1700 Pennsylvania Avenue, NW,
Suite 200 | Washington, DC 20006

202.827.9987

March 4, 2022

Via Electronic Submission

The Honorable Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-2022-0021
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Dear Director Seshamani:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the Part D provisions of the 2023 CMS Call Letter entitled, "Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies" (the "Call Letter" or the "Proposal"), CMS 2022-0021. SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 80% of all independent LTC pharmacies and our members serve one million residents daily in skilled nursing facilities and assisted living communities across the country.[1] Given the distinct characteristics of the LTC patient population and the enhanced clinical responsibilities of LTC pharmacies, we offer unique perspectives on CMS' initiatives and proposals, and particularly how Medicare Prescription Drug Benefit ("Part D") policies and requirements impact the pharmacy community.

In brief, our comments address CMS' proposed use pharmacy quality metrics to evaluate Medicare Prescription Drug Plans (PDPs). PDPs are insurance companies not pharmacies, and their performance should be evaluated using criteria relevant to the manner in which Part D beneficiaries evaluate insurance companies providing drug coverage, not pharmacies providing prescription drugs and related services. Our comments also address CMS' proposed use of Pharmacy Quality Alliance (PQA) pharmacy quality measures as a component of the Star Rating metrics without appropriate qualification and without metrics specific to the LTC patient population. We are concerned that the use of PQA Measures inadvertently could skew evaluation of LTC pharmacy quality, unintentionally mislead LTC patients in selecting a LTC pharmacy and unjustifiably

[1] This estimate is based on pre-pandemic facility occupancy rates.

empower Part D Plans (PDPs) and the pharmacy benefit managers (PBMs) that administer PDPs to penalize LTC pharmacies based on inaccurate quality assessments. We also are concerned that use of the proposed opioid utilization measures in determining Star Ratings for PDPs risks undermining the quality of care for LTC patients because those measures are inappropriate to the LTC patient population due to substantially different clinical needs. Specifically:

CMS Should Not Use Pharmacy Quality Metrics to Rate PDPs. The Advance Notice discussed the use of PQA quality metrics to evaluate the comparative performance of PDPs as part of the Part D Star Rating system, and proposes changes to the process. While SCPC applauds CMS' commitment to developing quality metrics through a stakeholder process or independent, third-party organization like PQA, and to assuring that pharmacy metrics meet additional criteria to assure better patient outcomes, we continue to believe use of pharmacy quality metrics to evaluate comparative quality of PDPs is inappropriate. PDPs are insurance companies. They are not health care providers and do not directly provide prescription drugs or pharmacy services to Part D beneficiaries. Information concerning the comparative quality of pharmacies in each PDP's pharmacy network is not a reasonable metric by which consumers would evaluate PDP performance as an insurance company, particularly given that many pharmacies in any given market participate in multiple and competing Part D networks. Indeed, since many PDPs offer competing plans within individual markets, each PDP likely offers multiple networks which include the same pharmacy.

Assuming that PDPs properly employ pharmacy quality metrics across plans, pharmacy quality metrics offer no useful information by which consumers could differentiate the comparative quality of PDPs. If different PDPs evaluate the same pharmacy differently, the comparative information undoubtedly would be even more confusing to consumers. Data points such as the frequency of coverage denials, the frequency by which prior authorizations are employed, the repeated use of step therapy over multiple plan years, the comparative out-of-pocket costs for consumers and enrollee satisfaction rates would be much more relevant to consumers in evaluating the comparative quality of PDPs, and we urge CMS to consider such metrics for ratings of PDPs. Unfortunately, CMS does not propose to use such data.

CMS Should Require that PDPs Use Quality Metrics to Evaluate Pharmacies Consistent with Specific Criteria. SCPC urges CMS not to use pharmacy quality metrics, whether developed by PQA, a similar organization, or a consensus stakeholder process as part of the Star Rating process for PDPs. Rather, we recommend that CMS establish criteria PDPs must use to evaluate the comparative quality of pharmacies participating in Part D networks and create metrics to evaluate PDPs regarding the degree to which PDPs satisfy those requirements. We also

recommend that CMS develop criteria more relevant to comparison of insurance plans for Star Rating purposes.

SCPC endorses use of appropriate quality metrics to evaluate the comparative performance of pharmacies participating in Part D networks. Appropriate metrics should meet the following criteria:

- The metrics have been developed by an independent, third-party organization like PQA or through a consensus stakeholder process;
- The metrics have been independently validated;
- The metrics are reasonably related to quality outcomes for patients;
- The metrics pertain to processes, practices and procedures that are within the control of individual pharmacies;
- The metrics are unrelated to the financial performance of the PDP, the PBM with which it contracts or any corporate affiliate that provides health insurance, health care, or pharmacy services, such as affiliated retail, specialty, mail order or LTC pharmacies; and
- The metrics are specific to patient populations and care settings as appropriate.

CMS should promulgate regulations to require that PDPs use metrics consistent with these criteria to evaluate the quality of pharmacies participating in their respective networks. Such a requirement would assure consistency across PDPs and prevent use of metrics designed to financially benefit PDPs, PBMs or affiliated health insurance companies, health care providers, or pharmacies to the detriment of unaffiliated providers or pharmacies, a practice employed by at least two of the nation's three largest PBMs, each of which is part of a health care conglomerate with market-dominant positions in the PDP, PBM, retail pharmacy, mail order pharmacy, specialty pharmacy and LTC pharmacy markets.[2] As a result, consumers would have valid information relevant solely to comparative pharmacy quality to evaluate and select pharmacies.

---

[2] Today, three market-dominant conglomerates – Aetna/CVS Health, Cigna/ExpressScripts and UnitedHealth – continue to dominate the concentrated and integrated drug distribution and payment system. Their three affiliated and market-dominant PBMs, Caremark, ExpressScripts and Optum respectively – process nearly 80% of all prescriptions dispensed in America. For LTC pharmacies, these three PBMs process nearly 90% of all prescriptions. In addition to Caremark (the largest PBM in the country with 32% market share), CVS Health also owns Aetna (the third-largest health insurer in the country), CVS Retail (the largest retail chain in the country), Omnicare (the largest LTC pharmacy in the country), Coram (the largest home infusion company in the country), CVS Specialty (the largest specialty pharmacy in the country), and CVS Mail-Order (the second largest mail-order pharmacy in the country). *See* *https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html*. In addition to Optum (the third largest PBM in the country with 21% market share), UnitedHealth is the largest health insurer in the country, owns the second largest specialty pharmacy in the country and owns the third largest mail order company in the country. In addition to ExpressScripts (the second largest PBM in the country with 24% market share), Cigna/ExpressScripts also owns the largest mail-order pharmacy in the country and the third largest specialty pharmacy in the country. These vertically and horizontally integrated conglomerates raise further conflicts of interest and demonstrably result in sub-optimal outcomes for patients. Both Caremark and ExpressScripts, moreover, use a "quality metric" to compare pharmacies serving beneficiaries in assisted living communities. The higher the percentage of 90-day dispenses, the higher the purported quality and the greater the Part D reimbursement. The assisted

CMS Should Require that Quality Metrics Applicable to the LTC Patient Population Be Specifically Relevant to the LTC Patient Population Living in LTC Facilities and Settings. SCPC further urges CMS to require that pharmacy quality metrics used to evaluate LTC pharmacies be specific to the LTC patient population living in LTC facilities and settings. As CMS well knows, and as SCPC has commented repeatedly in response to prior CMS proposals, the LTC patient population is substantially different from the Medicare Part D population residing in the community. For example:

- The long-stay LTC patient population living in LTC facilities and settings is much older than the 65+ population living in the community, suffers a higher prevalence of multiple chronic conditions, impairments in activities and instrumental activities of daily living and dementia/cognitive impairments. Such medical and social complexity often limit medication alternatives due to potential adverse drug interactions and complications associated with use of certain medications in this population and may require different dosages to treat various conditions effectively.
- The typical nursing facility patient requires 8-9 prescription medications a day and averages 11-13 prescription medications per month. Medication utilization often may be higher in other LTC settings like assisted living communities, apparently due to less clinical oversight, medication management and LTC pharmacy consultative services than in nursing facilities. Such utilization rates are much higher than for the 65+ population in the community.

PQA does acknowledge that different types of pharmacies exist, including "individual outpatient pharmacies, inclusive of community (independent and chain), specialty, mail order and long-term care pharmacies."[3] However, PQA does not appear to consider the substantially greater clinical and consultative services LTC pharmacies provide as compared to pharmacies typically serving patients in the community (e.g., retail [independent and chain], specialty and mail order) and many PQA metrics are not specific to the LTC patient population or the unique characteristics of LTC pharmacies.

More importantly, the vast majority of PQA's current metrics apply to all patients regardless of age or care setting. As a result, blanket application of PQA metrics to the LTC patient population served by LTC pharmacies could skew the comparative results of such metrics, misleading

---

living population takes 9 or more prescriptions/day, suffers from some form of cognitive impairment, and receives little assistance in medication administration or supervision. For this patient population, the longer the period covered by each medication dispensing, the lower the rate at which patients take their medications properly. Thus, ***for the assisted living patient population, length of dispense is inversely related to quality.*** However, since mail-order pharmacies typically dispense in 90-day doses while LTC pharmacies typically dispense in 14-day or 28-day doses, this purported quality metric benefits the CVS and ExpressScripts mail-order pharmacies to the comparative detriment of unaffiliated LTC pharmacies and to the detriment of Part D beneficiaries.

[3] *Three New Pharmacy Performance Measures Recommended For Endorsement*, By PQA (December 18, 2019) https://www.pqaalliance.org/assets/docs/PDC-PH_Summary_2019-12-18.pdf.

consumers and potentially undermining the quality of care for Part D beneficiaries. If CMS were to include such metrics in evaluating PDPs, SCPC is especially concerned that PDPs in turn would use these metrics to evaluate and adjust payments to LTC pharmacies based on comparative "quality." Absent metrics specifically applicable to the LTC patient population in facilities and settings served by LTC pharmacies, these secondary or indirect effects would result in use of metrics that have no demonstrable relationship to quality outcomes or pharmacy performance, but that impact payments to LTC pharmacies by PDPs.

Beginning in 2019, CMS has been stratifying its quality measure analysis by age, gender, dual eligibility/LIS status, and disability status in the Medication Adherence patient safety reports to Part D sponsors. *See* Call Letter at 98-99. Curiously, CMS even calculates the proportion of days that a beneficiary stays in the inpatient settings and in a skilled nursing facility (SNF). Yet, CMS does not adjust the quality measures to accommodate for the fact that beneficiaries residing in SNFs have different needs, and should have different quality measures, than the general population.

To the extent that CMS includes the PQA metrics in the Star Rating system, we recommend that the agency: (a) modify its practices so that PQA metrics not be used to determine PDP Star Ratings vis-à-vis the LTC patient population among each PDP's beneficiaries; and (b) expressly prohibit PDPs from using PQA metrics to evaluate and compensate LTC pharmacies participating in Part D networks until metrics are designed and developed specifically to assess quality outcomes in the LTC patient population.[4] We also recommend that, rather than including such metrics in the Star Rating system, CMS modify its regulations specifying the criteria PDPs must use to develop and implement quality metrics applicable to pharmacies, including a requirement that PDPs develop and implement pharmacy quality metrics specific to the LTC patient population to evaluate LTC pharmacies participating in Part D networks.

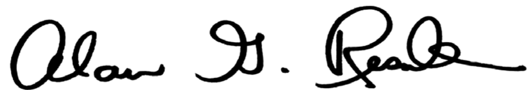
* * * * * * * * *

In conclusion, use of comparative pharmacy quality metrics to rate PDPs provides limited meaningful information to, and in some cases are misleading for, Part D beneficiaries seeking information to determine comparative quality among PDPs. Most existing pharmacy quality metrics are not specific to the LTC patient population in LTC facilities and settings, despite obvious differences between this population and the Medicare-eligible population living in the community. Consequently, we again urge CMS to not use pharmacy quality metrics to rate PDPs and should require that PDPs develop and implement pharmacy quality metrics that satisfy specific criteria, including use of metrics appropriate to the LTC patient population.

[4] We note that CMS does use one SNF-specific quality measure for Antipsychotic Use in Persons with Dementia, Overall (APD)/Antipsychotic Use in Persons with Dementia, in Long-Term Nursing Home Residents (APD-LTNH) (Part D). Draft Call Letter at 103. We urge CMS to develop other LTC pharmacy SNF specific quality measures as well.

We thank you for consideration of these comments and welcome any questions or follow up that you may have. Please feel free to contact me at arosenbloom@seniorcarepharmacies.org or (717) 503-0516 if we can provide any additional information.

Sincerely,



Alan G. Rosenbloom
President & CEO
Senior Care Pharmacy Coalition