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August 30, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via regulations.gov

Re: 87 FR 46918 – Medicare Program; Request for Information on Medicare [CMS-4203-NC]

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its Request for Information (RFI) regarding Medicare Advantage (MA), published in the Federal Register on August 1, 2022.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

It is important to acknowledge the existence of disparities in health care based on factors such as race, ethnicity, gender and gender identity, limited English proficiency, disability, and geographical location. Additionally, social determinants of health (SDOH), such as income, education, employment, food insecurity, housing, transportation, and access to quality health care services, can have a significant impact on health outcomes.[1] As a leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and reducing health

[1] University of Wisconsin Population Health Institute. "County Health Rankings Model," 2014, https://www.countyhealthrankings.org/explore-health-rankings/measures-data-sources/county-health-rankings-model. Accessed Aug. 18, 2022.
See also World Health Organization. "Social determinants of health," 2022. https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1. Accessed Aug. 18, 2022.

disparities, AMCP is a vocal advocate for health equity,[2] focuses on the need to address health disparities in medication use as an ongoing strategic priority,[3] and is leading the conversation on value-based contracting.[4]

AMCP commends CMS on its ongoing efforts, through programs like the Part D Senior Savings Model and Value-Based Insurance Design (VBID) model, to provide health plans with the opportunity to innovate while maintaining the flexibility needed to address the disparate needs of each plan's specific demographics and encourages CMS to make the outcomes from these programs more publicly available. AMCP appreciates the opportunity to leverage our members' expertise in offering feedback on this RFI.

Advance Health Equity

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?

AMCP recommends that CMS implement solutions to advance health equity in MA, including standardizing the collection and sharing of data to identify and analyze disparities, addressing health equity in formulary development, addressing disparities in MTM eligibility, expanding access to the Low-Income Subsidy (LIS), and incentivizing mail order pharmacy to address disparities caused by geographical proximity to a pharmacy as well as racial disparities in medication adherence. Additionally, CMS should make allowances for co-pay assistance programs for needed prescriptions as part of supplemental benefits to fundamentally enhance the adherence rates of historically marginalized communities.

Standardizing Data Collection

CMS should adopt policies that incentivize the collection of health equity data and expand the use of data collection tools within MA. Gathering data is central to identifying gaps in access to care and analyzing the causes of such gaps. However, current data collection efforts are hampered by a lack of granularity and standardization, leading to incomplete data and raising concerns about accurately identifying and measuring disparities in care.[5] Greater use of "z-codes," a set of ICD-10 diagnosis

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[2] On June 9, 2022, AMCP brought experts together for a Health Disparities summit, https://www.amcp.org/education-meetings/events-meetings-webinars/amcp-summit-addressing-health-disparities, and prior to that, in 2021, AMCP held a Partnership Forum, "Racial Health Disparities: A Closer Look at Benefit Design," which brought together managed care experts to identify structural issues in prescription drug formulary and benefit design processes and propose concrete solutions to reduce racial health disparities, https://www.amcp.org/sites/default/files/2021-04/AMCP%20PF%20ExecSumm%200421_6.pdf.

[3] https://www.amcp.org/about/about-amcp/amcp-strategic-priorities

[4] https://www.amcp.org/resource-center/value-based-contracts/value-based-contracts-resources. AMCP's Public Policy and Professional Practice committees also developed a set of pay-for performance principles which provide unique insight into value-based contracting for managed care pharmacy: https://www.amcp.org/sites/default/files/2022-05/PayforPerformance_Apr2022.pdf

[5] NCQA Issue Brief, "Health Equity and Social Determinants of Health in HEDIS: Data for Measurement," June 2021. https://www.ncqa.org/wp-content/uploads/2021/06/20210622_NCQA_Health_Equity_Social_Determinants_of_Health_in_HEDIS.pdf. Accessed August 18, 2022.

codes related to SDOH, should also be incentivized.[6] Increasing the use of z-codes by health care providers will help with identification of the root causes of disparities and will increase the available data to be used for analysis.

Additionally, CMS should define a consistent set of data elements to ensure that stakeholders are collecting the same type of data. CMS should also incentivize the sharing of health equity data among social service agencies, health plans, and community-based providers to allow for more accurate identification and management of disparities. Incentives could include subsidies to local, regional, or state health information exchanges that deliver provider-collected data to health plans and other partners.

Formulary Development

Formulary development is another area where health equity should be explored to ensure that gaps in access to prescription drugs are addressed. A pharmacy and therapeutics committee (P&T committee) is responsible for developing, managing, updating, and administering a health plan's formulary. The P&T committee also designs and implements formulary system policies on utilization and access to medications. It is important to recognize that biases may be unintentionally built into current algorithms and artificial intelligence platforms.[7]

AMCP recommends that CMS consider policies to address health disparities within the formulary process, including incentivizing:

- P&T committee representation by a member with expertise in health equity or a subcommittee to evaluate equity in the formulary decision process;
- review of medications by type and adherence-rates using available race or ethnicity data; and
- adjustments of cost-sharing models for disease states where minority or other at-risk populations are disproportionally affected.

Addressing Disparities in MTM Eligibility

AMCP urges CMS to address disparities in medication therapy management (MTM) by expanding eligibility criteria. This could include lower-income populations as well as individuals with certain disease states.

MTM is a patient-centered program that optimizes health outcomes. MTM promotes collaboration between the patient and their health care team while encouraging medication adherence. Under existing eligibility criteria, a beneficiary must have at least two to three chronic conditions; be taking two to eight Part D drugs; and be expected to incur annual drug costs of $4,935 (for 2023).[8]

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[6] Shulte, A.S., Donova, A.L., McAdam-Marx, C., From Access to Equity: The Devil is in 'Z' Details, J Manag Care Spec Pharm, 2022 Jun;28(6):685-687. https://www.jmcp.org/doi/full/10.18553/jmcp.2022.28.6.685?mobileUi=0. Accessed Aug. 23. 2022.

[7] https://www.amcp.org/sites/default/files/2021-09/AMCPHealthDisparitiesPartnershipForumWebinarSep2021.pdf

[8] 42 C.F.R. 423.153(d)(2)(i). Because the annual drug cost threshold increases annually, there is a potential for further widening of disparities relating to MTM eligibility. See 42 C.F.R. 423.153(d)(2)(i)(C)(2) and § 423.104(d)(5)(iv).

Alternative methodologies can be used to expand MTM eligibility in targeted ways. For example, CMS expanded eligibility for MTM to include at-risk-beneficiaries (ARBs), regardless of whether those beneficiaries meet other MTM eligibility criteria.[9]

CMS should consider implementing additional alternative criteria that would expand MTM to include beneficiaries below a certain income threshold or who have specific disease states that are more common in certain populations (e.g., sickle cell disease,[10] hypertension,[11] diabetes,[12] etc.). Racial and ethnic minorities have historically used fewer prescriptions and have lower drug costs[13] and may therefore be less likely to meet the MTM eligibility criteria. However, by expanding eligibility based on conditions with higher prevalence rates in marginalized populations, regardless of co-morbid status, MTM could better serve these groups.

Removing Barriers to Enrollment in the Low-Income Subsidy

CMS should reduce barriers to LIS enrollment for eligible MA-PD beneficiaries by offering additional opportunities for automatic enrollment or additional assistance with the enrollment process. CMS should also consider using available data sources such as SSA records, tax records, or enrollment data from other federal programs for low-income individuals to identify LIS-eligible, but not enrolled, MA-PD beneficiaries.

Enrollees who qualify for full Medicaid benefits (dual eligibles), enrollees in Medicare Savings Programs, and individuals receiving Supplemental Security Income are automatically enrolled in the LIS program. Other eligible beneficiaries must apply through either the Social Security Administration or their state Medicaid program. Eligibility for the LIS is based on an enrollee's income and assets. Beneficiaries enrolled in the LIS receive subsidies for the monthly Part D premium, deductibles, and expenses in the Part D coverage gap and pay lower, statutorily set, copayments for formulary drugs. These subsidies lower cost barriers, increasing access to needed prescription drugs and encouraging medication adherence. The recent Inflation Reduction Act

[9] 42 C.F.R. 423.100 and 42 C.F.R. 423.153(f) (relating to individuals at-risk for misuse or abuse of frequently abused drugs). *See also* CMS Contract Year 2022 Part D Medication Therapy Management Program Guidance and Submission Instructions, April 20, 2021. https://www.cms.gov/files/document/memo-contract-year-2022-medication-therapy-management-mtm-program-submission-v-043021.pdf. Accessed Aug. 26. 2022.
[10] CDC Data & Statistics on Sickle Cell Disease, https://www.cdc.gov/ncbddd/sicklecell/data.html. Accessed Aug. 26, 2022.
[11] Centers for Disease Control and Prevention. Hypertension Cascade: Hypertension Prevalence, Treatment and Control Estimates Among U.S. Adults Aged 18 Years and Older Applying the Criteria from the American College of Cardiology and American Heart Association's 2017 Hypertension Guideline—NHANES 2015–2018. Atlanta, GA: U.S. Department of Health and Human Services; 2021. https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html. Accessed Aug. 26, 2022.
[12] Spanakis, E.K., Golden, S.H., Race/Ethnic Difference in Diabetes and Diabetic Complications. Curr Diab Rep. 2013 December ; 13(6). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3830901/pdf/nihms-524798.pdf. Accessed Aug. 26, 2022.
[13] Spivy, C.A, Wang, J., Qiao, Y. et al, Racial and Ethnic Disparities in Meeting Medication Therapy Management Eligibility Criteria Based on Star Ratings Compared to the Medicare Modernization Act, 2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5793919/. Accessed Aug. 17, 2022.

expands eligibility for full benefits to those who earn between 135% and 150% of the federal poverty level.[14]

Although Part D enrollment is generally high, research has shown that minority enrollment, in particular Hispanic enrollment, is significantly lower than in the white population. A study found that Hispanic beneficiaries are 35% less likely than non-Hispanic whites to have Part D coverage and, further, that this disparity is driven in part by those individuals eligible for the LIS program but not automatically enrolled.[15] Beyond this racial disparity, enrollment of LIS-eligible beneficiaries who are not automatically enrolled is low overall, with some evidence that enrollment rates for this population are as low as only 30%.[16]

For this reason, AMCP recommends that CMS consider expanding automatic enrollment to include low-income MA-PD beneficiaries who are enrolled in other federal programs and offering additional assistance with the enrollment process.

Mail Order Pharmacy

CMS should also consider adopting policies that incentivize MA plans to address barriers to the expanded use of mail order pharmacies.

An estimated 100 million Americans live in pharmacy deserts.[17] Mail order pharmacies can often address disparities caused by this lack of access to a local pharmacy. Mail order pharmacies also reduce racial disparities in patient medication adherence, increase patient safety, meet the rising consumer demands for medication delivery, improve access to specialty medications, and maintain the affordability of the prescription drug benefit.[18]

Despite this, not everyone is able to receive medications by mail.[19] The barriers to receiving medications by mail include a wide variety of situations such as living in an apartment where packages are not able to be delivered securely, privacy concerns when a third party may have access to the mail, or housing insecurity where the individual is without a reliable location to receive mail. Health plans and the mail order pharmacies in their preferred provider networks should be

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[14] Inflation Reduction Act of 2022, H.R. 5376 117th Cong. § 11404 (2022).
[15] Federal Evaluation of Montana Health and Economic Livelihood Partnership (HELP): Draft Interim Evaluation Report, July 22, 2019, https://www.medicaid.gov/medicaid/downloads/mt-fed-eval-draft-interim-eval-rpt.pdf. Accessed Aug. 17, 2022.
[16] Shoemaker, J.S., Davidoff, A.J., Stuart, B. et al, Eligibility and Take-up of the Medicare Part D Low-Income Subsidy, Fall 2012 https://journals.sagepub.com/doi/pdf/10.5034/inquiryjrnl_49.03.04. Accessed Aug. 17, 2022.
[17] Sobeski, L.M., Schumacher, C.M., Alvarez, N.A. et al. ACCP WHITE PAPER Medication Access: Policy and Practice Opportunities for Pharmacists, 2020, p. 22. https://www.accp.com/docs/positions/White_Papers/Sobeski_White_Paper_on_Medication_Access_FINAL.pdf. Accessed Aug. 18, 2022.
See also Gebhart F. The growing problem of pharmacy deserts. Drug Top 2019; 163:1–4. https://www.drugtopics.com/view/growing-problem-pharmacy-deserts. Accessed Aug. 18, 2022.
[18] https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/mail-service-pharmacies
[19] Schmittdiel, J.A., Marshall, C.J., Wiley, D. *et al.* Opportunities to encourage mail order pharmacy delivery service use for diabetes prescriptions: a qualitative study. *BMC Health Serv Res* 19, 422 (2019). https://doi.org/10.1186/s12913-019-4250-7. Accessed Aug. 26, 2022.

incentivized to find innovative ways to broaden access to mail order prescriptions,[20] meeting people where they are, or investing in other alternative delivery/dispensing methods to ensure prescription access for all.

Drive Innovation to Promote Person-Centered Care

What steps within CMS's statutory or administrative authority could CMS take to support more value-based contracting in the MA market? How should CMS support more MA accountable care arrangements in rural areas?

Standardized performance measures

AMCP encourages CMS to adopt a core set of standardized pharmacy performance measures based on consensus and input from pharmacy providers, pharmacy benefit managers, health plans, and other pharmacy stakeholders, while allowing plan sponsors the flexibility to utilize additional measures that are reported to CMS. Limited interoperability across multiple sources limits the ability to use data analytics necessary to support coordinated care.[21]

Pharmacy performance measures should be specific to the type of pharmacy, such as retail, specialty, mail order, or long-term care pharmacies, and the patient populations they serve. Measures that are developed for one type of pharmacy may not be relevant for another. For example, measures developed for retail pharmacies that serve a broad population are often a poor fit to evaluate specialty pharmacies that serve those with specific health conditions, such as end-stage renal disease (ESRD), cystic fibrosis, or multiple sclerosis.

Once standardized pharmacy performance measures have been developed and implemented, the uptake of such measures could be incorporated, through notice-and-comment rulemaking, into CMS's Star Ratings program. It is important to note that pharmacies generally support standardized performance measures in large part because of the challenges associated with meeting inconsistent, duplicative, and often opaque criteria imposed by various health plans.

In developing these measures, CMS should consider the role that socioeconomic disparities can play in measuring pharmacy performance. Because pharmacies are in a variety of geographic regions with vastly different health indicators, head-to-head measurement of unlike populations may disadvantage a pharmacy that serves, for example, a disproportionate share of individuals living below the federal poverty level. Benchmarking against such differences to produce a fair and equitable accounting of actual performance will be critical in creating a just pharmacy performance measurement system.

[20] For example, package delivery services such as Amazon, UPS, and Fed-Ex often use self-service lockers or staffed counters to allow recipients to pick up deliveries without worrying about their package being stolen or when there is not a reliable physical address at which to deliver a package.

[21] AMCP Partnership Forum: Integrated Delivery Networks' Role in Pharmaceutical Value-Based Agreements. J Manag Care Spec Pharm. 2019;25(5):526–531. https://www.jmcp.org/doi/full/10.18553/jmcp.2019.25.5.526?mobileUi=0. Accessed Aug. 26, 2022.

Unifying language

Value-based purchasing agreements are increasingly being used, as nearly one in two health plans entered into at least one agreement in recent years.[22] However, many discussions do not result in finalized contracts.[23] Among the reasons for this is the absence of a common framework for discussion and design of value-based contracts and alternative payment models.[24]

AMCP determined that a common, unified language would facilitate discussions and lead to greater use of value-based purchasing agreements. AMCP developed a Lexicon to assist payers, provider systems, and manufacturers in discussing and designing value-based contracts.[25] AMCP encourages CMS to publish guidance aligned with the idea that language helps expedite negotiations and encourages stakeholders to adopt new approaches.

AMCP appreciates the opportunity to comment. We are committed to be being a valuable resource to CMS for improving access to prescription drugs at lower costs and reducing costs in the health care system for Medicare beneficiaries. If you have any questions regarding AMCP's comments or would like further information, please contact Geni Tunstall at etunstall@amcp.org or (703) 705-9358.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

[22] Avalere. Over Half of Health Plans Use Outcomes-Based Contracts. November 4, 2021. Available at: https://avalere.com/insights/avalere-survey-over-half-of-health-plans-use-outcomes-based-contracts. Accessed on Aug. 19, 2022.
[23] Mahendraratnam N, Sorenson C, Richardson E, Daniel GW, Buelt L, Westrich K, et al. Value-based Arrangements May be More Prevalent Than Assumed. Am J Manag Care. 2019; 25(2):70–76.
[24] AMCP Partnership Forum: Integrated Delivery Networks' Role in Pharmaceutical Value-Based Agreements. J Manag Care Spec Pharm. 2019;25(5):526–531.
[25] https://www.amcp.org/sites/default/files/2022-08/VBCLexicon_0726.pdf