POCTA
POINT OF CARE TESTING ASSOCIATION

August 31, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Re: CMS-4203-NC— Medicare Program; Request for Information on Medicare

Dear Administrator Brooks-LaSure:

On behalf of the Point of Care Testing Association (POCTA), I am pleased to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS's or Agency's) August 1, 2022 Request for Information (RFI) regarding ways to strengthen the Medicare Advantage (MA) program.[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.

In response to the RFI, POCTA offers the following comments for the Agency's consideration. POCTA's comments specifically address issues concerning health equity (i.e., questions A.2 and A.3) and expanded access to care (i.e., question B.6). For ease of reference, the applicable RFI questions are reproduced in bold with POCTA's comments below:

Health Equity

A.2. What are examples of policies, programs, and innovations that can advance health equity in MA? How could CMS support the development and/or expansion of these efforts and what data could better inform this work?

To advance health equity, CMS should consider enhancing and protecting MA beneficiary access to POC testing.

POC testing provides information to clinicians in real time with levels of sensitivity and specificity that are appropriate for patient management. POC tests are needed to timely diagnose

[1] CMS, U.S. Department of Health and Human (HHS), *Request for Information – Medicare Program; Request for Information on Medicare*, 87 Fed. Reg. 46918 (Aug. 1, 2022).

diseases or monitor conditions when rapid turnaround is important (e.g., when managing contagious or rapidly evolving conditions) to reduce treatment time and cost, and to reach the best outcome for the patient.

When providers are required to outsource testing and wait for results, patients will be denied or delayed access to medically necessary care. Further, in instances in which providers are working hard to manage infectious diseases, such as COVID-19, real time results have a direct impact on the recommendation and implementation of appropriate infection control measures. POC testing allows providers make important treatment decisions in real time based on test results.

The quality of POC testing is supported by the appropriate level of certification required under the Clinical Laboratory Improvement Amendments (CLIA) for the type of testing performed. Many POC labs operate under a CLIA Certificate of Waiver, which allows them to perform "waived" tests – i.e., tests that FDA has determined are simple laboratory examinations and that have an insignificant risk of an erroneous result, or that have been approved for home use. For those tests that are not "waived,", CLIA certification as a non-waived laboratory and requirements for proficiency testing and inspection as a non-waived laboratory ensure the quality of testing.

While widespread adoption of POC testing in primary care and other settings is not without challenges, studies show that there is general agreement that POC testing can increase diagnostic certainty, result in more efficient care and fewer additional office visits.[2] Such outcomes should result in a healthier patient population and lower overall treatment costs. Given the transportation and economic barriers that underserved and vulnerable populations often face when seeking care,[3] CMS should implement policies that make it easier for such groups to receive care informed by reliable diagnostic technologies, and ensure that MA plans do not impose unnecessary barriers to access.

Notwithstanding the above, certain MA plans impose significant restrictions on the types of tests that may be performed in a physician office laboratory or other POC settings, and only give beneficiaries access to a fraction of the tests that may lawfully be performed at such laboratories. For example, some MA policies do not permit POC settings and laboratories to perform critical testing for COVID-19, influenza A/B, and other infectious illnesses or even routine testing, such as glucose.

POCTA understands and acknowledges that the MA program gives MA plans a financial incentive to deliver care in the most cost-effective manner possible. However, policies that expand access to POC testing support improved health outcomes and may generate efficiencies within the larger health care system.

In light of the above, POCTA respectfully recommends that CMS:

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[2] *See* Jones, Caroline H. D. et al., *Primary care clinicians' attitudes towards point-of-care blood testing: a systematic review of qualitative studies*, 14 BMC FAM. PRAC. 117 (Aug. 14, 2013), doi:10.1186/1471-2296-14-117.
[3] Syed ST, Gerber BS, Sharp LK, *Traveling towards disease: transportation barriers to health care access* 8(5) J COMMUNITY HEALTH 976-93 (Oct. 2013) (doi: 10.1007/s10900-013-9681-1. PMID: 23543372; PMCID: PMC4265215).

- Require MA plans with existing policies that unduly restrict beneficiary access to POC testing in a variety of settings to modify such policies;
- Instruct MA plans that CMS's annual assessment of MA plan proposals will include an assessment of the adequacy of beneficiary access to POC testing services in a variety of setting; and
- Monitor MA plan policies to ensure continued, medically-appropriate access to POC testing.

In addition to its efforts to expand access to POC testing in settings that are decentralized (e.g., clinics, urgent care facilities) and non-traditional (e.g., community centers or shelters affiliated with providers), POCTA suggests that CMS allow MA plans to cover additional diagnosis and treatment services offered by pharmacists, which would expand MA enrollee access to fast and convenient health services. During the COVID-19 PHE in particular, pharmacists have proven to be an invaluable source of care for individuals across the country by offering COVID-19 diagnosis and treatment services in a single location. After the PHE ends, however, it is critical to ensure that Medicare beneficiaries maintain access to services in the pharmacy setting, particularly in underserved communities where access issues such as transportation and lack of regular physician services make traditional paradigms of care more difficult or impossible.

The COVID-related services offered during the PHE build on other critical services offered by pharmacies in more than 40 states, including POC testing for HIV, hepatitis C, flu, streptococcus pharyngitis (strep throat), and tuberculosis. By offering prompt diagnosis and treatment in a single, convenient location, local pharmacies can enable individuals to start treatment regimens without delay, which may reduce the duration, severity, and cost of an illness. Expanded access to diagnostic testing also ultimately could reduce health care costs by promoting use of a lower-cost site of care, encouraging earlier testing and treatment, limiting exposure associated with travel to distant sites, and preventing unnecessary hospitalizations due to delayed medical intervention.

Encouraging MA plans to incorporate appropriate testing and treating in the neighborhood pharmacy setting would help address health disparities in medically underserved communities. CMS recently noted that transportation issues and workforce challenges are "known factors that impede efficient and equitable healthcare." A recent study determined that more than 90% of Americans live within 5 miles of a pharmacy, and "[c]ommunity pharmacies are highly accessible healthcare locations for the majority of the U.S. population." Pharmacies generally have extended, flexible hours, enabling individuals to access care outside of work hours. They also offer an additional site of services for communities adversely impacted by rural or urban hospital closures.

We therefore recommend that CMS work with MAOs to offer diagnosis and treatment services in the pharmacy setting as a way to support MA benefit design and care delivery innovations to achieve convenient, equitable health care.

Furthermore, in order to promote enrollee access to convenient diagnostic tests, we encourage CMS to review MA reimbursement for POC testing. Pharmacies and other providers have informed us that that low MA payment relative to Medicare FFS rates is the primary barrier to

offering POC tests. We therefore recommend that CMS conduct a study of MA payment rates to understand the extent to which insufficient reimbursement creates a financial burden that limits access of MA enrollees, including the most vulnerable populations, to POC tests.

A.3. What are effective approaches in MA for screening, documenting, and furnishing health care informed by social determinants of health (SDOH)?[4] Where are there gaps in health outcomes, quality, or access to providers and health care services due partially or fully to SDOH, and how might they be addressed? How could CMS, within the scope of applicable law, drive innovation and accountability to enable health care that is informed by SDOH?

While socioeconomic factors often influence patients' ability to access high-quality care, increased access to POC testing at both traditional and non-traditional sites (e.g., community centers or shelters affiliated with providers) may help close such gaps. POC testing "can improve health care provision in settings with limited access to health care services."[5] In "resource-constrained settings," POC is crucial,[6] as it allows providers to obtain actionable information to treat patients who do not have the resources to travel to multiple appointments or testing laboratories. Indeed, "the availability of a test or onsite provision . . . during a single [visit] is of importance to save patients from having to return for results, transportation costs, and loss to follow-up."[7]

Therefore, consistent with our previous recommendations, POCTA respectfully recommends that CMS:

- Require MA plans with existing policies that unduly restrict beneficiary access to POC testing in a variety of settings to modify such policies;
- Instruct MA plans that CMS's annual assessment of MA plan proposals will include an assessment of the adequacy of beneficiary access to POC testing services in a variety of settings; and
- Monitor MA plan policies to ensure continued, medically-appropriate access to POC testing.

Expanded Access

B.6. What factors do MA plans consider when determining whether to make changes to their networks? How could current network adequacy requirements be updated to further support enrollee access to primary care, behavioral health services, and a wide range of specialty services? Are there access requirements from other federal health insurance

[4] CMS defines social determinants of health (SDOH) as ''the conditions in the environments where people are born, live learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.'' Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, https:// health.gov/healthypeople/priority-areas/socialdeterminants-health.
[5] Katoba J, Kuupiel D, Mashamba-Thompson TP, *Toward Improving Accessibility of Point-of-Care Diagnostic Services for Maternal and Child Health in Low- and Middle-Income Countries* 18(1) POINT CARE 17-25 (Mar. 2019) (doi: 10.1097/POC.0000000000000180. Epub 2019 Mar 5. PMID: 30886544; PMCID: PMC6407818).
[6] *Id.* at 21.
[7] *Id.* at 19.

options, such as Medicaid or the Affordable Care Act Marketplaces, with which MA could better align?

While the *Managed Care Manual* provides that MA plans have "considerable discretion" to select providers and make changes to providers to build "high-performing, cost effective provider networks," they must "continue to furnish *all Medicare-covered services* in a non-discriminatory manner, meet established access and availability standards and timely notice requirements, and ensure continuity of care for enrollees."[8] As discussed above, though, certain MA plans restrict coverage for clinical laboratory testing services performed at the POC, notwithstanding the fact that such tests may be performed accurately and safely at the POC.

We urge CMS to update its network adequacy requirements to specifically assure that MA plan beneficiaries have clinically appropriate access to POC testing in a variety of settings. Evaluating plans on this basis would be consistent with existing requirement that a "network-based MA plan . . . must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards," including the "community pattern of health care delivery in the areas where the network is being offered."[9]

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If you have any questions regarding this correspondence, please contact Mike Ryan, Reimbursement Counsel to POCTA, at 202.756.8088, or via e-mail to mryan@mwe.com.

Sincerely yours,

Mike Ryan
(on behalf of) Point of Care Testing Association

[8] CMS, Publication 100-16: *Medicare Managed Care Manual*, Chapter 4, § 110.1.2.1. Emphasis added.
[9] 42 C.F.R. §§ 422.112(a)(10); 422.116(a)(1)(i). *See* 42 C.F.R. § 422.114(a); *see also* CMS, *Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance* (updated Mar. 4, 2022), *available at* https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance03042022.pdf.