
MedPAC Comment Letter - Laboratorio Clínico Irizarry Guasch

Medicare Payment Advisory Commission

Meeting on: 8 October 2026, 2:00 PM - 3:20 PM, *Issues affecting the payment accuracy of the physician fee schedule and the clinical laboratory fee schedule*

By email: meetingcomments@medpac.gov

October 4, 2026

October 4, 2026

Medicare Payment Advisory Commission

Meeting on: 8 October 2026, 2:00 PM - 3:20 PM, *Issues affecting the payment accuracy of the physician fee schedule and the clinical laboratory fee schedule*

By email: meetingcomments@medpac.gov

Re: Request for Puerto Rico-Specific Review of Medicare Clinical Laboratory Payment Adequacy and Access

Dear Commissioners:

On behalf of Laboratorio Clínico Irizarry Guasch, Inc., I respectfully submit this comment for MedPAC's discussion of Medicare payment for clinical laboratory tests. I ask MedPAC to examine whether current Medicare rates preserve access in Puerto Rico and to recommend concrete measures to establish adequate payment and protect patients' health and safety.

Although I might be the only one writing MEDPAC from PR, I know this is serious and common problem for all labs, including local reference labs in the Island. Patients are facing the consequences of not having timely access to healthcare.

The finding is straightforward: at 2023 Medicare Clinical Laboratory Fee Schedule (CLFS) rates, a large group of routinely ordered, covered tests cannot be performed in-house or purchased from a reference laboratory without a loss, once documented Puerto Rico costs are included [1][2]. The laboratory coverage described in the Social Security Act, CMS test lists, and Medicare Advantage and Medicaid plan documents is therefore not reliably available in practice to Traditional Medicare, Medicare Advantage, and Medicaid beneficiaries in Puerto Rico. **The advertised coverage is a farce** when most specialized tests cannot be performed or purchased, especially from LabCorp and Quest, because the Medicare payment is below their acquisition price.

1. Evidence from high-volume tests with losses at 2023 rates

Our workbook, **Tests Cost MedPAC.xlsx**, compares the 2023 Medicare rate with the lowest available reference price among LabCorp, Quest, and three local reference labs, plus \$2.66 in laboratory fixed cost and \$1.88 in collection and handling per test (based on 2024 economic data). Total Cost equals lowest reference plus \$4.54. Deficit equals Total Cost minus Medicare Rate. Coverage equals Medicare Rate divided by Total Cost.

For this letter, I highlight the most frequently used loss tests, because they show that the problem is not limited to rare assays:

- a. Electrolyte Panel, CPT 80051: Medicare \$7.01, lowest \$4.00, total \$8.54, loss \$1.53, coverage 82.1%.
- b. Microalbumin/Creatinine Ratio, CPT 82043: Medicare \$5.78, lowest \$5.00, total \$9.54, loss \$3.76, coverage 60.6%.
- c. Occult Blood, CPT 82270: Medicare \$4.38, lowest Quest \$10.50, total \$15.04, loss \$10.66, coverage 29.1%.
- d. Protein Urine Spot, CPT 84156: Medicare \$3.67, lowest \$2.00, total \$6.54, loss \$2.87, coverage 56.1%.
- e. Uric Acid Serum, CPT 84550: Medicare \$4.52, lowest \$1.75, total \$6.29, loss \$1.77, coverage 71.9%.
- f. Sickie Cell Test, CPT 85660: Medicare \$5.51, lowest Quest \$3.05, total \$7.59, loss \$2.08, coverage 72.6%.
- g. Blood Typing ABO, CPT 86900, and Rh Type, CPT 86901: Medicare \$2.99 each, lowest \$2.00, total \$6.54 each, loss \$3.55 each, coverage 45.7%.
- h. Culture Urine, CPT 87086: Medicare \$8.07, lowest \$4.75, total \$9.29, loss \$1.22, coverage 86.9%. **Assuming a single organism.**
- i. Culture Throat, CPT 87070 group: Medicare \$8.62, lowest \$4.90, total \$9.44, loss \$0.82, coverage 91.3%. **Assuming a single organism.**
- j. Gram Stain, CPT 87205: Medicare \$4.27, lowest \$2.00, total \$6.54, loss \$2.27, coverage 65.3%.
- k. Syphilis Quantitative, CPT 86593: Medicare \$4.40, lowest \$4.00, total \$8.54, loss \$4.14, coverage 51.5%.
- l. Vancomycin, CPT 80202: Medicare \$13.54, lowest \$10.00, total \$14.54, loss \$1.00, coverage 93.1%.
- m. Cyclosporine, CPT 80158: Medicare \$18.05, lowest LabCorp \$23.46, total \$28.00, loss \$9.95, coverage 64.5%.
- n. Tacrolimus, CPT 80197: Medicare \$13.73, lowest \$40.00, total \$44.54, loss \$30.81, coverage 30.8%.
- o. Carbamazepine Free, CPT 80157: Medicare \$13.25, lowest \$70.00, total \$74.54, loss \$61.29, coverage 17.8%.
- p. Hepatitis C RNA Quantitative, CPT 87522: Medicare \$42.84, lowest \$90.00, total \$94.54, loss \$51.70, coverage 45.3%.
- q. Microarray Postnatal, CPT 81229: Medicare \$1,160.00, lowest Quest \$1,590.00, total \$1,594.54, loss \$434.54, coverage 72.8%.

Three points define the limit of this evidence. First, this is a single independent laboratory study using actual vendor lowest quotes using reference cost as per test cost because of high volume testing; reference cost are lower than tests performed in lower volume laboratory settings; it proves loss on the listed tests for this laboratory,

not a national average. Second, a minority of automated high-volume tests show a surplus at 2023 rates and are excluded from the loss claim. Third, the \$4.54 add-on is conservative: it does not include freight surcharges, inventory carrying cost, generator fuel, or financing cost, and reference prices exclude phlebotomy, accessioning, shipping preparation, reporting, and billing unless stated in the quote.

The LabCorp and Quest comparison is central. For transplant drugs, therapeutic drug monitoring, immunology, genetics, and molecular infectious disease testing, LabCorp and Quest quotes exceed the Medicare rate by multiples. Examples include Carbamazepine Free at LabCorp \$134.50 and Quest \$85.94 against Medicare \$13.25, and NMO IgG at \$325.00 to \$408.00 against Medicare \$17.27. When the only available source charges more than Medicare pay, the test cannot be offered without absorbing the difference.

1. Puerto Rico island higher costs than in the mainland median does not capture:
 - a. Electricity and continuity of services: recurrent outages and voltage instability require generators, fuel storage, batteries, transfer switches, and maintenance to protect refrigeration, analyzers, and reporting.
 - b. Freight and cold chain: reagents, calibrators, controls, and consumables arrive by air and sea with cold-chain packing, longer lead times, and expensive emergency orders. Temperature excursions create waste and early expiration time.
 - c. Inventory: to prevent stockouts during storms and supply delays, we carry larger safety stock and absorb more expiration loss.
 - d. IVU sales and use tax: 11.5% on taxable acquisitions, as reported by the laboratory and subject to Hacienda rules, exemptions, and invoice verification [3].
 - e. Inventory tax: annual tax on inventory of up to 10.5% per year on assessed value under applicable municipal and CRIM rules, as reported by the laboratory pending contributive invoices and assessments [4].
 - f. Equipment property tax: annual movable-property tax on laboratory equipment of up to 10.5% on assessed value, as reported by the laboratory pending CRIM assessments [4].
 - g. Labor mandate: Medical Technologist-only workforce. Puerto Rico law and regulation require that all testing phases, including sample handling and preparation, testing, and quality control (QC), be performed by a certified, licensed Medical Technologist / Medical Scientist at a cost of approximately \$.50 per minute (\$30.00 per hour), all that current reimbursements allow us to pay. Even with low salaries, labor cost has a high impact on test cost because highly credentialed personnel must perform even routine pre-analytical and QC tasks. There are no laboratory assistants or MLTs allowed to work in our laboratories.

- h. Specimen collection restriction and rate: the blood collection (phlebotomy) rate is also critical, as it helps cover sample collection and preparation cost. In Puerto Rico only MTs, nurses and doctors are allowed to collect samples. Low-cost phlebotomists and ancillary personnel used on the mainland may not be used, further elevating cost before testing begins. Additional compliance and systems costs include difficult recruitment, overtime and contracting, validation, calibration, proficiency testing, CLIA compliance, information systems, cybersecurity, billing, insurance, and interest on credit lines when payers delay payment.

Tariffs on imported instruments, reagents and supplies: Puerto Rico laboratories depend almost entirely on imported instruments, reagents and supplies. Price increases due to tariffs imposed by the current Administration on all imported instruments, reagents and supplies have directly increased acquisition costs for analyzers, reagents, controls, calibrators, plastics and general supplies, plus added freight costs. These increases are not reflected in the CLFS and compound PAMA erosion.

These are recurring annual costs of producing a reliable result in Puerto Rico and must be part of any adequacy analysis.

Payer concentration leaves no margin to absorb the loss: Coverage in Puerto Rico for this filing is approximately 50% Medicaid, 30% Medicare Advantage, 7% uninsured, and less than 3% served by Section 330 health centers, with the remainder in commercial and other coverage. Dual eligibility requires care to avoid double-counting lives, but the economic conclusion is unchanged: an independent laboratory depends overwhelmingly on Medicare Advantage, Medicaid managed care, and a small commercial base, all of which reference Medicare reimbursement rates.

In this concentrated market, contracts tie laboratory schedules to the Medicare CLFS and then apply additional discounts, bundling, and restrictive utilization rules. When the anchor is already below acquisition cost, no negotiation can restore sustainability. **MedPAC should test as an economic hypothesis whether Medicare-linked discounting feeds back into future PAMA weighted medians without ever measuring service cost [5].**

In summary, because of PAMA and low Medicare rates, neither Traditional Medicare, Medicare Advantage plans, Medicaid contracted plans, nor private insurance referencing Medicare rates are providing access to needed laboratory testing to their beneficiaries, in violation of federal and state laws and regulations on access, coverage and network adequacy. Despite billions of dollars in direct and indirect profits generated, their political and economic power has left the government unable to force them into compliance. Immediate congressional corrective action to establish an adequate, cost-based floor for Puerto Rico is required to protect access.

PAMA representativeness must be reviewed on that basis. Traditional Medicare CLFS payment, imposed Medicare Advantage rates, Medicaid and Medicaid managed-care payments, and commercial payments are legally distinct, and only qualifying private-payer rates for applicable laboratories and tests during the statutory collection period enter the calculation. **MedPAC should ask whether Puerto Rico independent laboratories are adequately represented and whether concentrated discounted rates distort the median.**

1. Patient consequences

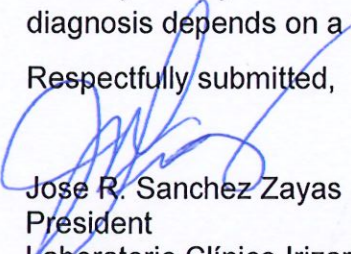
The foreseeable effects of below-cost payment are reduced test menus, referral delays, longer turnaround, repeat venipuncture, fewer draw sites, longer travel and wait times, deferred diagnosis, and service elimination or closure. For diabetes, kidney disease, cardiovascular disease, cancer, maternal health, syphilis and other infections, and transplant management, delay changes outcomes and raises downstream cost. We distinguish economic incentive from proven intent, but where rates predictably make covered tests unavailable, MedPAC should describe that effect and request investigation of contracting, denial, delay, and network-adequacy practices.

2. Specific requests: We ask MedPAC to recommend:

- a. **A Puerto Rico-specific laboratory payment-adequacy and access study using independent-laboratory acquisition costs and island logistics as the baseline.**
- b. CMS review of PAMA representativeness for Puerto Rico.
- c. Evaluation of a geographic, insular-cost, or access-protection mechanism for essential laboratory services, stating whether legislation is required.
- d. An inflation and sustainability update reflecting freight, energy resilience, inventory and equipment taxes, IVU, and compliance cost.
- e. **Protection against further reductions that would predictably compromise access, within available authority.**
- f. Greater transparency by Medicare Advantage, Medicaid managed-care, and commercial payers of contracted rates, denials, prompt payment, and network adequacy.
- g. Assessment of payer concentration and Medicare-linked discounting effects.
- h. **Direct participation by Puerto Rico independent laboratories in evidence collection and future deliberations, including surveillance and emergency-continuity capacity.**
- i. **Request a congressional mandate for a GAO investigation on this situation in Puerto Rico.**

Thank you for your attention to beneficiaries and patients in Puerto Rico whose diagnosis depends on a laboratory remaining open and able to offer the test ordered.

Respectfully submitted,



Jose R. Sanchez Zayas
President
Laboratorio Clínico Irizarry Guasch, Inc.
josersanzay@gmail.com
(787) 317-6654

References

1. CMS Clinical Laboratory Fee Schedule:
<https://www.cms.gov/medicare/payment/fee-for-service-providers/clinical-lab-fee-schedule>
2. MedPAC meetings and comment procedures: <https://www.medpac.gov/>
3. Puerto Rico Department of Treasury: <https://www.hacienda.pr.gov/>
4. CRIM: <https://www.crim.pr.gov/>
5. PAMA statute, 42 U.S.C. 1395m-1: <https://www.govinfo.gov/>