POINT OF CARE TESTING ASSOCIATION

September 3, 2025

VIA Electronic Submission to www.regulations.gov

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: [CMS-1834-P] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

Dear Dr. Oz:

On behalf of the Point of Care Testing Association (POCTA),[1] we are pleased to provide the following comments responding to proposals and other policy discussions included within CMS's Hospital Outpatient Prospective Payment System (OPPS) proposed update for CY 2026. For the reasons outlined below, we respectfully request that CMS:

1. Create a new exception from the OPPS packaging rules for clinical diagnostic laboratory tests that accurately and reliably distinguish acute bacterial infections from viral infections to support proper use of antimicrobial therapy; and

2. Extend the transitional pass-through payment program under OPPS to allow make clinical diagnostic laboratory tests eligible if such tests meet the newness, substantial clinical improvement, and costs not insignificant criteria that apply to all other devices

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[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, Roche Diagnostics Corporation, and Sekisui.

1. **Requests for Exemption from OPPS Packaging Rules**

Under current OPPS packaging policy, Medicare payment for most clinical laboratory tests furnished to hospital outpatients is packaged into the Ambulatory Payment Classification (APC) for other services furnished during the admission.[2] However, certain types of tests – e.g., preventive services[3] and molecular pathology tests[4] – are excluded from packaging and paid separately under the Clinical Laboratory Fee Schedule (CLFS). CMS implemented the packaging policy in 2014 before many innovative diagnostic tests became available, and the current exceptions to this policy only apply to a handful of tests (and are not applied to all tests they might otherwise be eligible for).

The application of these packaging policies is problematic for novel diagnostic testing services because they are not eligible for either of the temporary payment programs intended to incentivize the use of novel technologies that substantially improve clinical care. The tests are not currently eligible for transitional pass-through status because they are not surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.[5] (See below for more discussion on this specific point.) Similarly, many of these tests are unlikely to be eligible for new technology APC classification, as they are appropriately reported by an existing HCPCS code.[6] As a result, payment for these tests is packaged into the payment for other services furnished during a hospital outpatient encounter, without the possibility of incremental payment.

In the absence of incremental payment, hospital outpatient departments have a financial disincentive to offer tests subject to the packaging rules, notwithstanding the demonstrated ability of many such tests to improve beneficiary outcomes, drive down costs, and reduce overutilization.

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[2] 42 C.F.R. § 419.2(b)(17); see also CMS-1736-FC, 85 FED. REG. 85866, 85899 (Dec. 29, 2020).
[3] CMS, Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 18, § 1.2.
[4] ADLTs are excluded if they meet the criteria of section 1834A(d)(5)(A) of the Social Security Act (i.e., the test is a CDLT as defined in Section 1834A(d)(5) of the Act that is offered and furnished in a single laboratory, is not sold for use by a laboratory other than the original developing laboratory (or a successor owner), and is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.
[5] 42 C.F.R. § 419.66(b)(3) provides that a "medical device" must meet certain requirements to be eligible for pass-through payments, including "The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion."
[6] See CMS, "Process and Information Required for a New Technology Ambulatory Payment Classification (APC) Assignment Under the Hospital Outpatient Prospective Payment System (OPPS)" (July 2021), available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/newtechapc.pdf.

a. Request for Exception for Tests to Facilitate Antibiotic Stewardship

Antibiotic resistant infections are a growing public health threat with a disproportionate impact on the Medicare beneficiary population. While 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. The U.S. healthcare system incurs an estimated additional $1.9 billion in costs when treating Medicare-age patients for antibiotic resistant infections.[7] In the CY 2025 Inpatient Prospective Payment System Proposed Rule, CMS itself acknowledged that it shared "concerns related to antimicrobial resistance and its serious impact on Medicare beneficiaries and public health overall." CMS further acknowledged that Medicare beneficiaries may be disproportionately impacted by antimicrobial resistance and stated that "antimicrobial resistance results in a substantial number of additional hospital days for Medicare beneficiaries, resulting in significant unnecessary health care expenditures."[8]

Antibiotic resistance is driven, in part, by antibiotic misuse. Because inappropriate use of antibiotics can increase the risk of antibiotic-resistant infections and other complications like *C. diff.* infections,[9] the Infectious Diseases Society of America (IDSA) recommends that healthcare providers minimize the frequency and duration of high-risk antibiotic therapy and the number of agents prescribed, and implement an antibiotic stewardship program.[10] A major challenge to appropriate antibiotic stewardship is the difficulty in distinguishing between bacterial infections and viral or other infections. This clinical uncertainty drives antibiotic misuse, both underuse and overuse, with detrimental ramifications for the patient, the health care system, and society.[11,12] Using National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey data, Fleming-Dutra *et al*. estimated that nearly 50% of antibiotic prescriptions for acute respiratory conditions are not clinically appropriate.[13]

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[7] See Nelson RE, Hyun D, Jezek A, Samore MH. Mortality, length of stay, and healthcare costs associated with multidrug-resistant bacterial infections among elderly hospitalized patients in the United States. Clin Infect Dis 2021;74(6):1070-1080.
[8] 89 Fed. Reg. 36138 (May 2, 2024)
[9] See CDC, About C. diff (Dec. 18, 2024), https://www.cdc.gov/c-diff/about/index.html.
[10] See McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7):e1-e48.
[11] Centers for Disease Control and Prevention, Antibiotic resistance threats in the United States 2019 (Dec. 2019), https://www.cdc.gov/antimicrobial-resistance/media/pdfs/2019-ar-threats-report-508.pdf?CDC_AAref_Val=https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.
[12] World Health Organization, Antibiotic resistance (Nov. 21, 2023), https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance.
[13] Fleming-Dutra KE, Hersh AL, Shapiro DJ, et al. Prevalence of inappropriate antibiotic prescriptions among US ambulatory care visits, 2010-2011. JAMA. 3 May 2016;315(17):1864-1873.

To address this driver of antibiotic misuse, IDSA states that "[n]ew tests are needed that can identify a specific pathogen or at a minimum, distinguish between bacterial and viral infections…".[14] Indeed, clinicians can use certain clinical diagnostic laboratory tests to accurately and reliably distinguish between bacterial and viral infections and which facilitate proper antibiotic stewardship. For example:

- **MeMed BV (0351U)** is highly effective at detecting when no bacterial infection is present in patients.[15] MeMed BV has been shown to aid physician patient management in 82% of cases, and reduce potentially unwarranted prescriptions in 62% of relevant cases.[16]
- **Monocyte Distribution Width (0427U)** reduces time to antibiotic administration, resulting in better clinical outcomes for sepsis patients.[17]
- In a randomized controlled trial, antibiotic administration based on a **procalcitonin (84145)** guided algorithm produced lower rates of antibiotic exposure and antibiotic-associated adverse events with no impact on adverse outcomes compared to treatment consistent with standard guidelines.[18]
- A meta-analysis shows that **C-reactive protein (86140, 86141)** guided care significantly reduces immediate antibiotic prescribing at index consultation compared with usual care, while not impacting clinical recovery, resolution of symptoms or hospital admissions.[19]

However, hospital outpatient departments face a financial disincentive to use these tests – and others that accurately and reliably distinguish between bacterial and viral infections and which facilitate proper antibiotic stewardship – because payments for these tests are

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[14] Caliendo AM, Gilbert DN, Ginnochio CC, et al. Better tests, better care: improved diagnostics for infectious diseases. CID 2013;57 (suppl 3):S139-S170.
[15] *See* U.S. Food and Drug Administration, 510(k) Summary – K230944 (June 30, 2023), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230944.pdf.
[16] Ben David SS, Rahamin-Cohen D, Kalmovich B. 876. Real-world impact of a novel host response test for distinguishing between bacterial and viral infections in pediatric patients at ten Urgent Care Centers. Open Forum Infect. Dis. 2023;10(2), https://doi.org/10.1093/ofid/ofad500.921.
[17] Paoli, Carly J. PharmD, MPH; Reynolds, Mark A. PhD; Coles, Courtney MPH2; Gitlin, Matthew PharmD; Crouser, Elliott MD. Predicted Economic Benefits of a Novel Biomarker for Earlier Sepsis Identification and Treatment: A Counterfactual Analysis. Critical Care Explorations 1(8):p e0029, August 2019. | DOI: 10.1097/CCE.0000000000000029; Basol, Roberta and Burris, Jennifer, "SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock" (2016). Nursing Posters. 74. https://digitalcommons.centracare.com/nursing_posters/74.
[18] Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA 2009;302(10):1059-1066.
[19] Martinez-Gonzalez NA, Keizer E, Plate A, et al. Point-of-care C-reactive protein testing to reduce antibiotic prescribing for respiratory tract infections in primary care: systematic review and meta-analysis of randomized controlled trials. Antibiotics 2020;16(9):610.

packaged into the payment for other services furnished during a hospital outpatient encounter.

Proposed Solution

We respectfully request that **CMS create a new exception from the OPPS packaging rules for clinical diagnostic laboratory tests that accurately and reliably distinguish acute bacterial infections from viral infections to support proper use of antimicrobial therapy (as evidenced either by FDA-approved/cleared labeling or publications in peer-reviewed literature) including (but not limited to) the following tests: (i) MeMed BV (0351U), (ii) Monocyte distribution width (0427U), (iii) Interleukin-6 (83529), (iv) Procalcitonin (84145), (v) C-reactive protein (86140), and (vi) C-reactive protein; high sensitivity (86141).**

Excluding these types of tests from the OPPS packaging rules advances public health and is consistent with the rationale for CMS's previous exceptions to OPPS packaging rules. Historically, CMS has paid separately for clinical diagnostic laboratory test services furnished to hospital outpatients when required to address concerns that the "usual" packaging rules would limit appropriate (and clinically desirable) utilization. For example, Medicare has historically excluded preventive testing services from bundling due to the significant benefit of such testing, both from an individual patient management perspective and a broader public health perspective. Like preventive testing services, the usual bundling policies may impose roadblocks to the adoption of clinically desirable testing to facilitate appropriate utilization of antibiotics. As such, creating an exception for such tests from the OPPS packaging rules would be an appropriate response from CMS and consistent with its past precedent.

b. Request for Exemption for Recommended Screening Tests

As noted above, CMS has historically exempted recommended screening services from its usual OPPS packaging rules for laboratory services. Specifically, in the CY 2015 OPPS Final Rule, CMS announced that preventive services as defined in 42 C.F.R. § 410.2 would be excluded from the OPPS packaging rules to "encourage the provision of preventive services and provide maximum flexibility to beneficiaries across different sites of service in receiving preventive services."[20]

Typically, CMS has implemented this policy by assigning OPPS status indicator "A" to HCPCS G-codes created to report associated screening tests. (For example, CMS recently created a new HCPCS code – G0567 – to facilitate reporting for Hepatitis C screening services.) However, certain recommended screening services lack assigned G-codes and

[20] 79 Fed. Reg. 66,800-66,801 (Nov. 10, 2014).

the established Category I CPT codes that would otherwise be appropriate to report these services are packaged (assigned status indicator of "Q4").

For example, the United States Preventive Services Task Force (USPSTF) currently recommends chlamydia and gonorrhea screening for all sexually active women aged 24 years or younger, and in women aged 25 years or older who are at increased risk.[21] However, these tests have not been assigned a HCPCS G-code, and the existing Category I CPT codes for such services (87491, 87591) continue to be assigned OPPS status indicator "Q4". As a result, CMS is only "encouraging the provision" of *certain* recommended preventive services, undermining CMS's policy goal of preserving beneficiary access to preventive services regardless of the location where patients seek care.

Proposed Solution

To ensure beneficiaries have access to recommended screening services and providers are not financially disincentivized from providing such screening services, we respectfully request that CMS:

(1) **Add the CPT codes for chlamydia and gonorrhea testing (87491, 87591, and 8XXX2[22]) to the list of qualifying, USPSTF-recommended preventive services excluded from OPPS packaging rules by assigning these codes OPPS status indicator "A".** This change would be consistent with CMS's historical practice of unpackaging similarly supported screening tests and help ensure that Medicare beneficiaries have access to important, USPSTF-recommended screening services.

(2) **Confirm that the new G-code for Hepatitis C screening (G0567) will be assigned an OPPS status indicator of "A".** Assigning "A" status would be fully consistent with CMS precedent for other "screening" G-codes, such as G0472 (hepatitis c antibody), G0475 (HIV antigen/antibody), G0476 (HPV co-testing), G0499 (Hep B screening)).

(3) **Expedite revision of existing NCDs and/or creation of new NCDs to bring Medicare coverage policies in alignment with current USPSTF**

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[21] United States Preventive Services Task Force, Chlamydia and Gonorrhea: Screening (Sept. 14, 2021), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/chlamydia-and-gonorrhea-screening.

[22] Effective January 1, 2026, the CPT Editorial Panel created new a CPT code for multiplex amplified probe testing for chlamydia and gonorrhea. This code is temporarily assigned placeholder 8XXX2, and will be assigned a permanent code number when the AMA publishes *CPT 2026* later this year. For more information, please see CPT Editorial Panel Summary of Panel Actions (May 2025), https://www.ama-assn.org/system/files/may-2025-summary-of-panel-actions.pdf.

recommendations. Though perhaps outside the scope of what CMS traditionally addresses in the MPFS and OPPS rules, we encourage CMS to expedite its efforts to bring NCDs for screening services into alignment with USPSTF recommendations. In certain cases (e.g., for cervical cancer screening, last updated in 2018), several years have passed since USPSTF finalized a favorable recommendations without CMS issuing a draft NCD that would give Medicare beneficiaries coverage consistent with the updated recommendation. We understand the Social Security Act contemplates that CMS will follow the usual NCD process after USPSTF issues a favorable recommendation, and that this process typically takes 9-12 months once CMS decides to take up a new topic. Nevertheless, we encourage CMS to take all appropriate steps to assure NCDs are updated to provide Medicare beneficiaries with access to USPSTF-recommended services as quickly as possible, including considering its authority to issue updates outside the usual NCD reconsideration process (such as through rulemaking).

2. **Request to Extend the Transitional Pass-Through Payment Program Under OPPS to Allow Diagnostic Laboratory Tests to be Eligible**

Both the Inpatient Prospective Payment System (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 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 – i.e., to delete the "surgically implanted or inserted" requirement**.** The "surgically implanted or inserted" requirement is not mandated by the statutory framework authorizing transitional pass-through payments for

devices,[23] so CMS could accomplish by removing the above referenced requirement from the relevant regulation[24] – potentially via interim final rule (IFR) on which CMS seeks comments. Making this change would put clinical diagnostic laboratory tests on an equal footing with devices that are "implanted or inserted…"

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Thank you for your consideration of our comments. 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

[23] Soc. Sec. Act § 1833(t)(6)(A)(iv).
[24] 42 C.F.R. § 419.66(b)(3).