SENIOR CARE PHARMACY COALITION

1700 PENNSYLVANIA AVENUE, NW, SUITE 200, WASHINGTON, DC 20006

March 6, 2020

Via Electronic Submission

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2020-0003
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-2020-0003: Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II

Dear Administrator Verma:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the Part D provisions of the CMS notice entitled, "Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II" (Advance Notice). SCPC is the only Washington-based organization exclusively representing the interests of LTC pharmacies. SCPC's membership includes 80% of all independent LTC pharmacies. Our members serve 850,000 residents daily in skilled nursing facilities and assisted living communities across the country. 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.

In brief, our comments 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 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 anticipated use of PQA quality metrics to evaluate the comparative performance of PDPs as

part of the Part D Star Rating system. These metrics would be incorporated into the rating system beginning in 2022. The Advance Notice appropriately acknowledges that CMS would have to propose regulations through a notice-and-comment rulemaking process before implementing this proposal.

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. The agency's commitment is reflected not only in the Advance Notice but also in recent related agency actions and proposals.

That being said, we 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 would offer no useful information by which consumers could differentiate the comparative quality of PDPs. Of course, if different PDPs evaluate the same pharmacy differently from PDP to PDP or plan to plan, the comparative information undoubtedly would be 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.

CMS Should Require that PDPs Use Quality Metrics to Evaluate Pharmacies Consistent with Specific Criteria. SCPC therefore 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 does endorse 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, 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 or pharmacies to the detriment of unaffiliated 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.[1] As a result, consumers would have valid information relevant solely to comparative pharmacy quality to evaluate and select pharmacies.

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 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:

[1] Today, three market-dominant conglomerates – Aetna/CVS Health, Cigna/ExpressScripts and UnitedHealth – dominate an increasingly concentrated and integrated drug distribution and payment system. Their three affiliated and market-dominant PBMs, Caremark, ExpressScripts and Optum respectively – process nearly 75% 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 30% 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). In addition to Optum (the second largest PBM in the country with 23% 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 23% 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 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.

- 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."[2] 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 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.

To the extent that CMS includes the PQA metrics in the Star Rating system, we recommend that the agency: (a) modify the proposal so that PQA metrics not be used to determine PDP Star Ratings vis-à-vis the LTC patient population among each PDP's beneficiaries; or (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. We also recommend that, rather than including such metrics in the Star Rating system, CMS promulgate regulations specifying the criteria PDPs must use to develop and implement quality metrics applicable to pharmacies, including a requirement that PDPs develop

[2] *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.

and implement pharmacy quality metrics specific to the LTC patient population to evaluate LTC pharmacies participating in Part D networks.

CMS Should Evaluate Opioid Utilization in LTC Facilities Differently from the General Population. CMS also proposes that Part D Star Ratings be measured against opioid utilization rates generally, including evaluation of initial prescribing rates for drugs with opioid dosage levels over 50 Morphine Milligram Equivalents (MMEs) per day. SCPC respects the reasoning behind this proposal and its applicability in the general population. This proposal offers an excellent example of the reasons the LTC patient population require assessment and evaluation distinct from the 65+ population living in the community.

First, for the reasons described above, rates of opioid utilization should not be used to evaluate comparative PDP quality, and therefore should not be included in the rating system for PDPs. Second, to the extent PDPs use opioid utilization to evaluate comparative pharmacy performance, metrics specific to the LTC patient population must be developed and employed.

The LTC patient population differs substantially from the 65+ patient population in the community, such that use of metrics developed for the population in the community would lessen the quality of care for the LTC patient population. Clinical needs in LTC facilities and settings require both more timely opioid dispensing and consistently higher therapeutic doses of opioids and other pain control prescription medications. Also, in LTC settings beneficiaries are much more likely to be opioid-resistant. Opioid resistance (or opioid tolerance) occurs when a patient no longer responds to a pain medication drug in the way that he or she initially responded, and it is not uncommon that LTC residents achieve some level of tolerance over the course of treatment, thereby requiring more than 90 MMEs per day (the standard recommended by the Centers for Disease Control [CDC]), much less 50 MME per day of medication discussed in the Advance Notice. [3] For example, there are bone cancer patients in LTC facilities that require 200 MMEs per day to address their breakthrough cancer pain. Moreover, in the LTC patient population, alternatives to opioids are more frequently contraindicated for a geriatric population suffering from multiple chronic conditions. Finally, we note that the risk of opioid abuse among patients in LTC facilities is low and that CMS already has recognized the need to evaluate opioid use in discrete patient populations such as cancer patients, differently from general opioid utilization standards.

We appreciate that the Centers for Disease Control (CDC) "recommended" the 90 MME limit and that CMS now proposes a 50 MME per day limit. The CDC developed its recommendation based on data gleaned from the general population, not the 65+ population (much less the LTC patient population in LTC facilities and settings). We therefore urge that CMS similarly recognize the

[3] The CDC developed the recommendation that opioids be limited to 90 MMEs per day or less for the general population. It did not consider, or make recommendations specific to, the LTC patient population in LTC facilities or settings. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Dowell, Haegerich & Chou, Morbidity and Mortality Weekly Reports, Recommendations and Reports, March 18, 2016/65(1); 1-49, available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm. It is noteworthy that Guideline is limited to treatment of chronic pain and exempts certain patient populations and conditions, and the its the authors recently criticized misplaced reliance on the Guideline or any guideline. Dowell, Haegerich & Chou, No Shortcuts to Safer Opioid Prescribing, N. Engl. J Med 2019; 380: 2285-87, available at https://www.nejm.org/doi/full/10.1056/NEJMp1904190.

unique characteristics of the LTC patient population in LTC facilities and settings served by LTC pharmacies by treating this discrete patient population differently from the general 65+ population as well.

Measurement of Antipsychotic Use. CMS plans to begin tracking three different measures of antipsychotic use in the Part D Program for Star Rating purposes: Antipsychotic Use in Persons with Dementia Overall (APD), Antipsychotic Use in Persons with Dementia, for Community-only Residents (APD-COMM), and Antipsychotic Use in Persons with Dementia, for Long-term Nursing Home Residents (APD-LTNH) (Part D). CMS certainly appreciates that use of antipsychotics in dementia patients present a complex set of issues and concerns and has been working to address these matters with its Partnership to Improve Dementia Care. SCPC appreciates the agency's proposal to track antipsychotic utilization for patients in LTC facilities and in the community separately. However, as discussed earlier, we are concerned that such utilization rates would be used to evaluate comparative PDP performance, which in turn likely would be used to evaluate pharmacy quality and adjust payments to pharmacies based on comparative "quality." Once again, we recommend that CMS exclude antipsychotic utilization rates from the rating system for PDPs, and prevent PDPs from evaluating pharmacy performance or adjusting payment to pharmacies based on antipsychotic utilization rates, at least until a comprehensive plan has been developed to address the complex issues and concerns surrounding use of antipsychotics in dementia patients.

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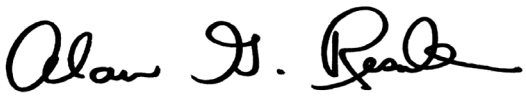
In conclusion, use of comparative pharmacy quality metrics to rate PDPs would provide limited meaningful information to, and in some cases could be misleading for, Part D beneficiaries seeking information to determine comparative quality among PDPs. Most existing pharmacy quality metrics are not specific 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, CMS should 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. CMS also should recognize the distinct factors that impact appropriate use and dosage of opioids in the LTC patient population, exempting LTC patients from dosage limits or evaluation of utilization until such time as standards specific and appropriate to the LTC patient population have been developed and validated. Finally, CMS should prevent PDPs from using antipsychotic utilization rates in dementia patients for quality assessment of pharmacies or quality-based payment adjustments to pharmacies.

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 (717) 503-0516 or arosenbloom@seniorcarepharmacies.org if we can provide any additional information.

Sincerely,



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