Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

VARIATION IN THE CLINICAL LABORATORY FEE SCHEDULE

Daniel R. Levinson
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EXECUTIVE SUMMARY

OBJECTIVE

To determine the extent to which Medicare Clinical Laboratory Fee Schedule rates varied in 2007.

BACKGROUND

Medicare Part B covers most outpatient clinical diagnostic laboratory tests (hereinafter referred to as lab tests) and pays 100 percent of their costs because there are no beneficiary copayments or deductibles for lab tests. In 2007, lab tests accounted for 3 percent of all Medicare Part B payments. Each laboratory submits claims to the Medicare carrier responsible for the area in which the laboratory is located. Carriers process Medicare Part B payments in 56 carrier localities that correspond mostly with State borders.

Medicare Part B payments for lab tests are determined by the Clinical Laboratory Fee Schedule. The Deficit Reduction Act of 1984 mandated that fee schedules be established for each lab test on a regional, statewide, or carrier basis. As a result, each carrier established its own fee schedule rates (hereinafter referred to as carrier rates), which are collectively known as the Clinical Laboratory Fee Schedule. The Consolidated Omnibus Budget Reconciliation Act of 1985 mandated a national limit amount (NLA) that capped carrier rates. The NLA is set at 74 percent of the median carrier rate for each lab test (or 100 percent of the median for new tests for which an NLA was not established before January 1, 2001). Carriers pay laboratories the lower of the laboratories' charges or the carrier rate as capped by the NLA.

To determine the extent of variation, we assessed carrier rates as well as utilization and payments for Medicare-covered lab tests in 2007. To do this, we used the 2007 Clinical Laboratory Fee Schedule and a 1-percent random sample of 2007 Medicare Part B claims data for lab tests paid under the Clinical Laboratory Fee Schedule.

FINDINGS

Carrier rates for nearly all lab tests varied, but 83 percent of carrier rates were at the National Limit Amount. In 2007, 97 percent of lab tests had at least one carrier rate that varied from the NLA. However, 83 percent of all carrier rates were at the NLA and 89 percent of lab test claims were paid at the NLA.

Variation in carrier rates did not appear to reflect geographic differences in cost. Variation from the NLA was inconsistent within each carrier and thus did not appear to reflect geographic differences in costs. For instance, we found that each carrier had rates dispersed at varying percentages below the NLA. If a geographic assessment of costs had been factored into the establishment of each carrier's rates, each carrier might have been expected to have most, if not all, rates at the same percentage below the NLA.

Methods for setting carrier rates created inconsistent variation across carriers. In 2007, all carriers had rates that varied from the NLA. Variation was greater for some carriers than others because of methods for setting and updating carrier rates. In establishing rates in 1985, carriers used laboratory charge data that may not have reflected lab tests' costs. Since then, methods used to update carrier rates have incrementally added to the variation in carrier rates.

Because carriers pay different rates for the same lab test, variation affects Medicare payments. Medicare paid over $3.4 billion for lab tests in 2007. Medicare payments would have been $3.5 billion if all lab tests had been paid at the NLA or $2.4 billion if the NLA had been reduced to 50 percent of the median carrier rate. Setting all carrier rates at 73 percent of the median carrier rate would have eliminated variation without a change in overall Medicare payments.

RECOMMENDATION

The Centers for Medicare & Medicaid Services should seek legislation that would allow it to set accurate and reasonable payment rates for lab tests. The Centers for Medicare & Medicaid Services (CMS) should request legislative authority to institute a new process for setting accurate and reasonable payment rates. CMS could use several methods to achieve this result. Whatever method CMS implements should be determined after careful consideration of the impact on Medicare costs and on the laboratory industry.

One approach would be for CMS to seek legislation to set a base payment rate for each lab test. If a single base payment rate for each lab test is set, CMS should consider adjusting these rates to reflect any geographic differences in cost.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur, at this time, with our recommendation to seek legislation that would allow it to set accurate and reasonable payment rates for lab tests. Although it did not concur at this time, CMS stated that it will consider our recommendation and that it is committed to improving payment policies for lab tests and to refining methodologies for establishing new payment rates. We encourage CMS to pursue legislation that would allow it to set accurate and reasonable payment rates for lab tests.

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OBJECTIVE

To determine the extent to which Medicare Clinical Laboratory Fee Schedule rates varied in 2007.

BACKGROUND

Clinical diagnostic laboratory tests (hereinafter referred to as lab tests) are tests performed on specimens taken from the human body and provide information integral to preventing, diagnosing, and treating disease. Most lab tests are conducted in hospital, physician-office, or independent laboratories.

Medicare Part B Coverage and Payment for Lab Tests

Medicare Part B covers most outpatient lab tests and pays 100 percent of their costs because there are no beneficiary copayments or deductibles for lab tests.[1] In 2007, lab tests accounted for 3 percent of all Medicare Part B payments.[2]

Each laboratory submits claims to the Medicare carrier responsible for the area in which a laboratory is located.[3] Carriers process Medicare Part B payments in 56 carrier localities that correspond mostly to State borders. By 2011, the 56 carrier localities are scheduled to be replaced by 15 Medicare Administrative Contractor (MAC) jurisdictions. However, MACs will not consolidate payment policies. MACs will continue to administer the same payment policies used in each of the 56 carrier localities.

The Clinical Laboratory Fee Schedule

The Deficit Reduction Act of 1984 (DRA of 1984) mandated that fee schedules be established for each lab test on a regional, statewide, or carrier basis.[4] Consistent with the DRA of 1984, each carrier established its own fee schedule rates based on the prevailing charges

[1] Social Security Act § 1866(a)(2)(A)(ii), 42 U.S.C. § 1395cc(a)(2)(A)(ii); Social Security Act § 1833(b)(3), 42 U.S.C. § 1395l(b)(3).

[2] Centers for Medicare & Medicaid Services (CMS), "Data Compendium: Table II.3." Available online at http://www.cms.hhs.gov/DataCompendium/downloads/2008Expenditures.zip. Accessed on February 26, 2009.

[3] Each hospital laboratory submits claims to the fiscal intermediary responsible for the area in which the hospital is located. Fiscal intermediaries use the same payment system as carriers.

[4] DRA of 1984, P.L. No. 98-369 § 2303(d).

for lab tests in its locality between 1984 and 1985.[5] The fee schedule rates established by carriers (hereinafter referred to as carrier rates) are collectively known as the Clinical Laboratory Fee Schedule. Currently, the Clinical Laboratory Fee Schedule covers 1,105 unique lab tests.

In addition to establishing the Clinical Laboratory Fee Schedule, the DRA of 1984 mandated two further changes. First, it mandated the establishment of a single national fee schedule after July 1, 1987.[6] Congress repealed this mandate in 1989 following an Office of Inspector General (OIG) report.[7] The OIG report found that setting a national fee schedule at rates equal to 100 percent of the median carrier rate for each lab test would have been more costly than the range of carrier rates on the Clinical Laboratory Fee Schedule.[8] Second, the DRA of 1984 mandated the use of the Consumer Price Index for All Urban Consumers (CPI-U) to annually adjust carrier rates for inflation.[9] In 2003, Congress eliminated the CPI-U adjustments for 2004 through 2008.[10] In 2008, Congress reinstated the CPI-U adjustments but lowered the CPI-U by 0.5 percentage points for 2009 through 2013. [11]

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) mandated a national limit amount (NLA) that capped carrier rates at 115 percent of the median carrier rate for each lab test.[12] For example, if the median carrier rate for a particular lab test was $100, the NLA capped carrier rates at $115. Over time, Congress incrementally lowered the percentage of the national median carrier rate used to calculate the NLA as part of a process to implement cost constraints.[13] Since 1998, the NLA has been set at 74 percent of the median carrier rate for each lab test (or 100 percent of the median for new lab tests for

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[5] DRA of 1984, P.L. No. 98-369 § 2303(d).

[6] Ibid.

[7] The Omnibus Budget Reconciliation Act of 1989, P.L. No. 101-239 § 6111(a).

[8] OIG, "Medicare Reimbursement for Outpatient Laboratory Services," OAI-04-88-01080, p. 9, March 1989.

[9] DRA of 1984, P.L. No. 98-369 § 2303(d).

[10] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. No. 108-173 § 628.

[11] Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275 § 145(b).

[12] COBRA, P.L. No. 99-272 § 9303(b).

[13] Social Security Act, § 1833(h)(4)(B), 42 U.S.C. § 1395l(h)(4)(B).

which an NLA was not established before January 1, 2001).[14] Under the Clinical Laboratory Fee Schedule, carriers pay laboratories the lower of the laboratories' charges or the carrier rate as capped by the NLA.[15]

In 2003, Congress mandated that CMS implement a demonstration project to explore whether competitive bidding could provide rates for lab tests below those on the Clinical Laboratory Fee Schedule.[16] However, a lawsuit brought by two laboratories resulted in a court-ordered preliminary injunction that stopped implementation of the demonstration project in April 2008.[17] In July 2008, Congress repealed the authority for the demonstration, thereby eliminating the demonstration project.[18]

Updating the Clinical Laboratory Fee Schedule

To keep pace with industry changes, CMS annually determines which lab tests to cover under Medicare. As a result, CMS either adds or deletes lab tests from the Clinical Laboratory Fee Schedule. When CMS adds a new lab test to the Clinical Laboratory Fee Schedule, it must determine the appropriate carrier rates. CMS uses one of two methods to set the carrier rates for each new lab test: cross-walking or gap-filling.[19]

Cross-walking new lab tests. CMS uses the cross-walking method to assign carrier rates when it considers a new lab test to be clinically or technologically similar to an existing lab test, multiple existing lab tests, or a portion of an existing lab test. Under this method, CMS assigns an existing lab test's NLA and carrier rates to the new lab test.[20] According to CMS staff, CMS uses this method to set carrier rates for the majority of lab tests.

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[14] Social Security Act, § 1833(h)(4)(B)(viii), 42 U.S.C. § 1395l(h)(4)(B)(viii).

[15] Social Security Act, § 1833(a)(1)(D)(i), 42 U.S.C. § 1395l(a)(1)(D)(i).

[16] MMA, P.L. No. 108-173 § 302(b).

[17] Sharp Healthcare v. Leavitt, No. 08-CV-0170 W (POR), 2008 U.S. Dist. LEXIS 28623 (S.D. Cal. Apr. 8, 2008).

[18] Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275 § 145(a).

[19] 42 CFR 414.508; see also 73 Fed. Reg. 33825, 33825 (June 13, 2008) (describing the two methods).

[20] 42 CFR 414.508(a).

Gap-filling new lab tests. CMS uses the gap-filling method to establish carrier rates for a new lab test if no similar lab test exists.[21] Under this method, CMS assigns each carrier the responsibility for setting the new rates in the first year. Carriers may use several sources of information to set rates, such as lab test charges and payment amounts determined by other payers. Carriers may also consider other sources of information as appropriate.[22] In the second year, CMS uses the carrier-specific amounts to establish the NLA.[23]

Office of Inspector General and Related Work

Previous OIG work on laboratories included studies that examined payment safeguards,[24] Clinical Laboratory Fee Schedule rates compared to other payers,[25] utilization and alternative payment approaches,[26] and potential costs for establishing a national fee schedule for outpatient lab tests.[27]

In 2000, the Institute of Medicine (IOM) of the National Academies published "Medicare Laboratory Payment Policy: Now and in the Future."[28] IOM found that the Clinical Laboratory Fee Schedule and methodology for setting rates have not evolved to account for technology, market, and regulatory changes. Among other recommendations, IOM recommended that Medicare payments for lab tests be based on a single, rational, national fee schedule that should be adjusted for geographic location to account for differences in costs of labor and supplies.[29]

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[21] 42 CFR 414.508(b).

[22] 42 CFR 414.508(b)(1)(iv); CMS, "Medicare Claims Processing Manual," Pub. No. 100-4, ch. 23 § 40.4. Available online at http://www.cms.hhs.gov/manuals/downloads/clm104c23.pdf. Accessed on September 15, 2008.

[23] 42 CFR 414.508(b)(2).

[24] OIG, "Common Working File Edits for Unauthorized Laboratory Tests," OEI-05-00-00050, January 2002.

[25] OIG, "Follow-Up Report to Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests," A-09-93-00056, January 1996.

[26] OIG, "Ensuring Appropriate Use of Laboratory Services," OEI-05-89-89150, October 1990.

[27] OIG, "Medicare Reimbursement for Outpatient Laboratory Services," OAI-04-88-01080, March 1989.

[28] Dianne Miller Wolman, et al., Institute of Medicine of the National Academies, "Medicare Laboratory Payment Policy: Now and in the Future," 2000.

[29] Wolman, et al.., op. cit., pp. 146–147.

METHODOLOGY

This study assesses carrier rates and utilization of Medicare-covered lab tests in 2007 to describe variation in the 2007 Clinical Laboratory Fee Schedule. This study also assesses the effect of variation on Medicare Part B payments for lab tests.

Data Sources

To describe variation across lab tests and carriers for the 2007 Clinical Laboratory Fee Schedule, we obtained the corresponding 56 carrier rates and NLA for each of the 1,105 unique Medicare-covered lab tests. We defined lab tests using the Healthcare Common Procedure Coding System. To determine whether variation had changed over time, we obtained the 56 carrier rates and the NLA for each of the 1,059 unique Medicare-covered lab tests on the 2002 Clinical Laboratory Fee Schedule to contrast with those on the 2007 Clinical Laboratory Fee Schedule. We selected the 2002 Clinical Laboratory Fee Schedule to provide a historical perspective over a 5-year period.

To determine utilization of and payment for lab tests, we obtained a 1-percent random sample of 2007 Medicare Part B claims data for lab tests paid under the Clinical Laboratory Fee Schedule. The Part B claims data identify the paying carrier, the type of lab test performed, and the amount the carrier paid for each lab test. This sample includes a record for each lab test that a laboratory billed. It does not include claims from hospital outpatient laboratories. We chose not to obtain hospital outpatient laboratory claims because some hospital laboratories are paid with a special adjustment for outpatient lab tests or are paid on a reasonable-cost basis.

Data Analysis

We analyzed the 2007 Clinical Laboratory Fee Schedule by lab test and by carrier to determine the extent of variation in carrier rates. To determine whether the extent of variation changed over time, we compared the number of carrier rates for lab tests below the NLA in 2002 to the number of carrier rates below the NLA in 2007.

Determining the extent of carrier rate variation for lab tests. To determine the variation in carrier rates for each lab test, we calculated how far below the NLA all 56 carrier rates were for each lab test. We then calculated several measures of carrier rate variation across all lab tests.

We determined the utilization of lab tests paid at or below the NLA. For lab tests paid below the NLA, we determined how much they were

paid below the NLA and the corresponding level of utilization. To do this, we identified the allowed lab tests paid below the NLA, determined the percentage of the NLA each of these allowed lab tests was paid, and grouped the allowed lab tests by the different percentages of the NLA that they were paid. We could not match the payment methodology to the corresponding claim or claims for less than 1 percent of allowed lab tests and therefore did not include them in our analysis.

Determining the extent of variation in each carrier's rates. To determine the extent of variation in each carrier's rates, we assessed the range and distribution of all rates for each carrier at different percentages of the NLA.

To provide an example of the variation in each carrier's rates, we assessed the rates for the carrier with the highest lab test utilization. To identify the carrier with the highest lab test utilization, we summed the total number of allowed lab tests for each carrier. We then assessed the extent and range of variation in this carrier's rates for lab tests.

Determining the extent of variation across carriers and the effect of variation on Medicare payments. To determine the extent of variation in rates across carriers, we counted the number of rates that each carrier had below the NLA. We then calculated several measures of variation across all 56 carriers.

To provide an example of the effects of variation on Medicare payments, we chose to use the claims and payments for the 10 most utilized lab tests nationally in 2007. We identified the 10 most utilized lab tests nationally by calculating the number of allowed lab tests for each claim and ranking each lab test by the number of allowed lab tests. We then assessed variation in their carrier rates. These 10 lab tests accounted for 48 percent of all lab test utilization in 2007.

To see how variation across carriers affects Medicare payments, we first calculated the amount Medicare actually paid for lab tests in 2007. Then, we calculated how much Medicare hypothetically would have paid if variation had been eliminated. We calculated three examples: (1) a single payment rate based on the current NLA, (2) a single payment rate based on a cost-neutral NLA, and (3) a single payment rate based on an NLA set at a reduced percentage of the median carrier rate. To do so, we chose to reduce the NLA to 50 percent of the median carrier rate.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency (now Council of the Inspectors General on Integrity and Efficiency).

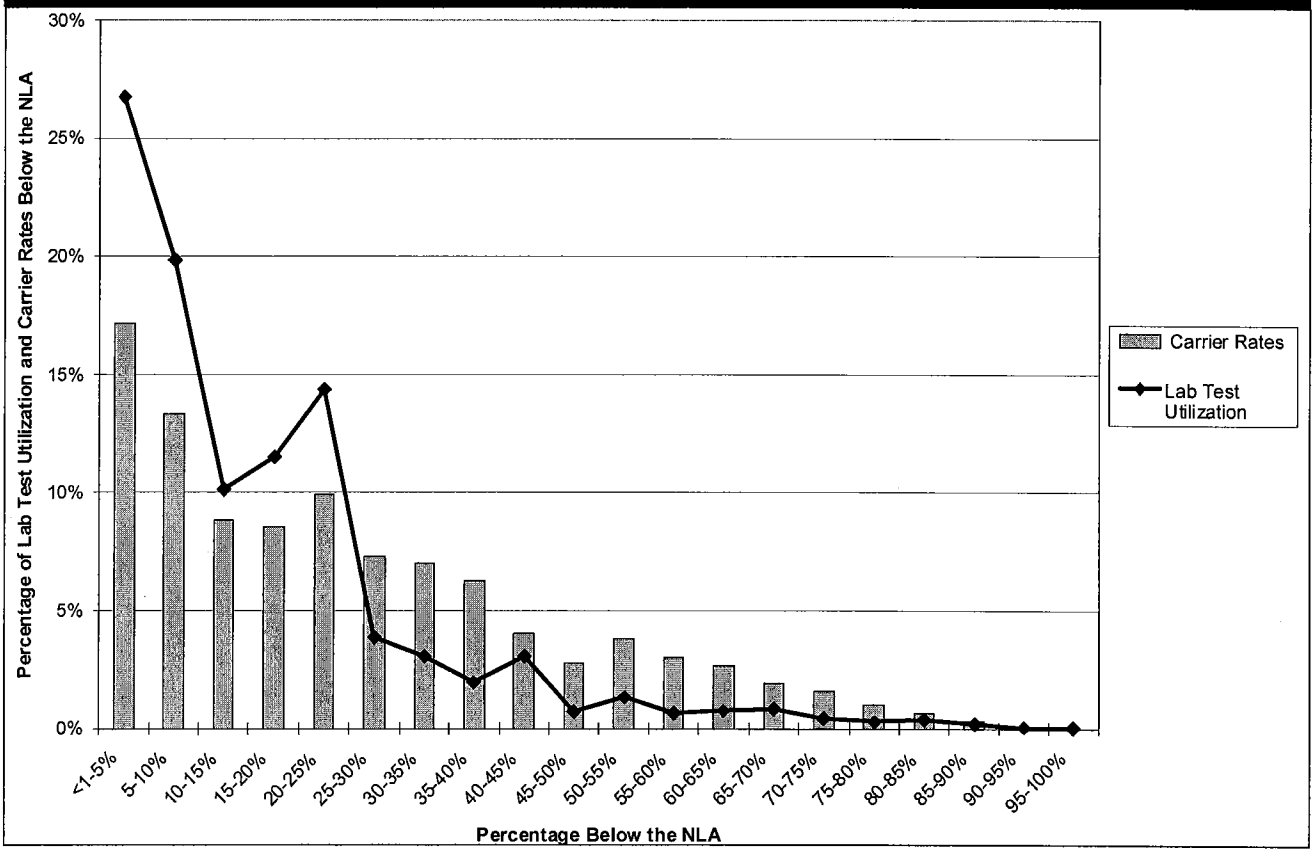
Carrier rates for nearly all lab tests varied, but 83 percent of carrier rates were at the National Limit Amount

In 2007, although 97 percent of lab tests had at least one carrier rate that varied from the NLA, most carrier rates for lab tests were at the NLA. Overall, 83 percent of carrier rates were set at the NLA. For the 17 percent of carrier rates below the NLA, carrier rates ranged from less than 1 percent to 93 percent below the NLA. On average, these carrier rates were 25 percent below the NLA.

Similarly, most lab test utilization was paid at the NLA. Overall, 89 percent of lab test utilization was paid at the NLA. In addition, most of the 11 percent of lab test utilization that was paid below the NLA was for lab tests that were paid near the NLA. For example, 47 percent of utilization for lab tests paid below the NLA was paid within 10 percent of the NLA.

As illustrated in Chart 1, lab test utilization generally declined as the amount paid moved farther below the NLA, with a noticeable drop in lab test utilization when the amount paid was 25 percent or more below the NLA. In addition, Chart 1 demonstrates that carrier rates below the NLA were most prevalent where the percentage below the NLA was the smallest. The percentage of carrier rates below the NLA generally declined as the carrier rates moved farther below the NLA.

Chart 1: Percentage of Lab Test Utilization and Carrier Rates at Different Percentages Below the NLA

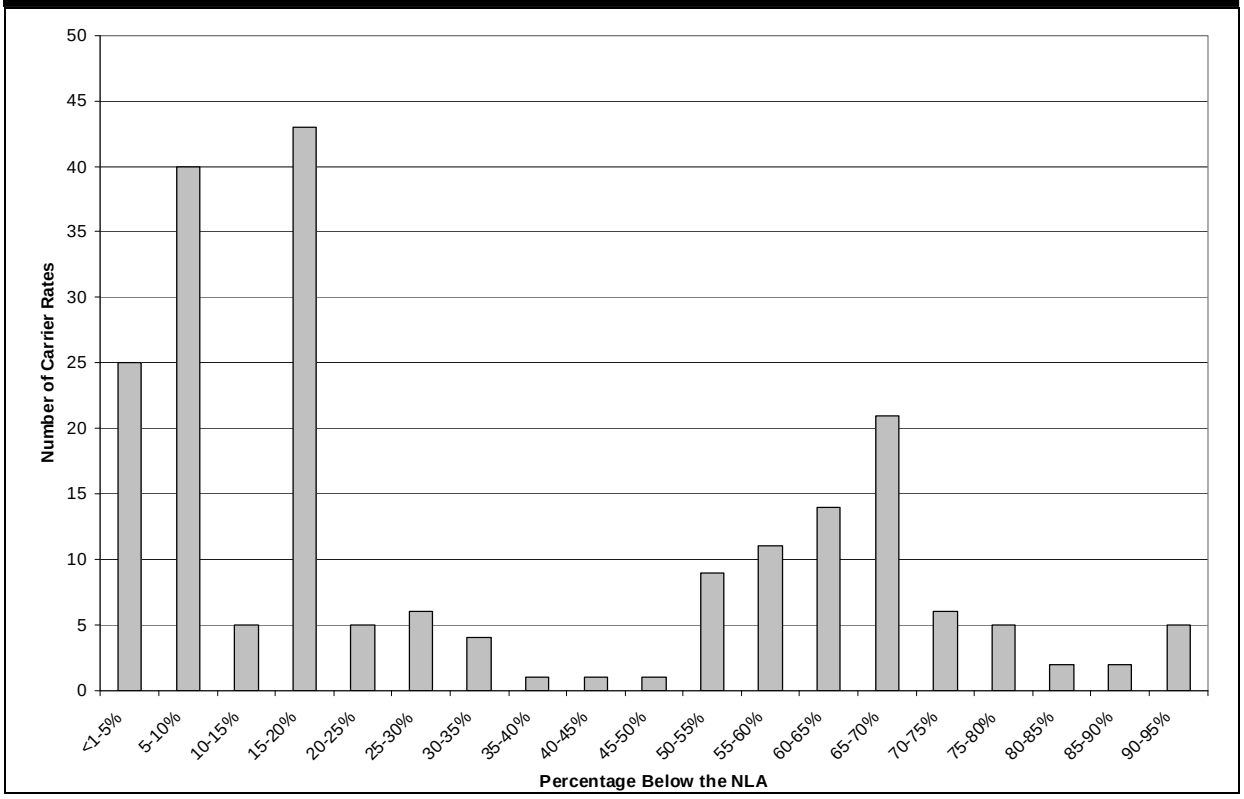


Source: OIG analysis of the 2007 Clinical Laboratory Fee Schedule and Medicare Part B Claims data, 2008.

Variation in carrier rates did not appear to reflect geographic differences in cost

No carrier consistently had all rates at the same percentage below the NLA. Instead, each carrier had rates dispersed at varying percentages below the NLA. For example, Florida's carrier, the carrier with the highest utilization of lab tests, illustrates how carriers' rates were dispersed below the NLA. Overall, 21 percent of Florida's carrier rates were below the NLA. These rates ranged between less than 1 percent and 92 percent below the NLA. See Chart 2 for the number of Florida's carrier rates at different percentages below the NLA.

Chart 2: Florida's Carrier Rates Below the NLA



Source: OIG analysis of the 2007 Clinical Laboratory Fee Schedule and Medicare Part B Claims data, 2008.

If a geographic assessment of costs had been consistently factored into the establishment of each carrier's rates, each carrier might have been expected to have most, if not all, rates at the same percentage below the NLA. For example, under Medicare's physician fee schedule and hospital outpatient prospective payment system, base rates from a single national fee schedule are adjusted to reflect geographic differences in costs, such as wages. As a result, rates for each physician or hospital outpatient service are adjusted by the same percentage from the corresponding fee schedule for each individual locality.

Methods for setting carrier rates created inconsistent variation across carriers

Variation in carrier rates originates from the methods used to establish and update the Clinical Laboratory Fee Schedule. When carriers established the Clinical Laboratory Fee Schedule in 1985, they used laboratory charge data from their localities to set payment rates. Although this

report did not assess the charge data used to establish the Clinical Laboratory Fee Schedule, evidence suggests that laboratory charge data may not have reflected the actual costs of performing lab tests.[30] In some cases, laboratory charge data may have reflected laboratories' decisions on acceptable profit levels and market share. As a consequence, charge data may also not have reflected real differences in cost from carrier to carrier.[31]

Since the establishment of the Clinical Laboratory Fee Schedule, the cross-walking and gap-filling methods used to update it have incrementally added to the variation in carrier rates. The cross-walking method builds upon existing variation because CMS assigns new lab tests the carrier rates of existing lab tests. Thus, if the existing lab test has variation, the new lab test has the same variation. The gap-filling method may also add to variation because CMS allows carriers, at their discretion, to use different sources of information to assign rates for new lab tests.

If CMS continues to use these two methods for updating the Clinical Laboratory Fee Schedule, variation that does not reflect actual costs will remain and possibly increase over time. For example, between 2002 and 2007, CMS added 70 new lab tests to the Clinical Laboratory Fee Schedule and deleted 24 lab tests. During this time, the variation in the Clinical Laboratory Fee Schedule increased slightly, from 16.8 percent of carrier rates below the NLA to 17.1 percent. IOM found that about 15 percent of carrier rates were below the NLA in 2000.[32]

Variation was greater for some carriers than others

The methods used to establish and update the Clinical Laboratory Fee Schedule resulted in the proportion of rates below the NLA varying across carriers. At one end, Alaska's carrier had 3 percent of its rates below the NLA. At the other end, Utah's carrier had 31 percent of its rates below the NLA. Most carriers (34 of 56) had between 10 and 24 percent of their rates below the NLA. See Appendix A for the proportion, average, and range of rates below the NLA for each carrier.

[30] Wolman, et al., op. cit., p. 89.

[31] Wolman, et al., op. cit., p. 95.

[32] Wolman, et al., op. cit., p. 90.

Carriers also differed with respect to the amounts at which their rates were below the NLA. At the low end of the range of variation, Kentucky's carrier had an average rate 16 percent below the NLA. At the high end of the range, Wisconsin's carrier had an average rate of 38 percent below the NLA.

Variation of rates across carriers means that some carriers paid different amounts for the same lab test. For example, the carrier rate for one genetic test was $12.82 in California and $95.84 in Wyoming. Similarly, the carrier rate for one breath analysis test was $60.66 in New Jersey and $94.11 in Kentucky. Another example concerns the two most utilized tests. For the most utilized lab test, the carrier rate for Kentucky was at the NLA (the highest possible carrier rate), whereas the carrier rate for Kansas was 40 percent below the NLA (the lowest carrier rate for this lab test). However, the reverse was true for the second most utilized lab test. The carrier rate for Kansas was at the NLA, whereas the carrier rate for Kentucky was 21 percent below the NLA (the lowest carrier rate for this lab test). See Appendix B for examples of variation in the carrier rates for the 10 most utilized lab tests.

Because carriers pay different rates for the same lab test, variation affects Medicare payments. Medicare paid over $3.4 billion using the current carrier rates for lab tests in 2007. If variation had been eliminated by setting all carrier rates at the current NLA, Medicare payments would have increased by $74 million, bringing the total to almost $3.5 billion. On the other hand, if variation had been eliminated using a single rate based on a reduced NLA, Medicare would have paid less. For example, if all lab tests had been paid at 50 percent of the median carrier rate, Medicare payments would have been reduced to $2.4 billion, a reduction of $1 billion. Only if carrier rates had been set at 73 percent of the median carrier rate would variation have been eliminated with no change in overall Medicare payments.

RECOMMENDATION

Although variation affected nearly all lab tests, most carrier rates were at the NLA and the majority of lab test utilization was for lab tests paid at the NLA. The variation that existed in 2007 did not appear to reflect geographic differences in cost. Instead, the variation originated from the methods used to establish and update the Clinical Laboratory Fee Schedule. Variation of rates across carriers means that some carriers paid different amounts for the same lab test.

In light of our findings, we make the following recommendation for setting payment rates for lab tests.

CMS should seek legislation that would allow it to set accurate and reasonable payment rates for lab tests

CMS should request legislative authority to institute a new process for setting accurate and reasonable payment rates that would represent costs, adjusted for any geographic differences. Whatever method CMS implements to set rates accurately and reasonably should be determined after careful consideration of the impact on Medicare costs and on laboratories.

One approach would be for CMS to seek legislation to set a base payment rate for each lab test. IOM also recommended moving to a single base payment rate as a first step to a simplified and more rational payment system.[33] If a single base payment rate for each lab test is set, CMS should consider adjusting these rates to reflect any actual geographic differences in cost. In addition, CMS may wish to consider adjusting base payment rates to take into account other factors affecting the cost of providing lab tests.

One way to establish a base payment rate for each lab test would be to pay all lab tests at the current NLA or at a reduced NLA. In an earlier report, OIG found that setting a base payment rate using the NLA could be costly because doing so would require increasing some carrier rates.[34] However, cost-neutral base payment rates could be achieved by adjusting all carrier rates to a percentage of the NLA. We estimate that in 2007, a single payment rate based on 73 percent of the median carrier rate would not have resulted in a change in overall Medicare payments.

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[33] Wolman, et al., op. cit., pp. 146–147.

[34] OIG, "Medicare Reimbursement for Outpatient Laboratory Services," OAI-04-88-01080, March 1989.

While using the NLA as a base payment rate would eliminate the current variation, payment rates using this approach may not accurately reflect cost because the NLA would still be derived from the same suspect data used to establish and update the Clinical Laboratory Fee Schedule.

In seeking legislation to set accurate and reasonable payment rates for existing lab tests, CMS should include a process to set accurate and reasonable payment rates for new lab tests.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur, at this time, with our recommendation to seek legislation that would allow it to set accurate and reasonable payment rates for lab tests. CMS noted that the President's budget for fiscal year 2010 does not propose amending the payment methodology for lab tests. CMS also noted that it does not have the authority to standardize payment rates across the Clinical Laboratory Fee Schedule without a legislative change. We have clarified the recommendation language to reflect this.

Although it did not concur at this time, CMS stated that it will consider our recommendation and that it is committed to improving payment policies for lab tests and to refining methodologies for establishing new payment rates. CMS suggested that using the gap-filling method for establishing payment rates for new lab tests in place of the cross-walking methodology has the potential to establish rates more closely tied to cost, but it was uncertain of unintended consequences. CMS further noted that recently established annual meetings that invite public discussion on the payment rates for new lab tests may lead to more accurate rates for new lab tests.

We encourage CMS to pursue legislation that would allow it to set accurate and reasonable payment rates for lab tests.

Rates Below the National Limit Amount by Carrier

Table 1: The Percentage, Average, and Range of Rates Below the National Limit Amount* by Carrier

Carrier	Percentage of Carrier Rates Below the NLA	Average Percentage Below the NLA	Smallest Percentage Below the NLA	Largest Percentage Below the NLA
AK	3%	25%	0.92%	76%
NV	4%	24%	0.12%	65%
HI	4%	30%	1.51%	84%
CT	6%	27%	2.88%	81%
MT	6%	26%	0.37%	91%
OR	6%	22%	0.04%	82%
MN	7%	18%	0.42%	67%
OK	8%	27%	0.37%	69%
CA2	8%	24%	0.77%	87%
CA1	8%	24%	0.77%	87%
AZ	9%	21%	0.54%	62%
NM	9%	26%	0.20%	82%
PR	10%	18%	0.26%	86%
ND	10%	25%	0.03%	78%
NJ	11%	17%	0.39%	73%
IL	12%	27%	0.05%	81%
LA	13%	31%	0.62%	73%
MO2	13%	31%	0.13%	88%
WI	14%	38%	0.45%	77%
CO	14%	29%	0.03%	88%
RI	15%	25%	0.31%	73%
WV	15%	26%	1.66%	86%
WA	16%	26%	0.17%	84%
DC	16%	19%	0.22%	80%
OH	16%	27%	0.93%	86%
PA	16%	20%	0.19%	87%
ID	17%	20%	0.59%	75%
VA	17%	21%	0.90%	76%

* National Limit Amount = NLA.

Table 1: The Percentage, Average, and Range of Rates Below the National Limit Amount by Carrier (Continued)

Carrier	Percentage of Carrier Rates Below the NLA	Average Percentage Below the NLA	Smallest Percentage Below the NLA	Largest Percentage Below the NLA
AR	17%	28%	0.05%	77%
DE	18%	19%	0.22%	83%
GA	18%	30%	0.08%	83%
IA	18%	30%	0.05%	91%
TX	18%	31%	0.21%	75%
KS	18%	30%	0.09%	84%
SD	19%	27%	0.03%	84%
MD	20%	25%	0.14%	92%
KY	21%	16%	0.29%	88%
FL	21%	26%	0.23%	92%
MA	22%	23%	0.68%	74%
ME	22%	23%	0.68%	74%
MO1	23%	33%	0.41%	85%
NH	23%	23%	0.68%	82%
SC	24%	27%	0.12%	85%
MS	24%	27%	0.37%	85%
TN	24%	21%	0.37%	87%
IN	24%	25%	0.50%	87%
AL	25%	22%	0.24%	87%
NC	25%	19%	0.15%	88%
NY3	26%	28%	0.42%	86%
NY2	27%	31%	0.42%	86%
NE	27%	32%	0.05%	93%
WY	28%	29%	0.03%	79%
NY1	29%	20%	0.04%	92%
VT	29%	22%	0.29%	77%
MI	30%	25%	0.09%	90%
UT	31%	27%	0.03%	92%

Source: Office of Inspector General analysis of the 2007 Clinical Laboratory Fee Schedule, 2008.

APPENDIX ~ B

Carrier Rates for the 10 Most Utilized Lab Tests

Below is a chart showing the National Limit Amount (NLA) and carrier rates for the 10 most utilized lab tests for 2007. Carrier rates below the NLA are bolded and underlined.

Table 2: Carrier Rates for the 10 Most Utilized Lab Tests for 2007

Carrier	Basic Metabolic Panel	Comp. Metabolic Panel	Lipid Panel	Urinalysis w/ Scope	Urinalysis Automated w/ Scope	Urinalysis w/out Scope	Glycosylated Hemoglobin	Assay Thyroid Stimulating Hormone	Complete Blood Count w/ Automated Differential White Blood Cell Count	Prothobin Time
NLA	*$11.83*	*$14.77*	*$18.72*	*$4.43*	*$4.43*	*$3.57*	*$13.56*	*$23.47*	*$10.86*	*$5.49*
AK	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
AL	$11.83	$14.77	**$15.88**	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
AR	$11.83	$14.77	**$17.77**	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
AZ	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	**$8.97**	$5.49
CA1	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
CA2	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
CO	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	**$9.88**	$5.49
CT	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
DC	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
DE	$11.83	$14.77	$18.72	$4.41	**$4.41**	$3.57	$13.56	$23.47	$10.86	$5.49
FL	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
GA	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
HI	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
IA	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	**$4.89**
ID	$11.83	$14.77	**$15.85**	$4.43	$4.43	$3.57	**$9.77**	**$21.98**	$10.86	$5.49
IL	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
IN	**$8.93**	**$14.55**	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
KS	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	**$6.50**	$5.49
KY	**$9.37**	**$11.74**	**$15.91**	$4.43	$4.43	$3.37	$13.56	$23.47	$10.86	$5.49
LA	$11.83	$14.77	**$16.69**	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
MA	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
MD	$11.83	$14.77	**$17.05**	$4.43	$4.43	$3.57	**$13.00**	$23.47	$10.86	**$5.25**
ME	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
MI	$11.83	**$14.55**	**$17.85**	$4.43	$4.43	$3.57	$13.56	$23.47	$10.85	$5.49
MN	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
MO1	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
MO2	$11.83	$14.77	$18.72	$4.43	$4.43	**$2.92**	$13.56	$23.47	$10.86	$5.49

A P P E N D I X ~ B

Table 2: Carrier Rates for the 10 Most Utilized Lab Tests for 2007 (Continued)

Carrier	Basic Metabolic Panel	Comp. Metabolic Panel	Lipid Panel	Urinalysis w/ Scope	Urinalysis Automated w/ Scope	Urinalysis w/out Scope	Glycosylated Hemoglobin	Assay Thyroid Stimulating Hormone	Complete Blood Count w/ Automated Differential White Blood Cell Count	Prothobin Time
NLA	*$11.83*	*$14.77*	*$18.72*	*$4.43*	*$4.43*	*$3.57*	*$13.56*	*$23.47*	*$10.86*	*$5.49*
MS	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	**$22.73**	$10.86	$5.49
MT	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
NC	**$11.20**	**$11.80**	$18.72	$4.43	$4.43	$3.57	$13.56	**$22.77**	$10.86	$5.49
ND	$11.83	$14.77	**$17.05**	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
NE	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	**$6.50**	$5.49
NH	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
NJ	$11.83	**$13.36**	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
NM	$11.83	$14.77	**$17.16**	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
NV	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
NY1	**$11.20**	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	**$10.79**	$5.49
NY2	**$8.93**	**$13.36**	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
NY3	**$8.93**	**$13.36**	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
OH	**$10.25**	$14.77	**$17.77**	$4.43	$4.43	**$3.30**	$13.56	$23.47	$10.86	$5.49
OK	$11.83	$14.77	$18.72	$4.43	$4.43	**$3.28**	**$12.08**	$23.47	$10.86	$5.49
OR	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
PA	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
PR	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
RI	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	**$12.22**	$23.47	$10.86	$5.49
SC	$11.83	**$13.36**	**$13.69**	**$4.41**	**$4.41**	$3.57	$13.56	$23.47	**$10.36**	$5.49
SD	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	**$13.00**	$23.47	$10.86	$5.49
TN	**$9.64**	**$12.05**	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
TX	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
UT	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	**$7.39**	$5.49
VA	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
VT	$11.83	$14.77	**$15.34**	$4.43	$4.43	**$2.49**	$13.56	$23.47	$10.86	$5.49
WA	**$8.93**	**$11.92**	$18.72	$4.43	$4.43	$3.57	$13.56	**$23.39**	$10.86	$5.49
WI	$11.83	$14.77	$18.72	$4.43	$4.43	$3.57	$13.56	$23.47	$10.86	$5.49
WV	$11.83	$14.77	$18.72	$4.43	$4.43	**$3.29**	$13.56	$23.47	$10.86	$5.49
WY	**$10.74**	$14.77	**$15.56**	**$3.57**	**$3.57**	**$2.87**	**$10.61**	**$22.93**	$10.86	**$4.44**

Source: Office of Inspector General analysis of the 2007 Clinical Laboratory Fee Schedule and Medicare Part B Claims data, 2008.

APPENDIX ~ C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAY 21 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: "Variation in the Clinical Laboratory Fee Schedule" (OEI-05-08-00400)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and provide comments on the Office of Inspector General's (OIG) draft report entitled "Variation in the Clinical Laboratory Fee Schedule." The report assessed carrier rates as well as utilization and payments for Medicare-covered lab tests in 2007 and found variation across carriers that did not appear to reflect geographic difference in cost.

Medicare Part B payments for laboratory tests are determined by the Clinical Laboratory Fee Schedule (CLFS). The Deficit Reduction Act of 1984 mandated that fee schedules be established for each laboratory test on a regional, statewide, or carrier basis. As a result, each carrier established its own fee schedule rates that are collectively known as the CLFS. The Consolidated Omnibus Reconciliation Act of 1985 mandated a national limitation amount (NLA). The NLA is set at 74 percent of the median carrier rate for each laboratory test (or 100 percent of the median for new tests for which an NLA was not established before January 1, 2001). Based on section 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act (the Act), carriers pay the laboratories the lower of the laboratories' charges, the NLA, or the carrier rate.

OIG Recommendation:

CMS should request legislative authority to institute a new process for setting accurate and reasonable payment rates. CMS could use several methods to achieve this result. Whatever method CMS implements should be determined after careful consideration of the impact on Medicare costs and on the laboratory industry.

CMS Response:

We non-concur at this time. The President's budget for fiscal year 2010 does not include any proposals to amend the payment methodology for clinical laboratory tests. However, we will take this recommendation into consideration as we continue to monitor the effects of our current payment policies.

The OIG states that, in the interim, CMS could standardize payment rates across the CLFS and suggests that this could be done by paying for all laboratory tests at the current NLA or at a reduced NLA. They further note that while setting base payment rates based on the NLA would eliminate the current variation, those payment rates may still not accurately reflect cost. Therefore, they recommend that CMS consider adjusting these rates to reflect geography and other factors that affect cost.

Currently, CMS' authority to set payments at a different percentage of the NLA is limited by statute. Specifically, section 1833(a)(1)(D) and 1833(a)(2)(D) of the Act provide that, for clinical laboratory diagnostic services, CMS shall pay the lesser of the CLFS amount, the NLA, or the amount of charges billed for the test. The statute also specifies how the amount of the NLA shall be calculated. Therefore, we do not have the authority at the current time to standardize rates across the CLFS by paying all tests at the current NLA or a reduced NLA.

Finally, the OIG recommends that CMS develop a process to establish accurate and reasonable payment rates for new lab tests that would represent costs, adjusted for any geographic differences, and would not create new rate variations.

As described in the OIG's report, two methods are used to establish payment amounts for new lab test codes. Cross-walking is used when a new test is determined to be similar to an existing test, multiple existing test codes, or a portion of an existing test code. The new test code is then assigned the related existing local fee schedule amount and the related existing NLA. Gap-filling is used when no comparable, existing test is available, and presents an opportunity to establish rates based on more updated cost data. While the gap-filling methodology has the potential to establish new rates more closely tied to cost and to more narrowly limit variation within carriers, it is far more common for us to use cross-walking to establish the rates for new lab tests because new tests are frequently very similar to existing ones. If we were to use gap-filling even when it is possible to cross-walk, we might be able to establish payment that reflects national average costs adjusted for geographic area differences but might create new inconsistencies by having different rates within a single geographic area for laboratory services with similar costs.

We do note, however, that in the calendar year 2007 Physician Fee Schedule, CMS implemented section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which required that CMS establish procedures for consulting the public on how to establish payment for new clinical laboratory test codes to be included in the annual update of the CLFS. We now hold an annual public meeting to allow for public input on the pricing of new tests and we provide an additional opportunity for the public to comment once the proposed rates are posted. Attendees and those who provide comments are invited to submit cost data to aid CMS in accurately pricing new tests.

The CMS is committed to improving our CLFS payment policies and to refining our methodologies for establishing new payment rates. Therefore, we appreciate the opportunity to comment on this report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

Mark Stiglitz served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed include Mara Werner. Other principal central office staff who contributed include Cynthia Thomas, Scott Manley, and Robert Gibbons.