

March 5, 2018

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2017-0163
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

To Whom It May Concern:

The American Society of Consultant Pharmacists (ASCP), is pleased to have the opportunity to comment on select provisions of the Center for Medicare and Medicaid Services 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. ASCP is the only international professional society devoted to optimal medication management and improved health outcomes for all older persons. ASCP's members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, sub-acute care assisted living facilities, psychiatric hospitals, hospice programs, home and community-based care. ASCP has a long history of advocating for the medical best interests of people who reside in long-term care facilities and those enrolled in hospice programs. We appreciate CMS' continued concern for the welfare of the frail elderly who rely on the Medicare drug benefit as a vital lifeline.

Our comments are focused on the following sections:

1. Enforcement Actions for Provider Directories
2. Part D Enhanced MTM Model
3. Health Related Supplemental Benefits
4. Medicare Advantage (MA) Uniformity Flexibility
5. Improving Access to Part D Vaccines
6. Improving Drug Utilization Review Controls in Medicare Part D
 - a. Concurrent DUR
 - i. Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users
 - ii. Days Supply Limits for Opioid Naïve Patients
 - iii. Opioid Duplicative Therapy Safety Edits

1. Enforcement Actions for Provider Directories

CMS: In the 2017 Call Letter, CMS provided guidance on the future of provider directory requirements and best practices. CMS stated that inaccurate provider directories can impede access to care and bring into question the adequacy and validity of the Medicare Advantage Organization's (MAO's) network as a whole. In addition, CMS notified the industry that monitoring activities around provider directories could result in compliance and enforcement actions if non-compliance is detected. Since then, CMS has received several inquiries as to when CMS would impose enforcement actions for provider directory violations.

As in all instances of non-compliance, Civil Money Penalties (CMPs) and other enforcement actions may be imposed against MAOs that have received a compliance notice or notices for violations that have gone uncorrected. Also, CMS has the discretion to take enforcement actions when egregious instances of non-compliance are discovered. If CMPs are imposed for provider directory errors, penalty amounts would initially be calculated on a per determination basis.

ASCP Comments: ASCP is supportive of this reiteration of policy. Additionally, we would like to restate our continuing support for the Performance and Service Criteria for Network Long-Term Care Pharmacies as defined in Chapter 5 (50.5.2) of the Medicare Prescription Drug Benefit Manual. We believe that the ten criteria listed in the manual fairly define the minimum performance and service criteria for any pharmacy wishing to contract with a Part D sponsor as a Network Long-Term Care Pharmacy.

2. Part D Enhanced MTM Model

CMS: The Part D Enhanced MTM model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. The model is an opportunity for stand-alone basic Part D plans to right-size their investments in MTM services, identify and implement innovative strategies to optimize medication use, improve coordination of care between plans and providers, and strengthen system linkages.

ASCP Comments: ASCP supports the concept of improving the quality of care for Part D recipients while endeavoring to reduce costs. We also support CMS's goal of "better care, smarter spending, [and] healthier people." To this end, we ask that CMS consider current obstacles to seniors receiving MTM services from senior care and consultant pharmacists who practice outside a traditional pharmacy setting. Because these independent geriatric pharmacotherapy specialists are not affiliated with a dispensing pharmacy, they are often unable to work in conjunction with MTM providers who are only affiliated with pharmacies, not individual pharmacists. CMS has noted in previous Call Letters that consultant pharmacists are uniquely well-qualified and well-positioned to provide MTM to seniors in long-term care facilities and has instructed Part D plan sponsors to work with consultant

pharmacists to determine whether a beneficiary could benefit from a consultant-provided Comprehensive Medication Review. Despite this instruction to Part D plans, consultant pharmacists have faced many institutional barriers to providing needed MTM services. We feel that if the barriers to providing MTM could be addressed, perhaps by having Part D plans affiliate with independent pharmacist practitioners rather than only pharmacies, superior senior care therapy could be achieved while keeping costs under control.

3. Health Related Supplemental Benefits

CMS: CMS currently defines a supplemental health care benefit in the Medicare Managed Care Manual (section 30.1) as an item or service (1) not covered by Original Medicare, (2) that is primarily health related, and (3) for which the MA plan must incur a non-zero direct medical cost. An item or service that meets all three conditions may be proposed as a supplemental benefit in an MA plan's bid and submitted plan benefit package. The final determination of benefit status is made by CMS during the annual benefit package review.

An item or service is primarily health related if the primary purpose of the item or service is to prevent, cure, or diminish an illness or injury. CMS has not previously allowed an item or service to be eligible as a supplemental benefit if the primary purpose is daily maintenance. However, medical and health care research has demonstrated the value of certain items and services that can diminish the impact of injuries or health conditions and reduce avoidable emergency and health care utilization. For example, fall prevention devices can be an effective means to assist enrollees at high risk of fall and protect against the likelihood of additional injury resulting from a fall; CMS believes provision of a fall prevention device – and similar items and services that diminish the impact of injuries/health conditions and reduce avoidable utilization - could be provided as a supplemental benefit for a defined period of time and in certain situations.

CMS intends to expand the scope of the primarily health related supplemental benefit standard. Section 1852(a)(3) permits the offering of “healthcare benefits” as supplemental benefits but does not define the term. We therefore have authority to interpret the term more broadly than we have in the past, to permit MA plans to offer additional benefits as “supplemental benefits” so long as they are healthcare benefits. Under our new interpretation, in order for a service or item to be “primarily health related,” it must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. Any supplemental health benefit proposed by an MA organization must be reasonably and rationally encompassed by this standard. This will allow MA plans more flexibility in offering supplemental benefits that can enhance beneficiaries’ quality of life and improve health outcomes.

ASCP Comments: ASCP strongly supports the concept of expanding the scope of health-related supplemental benefits. Pharmacists, including senior care/consultant pharmacists routinely work to prevent adverse events that can occur secondarily to medication

misadventures. Through the monthly medication regimen review under F756 of Appendix PP in the State Operations Manual, the consultant pharmacist reviews a long-term care resident's medications at least once every thirty days to ensure that the regimen is both safe and effective. Suggestions to deprescribe medications that are redundant, or pose a fall risk, or could contribute to oversedation, are often made with the outcome of an optimized regimen that is streamlined and safer for the resident. These services are often offered in Assisted Living communities as well. Appropriate medication management by a consultant pharmacist can help reduce healthcare utilization by averting hospital readmissions. If plans are granted more flexibility in offering supplemental health benefits such as the preventative care that pharmacist-provided medication optimization offers, we are confident that medication errors and adverse outcomes will be substantially reduced in all healthcare settings.

4. Medicare Advantage (MA) Uniformity Flexibility

CMS: CMS has determined that providing access to services (or specific cost sharing and/or deductibles for services or items) that is tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the MA regulations at §422.100(d). We have determined that the statutory provisions at sections 1852(d)(1) and 1854(c) and the regulation at § 422.100(d) mean that we have the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits. Targeted supplemental benefits can be offered through a benefit package that ensures equal treatment of enrollees with the same clinical conditions for whom such services and benefits are useful consistent with section 1852's equal access and anti-discrimination provisions, and is priced at a uniform premium consistent with the requirement for uniform bids and premiums in section 1854(c) of the Act. CMS believes this flexibility will help MA plans better manage healthcare services for particularly vulnerable enrollees...

ASCP Comments: ASCP supports this change. By creating allowances for plans to provide services that help enrollees better manage medical conditions CMS will move closer to achieving the important goal of providing higher quality care at a more affordable cost, both for the enrollee and for the program.

Consultant pharmacists are well positioned to provide specialized services for enrollees with diabetes, heart failure, dementia and a host of other diseases with high prevalence among the Medicare population. We believe CMS' change in requirements will make it easier for Medicare Advantage plans to create effective programs and target them to beneficiaries with a demonstrated need.

5. Improving Access to Part D Vaccines

CMS: According to the Center for Disease Control and Prevention's (CDC) Surveillance of Vaccination Coverage among Adult Populations — United States, 2015, vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap)²⁹. While the Healthy People 2020 herpes zoster target vaccination rate has been achieved, approximately 70% of adults for whom the vaccine is recommended remain unprotected. In an effort to improve access to these and other Part D vaccines, we encourage Part D sponsors to either offer a \$0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

ASCP Comments: ASCP is supportive of the CMS recommendation to make more vaccines available to Part D beneficiaries. ASCP has long recognized the importance of providing vaccines to residents of long-term care facilities who are especially vulnerable to complications and death from influenza and pneumococcal pneumonia because of their age, underlying medical conditions, and residence in closed environments. This is also true regarding protection against tetanus/diphtheria.

ASCP developed a program called the 100% Immunization Campaign starting back in 1999-2000 designed to effect structural changes, including adoption of policies and procedures that would result in a lasting increase in the rates of immunization of nursing facility residents.

Consultant pharmacists, who provide monthly reviews of medication therapy for each of the millions of residents of nursing homes, as well as many of the millions of residents in assisted living facilities, are in a unique position to participate in the design, implementation, and evaluation of programs to assure that 100% of residents in long-term care are immunized against influenza, pneumococcus, and tetanus/diphtheria. With their extensive knowledge of disease management and the cost-effectiveness of immunization, consultant pharmacists can be a valuable resource in developing immunization policies and procedures for the facility.

ASCP applauds CMS efforts to make access to immunization more affordable and to remove this obstacle to immunizing Part D beneficiaries.

6. Improving Drug Utilization Review Controls in Medicare Part D

Concurrent DUR

Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users

CMS: ...Given the public health emergency and the fact that half of sponsors are already implementing hard MME edits, sponsors can and should do more to address chronic, high prescription opioid overuse. Therefore, we propose that all sponsors should implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME). This value aligns

with the CDC Guideline, which recommends to generally avoid increasing the daily dosage of opioids to 90 MME...

Days Supply Limits for Opioid Naïve Patients

CMS: ...We expect all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. CMS understands that implementing such restrictions may create important challenges. Any restrictions should not compromise appropriate pain treatment or result in an excessive burden on clinicians and their patients. We request feedback from stakeholders, especially Part D sponsors, providers, and PBMs, on the implementation of a days supply limitation at 7 days or if an alternative days supply limit would be more appropriate (such as 3 days or 5 days), including their experience with such limitations or the basis for their recommendations. We also solicit comment on whether a days supply limit with or without a daily dose maximum (e.g., 50 MME per day) would be more effective. In particular, we request information on both inclusions and exceptions for specific clinical situations (i.e., whether and to what extent a supply limit could be based on specific indications or other criteria) and other parameters and what safeguards should be in place to protect appropriate beneficiary access.

Opioid Duplicative Therapy Safety Edits

CMS: ...Based on these findings, we expect all Part D plan sponsors to implement a soft POS edit for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion. When such an edit is triggered for concurrent use of opioids and buprenorphine, the soft edit should only reject the opioid prescription following the buprenorphine claim and should not impede access to buprenorphine for MAT. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims...

ASCP Comments: ASCP appreciates the ongoing attention CMS has given to opioid stewardship, and we share CMS' concerns with finding solutions to address this critically important national crisis. However, as we have articulated in previous comments, we once again note that in long-term care (LTC), limits such as the previously suggested morphine equivalent dose (MED) of 120 mg, or the current proposed morphine milligram equivalent (MME) of 90 mg could unduly burden our senior patients with chronic pain who are opioid-tolerant and often requiring higher MED/MME doses. While we agreed then and continue to agree that abuse and diversion of prescription drugs poses serious and costly problems in the community, often requiring that dosing safeguards be implemented, we once again wish to point out that in the LTC setting, residents typically have one prescriber and one dispensing pharmacy, and as such, opioid abuse is much less likely than in other settings.

The consultant pharmacist routinely reviews all medications, including those prescribed for pain to ensure the regimen is safe and appropriate for the resident. This monthly review is far more robust than the average patient receiving pain treatment in the community might receive. Conversely, there can be a higher incidence of residents suffering from chronic pain in this setting, and MED/MME limits can hinder appropriate pain treatment. This enhanced

medication management in LTC settings prompted Congress to exclude LTC from the Medicare Part D drug management programs defined in the Comprehensive Addiction and Recovery Act of 2016 (CARA). Similarly, we request that residents in LTC settings be excluded from the Concurrent DUR edits being proposed.

Conclusion

Thank you for the opportunity to address comments on this important document and please accept our offer of any assistance we might provide in order to continue to improve the Medicare Drug Benefit.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Grosso', with a stylized, cursive script.

Frank Grosso
Executive Director & CEO