December 1, 2016

Centers for Medicare & Medicaid Services
Attn: Chad Buskirk
Mail Stop C1–24–23
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Listening Session Regarding the Implementation of Certain Medicare Part D Provisions in the Comprehensive Addiction and Recovery Act of 2016 (CARA) - [CMS–4183–N]

Dear Mr. Buskirk:

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments in response to notice CMS–4183–N published in the *Federal Register* on October 26, 2016. AMCP supports a holistic, comprehensive, and multi-stakeholder approach among health care providers and patients that is necessary to truly address the opioid epidemic.[1]

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 health care dollars. Through evidence- and value-based strategies and practices, the Academy's 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.

AMCP has long advocated for the ability of Medicare Part D sponsors to establish drug management programs for at-risk beneficiaries and is pleased that CARA included provisions to authorize such programs. AMCP offers the following comments in response to the specific issues outlined in section II.A of the *Federal Register* notice.

Clinical Guidelines That Indicate Misuse or Abuse of Frequently Abused Drugs

As the Secretary develops such guidelines in consultation with Part D sponsors and other stakeholders, AMCP recommends consideration of concurrent therapy of opioids with benzodiazepines or skeletal muscle relaxants as criteria for identification of an 'at-risk beneficiary for prescription drug abuse' as concurrent therapy can exacerbate opioid-induced respiratory depression and increase risk for overdose.[2] However, AMCP cautions CMS

[1] Academy of Managed Care Pharmacy. Role of Managed Care Pharmacy in Managing Controlled Substances for Medicare Part D Beneficiaries. 2014. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18556.. Accessed November 29, 2016.
[2] Witenko C, Moorman-Li R, Motycka C, et al. Considerations for the Appropriate Use of Skeletal Muscle Relaxants for the Management Of Acute Low Back Pain. *Pharmacy and Therapeutics*. 2014;39(6):427-435.

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to clarify that concurrent use of opioid pain medications with benzodiazepines or skeletal muscle relaxants is not a contradiction to use, but rather encourages health care providers and patients to first identify the clinical risks and benefits of using these medications concomitantly. AMCP believes it is important that a balance exists between treating patients with chronic pain and avoiding addiction or other unintended consequences, and therefore the focus should be on ensuring that patients be treated as individuals and receive access to necessary and appropriate medications.

The Anticipated Impact of Drug Management Programs for At-Risk Beneficiaries

Recent CMS data suggests that approximately 1-2% of Medicare beneficiaries inappropriately use controlled substances.[3] Therefore, the anticipated impact of drug management programs for at-risk beneficiaries should be minimal and limited to those truly identified at great risk.

The Use of an Expedited Appeals Process

The law provides for two beneficiary notices of an at-risk determination and each notice includes the option of an automatic escalation to external review. AMCP strongly supports beneficiary notification and ability to appeal; however, we expressed concerns during the legislative process about the time period for the notices and rights of appeal. Specifically, AMCP is concerned that once a beneficiary has been identified as at-risk that they be "enrolled" in a drug management program as soon as possible in order to address their prescription drug abuse. Therefore, we urge CMS to limit the overall time period between the first notice and the last opportunity for an external review. During the listening session, there were several participants advocating to increase the time frames. We strongly encourage CMS to keep in mind the end goal of the law which was to stop medication abuse in the Part D program – timely intervention will accomplish that goal.

Evidence-Based Prescribing Guidelines for Opiates

One major barrier to the implementation of evidence-based prescribing guidelines for opiates is the lack of interoperability for Prescription Drug Monitoring Programs (PDMPs) and the inability of Part D sponsors to access PDMP data. While forty-nine states and the District of Columbia have PDMPs that collect dispensing data for all opioid medications, including prescriptions paid for by insurance and cash, only five states provide PDMP access to Medicare plan sponsors and three states to commercial third-party payers.[4] The current legislative scheme at the state-level is a barrier to Part D sponsors' ability to properly assess the true opioid overutilization of their members. CMS must address how patients paying cash for their prescriptions, and the inability of plan sponsors to access PDMP information, will be factored into evidence-based prescribing guidelines as well as identification of at-risk beneficiaries. Furthermore, CMS must address how opioids that are administered in physician offices will be accounted for because this information is also traditionally not available to plan sponsors or reported to PDMPs.

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[3] Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Centers for Medicare and Medicaid Services, April 2, 2012 Available at http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15078. Accessed November 29, 2016.

[4] Alexander GC, Frattaroli S, Gielen AC, eds. The Prescription Opioid Epidemic: An Evidence-Based Approach. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015

Listening Session Comments

During the listening session there were two issues raised of concern to AMCP. Specifically that the health plans and pharmacy benefit managers would use the law to "steer" beneficiaries to preferred pharmacies and second, that prescribers should be able to override the plan's designation of at-risk. Health plans and pharmacy benefit managers have been operating drug management programs in both the commercial market and the Medicaid programs for many years and we are unaware of any studies or reports that members enrolled in those programs have been steered to preferred pharmacies. Lastly, to allow prescribers to override the designation of at-risk would defeat the whole purpose of the program. Members are given ample opportunities to appeal their designation and to select their prescriber. Also, the health plan is required to verify with the prescriber that the beneficiary is at risk. We believe that the law provides ample protection for the at-risk beneficiary.

Thank you for the opportunity to provide feedback and for your consideration of our comments. AMCP looks forward to continuing work on this issue with CMS. As you seek, stakeholder input, please consider including managed care pharmacists as many of our members work in health plans and for pharmacy benefit managers and have experience with drug management programs. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer