July 29, 2024

VIA Electronic Mail to: cures.rfi@mail.house.gov

The Honorable Diana DeGette
The Honorable Larry Bucshon
U.S. House of Representatives
Rayburn House Office Building
Washington, D.C. 20515

RE: Cures 2.0 Request for Information

Dear Ms. DeGette and Dr. Bucshon:

On behalf of the Point of Care Testing Association (POCTA), we appreciate the opportunity to respond to the June 6, 2024 request for information on next steps for Cures 2.0. We thank you both for your continued commitment to modernizing existing regulatory and reimbursement frameworks, including those affecting access to innovative technologies that can improve patient outcomes and achieve healthcare savings.

POCTA seeks to facilitate access to safe, effective, and cost-effective clinical diagnostic testing at the time of treatment. We work to achieve this goal by educating providers, payers, and patients about the benefits of point-of-care testing, and by advocating for public policies that foster innovation in and appropriate use of point-of-care testing. POCTA members[1] are developers and manufacturers of point-of-care in vitro diagnostic tests.

We provide our comments on several key areas in the attached table by briefly describing each issue area and proposing a policy solution.

We would be happy to meet with you and your staff to discuss our comments and recommendations. 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
Point of Care Testing Association

[1] POCTA is comprised of Abbott, Beckman Coulter, Becton, Dickinson and Company (BD), bioMérieux, Cepheid, Roche Diagnostics, and Siemens Healthineers.

Issue Area	Brief Issue Description	Comment
Transitional Coverage for Emerging Technologies (TCET) Proposal	In June 2023, CMS issued a Federal Register notice outlining its plans for a revised "Transitional Coverage for Emerging Technologies" (TCET) pathway to expedited Medicare coverage for innovative medical devices. CMS is expected to finalize the pathway later this summer.	In general, POCTA supports the agency's efforts to develop a transparent, predictable, collaborative, and expedited national coverage pathway for innovative medical devices. However, TCET (as currently conceived by CMS) would only expedite access to a small number of breakthrough devices each year, and would not address the coverage delays currently faced by patients and providers who wish to use these innovative technologies. In lieu of TCET, we urge Congress to create a new, expedited pathway to Medicare coverage for a broader group of innovative medical devices. This pathway could look like the previously withdrawn MCIT program, or the framework set forth in the Ensuring Patient Access to Critical Breakthrough Products Act of 2023 (H.R. 1691).
Digital health – developing a framework for establishing coding and payment for diagnostics that include digital health	Current perception is that anytime technology replaces human labor, payment for that service should be reduced or the software components may be considered indirect/overhead expenses. This is becoming increasingly relevant with the utilization of AI in healthcare.	POCTA encourages efforts to define clinical digital technologies and strongly supports harmonized regulatory pathways for product clearance/approval and the establishment of coverage and payment systems for these technologies. POCTA strongly recommends that any framework for establishing FDA clearance/approval as well as coding, coverage and payment for digital technologies specifically include diagnostic technologies, including clinical diagnostic laboratory tests, as well as therapeutic technologies.
Development and commercialization of point-of-care diagnostic tests	Point-of-care testing – patient laboratory testing that is done at, or near, the patient – is important to inform immediate or near-term patient management across a range of settings including, but not limited to inpatient hospital, physician office. Rapid test results can quickly help determine a course of action or treatment for a patient, as demonstrated during the COVID-19 PHE.	POCTA supports establishing an interagency taskforce comprised of the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services and the Food and Drug Administration to evaluate how existing statutory and regulatory requirements impact the development and commercialization of point-of-care diagnostic tests and

Issue Area	Brief Issue Description	Comment
	However, POC testing is often undervalued and current policies may not be adequate to support the development and commercialization of POC diagnostic tests. Current policy should be reviewed and evaluated to identify policies to support better the development and commercialization of POC diagnostic tests.	to develop recommendations that address identified barriers. The taskforce shall also include representatives from manufacturers of point-of-care diagnostic tests. A report with recommendations should be issued within one year of enactment.
Medicare Hospital Outpatient Prospective Payment System transitional pass-through payment	Both the IPPS and the OPPS include payment pathways to facilitate adoption of new technologies. Under the IPPS, NTAP provides additional payments for certain new technologies. Under the OPPS, additional payments are made for new technologies via Transitional Pass-Through Payments. Although both prospective payment systems have mechanisms for facilitating adoption of new technology, criteria are inconsistent between the IPPS and OPPS. Current policy limits OPPS transitional pass-through payments to those devices that are "surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion." This requirement excludes novel diagnostic tests from consideration for transitional pass-through payments despite their being packaged under the OPPS. This requirement does not exist under the IPPS and in recent years, novel diagnostic tests have been granted NTAP status.	POCTA supports the eligibility of breakthrough devices to receive NTAP or transitional pass-through payment under OPPS but believes that payments to facilitate adoption of new technologies should not be limited to breakthrough designated devices. POCTA also recommends that the transitional pass-through payment program under OPPS be extended to allow all clinical diagnostic laboratory tests to be eligible if such tests meet the newness, substantial clinical improvement, and costs not insignificant criteria that apply to all other devices. This change would put clinical diagnostic laboratory tests on an equal footing with devices that are "implanted or inserted…"
Reforms to National Correct Coding Initiative	CMS publishes several documents under the auspices of the National Correct Coding Initiative (NCCI) – i.e., manuals for Medicare and Medicaid services, procedure	Congress should require CMS to post the NCCI materials (and the MACs to post billing and coding articles) for notice and comment well in advance of

Issue Area	Brief Issue Description	Comment
(NCCI) process and MAC coding processes	to procedure edits, and medically unlikely edits. The information furnished in these documents are binding on MACs and state Medicaid programs. Similarly, the MACs routinely publish billing and coding articles that provide coding instructions to providers and suppliers. Unfortunately, these documents routinely conflict with longstanding, well-accepted coding principles, and are not subject to public comment. Furthermore, the documents themselves are routinely published just days before they become effective, leaving stakeholders with insufficient time to make any modifications to remain in compliance.	their effective date. Specifically, CMS (or the MACs, as applicable) should publish the documents in proposed form, solicit public comments for a minimum of 45 days, and then finalize any changes to the documents at least 60 days before they become effective. When issuing the final document, CMS should provide a written response to any substantive comments received. Congress should also prohibit CMS from promulgating any NCCI policies (or the MACs from establishing any local coding policies) that deviate or conflictwith explicit CPT instructions.
Issues with State Medicaid Processing and Coverage Requests for PLA Codes	Proprietary Laboratory Analysis (PLA) codes are CPT codes that describe proprietary clinical laboratory analyses. Under HIPAA's Administrative Simplification Rule, PLA codes are part of the designated code set for clinical laboratory tests, and state Medicaid plans must recognize and process claims that include PLA codes. However, approximately fifteen state Medicaid plans refuse to process claims that use PLA codes. Furthermore, several state Medicaid plans refuse to consider coverage requests for services described with PLA codes based solely on their status as PLA codes. As a result, Medicaid beneficiaries in these states are routinely denied access to necessary diagnostic testing.	Congress should direct CMS to provide written guidance to state Medicaid plans requiring them to (1) process claims for PLA codes as required under HIPAA, and (2) evaluate coverage requests for PLA codes using the same process/criteria as the state Medicaid plan uses for all other services.
Clinical Laboratory Fee Schedule (CLFS) Improvements: SALSA	Section 216 of the Protecting to Access to Medicare Act of 2014 (PAMA) significantly revised the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). On January 1, 2018, Medicare began using private payor rate information reported by	Congress should pass the Saving Access to Laboratory Services Act (SALSA), S. 1000/H.R. 2377, which would make several reforms to the CLFS data collection and rate-setting processes that would be specifically beneficial for point of care testing. This includes:

Issue Area	Brief Issue Description	Comment
	applicable laboratories to calculate Medicare payment rates for most laboratory tests paid under the CLFS. CMS's implementation of section 216 of PAMA skewed data collection toward large reference labs, and thus the data published by CMS and the rates that resulted beginning in 2018 do not represent the overall lab marketplace, and they especially under-represent physician office labs , and therefore point of care testing. CMS's chosen methodology and the resulting payment decreases have threatened to compromise patient access to point of care testing, particularly in physician office settings. If the cost for a physician or clinic to purchase and furnish point of care tests exceeds reimbursement, many physicians and clinics may discontinue offering these services to Medicare beneficiaries. Congress has acted five times to delay data reporting and payment cuts to laboratories. The next round of cuts will go into effect in January 2025 without congressional action.	• Suspends CDLT reporting requirement through 2026, and extend reporting frequency from every three years to every four years; • Replaces much of the current data collection program with a statistical sampling approach that requires that the sampling methodology (1) be representative of the range of private payor payment rates of the different types of applicable laboratories (independent labs, hospital labs, and physician office labs) that furnish the test, and (2) accurately and proportionally represent the range of private payor payment rates received by each such types of lab based on utilization of the test by each type of lab; • Revises eligible lab criteria in a way that enables more reporting from physician office labs; and • Labs would not be required to submit payment data from Medicaid managed care organizations.
CLFS Improvements: Lack of Clarity on Rules for Initial Ratesetting	When participating in the annual CLFS process, diagnostic laboratories and lab test developers are frequently informed of certain rules that CMS follows when making such determinations – e.g., that CMS cannot crosswalk to an unlisted code, cannot crosswalk to a code going through gapfill, or cannot crosswalk to a test with advanced diagnostic laboratory test (ADLT) status. However, CMS does not publish or explicitly	Congress should require CMS to publish a draft document setting forth these "unwritten" rules and give laboratory stakeholders an opportunity to provide comments. After considering such comments, CMS should finalize this list of rules, and update the document as needed (via the same notice and comment process) to address new or updated situations.

Issue Area	Brief Issue Description	Comment
	make these unwritten rules known and does not always apply them consistently. This practice places developers, especially those new to the process, at a significant disadvantage and undermines the predictability of the coverage and rate determination process.	
CLFS Improvements: Lack of Transparency in Clinical Diagnostic Laboratory Testing Advisory Panel Discussions	The Medicare Advisory Panel on Clinical Diagnostic Laboratory Services (the Panel) advises and makes recommendations to CMS on rate determinations for new diagnostic laboratory tests and meets publicly to discuss and vote on these recommendations. Although these public meetings are intended to provide transparency into the Panel's process and rationale for its recommendation, in recent years, the Panel's discussion of new tests has only included conclusory comments on how the code should be priced, without any meaningful discussion of the Panel's rationale. Without more fulsome discussion which expresses the Panel's thinking, the transparency of the process is undermined, and diagnostic test developers are deprived of necessary information to addressing the Panel's concerns (when a developer disagrees with the Panel's recommendation).	Congress should require the CDLT Advisory Panel to engage in a more complete, meaningful public discussion when making recommendations for Medicare ratesetting of new tests.
CLFS Improvements: Modifications to rates for new codes based on updates to crosswalked codes	CMS establishes payment rates for new laboratory tests using "crosswalking" or "gapfilling" methodologies. Under the "crosswalking" methodology, the payment rate for a new laboratory service is established based on the payment rate of a similar laboratory test or combination of tests. Under the "gapfilling" methodology, the payment rate is based on information such as charges and routine discounts to charges, resources required to perform the laboratory test,	For new laboratory tests for which payment rates are established via crosswalk, POCTA recommends that payment rates established by crosswalk shall be held constant at the rate in effect at the time the crosswalk was assigned until the next cycle of laboratory reporting and ratesetting under PAMA. Modifying this practice would provide consistency and stability to initial rate setting consistent with crosswalking principles until test-specific private payor payment data are collected and reported under current requirements.

Issue Area	Brief Issue Description	Comment
	negotiated payer rates, and payment amounts for other tests that may be comparable. Under the Protecting Access to Medicare Act of 2014 (PAMA), if the payment rate for a new laboratory test is set based on crosswalk and payment for the "crosswalk" test declines, those payment reductions apply to the new test's payment as well. However, those payment reductions are based solely on reported data for the crosswalk test and do not include any payment data for the new test.	
CLFS Improvements: Lack of Transparency When Tests Priced by MACs	A new or substantially revised code can become available/effective – in some cases, for several months – before CMS sets a rate via the annual CLFS process. During this period of time, the MACs set local payment rates after consideration of a number of factors – i.e., charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. The MACs follow a similar process when tests are assigned to gapfill during the annual CLFS ratesetting process. Stakeholders currently have minimal visibility into the above-described process. Prior to the national CLFS process, many MACs do not publicly post rates for contractor-priced tests, nor do they provide a rationale for their decisions. When a code is assigned to gapfill, CMS does not post preliminary rates until May, or final rates until September. CMS does include a brief rationale for the gapfill determinations, but it is	For codes that are locally priced prior to receiving a national CLFS rate, Congress should require MACs to publicly post locally-determined rates on their website, as well as a summary of the MAC's rationale for the same. The MAC's rationale should include an explanation of how the MAC considered each of the factors currently required by regulation. The MACs should not, however, disclose any confidential information when furnishing any public-facing rationale. The MACs should include a similar, detailed rationale when submitting their preliminary and final gapfill determinations to CMS.

Issue Area	Brief Issue Description	Comment
	generally not sufficiently detailed to facilitate meaningful public comment on the determinations.	
Expedited LCD Process for Innovative Technologies	The current LCD process – as set forth in the Program Integrity Manual following the enactment of 21st Century Cures – is lengthy and can take a minimum of 18-24 months even when all goes smoothly. The length of the LCD process can create serious delays in patient access to transformational medical technologies, especially given the rate of current medical device development. The LCD process was created, in part, to assure Medicare beneficiary access to new medical technologies by Medicare patients. The current timeline of the LCD process and lack of expedited processes to establish LCDs on an expedited basis for transformational technologies undermines this goal of the LCD process.	Congress should allow MACs to publish LCDs that increase access to transformational items and services on an expedited basis, without following the "full" process set forth in the Program Integrity Manual. Such processes could include, for example, allowing MACs to start the process by publishing a final LCD with comment period without first publishing a draft LCD. Such expedited procedures should not, however, be available for LCDs that restrict access to any item or service. Such LCDs should continue to follow the existing process set forth in the Program Integrity Manual.
LCD Request Status Transparency Issues	The MACs do not currently provide any information regarding the number of LCD requests currently on their "wait list." This lack of clear and public information on the status of LCD requests reduces the transparency of the process and allow MACs to avoid accountability for delays in responding to LCD requests. By contrast, CMS has created a status tracker for NCD requests, which it updates several times a year.	Congress should require each MAC to develop a public-facing tracker to provide information regarding the LCD requests currently on the MAC's "wait list." This wait list should be similar to the national NCD tracker maintained by CMS, and include information on the number of requests in the waitlist, how long each request has been on the MAC's waitlist, and the order in which the MAC intends to consider the outstanding requests. Furthermore, Congress should require MACs to update such trackers on a monthly basis.
Delay in MAC Responses to LCD Requests	Section 4009 of the 21st Century Cures Act updated the Social Security Act to enhance the LCD process by establishing a defined process for the development of LCDs. The parameters of this process were codified in Chapter 13 of the Medicare Program Integrity Manual.	Congress should require MACs to respond to new LCD requests or LCD reconsideration requests within [12 months] of the MAC's receipt of the request.

Issue Area	Brief Issue Description	Comment
	The Program Integrity Manual currently requires MACs to consider requests for new LCDs or requests to reconsider existing LCDs. MACs must currently confirm whether a request is valid – i.e., whether it contains all elements required for processing – within 60 days of receipt. Once deemed "valid," section 13.3.3 of the Program Integrity Manual permits MACs to place LCD requests on a waitlist. However, the Program Integrity Manual does not place any cap on how long a MAC may leave a request on its waitlist. In recent years, some LCD requests have sat on MAC waitlists for as long as 3 years. As a result, the existing process continues to produce substantial delays in access to novel items and services.	
Permanent flexibility to allow pharmacist involvement in testing	In general, a diagnostic test is only eligible for Medicare reimbursement if it is ordered by the physician who is treating the beneficiary. Pharmacists are not included in the list of nonphysician practitioners (NPPs) who are treated as physicians for purposes of this requirement, even if operating within the scope of their authority under state law. During the COVID-19 PHE, a physician (or other HCP) order was not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis when performed in conjunction with COVID-19 diagnostic laboratory test to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID-19 and related tests were reasonable and necessary when ordered by a physician or NPP in accordance with the usual	POCTA supports the inclusion of statutory language that would make permanent the recognition of pharmacist's authority to order reimbursable diagnostic tests for Medicare beneficiaries, subject to state law.

Issue Area	Brief Issue Description	Comment
	Medicare requirements, or when ordered by a pharmacist or other healthcare professional authorized under applicable state law to order diagnostic laboratory tests. The flexibility that allowed pharmacists to order tests ended when the PHE ended in May 2023.	
Expedited publication of Medicare guidance on CLIA-waived tests	Point-of-care labs can lawfully offer CLIA-waived tests as soon as a test receives FDA clearance/approval and "waived" designation from FDA. However, point-of-care labs cannot bill Medicare for claims for CLIA-waived tests until CMS updates its list of "waived tests" to include the test and its associated CPT code. CMS recommends that providers hold claims until the agency updates this list and the local Medicare Administrative Contractors (MACs) implement the change. Normally, the above-described process takes CMS and the local MACs 4-6 months to complete. However, during the COVID-19 PHE, CMS substantially expedited its usual process, and issued instructions quickly enough that waived laboratories were only required to hold claims for 1-2 months.	POCTA supports the inclusion of statutory language that would require CMS to update its claims processing instructions – and for the MACs to update their claims processing systems – to account for new CLIA-waived tests within one calendar quarter from FDA's decision to authorize a test for use in a CLIA-waived setting.
New Exception to OPPS Packaging Policy and Separate Payment for Novel Clinical Diagnostic Tests That Further	Antibiotic resistance is one of the biggest threats to global health. As the Centers for Disease Control and Prevention (CDC) recently observed, "[m]ore than 2.8 million antibiotic-resistant infections occur in the United States each year, and more than 35,000 people die as a result."[2] These infections have a disproportionate impact on America's seniors. While	To ensure Medicare beneficiaries have access to novel, high-performing diagnostic technologies with the ability to support diagnostic stewardship and appropriate antibiotic prescribing practices, we respectfully request that CMS create a new exception from the OPPS packaging rules for clinical diagnostic laboratory tests that further appropriate antibiotic stewardship, such as

[2] Centers for Disease Control and Prevention, Antibiotic resistance threats in the United States 2019 (Dec. 2019), https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

Issue Area	Brief Issue Description	Comment
Appropriate Diagnostic and Antibiotic Stewardship	just 15% of America's population is 65 or older, an estimated one-third of the deaths caused by antibiotic resistant pathogens – nearly 12,000 per year – occur in this population. A main driver in the development of drug-resistant pathogens is the misuse and overuse of antimicrobials. A major challenge to combatting antibiotic resistance is the availability and use of diagnostics, such as those that can distinguish between bacterial and viral infections. The U.S. Federal Task Force on Combating Antibiotic-Resistant Bacteria state "there is a critical need to leverage existing capabilities to promote the validation, adoption, and appropriate use of new and currently available diagnostics." Adding additional focus, the National Action Plan for Combatting Antibiotic-Resistant Bacteria (CARB) includes Goal 3, Objective 1.1: "Develop new or enhance existing diagnostics that use isolates and primary samples to determine the presence… of bacterial… infections and to identify appropriate treatment."[3] Similarly, IDSA states that "[n]ew tests are needed that can identify a specific pathogen or at a minimum, distinguish between bacterial and viral infections…".[4]	those that can accurately and reliably distinguish acute bacterial infections from viral infections and identify the most effective antimicrobials when necessary. Distinct from other exceptions, we propose that exceptions be optional and requested by test provider and/or manufacturer via an application process to CMS.
Providing CMS with sufficient appropriations to make timely coverage determinations	The CMS Coverage and Analysis Group (CAG) is responsible for developing national coverage determinations (NCDs) for items/services furnished to Medicare beneficiaries. Unfortunately, this group has been chronically understaffed, and is unable to timely take up requests for new coverage policies. Per the CMS NCD Status	We encourage Congress to provide CMS with sufficient appropriations to allow CAG to make better, more timely NCDs for novel items and services.

[3] Office of the Assistant Secretary for Planning and Evaluation, National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025 (Oct. 8, 2020), https://www.hhs.gov/sites/default/files/carb-national-action-plan-2020-2025.pdf.
[4] Caliendo AM, Gilbert DN, Ginnochio CC, *et al*. Better tests, better care: improved diagnostics for infectious diseases. *CID* 2013;57 (suppl 3):S139-S170.

Issue Area	Brief Issue Description	Comment
	Tracker, 8 requests are currently on the NCD Wait List, several of which have been on the waitlist for more than a year. These delays threaten Medicare beneficiary access to critical services.	
Policies to improve access to (and patient uptake of) testing for the early diagnosis of Alzheimer's	The U.S. Preventive Services Task Force, in a 2020 review and recommendation regarding routine screening for cognitive impairment in adults 65 years old and older, noted, "Although there is insufficient evidence to recommend for or against screening for cognitive impairment, there may be important reasons to identify cognitive impairment early. Clinicians should remain alert to early signs or symptoms of cognitive impairment (e.g., problems with memory or language) and evaluate the individual as appropriate. Other risk factors that could indicate the need for dementia screening include a history of type 2 diabetes, stroke, depression, trouble managing money or medications, and being older than 80." The Social Security Act does not currently require Medicare to cover tests for Alzheimer's early detection. Furthermore, Medicare beneficiaries may be reluctant to take tests for the early detection of Alzheimer's due to concerns about the disclosure of that information to – or use of information by – third parties.	As evidence builds establishing the clinical validity and clinical utility of point of care blood and cerebrospinal fluid tests for the early detection of Alzheimer's, Congress should consider instructing Medicare to include such tests as elements of its "Welcome to Medicare" visit and during annual "Wellness" visits. (We understand Congress is already considering certain modifications to such services – e.g., as reflected in H.R. 8816 – into which it may be possible to advance these concepts.) Including such tests in established Medicare visits may facilitate the early detection of Alzheimer's. To give Medicare beneficiaries comfort regarding the disclosure/use of such information, Congress should consider enacting provisions that restrict the ability of downstream entities to use or disclose such information. Such laws could be modeled after the laws that protect the confidentiality of genetic or sexually transmitted infection information, as informed by patient advocacy groups.