May 12, 2025

VIA Regulations.gov

Russel T. Vought
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

RE: Request for Information: Deregulation

Dear Mr. Vought:

On behalf of the Point of Care Testing Association (POCTA),[1] I am responding to the Office of Management and Budget's Request for Information seeking "proposals to rescind or replace regulation that stifle American businesses and American ingenuity."[2] **For the reasons outlined below, we respectfully request that the Centers for Medicare and Medicaid Services (CMS) (1) rescind its policy requiring clinical laboratories to add the -QW modifier to Medicare claims for CLIA-waived tests, and (2) revise the National Correct Coding Initiative Policy Manuals to remove or amend guidance inconsistent with longstanding CPT rules for coding laboratory services.**

Under current CMS policy, many point of care (POC) laboratories cannot bill Medicare for CLIA-waived tests they can lawfully perform until CMS takes administrative – and unnecessary – steps, which places a substantial financial burden on POC laboratories and delays Americans' access to new, potentially lifesaving technologies. Once claims can be submitted, the POC laboratories face inconsistent, contradictory guidance regarding proper coding practices. This inconsistent guidance creates ambiguity that cause laboratories to waste valuable resources.

[1] POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. Laboratory testing furnished at the point of care (POC) benefits patients and the health care system. POC testing enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients in a variety of care settings, from clinics to pharmacies to community centers to non-hospital facilities (e.g., assisted living). POCTA works to develop reimbursement policies that can improve health outcomes by supporting access to POC testing. POCTA is comprised of Abbott Rapid Dx, Abbott Point of Care, Beckman Coulter Diagnostics, Becton, Dickinson and Company (BD), bioMérieux, Cepheid, and Roche Diagnostics Corporation.

[2] 90 Fed. Reg. 15482 (April 11, 2025).

I. Request for CMS to Rescind the -QW Modifier Policy for CLIA-Waived Test Claims

The Clinical Laboratory Improvements Amendments of 1988[3] and its implementing regulations[4] (collectively, CLIA) set standards for clinical laboratory testing. Under CLIA, clinical laboratories must obtain a CLIA certificate to perform laboratory testing; the type of certificate required depends on the complexity of the test(s) to be performed. Each laboratory test is assigned a level of complexity – high, moderate, or waived. The simplest laboratory tests – i.e., those cleared for home use or that can be safely and accurately performed by individuals following FDA-approved or cleared instructions for use, without any special laboratory education or training – are designated "waived." For example, this category of tests includes certain urine drug tests, blood and urine tests for certain metabolites like albumin, creatinine or cholesterol, blood glucose testing, and certain infectious disease tests (e.g., COVID-19, influenza). Clinical laboratories operating under a CLIA Certificate of Waiver may lawfully offer such "waived" tests as soon as the test receives clearance or approval and "waived" designation from FDA.

However, Certificate of Waiver laboratories cannot bill Medicare for "waived" tests until CMS publishes a transmittal updating its list of "waived tests" to (a) include the name of the test and (b) assign the test an associated Current Procedural Terminology (CPT) code for which CMS requires the use of a -QW modifier. Historically, this process has taken CMS four to six months – if not longer – to complete from the date a test receives FDA authorization and "waived" designation.

These delays – which are solely administrative, are not related to a determination whether a test is safe or accurate – impose a substantial financial burden on POC laboratories, and may cause providers to defer implementation of novel tests for several months until Medicare updates its systems. Further, these delays stifle American innovation and deny Americans access to new diagnostic technologies.

POCTA appreciates and supports initiatives intended to support appropriate, efficient utilization of limited Medicare resources. However, the -QW modifier requirement does not advance these goals in any meaningful way, or give CMS access to information it did not already have. The only information added by the -QW modifier is confirmation that the clinical laboratory has performed a CLIA-waived test. However, any clinical laboratory – regardless of certificate type – may perform "waived" testing under CLIA. Information already available on a claim form – i.e., the performing laboratory's CLIA number –provides CMS with the information necessary to confirm the test has been performed by a certified laboratory.[5] Furthermore, because Certificate of Waiver laboratories may only perform

[3] 42 U.S.C. § 263a.
[44] 42 C.F.R. § 493.1 et seq.
[5] CMS Claims Processing Manual, Ch. 16 § 70.1.

"waived" tests, CMS already knows that any test furnished by such laboratories is a "waived" test.

In conclusion, the existing -QW modifier requirement is an unnecessary overregulation that financially burdens POC laboratories, delays access to new diagnostic advances, and wastes government resources (as required to update required lists). For these reasons, POCTA urges the Office of Management and Budget to eliminate the -QW modifier requirement by deleting the following language from § 70.8 of Chapter 16 of the Medicare Claims Processing Manual:[6]

> ***70.8 - Certificate of Waiver***
> *(Rev. 11463; Issued: 06-23-22; Effective: 07-25-22; Implementation: 07-25-22)*
>
> *Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver, certificate for provider-performed microscopy procedures, certificate of registration, certificate of compliance, or certificate of accreditation to legally perform clinical laboratory testing on specimens from individuals in the United States.*
>
> *The Food and Drug Administration approves CLIA waived tests on a flow basis. ~~The CMS identifies CLIA waived tests by providing an updated list of waived tests to the A/B MACs (A) and (B) on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.~~*
>
> *Information regarding CLIA test complexity categorization can be found by searching the U.S. Food and Drug Administration website (www.fda.gov).*

CMS could also streamline its own operations by eliminating its list of "waived" tests, which is updated semi-annually. The most recent of these announcements may be found at https://www.cms.gov/medicare/regulations-guidance/transmittals/2024-transmittals/r12935cp.

[6] Available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf (last accessed April 30, 2025).

II. Request for CMS to Remove NCCI Policy Manual Language that Contradicts the CPT Instructions

Clinical laboratories use CPT codes to report the provision of laboratory services to Medicare and Medicaid beneficiaries. To encourage appropriate coding, the CPT codebook includes explicit guidelines and parenthetical instructions. Furthermore, reliable resources published by the AMA – including CPT Changes and CPT Assistant – further assure the accuracy and consistency of coding.

Similarly, to promote proper coding and reduce improper payments, CMS created National Correct Coding Initiative (NCCI) programs for both Medicare and Medicaid. These NCCI programs issue their own coding guidance in the NCCI Policy Manuals.

Unfortunately, the NCCI Policy Manuals include language in Chapter X (Pathology/Laboratory Services) that contradicts both established CPT coding guidelines, particularly as it relates to the use of multiple codes to report a multiplex test procedure.[7] These inconsistencies create confusion for clinical laboratories and make it impossible for them to comply with both CPT instructions and the NCCI Policy Manuals. The conflicting guidance also wastes government resources by providing unnecessary instruction in areas that are already well-settled, and undermines core assumptions underlying the Clinical Laboratory Fee Schedule rate-setting framework.

To eliminate confusion, reduce the inefficient use of government and industry resources, and promote accurate coding consistent with longstanding CPT principles, POCTA urges the Office of Management and Budget to remove or amend language from the NCCI Policy Manuals that contradicts established CPT coding guidelines and other NCCI tools, including the following language from the Introduction to Chapter X:

> ~~*If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service.*~~

As well as the following language in section K.5:

> ~~*CPT codes 87483 (Multiplex infectious agent detection by nucleic acid methodology for central nervous system pathogens), 87505-87507 (Multiplex infectious agent detection by nucleic acid methodology for gastrointestinal*~~

[7] The current Medicare NCCI Policy Manual is available at https://www.cms.gov/files/document/2025nccimedicarepolicymanualcompletepdf.pdf; the Medicaid NCCI Policy Manual is available at https://www.cms.gov/medicare/coding-billing/ncci-medicaid/medicaid-ncci-policy-manual.

~~*pathogens), and 87631-87633 (Multiplex infectious agent detection by nucleic acid methodology for respiratory virus) describe multiplex testing procedures for multiple microorganisms using reverse transcription and/or amplified probe techniques. The codes describe an anatomic region and the number of "targets" tested. If one of these multiplex tests is performed and additional testing by these methodologies for additional microorganisms that might cause disease in the anatomic region described by the code descriptor is performed, only one multiplex testing code summing the testing for all "targets" shall be reported. The code descriptors identify some microorganisms, but not all, that might be tested by these methodologies for the respective anatomic regions. If it is medically reasonable and necessary to test by a different methodology or for other types of microorganisms not included in the multiplex test that might cause disease in the respective anatomic region, the test may be reported separately.*~~

The same organism could be a target in one panel reflecting one organ system and also a target in a different organ system when testing a different specimen. The same organism could be the target tested on each of 2 or more specimens from different anatomic sites.

And in section M.15 (medically unlikely edits):

In the case of tests for infectious agents, methodologies include detection by immunofluorescence, immunoassay, or nucleic acid probe techniques. ~~*A single laboratory procedure shall be reported as one unit of service whether it generates one or multiple results. CPT codes that test for a single infectious agent that employ one procedure, one methodology, or one test kit are reported with one unit of service.*~~

~~*CPT codes that test for multiple infectious agents are reported with one unit of service if one procedure, one methodology, or one test kit is used to perform the test (e.g., 87300, 87451, 87800, 87801). When multiple procedures, multiple methodologies, or multiple kits are medically necessary and used to perform a test for multiple infectious agents, the units of service reported for CPT codes that identify multiple infectious agents equals the number of different procedures, methodologies, or kits used to perform the test.*~~

~~*For example, if a provider/supplier tests for 5 different species of an infectious agent using a single multiple-result test kit, only 1 unit of service for that test kit may be reported. However, if a provider/supplier tests for 3*~~

~~*different species of an infectious agent by using 3 different single result test kits, the provider/supplier may report 3 UOS of the appropriate CPT code.*~~

* * *

Thank you for your consideration. If you have any questions or comments, please contact me at 202-756-8088 or via e-mail at mryan@mwe.com.

Sincerely,

Mike Ryan
On behalf of the Point of Care Testing Association