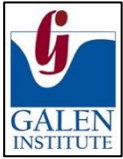




Can Medicare Pay Market Rates?

A Study of the Clinical Laboratory Fee Schedule Methodology

By Doug Badger



July 24, 2018

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Abstract

The Centers for Medicare and Medicaid Services (CMS) launched a new system of Medicare reimbursement for clinical diagnostic laboratory services in January 2018. The new fee schedule reduces 2018 rates by 10 percent, compared with 2017 rates, for 17 of the 25 tests that collectively accounted for 63 percent of Medicare lab test outlays in 2016. Since the statute limited cuts to 10 percent in each of the first three years, payments will be reduced for most or all of these tests in 2019 and in 2020. Congress directed CMS to devise a new clinical laboratory fee schedule based on the volume-weighted median price paid by private insurers for each of roughly 1,300 clinical tests. CMS chose to collect data from only a small segment of the clinical laboratory sector, giving disproportionate weight to rates paid by private insurers to the two largest clinical laboratory chains. The inescapable outcome of the CMS methodology is that the market data upon which Medicare reimbursement is based does not reflect the market composition of the clinical lab industry. The agency chose this methodology in order to minimize reporting requirements on the vast majority of clinical laboratories. In relieving most laboratories of the reporting burden, it imposed a more onerous burden on many clinical labs: sharp reductions in Medicare reimbursement rates based upon an unrepresentative segment of the clinical laboratory industry. CMS and Congress should consider alternative methodologies for aligning Medicare payment for clinical lab services with those of private payors.

Introduction

Medicare is the largest single purchaser of clinical diagnostic laboratory services.¹ The program paid \$6.8 billion for such tests in 2016,² largely unchanged since 2014 and accounting for about two percent of Medicare Part B spending.³

Until it began to phase in a new Medicare reimbursement methodology in January 2018, the Centers for Medicare and Medicaid Services (CMS) set payment rates based on a system that Congress devised in 1984.⁴ The clinical laboratory fee schedule (CLFS) relied on schedules established in 1984 by 56 separate Medicare carriers.⁵ Those rates were updated for inflation and subjected to national caps, except in years that Congress statutorily froze or rolled back the annual update.

The new CLFS system that took effect in 2018 seeks to establish national Medicare reimbursement rates based on rates paid by private insurers for laboratory tests. The system, established by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), requires CMS to collect data on private payor rates and associated volumes (“applicable information”) reported by “applicable laborator[ies]” to compute a volume-adjusted median rate on which Medicare reimbursement will be based.⁶ The Act provides for a phase-in of payment rate reductions that exceed 10 percent under the new CLFS.⁷ Due to the lateness of the final rule, which was promulgated by the Obama

administration, CMS delayed implementation of the new payment system for one year, until January 2018.⁸

The agency has been criticized for basing the new reimbursement rates on data collected from a small percentage of entities that received Medicare payments for clinical lab services.⁹ The American Clinical Laboratory Association (ACLA), a trade association for the industry, has sued HHS, seeking injunctive and declaratory relief. Its complaint alleges that the department arbitrarily and capriciously redefined “applicable laboratory” in a way that artificially restricted the types and numbers of entities reporting applicable information to CMS.¹⁰

This paper reviews Medicare reimbursement for clinical laboratory services under both the old and new CLFS and examines the challenges the agency has encountered in implementing a Medicare reimbursement methodology based on market rates. In particular, it looks at the dilemma the agency faces in gathering data from a broad segment of a highly diverse market without imposing undue reporting burdens. The paper reviews the reimbursement effects of the new CLFS. It then compares the new methodology for Medicare reimbursement of laboratory services with the system Medicare employs for physician-administered drugs, which also aims to align Medicare reimbursement with market prices.

The paper concludes that the new CLFS, unlike the system for reimbursing for physician-administered drugs, relies on data that are not broadly

¹ “Clinical Laboratory Services Payment System,” Medicare Payment Advisory Commission, October 2016. http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_clinical_lab_final.pdf?sfvrsn=0

² “Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016,” U.S. Department of Health and Human Services, Office of Inspector General, September 2017. <https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf>

³ “Medicare Payments for Clinical Diagnostic Laboratory Tests,” HHS/OIG, p. 2.

⁴ That payment methodology was established by section 2303(d) of the Deficit Reduction Act of 1984, PL 98-369.

<https://govtrack.us/congress/bills/98/hr4170/text>

⁵ “Clinical Laboratory Services,” MedPAC, p. 1.

⁶ Section 216(a) of PL 113-93, creating a new section 1834A of the Social Security Act. <https://congress.gov/113/plaws/publ93/PLAW-113publ93.pdf>

⁷ 1834A(b)(3) of the Social Security Act. https://ssa.gov/OP_Home/ssact/title18/1834A.htm

⁸ 42 CFR 414.507(d). <https://law.cornell.edu/cfr/text/42/414.507> They also extended the transition period for implement cuts in payment rates. It now runs from 2018 – 2023.

⁹ See Complaint of the American Clinical Laboratory Association (ACLA) in *ACLA v. Azar*, U.S. District Court for the District of Columbia, Civil Action No. 1:17-cv-2645, p. 3. <http://acla.com/wp-content/uploads/2018/02/ACLA-PAMA-Complaint.pdf>

¹⁰ ACLA complaint, p. 1.

representative of market prices and recommends that Congress and CMS pursue its revision.

Medicare Reimbursement of Clinical Diagnostic Laboratory Services

Medicare is the largest single purchaser of clinical diagnostic laboratory tests, which are tests of patient specimens that are used for diagnosis and treatment.¹¹ Unlike other services covered under Part B of Medicare, beneficiaries are not subject to deductibles or coinsurance.¹²

Clinical laboratory tests can be provided in a variety of settings. These include independent laboratories, physician offices, hospital inpatient and outpatient centers, “hospital outreach labs,” nursing homes, dialysis centers and other institutions.

Medicare uses the CLFS to reimburse for tests that don’t require the services of a pathologist.¹³

Reimbursement for anatomic pathology are reimbursed through the Medicare physician fee schedule. The HHS Office of Inspector General estimates that Medicare paid for 437 million tests for 28 million beneficiaries under 1,173 procedure codes in 2016.¹⁴ Some 58,593 labs received Medicare payments in that year, with payments per lab averaging \$115,546.¹⁵

Medicare spending on clinical diagnostic lab tests has grown steadily. Those increases are largely attributable to higher volume, rather than to higher payment rates.¹⁶

Reimbursement Methodology Established in the Deficit Reduction Act of 1984

Prior to January 2018, Medicare reimbursement was based on a system in which 56 carriers set rates for their respective jurisdictions, a methodology established by the Deficit Reduction Act of 1984.¹⁷ To contain costs, Congress in 1986 established caps on these payments, known as national limitation amounts (NLA). Medicare reimbursement under the CLFS was set at the lowest of: 1) the provider’s charge; 2) the carrier-specific fee schedule amount; and 3) the national limitation amount. As a practical matter, most tests have been paid at the NLA rate.¹⁸

Reimbursement Methodology Established in the Protecting Access to Medicare Act of 2014 (PAMA)

To help offset the costs of temporarily averting cuts in Medicare payments to physicians, Congress directed CMS to institute a new reimbursement methodology for laboratory services. Whereas the old system relied on Medicare carriers to establish rates based on regional prices (subject to national limitation amounts), the Protecting Access to Medicare Act of 2014 (PAMA) directed CMS to establish a new CLFS by computing a single, national, volume-weighted median

¹¹ “Clinical Laboratory Services Payment System,” MedPAC, p. 1.

¹² “Your Medicare Coverage,” medicare.gov. <https://medicare.gov/coverage/clinical-lab-services.html>

¹³ “Clinical Laboratory Services Payment System,” MedPAC, p. 1.

¹⁴ “Medicare Payments for Clinical Diagnostic Laboratory Services,” HHS-OIG, p. 2.

¹⁵ *Ibid*, p. 2.

¹⁶ “Clinical Laboratory Services,” MedPAC, p. 1. MedPAC notes that spending on lab services fell by 9 percent in 2014, the result of most hospital outpatient being included in the prospective payment rates, rather than billed separately. In the decade prior to that, spending increased at an average annual rate of 3.4 percent, largely due to volume increases.

¹⁷ Section 2303(d) of the Deficit Reduction Act of 1984 (PL 98-369) establishing section 1833(h) of the Social Security Act.

¹⁸ The Act also provided methodologies for establishing rates for new tests. Each carrier applies its schedule amount to a new test that is similar to an existing one in methodology and required resources, a process called “crosswalking.” Carriers adopt a more complicated methodology, known as “gapfilling,” for “breakthrough” tests. Each independently sets a rate that takes into account charges and discounts, resources required by the test, data from other payers and data on comparable tests. After one year, CMS sets a national payment rate based on the median of the carrier rates. “Clinical Laboratory Services Payment System,” MedPAC, p. 2.

amount that private health insurers pay for each laboratory test.¹⁹

CMS summarized the methodology established by PAMA in the preamble to its final rule:

“The statute requires that the amount for CDLTs [lab tests] furnished on or after January 1, 2017, be equal to the weighted median of private payor rates determined for the test, based on certain data reported by laboratories during a specified data collection period.”²⁰

More specifically, PAMA provides in relevant part:

“An applicable laboratory ... shall report to the Secretary applicable information ... for each clinical diagnostic laboratory test that the laboratory furnishes.”²¹ (*Emphasis added.*)

The statute further defines “applicable laboratory” as:

“A laboratory that, with respect to revenues under this title, a majority of such revenues are from section 1833(h) [which established the previous CLFS] or section 1848 [the Medicare physician fee schedule].”²²

PAMA defines “applicable information” as:

“(i) the payment rate ... that was paid by each private payor for the test during the period; and (ii) the volume of such tests for each such payor for the period.”²³

The rates reported by “applicable laboratories,” PAMA stipulates, “shall reflect all discounts, rebates, coupons, and other price concessions.”²⁴

PAMA permits the Secretary to establish “a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory.”²⁵

With that exception, the statute would appear to require that every laboratory that receives the majority of its Medicare revenue from the CLFS and under the Medicare physician fee schedule when the work of a pathologist is required to report the amount it receives for every test from every private payor. CMS uses this reported data to compute a volume-weighted median for each test and set that as the Medicare reimbursement rate for that test.

To understand the magnitude of that task, consider that CMS has established HCPCS codes for more than 1,300 tests,²⁶ that more than 58,000 labs received Medicare payments under those codes in 2016,²⁷ and

¹⁹ Section 216 of the Protecting Access to Medicare Act (PAMA), PL 113-93. <https://congress.gov/113/plaws/publ93/PLAW-113publ93.pdf> CMS devotes several pages of text and seven tables to explain how it computes the weighted median. In summary, it involves arraying all private payor rates for each test by the number of claims for which a laboratory was paid for such test. For example, a lab might have submitted 1,001 claims to private insurers for Test X. Let’s say that it was reimbursed \$10 for 200 of those claims, \$15 for 500 of them, \$30 for 200, and \$50 for 101. CMS would then construct an array with 1,001 rows (representing each claim), organized from lowest to highest reimbursement level. In each row, it would enter the reimbursement rate. The weighted median price would be the one found in row 501 (since there would be 500 rows above it and 500 rows below it). For a fuller explanation, see 81 *Federal Register* 41076-41078.

²⁰ 81 *Federal Register* 41036, June 23, 2016. As noted, the rule shifts the implementation date to January 1, 2018. It also specifies a separate methodology that would apply to advanced diagnostic laboratory tests (ADLTs). Since the vast majority of tests for which Medicare reimburses are not advanced tests, this paper does not address the agency’s ADLT methodology. <https://gpo.gov/fdsys/pkg/FR-2016-06-23/pdf/2016-14531.pdf>

²¹ 1834A(a)(1).

²² 1834A(a)(2). The statute does allow the Secretary to “establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory.”

²³ 1834A(a)(3).

²⁴ 1834A(a)(5). “Other price concessions” is further defined as including those described in 1847A(c)(3). This is part of the ASP+6 methodology, discussed at greater length below, for Medicare reimbursement of physician-administered drugs. 1847A(c)(3) specifically includes “volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates” (other than Medicaid rebates).

²⁵ 1834A(a)(2).

²⁶ These tests are catalogued and described at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Applicable-Information-HCPCS-Codes.zip>

²⁷ “Medicare Payments for Clinical Diagnostic Laboratory Tests,” HHS/OIG, p. 2.

that, on average, each “applicable laboratory,” according to information CMS attributes to “an association representing laboratories,” will bill approximately 1,500 private insurers.²⁸

The statute mitigates those requirements to some extent. Laboratories are not required to report payments that are “made on a capitated basis or other similar payment basis.”²⁹ And the Secretary, as noted above, is permitted to exempt some laboratories from the reporting requirements based on the volume of tests they analyze or the amount of Medicare reimbursements they receive.³⁰

Even with those exceptions, the reporting burden on “applicable laboratories” and on CMS itself could be considerable. Cognizant of these burdens, CMS in its final rule greatly reduced the types and number of laboratories on which it would impose reporting requirements. Those restrictions, as we will see, both opened the agency to a lawsuit and raised questions about the methodology’s consistency with PAMA’s goal of reimbursing for lab tests at market rates.

a. Narrowing the Definition of “applicable laboratory”

CMS devoted a considerable portion of its preamble to the final rule on defining the term “applicable laboratory.” PAMA defines such laboratories, as we have seen, as those that derive the majority of their Medicare revenue from the CLFS and/or the physician fee schedule.

The agency began its analysis by “defin[ing] ‘laboratory’ broadly enough to encompass every laboratory type that is subject to the clinical laboratory fee schedule.”³¹ To that end, the agency relied on the

Clinical Laboratory Improvement Amendments of 1988 (CLIA), which defines “laboratory” as:

“a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.”³²

That standard casts a broad net, embracing virtually every laboratory, regardless of whether it bills Medicare for its services. The clinical laboratory marketplace comprises entities that pursue a diversity of business models, as CMS acknowledges in the preamble.

“Some laboratories are large national networks with multiple laboratories under one parent entity. Some laboratories are single, independent laboratories that operate individually. Some entities, such as hospitals or large practices, include laboratories as well as other types of providers and suppliers ... Within our proposed definition of ‘applicable laboratory,’ we indicated that if the entity is not itself a laboratory, it has at least one component that is a laboratory.”³³

²⁸ 81 FR 41036 at 41094.

²⁹ 1834A(a)(3)(B).

³⁰ 1834A(a)(2).

³¹ 81 FR 41042.

³² 42 CFR 493.2. Congress enacted CLIA to ensure the accuracy and quality of testing performed on human specimens for the purpose of diagnosis. Even laboratories that do not receive reimbursements through Medicare must obtain CLIA certifications. CMS nevertheless used the CLIA definition of “laboratory” because no such definition exists in the Social Security Act.

³³ 81 FR 41042.

b. Defining “majority of such revenues”

Having begun with a broad definition that appears to be consistent with the statute, the agency then went on to considerably narrow the definition of “applicable laboratory.” They accomplished this by analyzing the “entity” in such a way as to exclude virtually every hospital laboratory from the definition.

While CMS used the CLIA definition of “laboratory” for some purposes, the final regulation rejects that definition for purposes of determining an entity’s “Medicare *laboratory* revenue” (emphasis added). Instead, CMS includes *any* Medicare payments to an entity as “laboratory revenue,” regardless of whether the service performed incorporated a significant laboratory component. By definition, this would exclude hospital laboratories since the total Medicare revenues of the *hospital* would invariably exceed Medicare revenues from that same hospital’s *laboratory*.

The rule does seek to include “hospital outreach laboratories”—facilities owned by hospitals that furnish test results to beneficiaries who are neither admitted inpatients nor registered outpatients of the parent hospital—in its definition of “applicable laboratory.”³⁴ But, as we shall see, almost none of these laboratories currently meets CMS’s criteria.

c. Low-Expenditure Threshold

The statute permits the Secretary to establish a “low volume or low expenditure threshold” for purposes of defining an “applicable laboratory.”³⁵ CMS chose not to establish a low volume threshold,³⁶ but it did apply a low expenditure threshold to its definition of

“applicable laboratory,” requiring that the entity receive at least \$12,500 of its revenue from the CLFS over the 6-month period during which applicable information is collected.³⁷ CMS estimated that this would exempt 94 percent of physician practices and 52 percent of independent laboratories from the statute’s reporting requirements.³⁸

Effects of the Regulation

Throughout the preamble to its final rule, CMS repeatedly cites the need to

“achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for laboratories that receive a relatively small amount of [Medicare] revenues” for clinical laboratory services.”³⁹

The concern is not misplaced. The clinical laboratory landscape is highly diverse and insurance reimbursement is a complicated affair. The rule notes:

“Sometimes laboratories are paid different amounts for the same [test] by a payor. Also, sometimes laboratories are paid different amounts for the same [test] by different payors. ... An applicable laboratory and a private payor may agree on a volume discount for a particular test whereby the first 100 tests would be reimbursed at \$100. The 101st test (and all thereafter) will be reimbursed at \$90. In reporting to CMS, the laboratory would report two different private payor rates for this private payor.”⁴⁰

³⁴ 81 FR 41046f. The agency, however, did not accomplish this. Most hospital outreach laboratories use their parent hospital’s national provider identifier (NPI). As a result, the Medicare revenue for laboratory services received by the outreach lab almost never satisfies the majority of Medicare revenue threshold.

³⁵ 1834A(a)(2).

³⁶ 81 FR 41044.

³⁷ 42 CFR 414.502.

³⁸ 81 FR 41044.

³⁹ The rule uses this or similar formulations at 81 FR 41044, 41048 and 41050.

⁴⁰ 81 FR 41052.

Those complexities would lead to substantial compliance costs, according to CMS.⁴¹ While the agency did not provide a detailed estimate of those costs, it did offer a back-of-the-envelope estimate that an applicable laboratory would produce 37,500 data points for the top 25 tests (25 x 1,500) payors.⁴² Assuming that these tests account for 85 percent of volume, that would translate into more than 44,000 data points per applicable lab.

Nor would these costs be confined to the laboratories. Since CMS must aggregate these data and produce a volume-weighted median for each test, the agency estimates that it would process around 600 million data points.⁴³ The final rule did not provide a point estimate of the resource or IT costs associated with these burdens.

Those burdens, however, must be weighed against the dictates of the statute, which requires CMS to devise a Medicare reimbursement system for clinical diagnostic laboratory tests that reflects private payor reimbursements in a vast and variegated marketplace. Moreover, the burdens of getting that reimbursement wrong are likely greater for many clinical laboratories than the burdens of reporting private insurance reimbursement data. Not all laboratories are required to report data, but all laboratories are required to live under a Medicare reimbursement system based on data collected from other laboratories. All clinical labs are affected by reductions in Medicare payments based on private payor rates for an unrepresentative segment of the clinical laboratory industry.

The inescapable result of the CMS regulation is that the market data on which Medicare reimbursement now is based does not reflect the market composition of the clinical lab industry.

That is the case for two reasons. First, CMS collected data from only a very small segment of clinical laboratories. Of the 58,593 clinical laboratories that received Medicare payments in 2016⁴⁴, CMS collected private payor information from only 1,942 of them—658 independent laboratories, 1,106 physician offices, 21 hospital laboratories and 157 “other” entities.⁴⁵ A representative random sample of that size might yield useful data. But the statute does not permit that. It requires “applicable laboratories” to provide “applicable information” on pain of civil money penalties.⁴⁶

Moreover, CMS forbids laboratories that it has excluded from the definition of applicable laboratories to submit data.⁴⁷ The agency’s reasoning on this point is curious. The preamble to the final rule notes that the statutory definition of applicable laboratories excludes entities “that do not receive the majority of their revenues” from the CLFS or the physician fee schedule.⁴⁸ CMS concluded that the provision “prohibit[s] any entity that does not meet the definition of applicable laboratory from reporting applicable information to CMS.”⁴⁹

As we have seen, CMS excludes tens of thousands of entities that derive the majority of their Medicare payments from the CLFS or the physician fee schedule from its definition of applicable laboratory. This was

⁴¹ 81 FR 41093.

⁴² 81 FR 41094.

⁴³ 81 FR 41095.

⁴⁴ “Medicare Payments for Clinical Diagnostic Laboratory Tests,” HHS-OIG, Exhibit 2, p. 2.

⁴⁵ “Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System,” CMS, September 22, 2017, p. 3. <https://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>

⁴⁶ 1834A(a)(9). The statute empowers the Secretary “apply a civil money penalty in an amount of up to \$10,000 per day for each failure to report.”

⁴⁷ 42 CFR 414.504(g).

⁴⁸ 81 FR 41043.

⁴⁹ *Ibid.*

an agency decision, not a statutory requirement. Indeed, it arguably frustrates the statute’s purpose.⁵⁰

Type of Lab	Share of CLFS payments, 2016	Share of reported lab test volume collected by CMS
Independent Lab	55%	90%
Physician Lab	18%	7.5%
Hospital Lab	26%	1%

The statute does not, in any event, appear to bar voluntary reporting. To say that certain laboratories *shall* report does not mean that other laboratories *may not* report.

Second, the segment of laboratories from which CMS has collected data does not reflect the composition of the larger marketplace. Table 1 above compares the share of Medicare Clinical Laboratory Fee Schedule payments by sector in 2016 with the share of reported laboratory test volume collected by CMS.

These data show that the information the agency collected for purposes of establishing a new Medicare clinical lab reimbursement methodology vastly overweights data from independent laboratories and vastly underweights data from labs based in hospitals and physician offices. These results suggest a skewed Medicare reimbursement methodology that rests on what appears to be a distorted sample of the overall market.

The potential distortions are greater than the table suggests. Further issues lurk within the categories. For example, CMS notes that it required fewer than half

the independent laboratories to report data.⁵² Those from whom it collected data were dominated by the two largest chains of independent laboratories. These laboratories are able to extract lower prices from insurers than are other independent labs, according to data compiled by CMS.⁵³

Their size, reach and revenue levels distinguish them from most other participants in the clinical laboratory market. One might reasonably expect, as CMS affirms, that these distinguishable characteristics would affect the reimbursement rates they negotiate with private payors. The agency acknowledges, for example, that clinical laboratories offer price concessions based on volume. Large independent labs are better positioned to offer sizable volume-based discounts than their competitors. These discounted rates heavily influence the CLFS in CMS’s methodology, while rates charged by most independent labs, physician labs and hospital outreach labs are ignored entirely. The disproportionate weight to information that large independent labs report can be expected to produce a skewed reimbursement system.

⁵⁰ The plaintiffs in *ACLA v. Azar*, while noting that the regulation does not permit voluntary reporting, argue that CMS arbitrarily and capriciously established a definition of “applicable laboratory” that excluded most clinical labs from the reporting requirements. This paper takes no position of the legal merits of that claim, which require a court to hold that the agency’s interpretation of the statute is “arbitrary and capricious.” But it is impossible to argue from the text of the statute that it *requires* CMS to exclude nearly all clinical labs from the definition of “applicable laboratory” and to *forbid* laboratories so excluded from reporting information to the government.

⁵¹ Sources: Share of MCLFS payments in 2016: “Medicare Payments for Clinical Diagnostic Laboratory Tests,” HHS/OIG. Share of reported laboratory test volume collected by CMS: “Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System,” CMS, September 22, 2017, p. 3. <https://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>

⁵² 81 FR 41051.

⁵³ *ACLA v. Azar*, *ACLA* complaint, p. 20.

The new CLFS has resulted in sizable cuts in Medicare reimbursement for some of the tests most commonly ordered for Medicare patients. Table 2 shows

reimbursement rates for the Top 25 lab tests by total Medicare reimbursements in 2016, as compiled by the HHS Inspector General.

Table 2. Top 25 Lab Tests (by Medicare payments) in 2016 and reimbursement rates, 2016-2018							
	<i>Test</i>	2016 NLA*	Number of tests**	Medicare Pymts**	2017 NLA	2018 CLFS Rate	Change from 2017
1	Blood test, thyroid-stimulating hormone	\$22.89	21.5	\$482	\$23.05	\$20.75	-10.0%
2	Blood test, comp grp of blood chemicals	\$14.39	41.6	\$470	\$14.49	\$13.04	-10.0%
3	Complete blood cell count	\$10.59	42.0	\$433	\$10.66	\$9.59	-10.0%
4	Blood test, lipids**	N/A	29.0	\$411	N/A	\$16.53	N/A
5	Vitamin D3 level	\$40.33	9.0	\$350	\$40.61	\$36.55	-10.0%
6	Hemoglobin A1C level	\$13.22	19.3	\$250	\$13.32	\$11.99	-10.0%
7	Drug test(s) definitive, 22 or more drug classes	\$215.23	1.2	\$241	\$253.87	\$246.92	-2.7%
8	Drug test(s), presumptive any number classes***	\$79.25	3.0	\$221	N/A	N/A	N/A
9	Blood test, basic group of blood chemicals***	\$11.53	13.7	\$133	\$11.60	\$10.44	-10.0%
10	Drug test, definitive, 15-21 drug classes	\$166.03	0.8	\$127	\$204.34	\$198.74	-2.7%
11	Parathormone (parathyroid hormone) level	\$56.23	2.2	\$120	\$56.62	\$50.96	-10.0%
12	Cyanocobalamin (vitamin B12)	\$20.54	5.6	\$113	\$20.68	\$18.61	-10.0%
13	Blood test (clotting time)	\$5.36	19.6	\$105	\$5.39	\$4.85	-10.0%
14	PSA measurement	\$25.06	4.2	\$103	\$25.23	\$22.71	-10.0%
15	Thyroxine measurement	\$12.28	7.1	\$85	\$12.37	\$11.13	-10.0%
16	Bacterial colony count, urine	\$11.00	7.6	\$82	\$11.07	\$9.96	-10.0%
17	Drug tests, 8-14 drug classes	\$122.99	0.6	\$73	\$160.99	\$156.59	-2.7%
18	Natriuretic peptide (heart & blood vessel protein)	\$46.24	1.5	\$69	\$46.56	\$41.90	-10.0%
19	Drug tests, 1-7 drug classes	\$79.94	1.0	\$69	\$117.65	\$114.43	-2.7%
20	Ferritin (blood protein) level	\$18.57	3.7	\$67	\$18.70	\$16.83	-10.0%
21	Gene analysis (colorectal cancer)	\$508.87	0.1	\$62	\$512.43	\$508.87	-0.7%
22	Detection of genes for breast cancer	\$3,419.40	0.02	\$60	\$3,443.36	\$3,873.00	12.5%
23	Complete blood cell count, automated test	\$8.81	6.8	\$58	\$8.87	\$7.98	-10.0%
24	Folic acid level	\$20.03	2.9	\$56	\$20.17	\$18.15	-10.0%
25	Evaluation of antimicrobial drug	\$11.78	4.5	\$51	\$11.86	\$10.67	-10.0%

2016 data derived from "Medicare Payments for Clinical Diagnostic Laboratory Tests," HHS/OIG, Exhibit 5, p. 4.

2018 data from Clinical Laboratory Fee Schedules January 2018, cms.gov.

*National limitation amount. No amount is available for blood test, lipids

Numbers in this column expressed in millions. *No 2017 or 2018 rate data available for this test.

These 25 tests collectively accounted for \$4.29 billion in Medicare outlays in 2016, or 63 percent of Medicare spending on lab tests in that year.⁵⁴ As the chart shows, Medicare reimbursement for 17 of the 23 tests for which complete data are available declined between 2016 and 2018 by 10 percent.

Reimbursement rates rose for just one test (detection of genes for breast cancer).

It is important to note that PAMA limits cuts in 2018, 2019, and 2020 to 10 percent from the prior year's rate, even if the volume-related median private payor reimbursement rate is more than 10 percent below the 2017 CLFS rate.⁵⁵ Reimbursement will drop again for

the 17 tests whose reimbursement fell by 10 percent in 2018.

Cuts for those tests are consequently not one-time events. The 10 percent cap on cuts that will be in effect for 2018-2020 slows their implementation, but it does not reduce them. Table 3, using data from the HHS/OIG study and a study prepared by the National Independent Laboratory Association (NILA), illustrates how the cuts, when completely phased in, will affect Medicare reimbursement for selected commonly performed tests.

Test*	2016 ⁵⁶			Fully Phased In Cuts ⁵⁷	
	Medicare Payment**	Number of tests***	Medicare Outlays***	Medicare Payment	Percent reduction
Complete blood count	\$10.59	42.0	\$433	\$6.88	35%
Prothrombin time	\$5.36	19.6	\$105	\$4.29	20%
Hemoglobin A1C	\$13.22	19.3	\$250	\$8.50	36%
Lipid panel	\$18.41	29.0	\$411	\$11.23	39%
Assay of ferritin	\$18.57	3.7	\$67	\$12.13	35%
Urine bacterial culture	\$11.00	7.6	\$82	\$7.19	35%
Vitamin D	\$40.33	9.0	\$350	\$26.37	35%
Thyroid-stimulating hormone	\$22.89	21.5	\$482	\$14.87	35%
Basic metabolic panel	\$11.52	13.7	\$133	\$8.06	30%

**Procedure code shown in parenthesis. **All Medicare payments are NLA, except lipid panel*

****Data expressed in millions.*

⁵⁴ "Medicare Payments for Clinical Diagnostic Laboratory Tests," HHS OIG, summary sheet and Exhibit 5, p. 4.

⁵⁵ 1834A(b)(3)(B).

⁵⁶ "Medicare Payment for Clinical Diagnostic Lab Tests," HHS-OIG, Exhibit 5, p. 4.

⁵⁷ "The Protecting Access to Medicare Act Jeopardizes the Nation's Community and Regional Independent Clinical Laboratory Infrastructure," National Independent Laboratory Association (NILA), Table 1, p. 3. Because of the limitation on annual cuts in payments for tests, cuts for most tests will not fully phase in until after 2020. https://www.nila-usa.org/images/nila/PAMA%20Key%20Informant%20Summary_FINAL.pdf

The NILA study predicts that cuts of this magnitude will “have extreme consequences for community and regional clinical laboratories,” effects the organization believes will impact services for beneficiaries, “especially those in small and rural communities, and those who receive home health care or reside in assisted living or skilled nursing facilities.”⁵⁸

NILA based those conclusions on interviews with “key informant laboratories,” independent facilities that operate on a community, state or regional level. The respondents said that they might take a range of actions in response to the cuts, including reducing workforces, limiting services and, in some cases, shuttering operations.⁵⁹

While such dire predictions are impossible to verify, the cuts appear to be running deeper than CMS itself expected. In the preamble to its June 2016 rulemaking, the agency estimated that the new payment system would reduce Medicare spending on laboratory tests by \$390 million, a 5.6 percent cut from estimated baseline spending of \$7 billion.⁶⁰ By September 2017, CMS had revised its estimate to \$670 million, a figure that is 72 percent higher than its estimate of 15 months earlier.⁶¹ That would amount to a reduction in reimbursements of nearly 10 percent in 2018 alone, a level sufficient to disrupt markets, particularly when subsequent rounds of reductions follow in 2019 and 2020 for many commonly used tests.

CMS nevertheless believes it is faithfully administering a statute that requires it to establish a fee system for lab services based on rates paid for those services by private insurers. While acknowledging that its approach is not a “perfect proxy for private payor rate data, it reflects the type of private payor rates that will

be reported as applicable information by applicable laboratories.”⁶²

The point at issue, of course, is whether the agency should have more expansively defined applicable laboratories and collected information from a broader swath of the marketplace.

The agency maintains that requiring additional entities to report “may not be likely to change payment amounts, irrespective of how many additional smaller laboratories are required to report.”⁶³ CMS says that despite exempting so many entities, it will capture “approximately 92 percent of CLFS spending on physician office laboratories and approximately 99 percent of CLFS spending on independent laboratories.”⁶⁴

CMS could arguably refine its methodology by weighting the data it collects by market share. Under such a methodology, price information from independent labs would be weighted at 55 percent, physician labs at 18 percent and hospital labs at 26 percent (see Table 1). CMS, however, does not believe that it should attempt to “achieve the ratio of physician office laboratories, independent laboratories and hospital-based laboratories.”⁶⁵

Despite widespread criticism from the industry and a lawsuit alleging that it has not faithfully implemented the statute, CMS believes that it has devised a reimbursement system that accurately captures market prices.

Its exclusion of most clinical laboratories from data-reporting requirements, in the agency’s estimation, is a feature, not a bug: It exempts thousands of laboratories from a burdensome process, while yielding information sufficient to construct a

⁵⁸ “The Protecting Access to Medicare Act Jeopardizes,” NILA, p. 4.

⁵⁹ *Ibid.*, pp. 7-8.

⁶⁰ 81 FR 41092.

⁶¹ “Summary of Data Reporting for the Medicare CLFS,” p. 1.

⁶² 81 FR 41049.

⁶³ *Ibid.*

⁶⁴ *Ibid.*, p. 41051.

⁶⁵ 81 FR 41050.

reimbursement scheme for laboratory services that mirrors rates negotiated by private payors.

CMS's sanguinity notwithstanding, its methodology for ascertaining market rates gleans a disproportionate share of its data from a unique and homogenous sector of a large and diverse market, producing a reimbursement system that, contrary to statutory intent, does not reflect the amounts private payors pay in the broader marketplace.

A Case Study of Market-Based Medicare Reimbursement Rates: ASP+6

Medicare is a jumble of overlapping and sometimes conflicting payment systems. MedPAC, Congress's advisory arm for Medicare policy, has published no fewer than 20 papers in its "Payment Basics" series.⁶⁶ The series attempts to describe the different methodologies Medicare uses to reimburse for medical goods and services. It includes descriptions of Medicare reimbursement for ambulance services, critical access hospitals, accountable care organizations, Medicare Advantage plans, durable medical equipment, outpatient dialysis services, and drugs paid for under Part B.

Each of these reimbursement systems has its own pedigree. Some, such as the CLFS that PAMA replaces and the hospital inpatient prospective payment system, trace their origins to the 1980s. Others, such as competitive bidding for certain durable medical equipment, sprang into existence in the previous decade. There are methodologies, such as the inpatient facility services payment system, that apply to a very specific set of providers. There are others, such as the Medicare Advantage program, that don't deal with providers at all, but with private insurance

companies. Then there are accountable care organizations, in which the government overlays legacy payment methodologies with incentives for participating organizations to provide care at less cost to the federal government.

Their evident differences aside, all of these systems aim to reduce Medicare spending without compromising quality, although dispositive evidence that any of them has achieved either goal is difficult to find. Nevertheless, they all persist, usually encrusted with layers of revisions, some temporary and others longer lasting, many added to hit an ephemeral deficit reduction target or to presumably offset the costs of increasing Medicare payments to some other industry segment.

The 30-year evolution of Medicare CLFS typifies how Medicare reimbursement arrangements are established and applied. Created in 1984, the program has been repeatedly changed over the years.⁶⁷ Congress has amended the program at least a dozen times (not counting overall changes to Medicare reimbursement that affected payments for clinical diagnostic laboratory tests), sometimes making technical changes, at other times modifying reimbursements to reduce Medicare spending.⁶⁸ The result is a 2,700 word subsection of the Social Security Act (now effectively a dead letter), elucidated (or obscured) by a sprawl of regulations, subregulatory guidance and other products of the bureaucratic enterprise.

Beneath this inscrutable superstructure lies a presumption of the Congress that laid its foundation: Medicare should pay market prices for clinical diagnostic laboratory tests. In 1984, Congress believed

⁶⁶ <http://medpac.gov/-documents-/payment-basics>

⁶⁷ Section 2303(d) of the Deficit Reduction Act of 1984, PL 98-369.

⁶⁸ PL 99-272, PL 99-509, PL 100-203, PL 100-360, PL 100-647, PL 101-239, PL 101-509, PL 103-66, PL 103-432, PL 105-33, PL 106-554, PL 113-93. This list represents the author's best efforts to chronicle amendments to the program. In addition, Congress has ordered up demonstration projects, HHS reports and GAO studies of various aspects of the program.

that 56 Medicare carriers could divine those prices within their respective domains.⁶⁹

In 2014, Congress voted to scrap this oft-revised methodology, in part to offset the costs of temporarily preventing a cut in Medicare payments to physicians. This new method of constructing the CLFS relies on the laboratories themselves to report market data but seeks the same end as its predecessor: to base Medicare reimbursement on market prices (in this case defined as the amount private insurers pay to “applicable laborator[ies]”).

That is a tricky proposition, since Medicare is the largest financing source for these services. Commercial rates are almost certainly more influenced by Medicare rates than the other way around. Moreover, as we have seen, the new system imposes enormous paperwork burdens on laboratories, leading the agency to exempt all but a small segment of the industry from the reporting requirements.

The methodology PAMA devised to tie Medicare spending to “market prices” is in some ways analogous to the system Congress established for physician-administered drugs. While most prescription medications are covered under Medicare Part D, drugs that are “not usually self-administered by the patient” are covered under Medicare Part B.⁷⁰ These drugs are ordinarily administered through injection or infusion.⁷¹ They include cancer therapies and treatments for macular degeneration and rheumatoid arthritis. Physician practices and hospital outpatient departments generally acquire and store the drugs and then administer them to patients. Medicare

reimburses physicians (and, with respect to certain Part B drugs, hospital outpatient departments) separately for the drugs and for their administration.⁷²

For a number of years, Medicare paid for the drugs at “average wholesale price.” That label is misleading, since it did not reflect an average price paid by wholesalers. Instead, it was more akin to a list price, which no one actually paid.⁷³ Manufacturers listed their products’ AWP in industry publications. Because Medicare reimbursed doctors at a rate of 95 percent of AWP, the system provided a perverse incentive for drugmakers to inflate their AWP, allowing doctors to pocket the difference between the AWP-based Medicare reimbursement and their actual acquisition cost. Between 1997, when Congress adopted the AWP-5 standard, and 2003, Part B drug spending increased from \$2.8 billion to \$10.3 billion, or around 25 percent per year.⁷⁴

In 2003, Congress enacted the Medicare Modernization Act, which established a new methodology for Medicare reimbursement for physician-administered drugs.⁷⁵ Under the new payment system, manufacturers of drugs that provide Medicaid rebates are required to report quarterly on the average volume-weighted sales price of their drugs covered under Medicare Part B, net of discounts, rebates and other price concessions.⁷⁶ In addition to costs associated with administering the drugs to patients, Medicare pays physicians who injected or

⁶⁹ Congress soon overlaid the system with national limitation amounts that largely pre-empted carrier-established reimbursement for most commonly-ordered tests.

⁷⁰ 1861(s)(2) of the Social Security Act.

⁷¹ “Part B Drugs Payment Systems,” MedPAC, October 2017, p. 1. Other drugs also are covered under Part B. These include oral anticancer drugs and oral antiemetic drugs, inhalation drugs administered by durable medical equipment covered by Part B, home infusion drugs and clotting factor.

⁷² Payments for these drugs in hospital outpatient settings are generally subsumed in the prospective payment rates, although CMS does permit hospitals to bill separately for some drugs.

⁷³ As was commonly observed at the time, AWP stands for “ain’t what’s paid.”

⁷⁴ Angela Boothe, “Primer: Part B Drug Payment System,” American Action Forum, January 21, 2015.

<https://americanactionforum.org/research/primer-medicare-part-b-drug-payment-system/>

⁷⁵ Section 303(c) of PL 108-173. <https://gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf>

⁷⁶ 1847A(c).

infused these drugs at the average sales price plus six percentage points (ASP+6).⁷⁷

The ASP+6 methodology reduced the growth in Part B Medicare spending in the first years of its implementation. After declining by eight percent in the first year (2005), Medicare spending on Part B drugs grew at an average annual rate of four percent.⁷⁸ That trend, however, did not hold. Medicare spending on Part B drugs increased from \$18.1 billion in 2012 to \$25.7 billion in 2016, an average annual increase of just over ten percent.⁷⁹

MedPAC has recommended that Congress reduce the ASP add-on and establish a parallel system—known as a Drug Value Program—in which Medicare would contract with a small number of private vendors to negotiate prices for Part B products.⁸⁰ That is not to suggest that the program has been unsuccessful, much less that it was worse than the methodology it supplanted. It is merely to say that even reimbursement systems based on comprehensive information about market prices, such as other methodologies to rein in Medicare spending, have generally ended in disappointment.

The ASP+6 program holds some lessons for the new CLFS. Table 4 compares and contrasts the two programs.

	Part B Drugs⁸¹	CDLTs⁸²
Number of products/tests	<500	1300+
Diversity of products	Physician-administered drugs and biologics	Broad range from simple tests to complex genetic analyses
Diversity of providers	Physician specialty offices and hospital outpatient departments	Independent labs, including chains and local/regional operators, hospital outreach labs, dialysis facilities, nursing homes
Reporting entity	Manufacturer	“Applicable labs”
Proportion of entities reporting	All manufacturers that participate in Medicaid rebates	Small percentage of labs
Frequency of reports	Every 3 months	Every 3 years

Although both programs seek to base Medicare reimbursement on actual prices paid in the private market, net of rebates, discounts and other price concessions, there are sharp contrasts between the

⁷⁷ 1847A(b)(1). The six percentage point add-on is intended to reimburse physician practices of the additional costs of mixing and storing of these drugs and also to take into account the fact that some practices will face acquisition costs that exceed the average sales price.

⁷⁸ Boothe, “Primer: Part B Drug Payment System,” p. 2.

⁷⁹ Author’s calculation using CMS Medicare Part B Spending Dashboard. <https://cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.html> Ironically, the ASP+6 methodology shares some of the flaws of the AWP system that it replaced. Since the 6 percent add-on payment is based on the price of the drug, the more expensive the drug, the greater the add-on payment, creating an inducement for physicians to order up more expensive medications.

⁸⁰ Report to the Congress: Medicare and the Health Care Delivery System, MedPAC, June 2017, Chapter 2. http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf It is worth noting that the Medicare statute already establishes a program for entities to competitively bid for such products (see section 1847B of the Social Security Act). https://ssa.gov/OP_Home/ssact/title18/1847B.htm The program has been moribund for some time, although HHS Secretary Alex Azar in May 2018 announced plans to revive it as part of the administration’s efforts to reduce drug prices. Mike Staniewicz, “Alex Azar to Resurrect Medicare Part B Price Bidding Program,” Fierce HealthCare, May 14, 2018. <https://fiercehealthcare.com/payer/azar-to-resurrect-medicare-part-b-price-bidding-program> Moreover, the Center for Medicare and Medicaid Innovation proposed a nationwide demonstration project that would have changed the way the payment system functioned throughout most of the country. CMMI ultimately abandoned the project before it was launched. See Doug Badger, “Resetting the Scoreboard: Why CBO Should Abandon Its Flawed Analysis of the Center for Medicare and Medicaid Innovation,” National Taxpayers Union, February 2018. <https://ntu.org/library/doclib/Why-CBO-Should-Abandon-Its-Flawed-Analysis-of-the.pdf>

⁸¹ Number of products is derived from the CMS Medicare Part B spending dashboard.

⁸² Number of Clinical Diagnostic Laboratory Tests (CDLT): 81 FR 41093.

two programs. These contrasts raise questions about the feasibility of the new CLFS and its capacity to capture market prices.

First, there are challenges of scale. The ASP methodology captures acquisition costs for physicians and hospital outpatient departments for around 500 drugs that they administer to their Medicare patients. By contrast, CMS has established more than 1,300 HCPCS codes for the CLFS.

Second, the ASP program deals with a relatively homogeneous group of medical specialists who inject or infuse medications generally in their own facilities or hospital outpatient departments. Lab tests, by contrast, are administered to 28 million beneficiaries at more than 58,000 labs that submit Medicare claims.⁸³

A third crucial distinction is the reporting entity. A manufacturer reporting average sales price is well-positioned to know the amount it charges for a product, as well as the value of price concessions it has made for that product. A laboratory, as CMS acknowledges, faces an administrative challenge in sorting out how much different insurers pay them for different tests and the volume of those claims.

Fourth, as discussed above, the CLFS is based on information reported by a very small proportion of laboratories. Since almost all manufacturers participate in the Medicaid rebate program, reporting of ASP data is nearly universal.⁸⁴

Finally, ASP is reported quarterly, while the CLFS will be updated every three years. Market prices can fluctuate frequently. While some complain about the lag in updating ASP (quarterly prices are not reported until two months after the quarter closes), those updates occur 12 times as frequently as has been proposed for the CLFS. Such lags introduce a high level of imprecision into the CLFS prices.

In sum, while the ASP+6 program is hardly perfect, its methodology inarguably captures data that broadly represents prices actually paid in the marketplace. Timely, near-universal reporting by manufacturers provides information that is far superior to that on which the CLFS is based. To the extent it offers any lessons at all, the Medicare Part B drug methodology teaches that a market-based reimbursement system requires timely reporting of information by virtually all relevant entities.

Conclusion

CMS faces a daunting task in implementing a CLFS based on market prices. Medicare reimburses tens of thousands of laboratories for hundreds of millions of tests for nearly 30 million beneficiaries every year. The agency must collect information on rates negotiated by numerous insurers for a vast and diverse array of products. In constructing such a system, the agency sought to balance fidelity to the statute with pragmatic concerns about imposing burdens on private entities.

It should be noted that the statute nowhere requires CMS to achieve such balance. Aside from allowing the agency to set “low volume” and “low expenditure” thresholds, it directs the agency to establish and administer a CLFS that closely tracks volume-weighted median prices across a broad and diverse spectrum of clinical laboratories.

The system CMS has established writes too many entities out of the definition of “applicable laborator[ies]” and constructs a system that places excessive weight on rates private insurers pay to large, publicly traded chains of clinical laboratories. In relieving most laboratories of the reporting burden, it imposed a more onerous burden: accepting Medicare reimbursement levels that may not reflect the rates they receive from private payors.

⁸³ “Medicare Payments for Clinical Diagnostic Laboratory Tests,” HHS/OIG, p. 2.

⁸⁴ MedPAC has proposed that Congress make reporting universal by placing the requirement on all manufacturers, irrespective of their participation in the Medicaid rebate program. Report to the Congress: Medicare and the Health Care Delivery System, MedPAC, June 2017, Chapter 2.

The CMS effort to strike a balance produced an unbalanced reimbursement system. The system should be rebalanced. There are a number of possible policy paths, some that can be pursued administratively, others that may require congressional action.

CMS could arguably retain its current reporting system but weight the data it collects to reflect the relative market shares of the reporting entities.⁸⁵ Or it could rethink its decision to exempt most labs from the definition of “applicable laboratory.” In its Calendar Year 2019 proposed revisions to the Physician Fee Schedule and other Part B provisions, CMS has proposed a modest change to its CLFS methodology for determining whether a lab meets the majority of Medicare revenue criterion.⁸⁶ It also has solicited public comment on whether it should halve or double the low expenditure threshold.⁸⁷ Halving it would increase the number of independent labs and physician labs that are required to report data. Doubling it would, of course, have the opposite effect.

CMS also has sought comment on whether hospital labs should be required to use a different form to report information used to determine whether they meet the majority of Medicare revenues criterion.⁸⁸ The agency believes that “all hospital outreach laboratories would meet the majority of Medicare

revenues threshold” under this system, exempting only those whose revenues fall below the revenue threshold from reporting requirements.⁸⁹

Congress could also seek alternative ways to collect data on private payor reimbursement. Surveying a representative sample of clinical laboratories would be one such option. CMS operates such a system to determine community pharmacy drug acquisition costs, as well as prices consumers pay at drug store counters.⁹⁰ The National Average Retail Price (NARP) consists of “a statistically weighted average of three types of consumers: cash-paying customers, commercial third-party insurance consumers, and Medicaid consumers.”⁹¹ An analogous system for laboratory tests would produce a reimbursement schedule that better reflects prices paid in the marketplace than does the CLFS. By requiring only a representative sample of labs to report, such a system would yield more accurate data, while limiting the reporting burden to labs that are part of the sample

It could be argued that Congress’s real intention was not to base reimbursement for lab services on market rates, but to reduce Medicare spending. The new CLFS appears to be exceeding expectations on cutting spending on this tiny slice of the Medicare program. Reducing that spending is an important and, in the

⁸⁵ Legal questions may arise whether such weighting is consistent with the requirement in in 1834A(b)(2) to “calculate a weighted median for [each] test.” The statute is highly prescriptive on this point. On the other hand, the statute nowhere contemplates a system that excludes the overwhelming majority of clinical labs from the definition of “applicable laboratory.” If the agency asserts the authority to do this, it could just as legitimately (or illegitimately, depending on your view of *ACA v. Azar*) weight the data it collects to reflect market share.

⁸⁶ The agency has proposed to revise its computation of whether a lab receives the majority of its Medicare reimbursement from the CLFS or the physician fee schedule by removing reimbursements from Medicare Advantage plans from the denominator. See pp. 405ff of the proposed rule. <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14985.pdf> The rule is scheduled for *Federal Register* publication on July 27, 2018 and will be available at: <https://federalregister.gov/documents/2018/07/27/2018-14985/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>

⁸⁷ *Ibid.*, pp. 420ff.

⁸⁸ *Ibid.*, pp. 414ff. The form hospital labs would be required to use is known as the CMS-1450 bill type 14x.

⁸⁹ CMS says that would be “inconsistent with the statute.” *Ibid.*, p. 417. CMS believes “the statute intended to limit reporting primarily to independent laboratories and physician offices” – that is, to by and large exclude hospital outreach labs from the definition of “applicable laboratories.” *Ibid.*, p. 412, which cross-references 81 FR 41041-41051. If the intent of the statute is to align Medicare reimbursement with that of private payors, it would be unusual indeed to exclude 26 percent of the clinical laboratory market from reporting data on private payor reimbursement.

⁹⁰ “Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs,” CMS, November 2013, p. 4. <https://medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf> The survey is mandated by section 1927(f) of the Social Security Act. https://ssa.gov/OP_Home/ssact/title19/1927.htm

⁹¹ *Ibid.*, p. 4.

opinion of the Medicare trustees, necessary undertaking.

But if that is all Congress wanted to do, it would not have needed to establish a new, radically different payment system. The statute plainly envisions a

system that shadows prices paid by private insurers for lab tests in a complex and variegated marketplace.

That is an elusive goal under any circumstances. A methodology based on a limited and skewed method of data collection does not achieve it.

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