each lab during enrollment. For labs for which enrollment records could not be found in PECOS, we reviewed specialty information from the Medicare NPI Crosswalk (NPIC).¹⁹ For 46 labs, no enrollment records could be found in PECOS or NPIC, so we used the main specialty code reported in the National Plan and Provider Enumeration System (NPPES).

We considered a lab to be an IL if it had a PECOS specialty description of “Independent Clinical Laboratories” or “Histocompatibility Laboratory,” an NPIC specialty of “Clinical Medical Laboratory,” or an NPPES specialty of “Clinical Medical Laboratory.” Labs not meeting these

¹⁷ An example of a placeholder NPI is 999999992, which was used on claims submitted by beneficiaries.

¹⁸ An IL is independent both of an attending or consulting physician’s office and of a hospital.

¹⁹ This crosswalk validates claims that contain a legacy number—such as a Medicare Provider Identification Number—and an NPI.

criteria were considered non-ILs. In our final data set, we identified 2,598 ILs and 92,011 non-ILs.

Additional Provider and Beneficiary Data. To obtain addresses for ordering physicians in our data set, we matched NPIs in NPPES. We also used NPPES data to determine whether ordering physicians' NPIs were valid in 2010.

We used CMS's Compromised Number Checklist (CNC) to identify compromised provider NPIs, ordering-physician NPIs, and beneficiary Health Insurance Claim Numbers (HICNs). In this report, we refer to lab provider NPIs as "provider numbers," ordering-physician NPIs as "ordering-physician numbers," and beneficiary HICNs as "beneficiary numbers." The CNC includes Medicare provider and beneficiary numbers that are suspected of being compromised or verified as being compromised. These numbers are obtained through fraud investigations, security breach reports, and complaints from providers or beneficiaries. CMS sends an updated CNC to each benefit integrity contractor monthly and incorporates the CNC into its Fraud Prevention System, which is an initiative to identify aberrant and suspicious billing patterns before claims are paid. We considered the identification number for a lab, ordering physician, or beneficiary to be compromised if the number was on the CNC with no removal date as of August 5, 2013.²⁰

All Part B Service Claims. In addition to obtaining claims for lab services, we obtained claims for Medicare Part B services from CYs 2009 and 2010 for all beneficiaries identified in our data set. Using beneficiaries' HICNs, ordering physicians' NPIs, and the dates of service from the lab claims, we matched the lab claims to Part B service claims to determine whether beneficiaries received other Part B services from the physician who ordered the lab service within the 6 months prior to the lab service. We extracted only claims in which the ordering physician on the lab claim was the performing provider on the Part B claim.²¹

Identification of Labs That Had Questionable Billing

For each lab in our data set, we calculated the total allowed amount, total number of claims, total number of ordering physicians, and total number

²⁰ A removal date indicates that the corresponding provider number or beneficiary number was not verified as compromised. However, these beneficiary and provider numbers are not physically removed from the CNC.

²¹ It is possible that a provider not enrolled in Medicare ordered a lab service for a beneficiary. In this case, the physician may have seen the beneficiary prior to the lab service, but did not bill Medicare for this visit. Therefore, there would be no Part B claim for this provider.

of beneficiaries.²² We then developed 13 measures to describe lab billing and to identify labs with questionable billing. These measures were based on information from previous studies on lab services, Federal criminal and civil investigations involving lab services, OIG work on questionable billing for other Medicare providers, discussions with CMS staff, and our own analysis.

The 13 measures are:

- (1) high average allowed amount per claim,
- (2) high average number of claims per beneficiary,
- (3) high average allowed amount per beneficiary,
- (4) high average number of claims per ordering physician,
- (5) high average allowed amount per ordering physician,
- (6) high percentage of claims for beneficiaries with no associated Part B services with the ordering physician,
- (7) high percentage of claims for beneficiaries living more than 150 miles from the ordering physician,
- (8) high percentage of duplicate lab tests,
- (9) high percentage of claims with invalid ordering-physician numbers,
- (10) high percentage of claims with ineligible ordering-physician numbers,
- (11) high percentage of claims with compromised beneficiary numbers,
- (12) high percentage of claims with compromised ordering-physician numbers, and
- (13) compromised lab provider number.

We calculated these 13 measures for each lab and analyzed the distribution of labs for each measure. We considered a lab's billing to be unusually high, or questionable, on a measure if the number or percentage was greater than the 75th percentile plus 3 times the interquartile range.²³ We calculated the thresholds for ILs and non-ILs separately.²⁴ We then

²² In cases where there was more than one lab NPI on a claim (0.01% of all claims), we grouped together the line items associated with each separate lab NPI.

²³ This is a standard exploratory method for identifying members of a population with unusually high values on a given statistic compared to the rest of the population when no established benchmarks exist. See J.W. Tukey, *Exploratory Data Analysis*, Addison-Wesley, 1977. The interquartile range is the value at the 75th percentile minus the value at the 25th percentile.

²⁴ One measure—compromised lab number—is a binary measure, as labs either did or did not have a compromised number. Because this measure is binary, it does not have a threshold.

determined the total number of measures for which each lab exceeded the threshold.

Appendix A provides a full description of the methodology used to calculate the 13 measures of questionable billing. Appendix B provides the calculated thresholds for each of the 13 measures and the number of labs that exceeded these thresholds.

Identification of Labs That Exceeded Thresholds for an Unusually High Number of Measures of Questionable Billing

After determining the total number of measures of questionable billing for which each lab exceeded the threshold, we determined whether each lab exceeded the threshold for an unusually high number of measures. We calculated this threshold using the 75th percentile plus 3 times the interquartile range. The threshold was four; therefore, any lab that exceeded the thresholds for five or more measures of questionable billing was an outlier.

Geographic Analysis of Labs That Exceeded Thresholds for Five or More Measures of Questionable Billing

For labs that exceeded the thresholds for five or more measures of questionable billing, we determined whether they were concentrated in certain States or counties. We used the ZIP Code on a lab's claim to determine its practice location. If a lab had multiple ZIP Codes, we used the ZIP Code that appeared on the highest number of claims. Using mapping software, we mapped labs' physical locations onto a national map.²⁵ We determined which States and counties had the highest concentrations of labs with questionable billing.

Analysis of Claims and Payments Associated with Measures of Questionable Billing

We calculated the total number of claims and total allowed amount associated with 8 of the 13 measures of questionable billing. Because we could perform these calculations only on measures of questionable billing that were binary at the claim level (e.g., a claim either did or did not have an invalid ordering-physician number), we excluded 5 of the 13 measures from this analysis.²⁶ To calculate the total number of claims and total allowed amount associated with the measures of questionable billing, we

²⁵ There were 30 labs that did not map by county in ArcGIS, Version 10.1.

²⁶ We excluded the following five measures: high average allowed amount per ordering physician, high average allowed amount per claim, high average number of claims per ordering physician, high average allowed amount per beneficiary, and high average number of claims per beneficiary. These measures were based on each lab's overall billing.

first identified the claims associated with each measure. For example, we identified all claims with an invalid ordering-physician number, regardless of whether the lab that submitted the claim exceeded the threshold for this measure. We then counted the number of claims associated with the measure and summed those claims' allowed amounts.

Limitations

We did not independently verify the accuracy of the data used for this study. Our findings are based on the analysis of claims; we did not conduct a medical record review to determine whether the services for which labs billed were inappropriate or fraudulent. The 13 measures included in our analysis are not intended to be a comprehensive set of characteristics for identifying labs with questionable billing.

We designed this study to identify labs that warrant further review. None of the measures analyzed confirm that a particular lab is engaging in fraudulent or abusive practices. Some labs may have legitimate reasons for exceeding certain thresholds, such as being highly specialized labs that provide unique or complex testing for beneficiaries across the country.

Several of the individual measures have additional limitations specific to that measure. These limitations are discussed in Appendix A.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In 2010, over 1,000 labs had unusually high billing for five or more measures of questionable billing for Medicare lab services

In total, 1,025 out of 94,609 labs exceeded the thresholds for at least 5 of the 13 measures of questionable billing. Together, these labs were allowed \$1 billion for lab services rendered in 2010 and had an average allowed amount of \$1 million. Although some of this billing may be legitimate, all labs that exceeded thresholds on five or more measures of questionable billing may warrant further scrutiny. Table 2 shows the distribution across labs of the numbers of measures of questionable billing for which labs exceeded thresholds. Appendix B provides the thresholds for the measures of questionable billing and the total number of labs that exceeded each threshold.

Table 2: Number and Percentage of Labs by Number of Measures of Questionable Billing for Which Labs Exceeded Thresholds

Number of Measures of Questionable Billing for Which Labs Exceeded Thresholds	Number of Labs	Percentage of Labs	Total Allowed
0	45,498	48%	\$956,247,883
1	27,920	30%	\$1,563,976,902
2	12,597	13%	\$2,086,588,887
3	5,496	6%	\$1,070,848,549
4	2,073	2%	\$546,665,650
5	691	0.7%	\$477,942,870
6	247	0.3%	\$295,634,078
7	63	0.07%	\$238,716,257
8	20	0.02%	\$13,941,546
9	4	<0.01%	\$8,353,267
Total	94,609	100%¹	\$7,258,915,889

Source: OIG analysis of claims for 2010 Part B clinical lab services.

¹The percentages do not sum to 100 percent because of rounding.

For labs that exceeded at least five thresholds, the number of labs that exceeded the threshold for each particular measure is shown in Table 3. The most frequently exceeded thresholds among these labs were those for the following measures: high average allowed amounts per ordering physician, high percentage of claims with ineligible ordering-physician numbers, high percentage of claims with compromised beneficiary numbers, and high percentage of duplicate lab tests.

Table 3: Labs That Exceeded the Thresholds for Five of More Measures of Questionable Billing, by Measure

Measure of Questionable Billing	Number of Labs That Exceeded the Threshold (N=1,025)	Percentage of Labs That Exceeded the Threshold (N=1,025)
High average allowed amount per ordering physician	810	79%
High percentage of claims with ineligible ordering-physician numbers	790	77%
High percentage of claims with compromised beneficiary numbers	704	69%
High percentage of duplicate lab tests	664	65%
High average allowed amount per claim	631	62%
High average number of claims per ordering physician	472	46%
High average allowed amount per beneficiary	450	44%
High percentage of claims with compromised ordering-physician numbers	333	32%
High percentage of claims for beneficiaries with no associated Part B services with ordering physician	229	22%
High percentage of claims with beneficiaries living more than 150 miles from the ordering physician	211	21%
High percentage of claims with invalid ordering-physician numbers	187	18%
High average number of claims per beneficiary	71	7%
Compromised lab provider number	22	2%

Source: OIG analysis of claims for 2010 Part B clinical lab services.

Below are some examples of billing patterns found for lab providers that exceeded the thresholds for five or more measures of questionable billing in 2010:

- An IL in Texas was one of four labs that exceeded the thresholds for nine measures of questionable billing. All of this lab’s claims contained compromised beneficiary numbers, none of these beneficiaries had an associated Part B service with the ordering physician within 6 months prior to the lab service, and 89 percent of claims were for beneficiaries who lived over 150 miles from the ordering physician. Furthermore, this lab was allowed an average of \$61,434 per ordering physician—15 times the overall average for ILs.

In addition, 13 percent of this lab's claims had ineligible ordering-physician numbers. This lab, whose provider number also was compromised, was allowed \$2 million.

- For a California IL, all 1,224 beneficiaries for whom this lab submitted claims had compromised beneficiary numbers. In addition, 45 percent of claims had ineligible ordering-physician numbers and 41 percent of claims had compromised ordering-physician numbers. This lab was also allowed an average of \$61,041 per ordering physician, which is 15 times the average among ILs. This lab was allowed almost \$1 million in 2010.
- More than 90 percent of one Ohio IL's claims had compromised beneficiary numbers, and 58 percent of its claims had compromised physician numbers. This lab's provider number was also compromised. In addition, 79 percent of the claims were for beneficiaries who had no Part B claim with the ordering physician within 6 months, and 10 percent of the claims had ineligible ordering-physician numbers. This lab was allowed \$2.8 million in 2010.
- A non-IL in Florida was allowed an average of \$1,193 per beneficiary, 16 times the average for non-ILs. The average allowed per ordering physician for this lab was \$107,700, or 24 times the overall average for non-ILs. This lab also exceeded the thresholds for the percentage of claims with a compromised beneficiary number, the percentage of claims for beneficiaries who lived more than 150 miles from the ordering physician, and the percentage of duplicate lab tests. This lab was allowed \$7.8 million in 2010.
- For a Michigan IL, almost all claims had an ineligible ordering-physician number, and none of the 68 beneficiaries associated with the claims had a prior Part B service with the ordering physician within 6 months prior to the lab claim. In addition, Medicare allowed this lab \$204,237 for 1,300 claims that were submitted by only 2 ordering physicians. This is an average of 650 claims per ordering physician (11 times the overall average for ILs) and an average allowed amount of \$102,119 per ordering physician (25 times the overall average for ILs).
- A non-IL in New York exceeded the thresholds for 8 measures of questionable billing and had an average allowed amount of \$2,422 per beneficiary (33 times the overall average for non-ILs) and an average allowed amount of \$253 per claim (7 times the average). In addition, 5 percent of this lab's claims had ineligible ordering-physician numbers. This lab was allowed \$1.1 million in 2010.

Eighty percent of labs that exceeded the thresholds for five or more measures of questionable billing had unusually high percentages of claims with ineligible and/or invalid ordering-physician numbers

A large majority of labs that exceeded the thresholds for 5 or more measures of questionable billing (821 out of 1,025 such labs) had an unusually high percentage of claims with invalid ordering-physician numbers, an unusually high percentage of claims with ineligible ordering-physician numbers, or both.

Of the 1,025 labs with 5 or more measures of questionable billing, 790 exceeded the threshold indicating an unusually high percentage of claims with ineligible ordering-physician numbers. Most of these labs had less than 10 percent of their claims with ineligible ordering-physician numbers. However, for 160 labs, more than a quarter of the lab's claims had ineligible ordering-physician numbers. The number of ineligible ordering-physician numbers for these labs ranged from 1 to 114, and the amount allowed per ordering physician ranged from \$221 to \$132,938. Furthermore, 50 of these labs had only 1 ordering physician, so all of their claims were for services ordered with an ineligible physician number. Four of these labs were allowed more than \$100,000 for claims ordered with one ineligible physician number.

Additionally, a number of labs that exceeded the thresholds for five or more measures of questionable billing also had unusually high percentages of claims with invalid ordering-physician numbers. Of the 1,025 labs that exceeded the thresholds for 5 or more measures of questionable billing, 187 had unusually high percentages of claims for lab services ordered with invalid physician numbers. Almost all of these labs had less than 3 percent of claims for lab services ordered with invalid physician numbers. However, one non-IL submitted 414 claims, of which 98 percent contained an invalid ordering-physician number.

A small number of labs had unusually high percentages of claims with both ineligible and invalid ordering-physician numbers. Among these labs, the highest amount associated with an invalid or ineligible ordering-physician number was \$60,097. One non-IL had invalid ordering-physician numbers on 8 percent of its claims and ineligible ordering-physician numbers on 20 percent of claims.

Almost 80 percent of labs that exceeded the thresholds for five or more measures of questionable billing had unusually high average allowed amounts per ordering physician

Many of the labs that exceeded the thresholds for 5 or more measures of questionable billing (810 labs out of 1,025) exceeded the threshold that indicated an unusually high average allowed amount per ordering physician. These labs had a range of \$902 to \$647,179 per ordering physician, with an average of \$11,576. More than half of these labs also had an unusually high average number of claims per ordering physician. Additionally, 10 of the 15 labs with an average of more than \$100,000 per ordering physician had less than 5 physicians order all of their lab services.

Many labs that exceeded the thresholds for five or more measures of questionable billing had unusually high percentages of claims with compromised numbers

Three-quarters of labs that exceeded the thresholds for five or more measures of questionable billing exceeded at least one of the thresholds indicating a high percentage of claims with a compromised number.

As shown in Table 3, 704 of the 1,025 labs had unusually high percentages of claims with compromised beneficiary numbers. Eleven labs had compromised beneficiary numbers on over 90 percent of their claims. These 11 labs were allowed a total of \$7.5 million.

Another 333 labs had unusually high percentages of claims with compromised ordering-physician numbers. These labs were allowed an average of \$4,981 per compromised ordering-physician number. Among these labs, the highest amount associated with one compromised ordering-physician number was \$1.2 million. Additionally, 15 labs had more than a quarter of their claims for lab services ordered with compromised physician numbers. These 15 labs were allowed an average of \$47,918 per compromised ordering-physician number.

Medicare allowed \$11.1 million to 22 labs that exceeded the thresholds for 5 or more measures of questionable billing and had compromised lab provider numbers. These labs were allowed an average of \$503,217. Twenty of these labs also had unusually high percentages of claims with compromised beneficiary numbers and unusually high percentages of claims with compromised ordering-physician numbers. For example, one IL with a compromised provider number was allowed \$556,403 for claims submitted for 820 beneficiaries—all of whom had compromised beneficiary numbers. In addition, 37 percent of this lab's claims had compromised ordering physician numbers.

Twenty-two percent of labs that exceeded the thresholds for five or more measures of questionable billing had unusually high percentages of claims for beneficiaries with no associated Part B services with the ordering physician

By regulation, lab services not ordered by the physician who is treating the beneficiary are not reasonable and necessary. Therefore, having an unusually high percentage of claims for beneficiaries with no recent, associated Part B services with the ordering physician could mean that the lab billed for unnecessary services. Of the 1,025 labs that exceeded the thresholds for 5 or more measures of questionable billing, 229 had unusually high percentages of claims for a beneficiary without recent contact with the ordering physician listed on the lab claim. These labs had between 70 and 100 percent of claims for beneficiaries for whom we could find no associated Part B service with the ordering physician within 6 months prior to the lab service.²⁷ For 70 of these labs, all of their claims were for beneficiaries without associated Part B services with the ordering physician. These labs billed claims for an average of 256 beneficiaries and had an average allowed amount of \$63,081 per lab. Medicare allowed \$4.4 million to these 70 labs.

Twenty-one percent of labs that exceeded the thresholds for five or more measures of questionable billing had unusually high percentages of claims for beneficiaries residing more than 150 miles from the physician who ordered the lab services

Although many lab services can be sent across the country for testing and review, it is unlikely that a lab would have many beneficiaries that reside far from their treating physician. In 2010, 21 percent of labs that exceeded the thresholds for five or more measures of questionable billing had unusually high percentages of claims for beneficiaries residing more than 150 miles from the physician who ordered the lab services. These labs had a range of 12 to 99 percent of claims for beneficiaries residing more than 150 miles from the ordering physician, with an average of 26 percent. For two labs, almost all of their claims were for beneficiaries living more than 150 miles from the ordering physician. The average distance between beneficiaries and ordering physicians for these 2 labs was 629 miles.

²⁷ There may be cases in which the ordering physician was not a Medicare-enrolled physician and, therefore, there would be no prior Part B service claim billed to Medicare for this beneficiary.

Almost half of the labs that exceeded the thresholds for five or more measures of questionable billing were located in two States

In 2010, 43 percent (439 of 1,025) of labs that exceeded the thresholds for five or more measures of questionable billing were located in California and Florida, areas known to be vulnerable to Medicare fraud. In comparison, only 13 percent of all labs were located in these two States. Each State had more than 150 labs with questionable billing in 2010. Overall, Medicare allowed a total of \$602 million to the 439 labs.

Six percent of all labs were located in California; however, 28 percent of labs with questionable billing were located in the State. As shown in Table 4, Medicare allowed \$347 million to 284 labs with questionable billing located in California. Of these 284 labs, almost half (49 percent) were located in Los Angeles County. These Los Angeles County labs were allowed \$46 million of the \$263 million allowed to all labs in the county. Overall, 14 percent of labs with questionable billing nationwide were located in Los Angeles County.

Additionally, 15 percent of labs with questionable billing, compared to 7 percent of all labs, were located in Florida. Medicare allowed \$255 million to the 155 labs with questionable billing in Florida. More than 40 percent of these labs were located in Miami–Dade and Palm Beach counties.

The remaining 586 labs with questionable billing were distributed among 42 other States, the District of Columbia, and Puerto Rico. Six States—Montana, New Hampshire, North Dakota, Rhode Island, South Dakota, and Wyoming—did not have any labs with questionable billing.

Table 4: Number of Labs With Questionable Billing Per State, 2010

State	Number of All Labs	Number of Labs That Exceeded the Thresholds for Five or More Measures of Questionable Billing	Total Allowed For Labs That Exceeded the Thresholds for Five or More Measures of Questionable Billing
California	6,046 (6%)	284 (28%)	\$347,040,141
Florida	6,520 (7%)	155 (15%)	\$254,809,844
Other	82,013 (87%)	586 ¹ (57%)	\$432,738,033
Total²	94,579 (100%)	1,025 (100%)	\$1,034,588,018

Source: OIG analysis of claims for Part B clinical lab services, 2010.

¹ These labs were located in 42 other States, the District of Columbia, and Puerto Rico.

² These totals do not include 30 labs for which addresses did not map by county.

Some labs that exceeded thresholds for fewer than five measures of questionable billing exhibited billing that may warrant further review

In 2010, 51 percent of labs exceeded the threshold for at least one measure of questionable billing, but did not exceed the thresholds for five or more measures. These 48,086 labs had a total allowed amount of \$5.3 billion for lab services in 2010. Although these labs exceeded the thresholds for fewer than five measures of questionable billing, some of these labs exhibited billing patterns that may require further scrutiny. Below are some examples of billing that could be problematic:

- One non-IL, which exceeded the thresholds on 4 measures of questionable billing, had 97 percent of its claims for beneficiaries who had no associated Part B service with the ordering physician within 6 months prior to the lab service. Additionally, 97 percent of the lab's claims were for beneficiaries living more than 150 miles from the ordering physician. This lab had a total allowed amount of \$669,781.
- One IL billed 16,351 claims, of which 41 percent had compromised beneficiary numbers and 30 percent had compromised ordering-physician numbers. This lab had a total allowed amount of \$1.5 million, but exceeded the threshold on only two measures of questionable billing.
- Another IL billed 85,416 claims and had a total allowed amount of \$4 million. Although this provider exceeded the threshold of only one measure of questionable billing, more than half of its claims were for services ordered by two physicians with ineligible numbers. The lab was allowed \$2,075,661 for lab services with ineligible physician numbers.
- One non-IL exceeded the thresholds on 3 measures of questionable billing but had an average allowed amount of \$5,547 per beneficiary (compared to an average of \$74) and billed for 21 claims per beneficiary (7 times the average). This lab was allowed a total of \$232,977.

In 2010, Medicare allowed \$1.5 billion for questionable claims across all labs

Across all labs, Medicare allowed a total of \$1.5 billion for claims associated with eight types of questionable billing. Table 5 provides the total Medicare-allowed amount for claims associated with each of the eight measures of questionable billing.

In 2010, Medicare allowed \$1.2 billion for claims with beneficiaries who had no associated Part B service with the ordering physician within 6 months prior to the lab service

Lab services must be ordered and used promptly by the physician or qualified nonphysician practitioner who is treating the beneficiary. However, Medicare allowed \$1.2 billion in 2010 for 23 million claims with beneficiaries who had no associated Part B service with the ordering physician within the 6 months prior to the lab service. Although there may be legitimate reasons why a beneficiary may not have a previous Part B service with the ordering physician on the lab service, the number of claims and total dollar amount for this measure were substantial.

Table 5: Total Allowed for Claims Associated with Certain Measures of Questionable Billing Across All Labs

Measure of Questionable Billing	Number of Claims Associated With Measure of Questionable Billing	Total Allowed¹
Claims for beneficiaries with no associated Part B service with ordering physician	22,944,979	\$1,178,173,922
Claims with beneficiaries living more than 150 miles from the ordering physician	5,281,457	\$324,531,514
Claims with ineligible ordering-physician numbers	1,743,997	\$93,530,304
Claims with compromised beneficiary numbers	1,251,264	\$76,323,259
Duplicate lab tests	997,151 ²	\$38,519,091
Claims with compromised ordering-physician numbers	400,153	\$23,551,040
Claims with a compromised lab provider number	200,000	\$13,654,926
Claims with invalid ordering-physician numbers	52,604	\$2,579,106

Source: OIG analysis of claims for 2010 Part B clinical lab service claims.

¹The total allowed in this table exceeds the \$1.5 billion for questionable claims because some claims were included in more than one measure of questionable billing.

²These are numbers of duplicate tests, not duplicate claims.

In 2010, Medicare allowed \$325 million for claims for which the beneficiary lived more than 150 miles from the ordering physician

One would expect that a beneficiary—in addition to having a previous Part B service with the physician who ordered the lab service—would reside within a reasonable distance from the ordering physician. Again, there may be legitimate reasons why a beneficiary would live far from an ordering physician, e.g., seeing a specialist outside of the area. However,

in 2010, Medicare allowed \$325 million for 5.3 million claims in which the beneficiary's address was more than 150 miles from the ordering physician's address. These claims had an average distance of 851 miles between the beneficiary and ordering physician. As with claims for a beneficiary who had no associated Part B service with the ordering physician within 6 months prior to the lab service, claims for which the beneficiary lives significantly far from the ordering physician may indicate that the ordering physician is not the treating physician.

In 2010, Medicare allowed \$96 million for claims with ineligible or invalid physician numbers

Medicare allowed \$93.5 million for 1.74 million claims ordered with physician numbers that were not eligible to order lab services. These claims were ordered by organizational providers, e.g., labs or group practices, which are not eligible to order Medicare lab services.²⁸ Medicare also allowed \$2.6 million for 52,604 claims ordered with invalid physician numbers.

In 2010, Medicare allowed \$96 million for claims associated with compromised numbers

Overall, Medicare allowed \$96 million for 1,601,710 claims with one or more compromised number on the claim.²⁹ Specifically, Medicare allowed \$76 million for claims for 144,554 beneficiaries with compromised numbers. Medicare allowed \$23.6 million for 400,153 claims ordered with 861 compromised physician numbers. Lastly, Medicare allowed \$13.7 million for claims submitted by labs with compromised provider numbers.

In 2010, Medicare allowed \$39 million for duplicate lab tests

Medicare allowed \$39 million for 997,151 duplicate lab tests. This means that a lab billed for the same test on the same day for the same beneficiary, raising questions about whether tests were reasonable and necessary.

²⁸ Only individual physicians and nonphysician practitioners are eligible to order or refer items or services.

²⁹ This dollar amount includes claims with just one compromised number, such as the beneficiary number, and claims that have two or three compromised numbers, i.e., a combination of compromised provider number, compromised ordering-physician number, and/or compromised beneficiary number.

CONCLUSION AND RECOMMENDATIONS

In 2010, 52 percent of labs nationwide exceeded the threshold for at least one measure of questionable billing. Prior OIG reports have found that lab services are vulnerable to fraud, waste, and abuse. This report found questionable billing by lab providers and continued vulnerabilities in Medicare payments for lab services.

In 2010, a total of 1,025 labs exceeded the thresholds for five or more measures of questionable billing. Almost half of these 1,025 labs were located in 2 States—California and Florida—that are known to be vulnerable to Medicare fraud. Additionally, questionable billing was associated with substantial Medicare payments. For example, Medicare paid \$325 million for claims for which the beneficiary lived more than 150 miles from the physician who ordered the lab service. In total, Medicare paid \$1.5 billion across all labs for questionable claims for lab services. Although there may be legitimate reasons for some of this billing, all of these types of questionable billing for lab services warrant further review.

Collectively, the findings identify specific vulnerabilities with Medicare payments for lab services that need to be addressed to more effectively safeguard the Medicare program. CMS must use all of the tools at its disposal to more effectively identify and prevent questionable payments for Part B lab services.

Therefore, we recommend that CMS:

Review the labs identified as having questionable billing and take appropriate action

In a separate memorandum, OIG will refer to CMS the 1,025 labs that we identified as exceeding the thresholds for 5 or more measures of questionable billing. To address labs' questionable billing, CMS and/or its contractors should adequately review the billing of these labs. After this review, CMS should implement actions, as appropriate. Such actions could include, but are not limited to (1) recouping any improper payments identified during review of labs' billing, (2) suspending payments to the labs with questionable billing, (3) educating labs as to how to properly bill for services, (4) revoking a lab's Medicare privileges, (5) referring a lab to law enforcement for criminal investigation, or (6) taking no action, if a lab's billing is determined to be appropriate.

Review existing program integrity strategies to determine whether they are effectively identifying program vulnerabilities associated with lab services

CMS should review existing program integrity strategies that are being implemented by Medicare Administrative Contractors (MACs), Medicare Zone Program Integrity Contractors (ZPICs), Recovery Audit Contractors (RACs), and the Fraud Prevention System to monitor labs and lab claims.³⁰ CMS should determine whether these program integrity strategies are sufficiently identifying vulnerabilities in lab claims and identifying labs with questionable billing patterns for further review. This should include reviewing strategies for identifying and addressing claims with compromised provider or beneficiary numbers.

Ensure that existing edits prevent claims with invalid and ineligible ordering-physician numbers from being paid

In October 2012, CMS stated (in an edition of *MLN Matters*) its plans to implement edits that would deny Part B claims for services ordered by physicians who are not eligible to order and refer or do not have a valid NPI. In March 2013, CMS announced that the edits to deny claims with ineligible ordering or referring physicians would become active in May 2013; however, in April 2013 CMS announced that there would be a temporary delay in implementing the edits. In November 2013, CMS stated (in *MLN Matters*) that denial edits would be effective as of January 6, 2014. CMS should ensure that these edits are preventing claims with ineligible and invalid ordering-physician numbers from being paid.

³⁰ MACs are responsible for processing Medicare claims, enrolling health care providers and educating providers on Medicare billing requirements. ZPICs and RACs perform program integrity work for Medicare Parts A and B. The Fraud Prevention System uses predictive analytics technology to identify and prevent the payment of improper claims.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all three of our recommendations. Regarding the first recommendation, CMS stated that it will direct the ZPICs to follow up and investigate the laboratories identified with questionable billing.

In response to our second recommendation, CMS stated that it is using the Fraud Prevention System to identify possible fraudulent, wasteful, or abusive activities associated with laboratory services, and to provide ZPICs and PSCs with actionable information to initiate and facilitate their investigations. CMS stated that as a result of this and other proactive analysis, 47 labs are under investigation by the ZPICs and PSCs. CMS also stated that MACs regularly analyze data to determine areas of highest risk for improper payments in their jurisdictions; currently, five MAC jurisdictions incorporate lab services within their medical review strategies.

CMS also concurred with our third recommendation and stated that effective January 6, 2014, the agency began denying claims for Part B clinical lab services if the provider who ordered or referred the service was not enrolled in Medicare or had obtained “opt-out” status. According to CMS, the edit has resulted in claims being denied for Part B lab services, and the agency will continue to closely monitor the number of denials due to implementation of these new edits.

OIG believes that consistent and ongoing use of these strategies will better enable CMS to more effectively identify and prevent improper payments made for lab services.

The full text of CMS’s comments is provided in Appendix C.

APPENDIX A

Detailed Methodology for Evaluating Questionable Lab Billing

Our first step in evaluating the billing patterns of labs was to calculate overall billing characteristics for the 94,609 labs included in our analysis. We did this by calculating the following five totals for each lab: total allowed amount, total number of claims, total number of ordering physicians, and total number of beneficiaries. We then developed 13 measures to describe lab billing and to identify labs with questionable billing. These measures were based on information from previous studies on lab services, Federal criminal and civil investigations involving lab services, OIG work on questionable billing for other Medicare providers, discussions with CMS staff, and our own analysis.

Below are the descriptions of the methodologies used to calculate each of the measures of questionable billing. After calculating each measure, we analyzed the distribution of labs for each measure. We considered a lab's billing to be unusually high, or questionable, on a measure if the number or percentage was greater than the 75th percentile plus 3 times the interquartile range.^{31, 32} We calculated the thresholds for ILs and non-ILs separately.

Any limitations with the data used to calculate each measure are also noted. Furthermore, some claims and/or labs were excluded from several of the measures. Table A1 shows the final number of labs used in the analysis of each measure.

- (1) *High average allowed amount per claim.* This measure identifies labs with unusually high average allowed amounts per claim. For each lab, we divided the total amount allowed by the total number of claims to determine the average allowed amount per claim. We did not exclude any claims or labs from this analysis.
- (2) *High average number of claims per beneficiary.* This measure identifies labs with unusually high numbers of claims per beneficiary. For each lab, we divided the total number of claims by the total number of beneficiaries to determine the average number of claims per beneficiary. We did not exclude any claims or labs from this analysis.

³¹ This is a standard exploratory method for identifying members of a population with unusually high values on a given statistic compared to the rest of the population when no benchmarks exist. See J.W. Tukey, *Exploratory Data Analysis*, Addison-Wesley, 1977.

³² As noted in footnote 24, one measure—compromised lab number—is a binary measure, as labs either did or did not have a compromised number. Because this measure is binary, it does not have a threshold.

- (3) *High average allowed amount per beneficiary.* This measure identifies labs with unusually high average allowed amounts per beneficiary. For each lab, we divided the total allowed by the total number of beneficiaries to calculate the average allowed amount per beneficiary. We did not exclude any claims or labs from this analysis.
- (4) *High average number of claims per ordering physician.* This measure identifies labs with unusually high numbers of claims per ordering physician. For each lab, we divided the total number of claims by the total number of ordering physicians to determine the average number of claims per ordering physician.

Section 1877 of the Social Security Act, otherwise known as the physician self-referral law or Stark Law, prohibits physicians from making referrals for certain designated health services payable by Medicare, including lab services, to an entity with which the physician or immediate family member has a financial relationship.³³ However, there are various exceptions to the Stark law, including physicians ordering and furnishing designated health services in the context of their own practices provided that certain criteria are met. (This is known as the in-office ancillary services exception.³⁴) Because physicians' self-referrals to non-ILs in their own offices might have qualified for a Stark exception, we did not include non-IL self-referred claims as questionable for this measure. Therefore, we excluded any claim submitted by a non-IL for which the performing provider was also the ordering physician (indicating a self-referral). In total, we excluded 40,859,967 claims and 22,260 non-ILs from this analysis.

- (5) *High average allowed amount per ordering physician.* This measure identifies labs with unusually high average allowed payments per ordering physician. For each lab, we divided the total allowed per lab by the total number of ordering physician to calculate the average allowed per ordering physician. As we did with the previous measure, we excluded 40,859,967 claims and 22,260 non-ILs from this analysis.

³³ Social Security Act, § 1877(a), 42 U.S.C. § 1395nn(a).

³⁴ Social Security Act, § 1877(b)(2), 42 U.S.C. § 1395nn(b)(2). See also 42 CFR § 411.355(b).

- (6) High percentage of claims for beneficiaries with no associated Part B services with the ordering physician. This measure identifies labs with unusually high percentages of claims for which beneficiaries did not receive a Part B service—excluding other lab services and durable medical equipment, prosthetics, orthotics, and supplies—from the ordering physician in the 6 months prior to the lab service. For each lab, we determined the total number of lab claims for beneficiaries without recent contact and divided that number by the total number of claims to determine labs' percentage of claims for beneficiaries without recent contact with the ordering physician.

Lab services must be ordered by the physician treating the beneficiary. Therefore, we expect that a claim for service from the ordering physician would generally precede the lab service by a reasonably short period of time. For each lab claim, we determined whether there was recent contact between the beneficiary and the ordering physician by matching the beneficiary's HICN and the ordering physician's NPI on the lab claim to the HICN and performing provider NPI on the Part B service claim. If the beneficiary had any Part B claim with a date of service in the 6 months prior to the lab claim, we considered this to be evidence of recent contact with the physician. One limitation to this analysis, however, is that there may be cases in which the ordering physician was not a Medicare-enrolled physician and, therefore, a prior Part B service claim billed to Medicare would not exist for this beneficiary. We did not exclude any claims or labs from this analysis.

- (7) High percentage of claims with beneficiaries living more than 150 miles from the ordering physician. This measure identifies labs with unusually high percentages of claims for beneficiaries residing more than 150 miles from the ordering physician. Because lab services must be ordered by the physician or nonphysician practitioner treating the beneficiary, we would expect that many beneficiaries would reside within a reasonable distance from the treating physician, i.e., ordering physician. For each lab, we determined the number of claims for beneficiaries who lived more than 150 miles away from the ordering physician and divided this number by the total number of claims to determine the percentage of claims with beneficiaries living more than 150 miles from the ordering physician.

Using SAS, we determined the geodetic distance (the shortest line between two points) in miles between beneficiary and ordering

physician. We used the beneficiary ZIP Code on the claim and the ordering physician practice location ZIP Code in the NPPES files. We used the *zipcitydistance* function in SAS to calculate the distance between the beneficiary and the ordering physician.

For a number of claims, distance could not be calculated using SAS because the ZIP Code of the beneficiary or the ordering physician was invalid. For these claims, we used ArcGIS, a platform for building and using geographic information systems, to calculate distances. We used either the city and State of the ordering physician's practice location, or the ZIP Code of that location. For any claim for which the distance could not be calculated because the ordering physician's practice location was outside of the United States, Canada, or Mexico, we considered the distance to be greater than 150 miles.

Several limitations exist for this analysis. First, the beneficiary ZIP Code on the claim may reflect the beneficiary's mailing address, not where the beneficiary actually resides. Additionally, a May 2013 OIG report that analyzed the accuracy and completeness of NPPES data found that the addresses for practice locations were often inaccurate.³⁵

For this analysis, we excluded claims that were missing the beneficiary's ZIP Code. We also excluded claims that were missing the ordering physician's practice location and claims with ordering physicians whose practice location addresses changed in 2010. Lastly, we excluded claims for which distances could not be calculated in either SAS or ArcGIS. We excluded a total of 4,620,875 claims and 943 labs from this analysis.

- (8) *High percentage of duplicate lab tests.* This measure identifies labs with unusually high percentages of duplicate lab tests. We considered tests to be duplicates if they matched on HICN, performing provider NPI, end date of service, and HCPCS code. For each lab, we divided the number of duplicate tests (not including the first occurrence of the test) by the total number of tests to determine the percentage of duplicate lab tests.

Medicare will pay for tests performed more than once on the same day for the same patient only in certain cases. For example, there

³⁵ OIG, *Improvements Needed to Ensure Provider Enumeration and Medicare Enrollment Data are Accurate, Complete, and Consistent*, OEI-07-09-00440, May 2013.

may be times when it is necessary to perform a test more than once on the same day to obtain multiple results in the course of a patient's treatment. In these cases, labs are required to report specific modifiers on the claim. For this measure, we did not consider tests with modifiers 59, 76, 77, 91—which are used to indicate repeat or distinct tests—as duplicates. We also did not consider tests with the modifiers indicating technical component (TC) or professional component (26) to be duplicates. Lastly, we did not consider methodology-based molecular pathology “stacked” test codes as duplicates because these tests could be billed multiple times to represent the performance of the entire test. We did not exclude any claims or labs from this analysis.

- (9) *High percentage of claims with invalid ordering-physician numbers.* This measure identifies labs with unusually high percentages of claims with invalid ordering-physician numbers. For each lab, we determined the number of claims for services ordered with an invalid physician number and divided that number by the total number of claims per lab to determine the percentage of claims with invalid ordering-physician numbers.

To determine whether an ordering physician had an invalid number, we compared the NPIs of our ordering physicians to NPPES. If an NPI was not in NPPES, we considered the ordering physician's number to be invalid. Additionally, we considered the numbers of ordering physicians with deactivated NPIs to be invalid. We also used NPPES to determine whether an ordering physician's number had been deactivated. If the ordering physician's NPI was deactivated prior to 2010 and either not reactivated or reactivated after 2010, we considered the physician's number to be invalid. We did not exclude any labs from this analysis.

- (10) *High percentage of claims with ineligible ordering-physician numbers.* This measure identifies labs with unusually high percentages of claims for services ordered with ineligible physician numbers. For each lab, we divided the number of claims that had an ineligible physician number by the total number of claims to calculate the percentage of claims with ineligible ordering physicians.

Lab services can only be ordered by individual physicians or nonphysician practitioners who treat the beneficiary. We determined whether an ordering physician was an individual using specialties found in PECOS. If the ordering-physician number did not have an enrollment record in PECOS, we used NPIC and NPPES data to

make the determination. We considered ordering physicians identified as nonindividuals, e.g., clinical labs, clinic or group practices, to be ineligible to order. We did not exclude any labs from this analysis.

- (11) High percentage of claims with compromised beneficiary numbers. For this measure, we first identified any beneficiary HICNs listed in CMS's CNC without a removal date as of August 5, 2013. We used the removal date because when CMS verifies that a number is not actually compromised, it adds a removal date and reason code, but does not physically remove the number from the CNC. We then calculated the percentage of claims with a compromised beneficiary number by dividing the number of claims with a compromised beneficiary number by the total number of claims for each lab.

Because the CNC contains suspected numbers in addition to verified numbers, we are not assuming that labs exceeding the thresholds for percentage of claims with compromised beneficiary numbers are necessarily fraudulent, only that they may warrant further review. In addition, OIG previously reported that some CMS contractors who refer provider and beneficiary numbers for inclusion in the database have concerns about the quality of the information in the database.³⁶ We did not exclude any claims or labs from this analysis.

- (12) High percentage of claims with compromised ordering-physician numbers. As we did for the previous measure, we first identified any ordering-physician NPI listed in the CNC without a removal date as of August 5, 2013. Then, for each lab, we calculated the percentage of claims with a compromised ordering-physician number by dividing the number of claims with a compromised ordering-physician number by the total number of claims. We did not exclude any claims or labs from this analysis.

- (13) Compromised lab provider number. We considered any lab that had an NPI listed in the CNC without a removal date as of August 5, 2013, to be questionable on this measure. We did not exclude any claims or labs from this analysis.

³⁶ OIG, *CMS Response to Breaches and Medical Identity Theft*, OEI-02-10-00040, October 2012.

Table A1: Total Labs Included in Analysis For Each Measure

Measure	N
High average allowed amount per claim	94,609
High average number of claims per beneficiary	94,609
High average allowed amount per beneficiary	94,609
High average number of claims per ordering physician	72,349
High average allowed amount per ordering physician	72,349
High percentage of claims for beneficiaries with no associated Part B service with the ordering physician	94,609
High percentage of claims with beneficiaries living more than 150 miles from the ordering physician	93,666
High percentage of duplicate lab tests	94,609
High percentage of ordering physicians with invalid numbers	94,609
High percentage of claims with ineligible ordering-physician numbers	94,609
High percentage of claims with compromised beneficiary numbers	94,609
High percentage of claims with compromised ordering-physician numbers	94,609
Compromised lab provider number	94,609

Source: OIG analysis of claims for 2010 Part B clinical lab services.

APPENDIX B

Labs That Exceeded Thresholds for Measures of Questionable Billing in 2010

Table B1: Labs That Exceeded Thresholds for Measures of Questionable Billing in 2010

Measure	ILs			Non-ILs			Number of Labs that Exceeded Questionable Threshold
	Median ¹	Questionable Threshold	Number of Labs	Median ¹	Questionable Threshold	Number of Labs	
Average allowed amount per claim	\$46	\$314	137	\$19	\$129	5,297	5,434
Average number of claims per beneficiary	3	13	23	2	9	1,157	1,180
Average allowed amount per beneficiary	\$140	\$536	179	\$47	\$303	1,810	1,989
Average number of claims per ordering physician	18	216	147	3	22	4,988	5,135
Average allowed amount per ordering physician	\$1,081	\$12,598	180	\$61	\$901	5,055	5,235
Percentage of claims for beneficiaries with no associated Part B services with ordering physician	17.7%	70.1%	113	5.9%	70.3%	3,417	3,530
Percentage of claims with beneficiaries residing more than 150 miles from the ordering physician	2.8%	17%	58	1.5%	12.5%	4,731	4,789
Percentage of duplicate lab tests	0%	0.1%	334	0%	0% ³	10,210	10,544
Percentage of claims with invalid ordering-physician numbers	0%	0% ³	455	0%	0% ³	3,736	4,191
Percentage of claims with ineligible ordering-physician numbers	0.4%	7.2%	170	0%	0% ³	19,277	19,447
Percentage of claims with compromised beneficiary numbers	0.05%	1.6%	330	0%	0.2%	17,118	17,448
Percentage of claims with compromised ordering-physician numbers	0%	0.08%	531	0%	0% ³	3,881	4,412
Compromised lab provider number ²			13			121	134

Source: OIG analysis of claims for Part B clinical lab services, 2010.

¹ The median (i.e., the 50th percentile) indicates that half of all labs were equal to or less than this value.

² This is a binary measure. Lab provider numbers were either compromised or not compromised. Therefore, no median or threshold was calculated for this measure.

³ A threshold of 0 percent indicates that not only was the median value 0, but the IQR, which measures the spread of the middle 50 percent of data values, was also 0. Therefore, any lab that exceeded 0 percent for the measure was considered to have questionable billing.

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAY 22 2014

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Questionable Billing for Medicare Part B Clinical Laboratory Services (OEI-03-11-00730)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above subject OIG draft report. The purpose of this report is to identify potentially questionable billing patterns among Medicare clinical laboratory services.

As the largest payer of clinical laboratory services in the nation, CMS is committed to identifying questionable billing practices and working with all stakeholders in an effort to develop stronger oversight of clinical laboratories. By focusing on specific vulnerabilities identified in this draft report, CMS will be able to prevent fraud, waste, and abuse more effectively in order to safeguard the Medicare program. CMS is committed to utilizing all available tools to identify and prevent improper payments made for clinical laboratory services.

We appreciate OIG's efforts in working with CMS to ensure that appropriate action is taken regarding questionable billing for clinical laboratory services. Our responses to each of the OIG recommendations are addressed below.

OIG Recommendation

The OIG recommends that CMS review the labs identified as having questionable billing and take appropriate action.

CMS Response

The CMS concurs with this recommendation and will direct the Zone Program Integrity Contracts (ZPICs) to follow up and investigate those laboratories identified with questionable billings.

OIG Recommendation

The OIG recommends that CMS should review existing program integrity strategies to determine if they are effectively identifying program vulnerabilities associated with lab services.

CMS Response

The CMS concurs with this recommendation. CMS is using the Fraud Prevention System (FPS) to identify possible fraudulent, wasteful or abusive activities associated with laboratory services, and to provide Zone Program Integrity Contractors (ZPICs) and Program Safeguard Integrity Contractors (PSCs) with actionable information to initiate and facilitate their investigations. Currently, there are several models operating in the FPS that address one or more program vulnerabilities associated with lab services. CMS is monitoring the performance of these models and working with ZPICs, PSCs and other stakeholders to optimize the models' actionable information and to create additional models to identify vulnerabilities associated with laboratory services. As a result of this and other proactive analysis, there are currently 47 laboratories under investigation by the ZPICs and PSCs.

The CMS uses other program integrity contractors to identify vulnerabilities within the Medicare program. The Medicare Administrative Contractors (MACs) perform data analysis regularly to determine areas of highest risk for improper payments in their jurisdictions. The MACs incorporate these high priority areas into their medical review strategies. That being said, the MACs must weigh the costs of conducting medical reviews of laboratory claims with other competing demands for review within their jurisdictions. Currently, five MAC jurisdictions incorporate laboratory services within their medical review strategies.

OIG Recommendation

The OIG recommends that CMS should ensure that implemented edits prevent claims with invalid and ineligible ordering physician numbers from being paid.

CMS Response

The CMS concurs with this recommendation. Under regulations implementing part of the Affordable Care Act physicians or eligible professionals who order and refer certain services must be enrolled in the Medicare program and claims for certain services, including Part B clinical laboratory claims, must contain such ordering provider's NPI to be eligible for payment. Effective January 6, 2014,¹ CMS began denying claims for Part B clinical laboratory and imaging, Part A home health agencies and durable medical equipment if the provider who ordered or referred the item or service was not enrolled in or obtained opt out status with Medicare. CMS established three basic requirements for ordering/referring which will aid in effectively preventing questionable payments:

¹ <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/se1305.pdf>

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- The physician or non-physician practitioner must be enrolled or obtain opt-out status in Medicare;
- The ordering/referring National Provider Identifier (NPI) on the claim must be for an individual physician or non-physician practitioner (not an organizational NPI) and therefore the organizational providers (i.e. clinic/group practices, hospitals, home health agencies) cannot order and refer; and
- The physician or non-physician practitioner must be of a specialty type that is eligible to order and refer.

The edit has resulted in claims being denied for Part B laboratory and imaging claims because they did not meet these three requirements. The CMS is continuing to closely monitor the number of denials due to implementation of these new edits.

The CMS thanks OIG for the work done on this issue and looks forward to working with OIG in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General.

Maria S. Johnson served as the team leader for this study. Other Office of Evaluation and Inspections staff from the Philadelphia regional office who conducted the study include Courtney Fanslau. Central office staff who provided support include Clarence Arnold, Mandy Brooks, Kevin Manley, and Christine Moritz.

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.