



March 5, 2018

[Submitted electronically to www.regulations.gov]

The Honorable Seema Verma
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services (CMS)
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (Docket number CMS-2017-0163)

Dear Administrator Verma:

The American Pharmacists Association (APhA) is pleased to submit our comments on the Centers for Medicare & Medicaid Services' (CMS) Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (the "Call Letter"). Founded in 1852 as the American Pharmaceutical Association, APhA represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services. APhA would like to provide feedback on the following areas included in the Call Letter.

I. Star Ratings and Display Measures

APhA's members are committed to continuous quality improvement and support the development and use of meaningful measures that help patients achieve optimal health and medication outcomes. APhA thanks CMS for the opportunity to offer our comments regarding enhancements to the Star Ratings and display measures in CY 2019.

A. Enhancements to the 2019 Star Ratings and Future Measurement Concepts

i. CMS/RAND-convened Technical Expert Panel (TEP) in 2018 (p. 106)

APhA applauds CMS for its plans to have its contractor convene this important TEP and highly recommends utilizing pharmacists with expertise in quality measurement and MTM services to serve on the TEP. APhA can help identify our pharmacist members who would

benefit this and other CMS TEPs, work groups and committees that leads to improved quality measures and a more robust MTM benefit.

B. New Measures for Star Ratings

i. Statin Use in Persons with Diabetes (SUPD) (Part D) (p. 107)

APhA supports this PQA-endorsed measure becoming a Star Ratings measure for 2019 as it will facilitate increased focus on the evidence-based use of statin therapy in persons with diabetes.

C. Potential Changes to Existing Star Ratings measures

i. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) (p. 114)

As CMS understands, utilization of MTM results in significant improvements of key health measures for patients.¹ Accordingly, APhA supports CMS's approach to reduce a contract's measure score to 1 star if they did not score at least 95% on data validation for these reporting sections and/or were not compliant with data validation standards/sub-standards for at least one of the data elements used to calculate the measure.

ii. 2019 Star Ratings Program and the Categorical Adjustment Index (pgs. 122-132)

APhA supports CMS's efforts to determine if risk adjustment is needed for any of its measures. APhA encourages CMS to continue to work with PQA, the measure steward that examined the need for sociodemographic status (SDS) risk adjustment for three medication adherence measures used in the Star Ratings Program.

D. Changes to Existing Display Measures

i. High Risk Medication (HRM) (Part D) (pg. 141)

APhA supports CMS keeping this measure on the display page for 2019 (based on 2017 data), using the updated PQA HRM drug list, due to concerns that the measure should not be punitive as medications on the HRM list are not contraindications and are only recommendations and considerations.²

ii. Drug-Drug Interactions (DDI) (Part D) (p. 141)

APhA continues to support this measure as a 2019 display measure. This measure will help to collect data to inform medication safety-related issues.

¹ Isetts, BJ. Et. al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. J Am Pharm Assoc. 2008; 48(2):203–11. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/18359733>

² CMS. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Pgs. 115-116. April 4, 2016. Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf>

iii. Antipsychotic Use in Persons with Dementia (APD) (Part D) (pgs. 141-142)

APhA supports CMS's proposal to display the rates for the two population breakouts, for community-only (COMM) residents and long-term nursing home (LTNH) residents, on the 2019 display page. As CMS is aware, pharmacists have extensive medication-related experience and training, and can assist in helping seniors with dementia avoid medications with safety problems. Pharmacists can also help address a number of concerns for care transitions for patients with dementia (i.e., medication reconciliation, comprehensive medication reviews, etc.).³ Therefore, we reiterate our call to CMS to implement measures and policies that encourage team-based care, and effectively optimize pharmacists and other practitioners' skills to improve patient care.

iv. Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D) (pgs. 142-143)

APhA generally supports CMS's proposal to implement the PQA-approved changes to these measures. We are also pleased the reporting of these measures to Part D plan sponsors is still through Patient Safety reports, with only the Use of Opioids at High Doses and from Multiple Providers (OHDMP) measure proposed to be added to the 2019 display page. APhA urges CMS to continue to monitor the application of these measures for unintended consequences to patients with legitimate pain needs, using the best available scientific evidence.

E. Potential Changes to Measures

i. Telehealth and Remote Access Technologies (Part C) (pgs. 146, 148)

APhA appreciates that CMS welcomes feedback on the appropriateness of including telehealth and/or remote access technology encounters as allowed under the current statutory definition of Medicare covered telehealth services and/or as provided by an MA plan as a supplemental benefit, as eligible encounters in various future Part C quality measures. In the Call Letter, the following services are called out: Use of Spirometry Testing in the Assessment and Diagnosis of COPD, Adults' Access to Preventative/ Ambulatory Health Services, Controlling High Blood Pressure and Comprehensive Diabetes Care. If CMS is looking for ways to increase Medicare beneficiaries' access to these services, APhA recommends CMS consider better utilizing pharmacists in its programs and services to the extent the Agency is able. As CMS is aware, due to legislative and regulatory barriers such as references to "provider," "eligible professional," or similar terms that do not include pharmacists in their definition, pharmacists are often an underutilized health care resource. APhA requests CMS employ its regulatory discretion, similar to efforts the Agency applied for chronic care management (CCM) and transitional care management (TCM) services, to remove barriers preventing qualified providers, like pharmacists, from being utilized. Such regulatory action has helped alleviate some of the restrictions preventing pharmacists from providing these services, which also positively impacts their inclusion on care teams and in value-based delivery models.

³ Burke, Robert. Et. al. Dementia in Care Transitions. The Society for Post-Acute and Long-Term Care Medicine. White Paper M16. Introduced in March 2016. Available at: <http://www.paltc.org/sites/default/files/M16-%20TOC%20Dementia%20White%20Paper.pdf>

- ii. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) (p. 147)

APhA supports CMS applying the PQA update of a denominator exception to the 2020 Star Ratings (based on 2018 data) for patients eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program.

F. Potential New Measures for 2020 and beyond

- i. Transitions of Care (Part C) (Notification of Inpatient Admission: Documentation of primary care practitioner notification of inpatient admission on the day of admission or the following day; Receipt of Discharge Information: Documentation of primary care practitioner receipt of specific discharge information on the day of discharge or the following day; Patient Engagement After Inpatient Discharge: Documentation of patient engagement (e.g., office visits, visits to the home, or telehealth) provided by primary care practitioner within 30 days after discharge; Medication Reconciliation Post-Discharge (which is currently a HEDIS measure): Documentation of medication reconciliation within 30 days of discharge.)) (pg. 148)

APhA is generally supportive of the new HEDIS measure. As stated in the medication reconciliation measure description, the review can be conducted by a clinical pharmacist. Pharmacists are often the first health care practitioner patients often encounter post-discharge and the provider generally responsible for coordinating medication-related information between the hospital and primary care physician, patients could benefit greatly if pharmacists were better included in transitioning patients from an inpatient setting to home. Pharmacists are frequently blocked from the electronic exchange of relevant clinical information, which is critical to maximize the benefit of coordinated team-based care, including transitional care services. Accordingly, if pharmacists had access to relevant information in the patients' record, including discharge information, pharmacists could have a more effective role in helping patients transition between care settings.

- ii. Care Coordination Measures (Part C) (pgs. 148-149)

APhA agrees with CMS and NQF that “[e]ffective care coordination, including care transition, contributes to improved health outcomes.” As CMS considers the activities that best represent care coordination, APhA requests that CMS consider examining the contributions of pharmacists to appropriate care coordination, especially as it relates to optimizing medication therapies. Medication-related problems often occur due to lack of care coordination, and pharmacists can play an important role in managing medications across multiple providers, including communicating medication information and exchanging reconciled medication lists. APhA recommends that the activities of pharmacists be included in the exploration of new care coordination measures.

iii. Polypharmacy Measures (Part D) (Pgs. 151-154)

PQA developed and endorsed three measures that identify potentially harmful concurrent drug use or polypharmacy: Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH). Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS), and Concurrent Use of Opioids and Benzodiazepines (COB). APhA supports CMS's decision to begin reporting of these three measures in the Patient Safety reports for the 2018 measurement year, and to add it to the display page for 2021 (2019 data) and 2022 (2020 data).

II. Part D Requirements

A. *Quality Payment Program* (pg. 43)

APhA appreciates that “[f]or 2019, CMS will begin implementing an additional way for eligible clinicians to become qualifying APM participants (QPs) that considers their participation not only in Advanced APMs, but also in innovative alternative payment arrangements through other payers such as Medicaid, Medicare Advantage and commercial payers (Other Payer Advanced APMs).”⁴ As CMS is aware, pharmacists are not eligible clinicians under the under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). With the increasing complexity of medications and the role that proper medication management will play under MIPS, APMs, and Advanced APMs, recognizing the unique and essential contributions that pharmacists make on patient care teams is fundamental to achieving successful APMs and will assist CMS to meet its triple aim goals. With 89 percent of Americans living within five miles of a community pharmacy,⁵ pharmacists, with more medication-related education and training than any other health care provider, are uniquely-equipped to reduce the nearly \$300 billion in annual health care costs due to medication-related problems.⁶ APhA recommends CMS take advantage of any regulatory discretion to remove regulatory barriers preventing physicians and eligible clinicians from utilizing pharmacists under team-based, patient-centered payment and delivery structures. Pharmacists are often an underutilized resource that can help ease the transition of physician and other eligible clinician practices to QPP participation. Many commercial payers already utilize pharmacists under alternative payment arrangements.⁷ Better utilizing pharmacists will improve patient access and choice, and increase efficiencies in the delivery of services, which is especially important as health care payment and delivery models become more value-based.

B. *Expanding the Part D OTC Program* (pgs. 196-197)

In the Call Letter, CMS requests feedback on its consideration of allowing additional flexibilities for Part D plan sponsors to offer access to over-the-counter drug products (OTCs).

⁴ The All-Payer Combination Option takes into account eligible clinician participation in both Advanced APMs and in Other Payer Advanced APMs, which are non-Medicare payment arrangements that meet criteria similar to Advanced APMs (§ 414.1420).

⁵ NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

⁶ NEHI. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Adherence for Chronic Disease. August 2009. Available at: http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf

⁷ Colla CH et al. Role of Pharmacy Services in Accountable Care Organizations. 2015. JMCP. 21 (4): 330-43. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4462340/>

APhA supports policies, which rely on the best-available evidence, to increase beneficiaries' access to safe, effective and affordable medications and treatments, including those that are available OTC. However, policies which expand access to OTCs should not restrict patients' ability to ascertain needed prescription medications.

C. Medication Therapy Management (MTM) Annual Cost Threshold (pg. 197)

APhA appreciates CMS's continued support for MTM programs, which improve medication-related and overall health outcomes. Studies indicate that for every \$1 spent on MTM services, anywhere from \$4 up to \$12 is saved—in addition to cost savings, patients also realize significant improvements in key health measures.⁸ Despite clear evidence supporting the value of pharmacist-led MTM services, these programs continue to be significantly underutilized. As APhA has previously stated, we strongly encourage CMS to revisit the cost threshold, as the current \$3,967 threshold, which is a \$48 increase on top of the \$412 increase from the previous year, excludes many beneficiaries with complex conditions, but smaller drug spends, potentially through the use of generic medications, who could benefit from MTM services. This point is reinforced by the fact that the United States spends \$300 billion annually on medication-related problems.⁹ While APhA appreciates CMS's ongoing efforts to expand and enhance MTM, including the Part D Enhanced MTM model, we hope that CMS will continue to work collaboratively with pharmacists, plans, and beneficiaries to improve and streamline MTM eligibility criteria (including the number of medications and chronic conditions) in order to maximize the services' benefits to both patients and the larger health care system.

D. Improving Access to Part D Vaccines (pgs. 56, 199)

APhA is pleased that the Call Letter restores the language that has been in every Call Letter since 2012, which was removed last year, encouraging Part D plans to offer vaccines in the \$0 vaccine tier. We share CMS's concern that vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap), and that approximately 70% of adults for whom the herpes zoster vaccine is recommended remain unprotected. The variable cost sharing requirements currently imposed on the majority of Part D vaccines discourage immunization among elderly, disabled and chronically ill populations who account for a disproportionate percentage of the morbidity and mortality from vaccine preventable conditions. Removing this financial barrier could have a significant impact on improving beneficiary access to and utilization of vaccines and will also help drive reductions in hospitalizations and avoidable medical expenditures in other parts of the Medicare program. Immunizations are vital to public health, and higher rates of adult immunization will improve patient health while reducing health costs associated with preventable conditions. Pharmacists are important members of the immunization neighborhood and improve patient access to vaccinations recommended by the CDC's Advisory Committee on Immunization Practices (ACIP). Therefore, CMS should encourage plans to maximize the inclusion of pharmacists as in-network clinicians providing vaccines in accordance with the National Vaccine Advisory Committee (NVAC) Adult Immunization Standards and as authorized under state practice acts.

⁸ Isetts, BJ. Et. al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. *J Am Pharm Assoc.* 2008; 48(2):203–11. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/18359733>

⁹ NEHI. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Adherence for Chronic Disease. August 2009. Available at: http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf

E. Improving Drug Utilization Review Controls in Medicare Part D Part D Opioid Overutilization Policy (pgs. 202-16):

Like CMS, APhA believes more needs to be done to address the opioid epidemic while simultaneously considering patient needs. In the Call Letter, CMS proposes several new strategies to more effectively address this national crisis. Several of these strategies rely on portions of the CDC Guideline for Prescribing Opioids for Chronic Pain. While APhA supports the use of data and guidelines to help inform policy decisions, we caution against the use of population-level data to make broad policy determinations for individual patients. In addition, we are concerned that each plan will rely on different data and criteria that will result in variable and inconsistent requirements that will negatively impact patients with legitimate pain and create increased administrative burden on providers that take away from patient care activities.

- i. Enhancing the OMS by adding additional flags for high risk beneficiaries who use “potentiator” drugs (such as gabapentin and pregabalin) in combination with prescription opioids

APhA recognizes concurrent use of some medications with opioids can pose risks to patients, including those between opioids and “potentiator” drugs, such as gabapentin and pregabalin. In addition, our members indicated that alerts can be helpful, but that it is important to be mindful of the quantity of alerts received in the pharmacy. While the Call Letter seeks to enhance the overutilization management system (OMS) by adding additional flags for potentiator drugs, limited detail is provided regarding how “potentiator” drugs will be identified. The Call Letter states, “We have been working with the Office of the Inspector General to identify other non-opioid potentiator drugs that may pose safety risks when misused with opioids.” Health care providers, including pharmacists, need to be part of the development of any process to identify potentiator drugs used in combination with opioids. Before a recommendation can be made regarding the inclusion of potentiator drugs to the OMS, APhA recommends CMS clarify its process to identify and include such drugs. In addition, as changes to the OMS are made, CMS should also monitor intended and unintended consequences, such as access issues for patients with legitimate needs, shifts in prescribing patterns, increased out-of-pocket expenditures, overdoses, and administrative burdens on prescribers and pharmacists.

- ii. Implementing revisions to the PQA opioid quality measures used by CMS, and consideration of a new PQA measure, Concurrent Use of Opioids and Benzodiazepines

APhA is aware PQA is evaluating proposed updates aligned with the CDC Guidelines for Prescribing Opioids for Chronic Pain (e.g., 90 morphine milligram equivalents [MME] per day as a high-dose threshold), to the three PQA opioid overuse measures, OHD, OMP, and OHDMP, which will also more closely align with current criteria used in the OMS. OMS already flags concurrent benzodiazepine use. APhA reiterates the need for a coordinated, multi-faceted approach to address the opioid epidemic, which is evidence-based and involves health care providers, including pharmacists, treating patients with legitimate pain.

- iii. Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at a dosage level of 90 MME per day, with a 7 days supply allowance

APhA encourages implementation of programs effectively targeting and deterring prescription drug abuse and misuse. APhA supports CMS's efforts to help address this epidemic, provided its policies are scientifically-based and carefully structured to ensure that patients with a legitimate need have access to medications. Currently, sponsors may implement POS edit at a dosage level of 200 MME per day. Outlined below are APhA's concerns with CMS' new expectation that all sponsors to implement hard edits at the POS at a dosage level of 90 MME per day.

a. Intent of the CDC Guidelines

The CDC Guideline recommends careful practitioner decision-making when prescriptions are for 90 MME or more. APhA is concerned the intent of CDC guideline in specifying an amount is lost when it is used as a threshold for a hard edit policy. The guideline provides for the anticipated clinical response to 90 MME, as described below:

“Clinicians should avoid increasing opioid dosages to ≥ 90 MME/day or should carefully justify a decision to increase dosage to ≥ 90 MME/day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists.”¹⁰

These types of hard edits, which are determined by entities other than a patient's clinician, are frequently based on limited information and should not be considered an individualized assessment as referenced in the CDC guidelines. As a result, a hard edit overrides a prescriber's decision by creating a presumption that the prescription is improper and thus, effectively allows plans to make clinical decisions based primarily on the amount of medication prescribed without consulting with the prescriber or more carefully assessing patient needs.

b. Implementation Concerns

APhA understands the difficulty in setting an MME upper limit for a hard edit and recognizes the CDC Guideline's recommendation to generally avoid increasing the daily dosage of opioids to 90 MME. However, APhA anticipates significantly more patients will require hard edits to obtain their medications, creating substantial access issues and administrative burden that will delay treatment for many patients with legitimate chronic noncancer pain and of whom cumulative daily dosages are above 90 MME have been reached due to tolerance, lack of alternative treatment options, and lack of access to treatments because are not available or not covered. Strong consideration must be given to the impact on patients with chronic noncancer

¹⁰ Centers for Disease Control and Prevention, CDC Guideline for Chronic Pain – United States 2016, available at: <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>, last accessed: February 26, 2018.

pain who have developed tolerance to opioids and the likely withdrawal symptoms they could experience if they don't receive their medications in a timely manner. In addition, any policy decisions should include coverage for services to help patients taper their opioid dosages when appropriate. APhA believes these issues will be amplified if sponsors do not properly implement the policy.

CMS noted in the Call Letter pertaining to the first months of hard edits in 2017, "...we [CMS] believed that some sponsors implemented these edits beyond their intended use as a safety edits. For example, the edits are not intended as a means to implement a prescribing limit or apply additional clinical criteria for the use of opioids..." Although CMS states the Agency has observed fewer complaints per month, no information has been provided detailing how CMS will protect patients by preventing plan sponsors from implementing new POS hard edits beyond their intended use. APhA encourages CMS to address this issue.

In addition, APhA's members requested clarification regarding the time that a safety edit may occur, if the policy is implemented. The Call Letter specifies safety edits are to occur at the POS. Yet, patients are often unable to obtain their medication at the POS because the plan seeks feedback from prescribers. To attempt to resolve hard edits at POS, pharmacists spend significant time on the phone with providers and sponsors, and even then, the edit may not be overridden. Consequently, patients often leave the pharmacy without their medication or an answer as to when they may pick up their medication. Patients may also return to their prescriber's office to receive a new prescription, but the new prescription may also trigger a hard edit. Throughout this process, patients, pharmacists and other health care providers may not be aware of the sponsor's process or reason for denying coverage. Therefore, a safety edit may not be resolved at the POS. APhA encourages CMS to clarify options for prescribers and pharmacists to earlier address this issue to prevent delays in access and increased work flow.

c. Exceptions Processes and Patient Access

The Call Letter relies heavily on patient access being maintained by utilizing exceptions processes and sponsors implementing hard edits to allow beneficiaries to receive a one-time 7 day supply of the prescription that triggered the hard edit. APhA is concerned this proposed solution will not be sufficient in many cases, creating gaps in patient access. The Call Letter recognizes some potential issues by stating, even when "...the exceptions request is approved, the patient may need to obtain a new prescription from their prescriber for amounts beyond the 7 days supply" and "...if the beneficiary attempts to fill a prescription for another opioid that triggers the MME hard edit, another 7 days supply would not be allowed". As proposed, APhA anticipates increased patient trips to prescribers, which for some patients is logistically difficult or cost-prohibitive, increased administrative burden, and decreased patient access to needed medications. APhA encourages CMS to proactively identify solutions to address these anticipated issues.

Specific to the one-time 7 day supply, the Call Letter states "...if a patient presents at the pharmacy with multiple opioid prescriptions on the same day, if only one 7 day supply was allowed, the pharmacist would help assess the immediate needs of the patient to help determine which prescription should be filled for a 7 days supply." APhA appreciates CMS's recognition of

the pharmacist's ability to help assess patient needs. Although pharmacists are an important part of the patient's health care team, they often do not have access to a patient's health information, including their diagnosis and complete list of medications. Therefore, depending on the patient, the pharmacist's assessment of the patient's immediate needs may not lead to an immediate recommendation because assessment can be time consuming and the pharmacist may need to communicate with the patient's provider(s) to better understand patient needs and provide care. Pharmacists need sufficient time, access to information, and reimbursement to carry out the steps needed to satisfy CMS's expectations. APhA recommends CMS modify the proposed policy to account for this need.

- iv. Implementing a days supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME per day)

APhA is aware several plans have implemented a days supply limit for initial fills of prescription opioids for the treatment of acute pain. APhA is concerned that plan-imposed supply limits for initial fills of prescription opioids stunts practitioners' abilities to exercise professional judgement when prescribing opioids and does not provide an opportunity for follow-up, which can have negative impacts on patients.

Currently, limited research is available regarding the effectiveness of such policies on patient outcomes. In addition, there may be harmful unintended consequences, especially if a plan implements an excessively restrictive days supply limit with a low daily dose maximum. Patients may end up making multiple trips to prescribers and pharmacies which may not be readily accessible, such as when closed over weekends or outside of business hours. As a result, patients may seek care in emergency departments or from different prescribers and pharmacists, making treatment more difficult to coordinate, among other issues. APhA encourages CMS to evaluate the impact of such policies on patients and costs to the health care system more broadly before advancing this proposal.

Due to the wide variability in day supply limits and the lack of research on the impact and unintended consequences, APhA recommends CMS hold off on implementing this policy until research can be evaluated. APhA also recommends CMS consider, "*Consensus Statement on Improving the Prior Authorization Process*"¹¹ and the American Medical Association's "*Prior Authorization and Utilization Management Reform Principles*"¹² to identify opportunities for plans to improve prior authorization and utilization management.

¹¹ American Hospital Association, America's Health Insurance Plans, American Medical Association, American Pharmacists Association, BlueCross BlueShield Association, Neducak Group Management Association, Consensus Statement on Improving the Prior Authorization Process, available at: <https://www.ama-assn.org/sites/default/files/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>, last accessed: February 26, 2018.

¹² American Medical Association, Prior Authorization and Utilization Management Reform Principles, available at: <https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf>, last accessed: February 26, 2018.

- v. Expecting all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and request feedback on concurrent prescription opioid and benzodiazepine soft edits

APhA encourages plans to improve the impact of soft POS safety edits by better using available evidence, conducting pilot programs, and considering expert panel recommendations as they are released by medical societies and other relevant organizations. After implementation, plans should test and evaluate soft POS edits to determine effectiveness. In addition, APhA sees an opportunity to improve the value of soft POS safety edits by also covering pharmacist-provided care that resolves the identified issue.

F. Comprehensive Addiction and Recovery Act of 2016 and the Overutilization Monitoring System (OMS) (pg. 204)

In the Call Letter, CMS references Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) which includes provision that permit Part D sponsors to establish drug management programs for at-risk beneficiaries. APhA provided comments in response to the recently-proposed rule (82 FR 56336) and encourages CMS to incorporate our recommendations in the final rule.¹³ Consistent with our comments regarding the proposed rule, APhA urges CMS to monitor the impact of drug management programs on patients. Failure to capture and address unintended consequences of DMPs, such as out-of-pocket opioid purchases by patients, will result in skewed quality measure results and negative impacted patient care, among other concerns.

Thank you for the opportunity to provide comments on the draft Call Letter. We support CMS's ongoing efforts to continue to improve Medicare's prescription drug programs and look forward to continuing to work with CMS to reach that goal. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,



Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPHarm, JD, Senior Vice President, Pharmacy Practice and Government Affairs
Anne Burns, Vice President, Professional Affairs

¹³ See American Pharmacists Association, Comments in response to Centers for Medicare Medicaid Services (CMS) Proposed Rule: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, RIN: 0983, available at: <https://www.regulations.gov/contentStreamer?documentId=CMS-2017-0156-1619&attachmentNumber=1&contentType=pdf>, last accessed: February 26, 2018.