AMCP Academy of Managed Care Pharmacy®

January 16, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: 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 [CMS-4182-P]

Dear Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services for the opportunity to provide comments in response to the 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 [CMS-4182-P]*" published in the *Federal Register* on November 28, 2017. AMCP commends CMS for considering how the Medicare Advantage and Part D prescription drug programs can be transformed through innovation to best meet the individual health needs of Medicare beneficiaries. AMCP offers comments on the following areas of the proposed rule:

A. Drug Management Programs
B. Medication Therapy Management
C. Benefit Design & Utilization Management
D. Health Information Technology & Data Interoperability
E. Fraud, Waste, & Abuse

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.

A. Drug Management Programs

AMCP is pleased to see CMS move forward with implementation of the drug management program provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA). For the successful implementation of drug management programs, it is critical that a balance exists between beneficiary notice/choice and appropriate clinical care. In many instances, CMS appears to struggle with finding this balance as several of its proposals are inconsistent with legislative intent and add timeframes that delay a plan sponsor's ability to enroll a beneficiary in a drug management program. In addition, there are several inconsistencies in the proposed requirements for prescriber lock-in versus pharmacy lock-in. Overall, AMCP believes that the drug management program provisions require significant revisions prior to finalization and that CMS should carefully consider whether implementation for CY 2019 is feasible.

Integration

CMS Proposal: CMS proposes to implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS), which would be codified. By integrating the programs, a sponsor could limit a beneficiaries' access to coverage for such drugs through pharmacy lock-in, prescriber lock-in, and/or a beneficiary-specific point-of-sale (POS) claim edit after case management and notice to the beneficiary.

AMCP Comments: AMCP is concerned with CMS's proposal to integrate the drug management program provisions with the DUR and OMS programs. The legislative intent of CARA was to provide plan sponsors with a tool with proven success in Medicaid and the commercial market to address the documented problem of opioid overutilization in the Medicare population. AMCP is concerned that integration with the OMS and DUR programs may further delay beneficiary enrollment in a drug management program as OMS and DUR use retrospective data. Furthermore, AMCP believes integration with the OMS and DUR provisions is contrary to legislative intent as during the legislative process Congress heard testimony about tying drug management programs to the OMS program and ultimately chose not to in legislation. Therefore, AMCP recommends that CMS reconsider its proposal to integrate the drug management program with the OMS and DUR programs and instead proceed with considering the drug management programs as a stand-alone program.

Frequently Abused Drugs

CMS Proposal: CMS proposes to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables. CMS proposes to not include benzodiazepines, muscle relaxants, or other non-opioid controlled substances at this time. CMS proposes to update the list of frequently abused drugs annually via the annual *Advance Summary of Methodological Changes for Calendar Year (CY) for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and Call Letter* (aka Call Letter).

AMCP Comments: AMCP is concerned with CMS's proposal that frequently abused drugs be limited to opioids only and does not include benzodiazepines or other medications associated with greater risk for overdose. The Centers for Disease Control and Prevention (CDC) recently reported that opioids were associated with the most pharmaceutical-related overdose deaths in 2010 (75.2%), followed by benzodiazepines (29.4%). In addition, benzodiazepines use was associated with 30.1% of opioid overdose deaths and opioid use was associated with 77.2% of benzodiazepine overdose deaths.[1] More recently, a 2016 study confirmed that misuse of benzodiazepines has increased over the past two decades and nearly a third of all prescription overdose deaths now involve benzodiazepines.[2] Additionally, the *CDC Guideline for Prescribing Opioids for Chronic Pain* advises clinicians to avoid co-prescribing opioids and benzodiazepines whenever possible and the Pharmacy Quality Alliance (PQA) has developed a performance measure titled *Concurrent Use of Opioids and Benzodiazepines* to help identify patients at-risk for overdose.[3] [4] Given the evidence demonstrating the risk of overdose with benzodiazepines, AMCP recommends that CMS expand the list of frequently abused drugs to include opioids and benzodiazepines. AMCP also supports CMS's proposal that the list of frequently abused drugs be updated annually via the Call Letter process and recommends that CMS work collaboratively with other federal agencies, such as the Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), CDC, and the Food and Drug Administration (FDA), providers, pharmacists, and patients to understand the current landscape of opioid overutilization and update the list of frequently abused drugs.

Clinical Guidelines

CMS Proposal: CMS proposes the clinical guidelines for use in drug management programs should be based on the OMS criteria established for plan year 2018. Specifically, use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either A) 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies; or B) 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. Under the proposal, sponsors would not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs, except sponsors will continue to be permitted to apply the criteria more frequently than CMS would apply them (e.g. CMS evaluates every six months whereas a sponsor may evaluate monthly).

AMCP Comments: AMCP is concerned with the stringent, rigid, and very prescriptive approach CMS is proposing. AMCP believes it is critical for plan sponsors to innovate using evidence-based approaches and

[1] Jones CM, Mack KM, Paulozzi LJ. Pharmaceutical Overdose Deaths, United States, 2010 JAMA. 2013; 309(7):657-659. doi:10.1001/jama.2013.272.

[2] Bachhuber MA, Hennessy S, Cunningham CO, Starrels JL (2016). Increasing Benzodiazepine Prescriptions and Overdose Mortality in the United States, 1996-2013, Am J Public Health,106(4):686-8.

[3] CDC Guideline for Prescribing Opioids for Chronic Pain. http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

[4] Pharmacy Quality Alliance *Concurrent Use of Opioids and Benzodiazepines*. https://pqaalliance.org/measures/default.asp.

identify best practices as a single approach to addressing the opioid epidemic has not been identified. AMCP recommends that CMS reconsider its proposal for prescriptive clinical guidelines and instead implement a flexible approach where CMS sets minimal guidelines and standards that plan sponsors must abide by, allowing plan sponsors the ability to innovate and identify best practices. AMCP also recommends that CMS create a learning network for health plans to share their innovative approaches and best practices to help inform and improve how Medicare beneficiaries at-risk for opioid overutilization are cared for.

Exemptions

CMS Proposal: CMS proposes to add cancer patients to the list of exempted individuals.

AMCP Comments: AMCP supports exempting cancer patients as it is consistent with the *CDC Guideline for Prescribing Opioids for Chronic Pain*.[5] AMCP also notes an inconsistency between legislative language and the proposed regulatory language in relation to the exemption for patients in hospice care. The legislative language states "an individual who receives hospice care" whereas the proposed regulatory language states "an individual who has *elected* to receive hospice care." AMCP notes that not all individuals may have the ability to "elect" hospice care for themselves and therefore recommends that the proposed regulatory language be amended to be consistent with the legislative language.

Prescriber Verification and Agreement

CMS Proposal: CMS proposes that in addition to case management, a sponsor must first obtain the agreement of the prescribers of frequently abused drugs to enter the beneficiary into a drug management program, unless the prescribers were not responsive to the required case management.

AMCP Comments: AMCP is concerned with the prescriber agreement requirements as proposed. AMCP is concerned that beneficiaries may be delayed in being entered into a drug management program if one or more of their prescribers does not agree or is not responsive. In addition, exceptions are not included for prescribers that may be under sanction or investigation for their prescribing practices (e.g. pill mills). AMCP also notes that the same requirement is not being proposed for pharmacy lock-in and that notification alone is considered sufficient. Finally, AMCP believes prescriber agreement is inconsistent with legislative intent as the legislation only requires prescriber verification and not agreement. Therefore, AMCP recommends that CMS reconsider its proposal and not require prescriber agreement. Prescriber notification should be considered sufficient and also aligns with the requirements for pharmacy lock-in.

[5] CDC Guideline for Prescribing Opioids for Chronic Pain. http://www.cdc.gov/drugoverdose/prescribing/guideline.html

Waiting Period

CMS Proposal: CMS proposes that a sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber until at least six months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary.

AMCP Comments: AMCP is concerned with the six month waiting period as plan sponsors would not be able to expedite enrollment in a drug management program and act in the best interest of the beneficiary when the beneficiary is in serious or imminent danger. In addition, as proposed, a plan sponsor would have to wait six months before enrolling a beneficiary in a drug management program even if all of the other requirements for enrollment were met. Furthermore, the six month waiting period applies only to prescriber lock-in and is not consistent with the proposed requirements for pharmacy lock-in. AMCP recommends that CMS reconsider the waiting period proposal and instead permit enrollment in a drug management program as soon as all other requirements are met. In addition, AMCP recommends that CMS develop an exceptions process that allows plan sponsors to expedite enrollment in a drug management program when the beneficiary is identified as being in serious or imminent danger.

Termination

CMS Proposal: CMS proposes a maximum 12-month period for drug management programs. Therefore, a beneficiary should be terminated from a drug management program the sooner of the 12-month maximum period or once they demonstrate that they are no longer at-risk.

AMCP Comments: AMCP is concerned with the 12-month maximum enrollment period proposed by CMS as it does not require an assessment prior to termination. AMCP believes that all patients in a drug management program should be evaluated to determine if they continue to meet the definition of at-risk and therefore should continue to be enrolled in a drug management program. AMCP believes that automatic termination from a drug management program is not in the best interest of patients as over 90% of patients report a relapse upon discharge from a program with 59% of patients reporting a relapse within one week of discharge.[6] Therefore, AMCP recommends that CMS require an assessment of a beneficiary at 12 months to determine their at-risk status prior to discharge. If a beneficiary is identified as still being at-risk, the plan sponsor should be permitted to continue enrollment for the beneficiary for an additional 12-month period.

[6] Smyth BP, Barry J. Keenan E, Ducray K. Lapse and Relapse Following Inpatient Treatment of Opiate Dependence. Ir Med J. 2010 June;103(6):176-9.

B. Medication Therapy Management

Medical Loss Ratio

CMS Proposal: CMS proposes that that all Medication Therapy Management (MTM) programs that comply with § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans) are Quality Improving Activities (QIA) and therefore will be included in the Medical Loss Ratio (MLR) calculation.

AMCP Comments: AMCP strongly supports the inclusion of MTM programs in the medical loss ratio (MLR) as quality improving activities. AMCP believes the inclusion of MTM programs in the MLR as a quality improving activity will further encourage and incentivize providers to strengthen their MTM programs, resulting in increased health care outcomes and decreased health care costs.

C. Benefit Design & Utilization Management

Biosimilars

CMS Proposal: CMS proposes to revise the definition of generic drug at § 423.4 to include follow-on biological products approved under section 351(k) pathway. CMS proposes this change to lower cost sharing for lower cost alternatives and improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and reduce costs to both Part D enrollees and the Part D program. CMS notes that its classification of follow-on biologics as generic drugs is only for the purpose of non-LIS catastrophic cost sharing and LIS cost sharing and is not to be universally applied across all CMS policy.

AMCP Comments: AMCP supports the classification of biosimilars as applicable drugs under Medicare Part D and believes CMS's proposal is a step in the right direction. However, AMCP remains concerned that biosimilars will continue to be treated as non-applicable drugs during the "donut hole" and encourages CMS to work with Congress to address this.

Midyear Formulary Changes

CMS Proposal: CMS proposes to provide sponsors with more flexibility to implement generic substitutions by permitting sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met. CMS also proposes reducing the 60 day advanced notice period for 30 days.

AMCP Comments: AMCP supports increased flexibility for sponsors to implement midyear formulary changes and the reduction in the advanced notice period. AMCP recommends that CMS also clearly articulate that the midyear formulary changes are also applicable to interchangeable biosimilars. While no interchangeable

biosimilars are on the market at this time, it is anticipated that they will be soon and therefore it would behoove CMS to be proactive and ensure that its regulations also address interchangeable biosimilars and the ability of plan sponsors to perform midyear formulary changes for them.

Tiering Exceptions

CMS Proposal: CMS proposes to make regulatory changes to prohibit sponsors from excluding non-preferred generic-drug tiers from tiering exceptions. CMS proposes to base eligibility for tiering exceptions on the tier that contains the preferred alternative drug to the higher-cost requested drug, rather than based on tier labels established by the plan.

AMCP Comments: AMCP does not support CMS's interpretation of "applicable lower cost-sharing tier" and believes it undermines the development of evidence-based formularies which enhance the quality of patient care by selecting the most appropriate medications for patients with the goals of reducing treatment failures, adverse drug events and hospitalizations and improving patient adherence and health outcomes. AMCP also believes that CMS's interpretation of tiering exceptions is causing confusion in the marketplace and recommends that CMS clearly articulate their interpretation using concrete examples of how it would be applied.

Manufacturer Rebates and Pricing Concessions

CMS Proposal: The proposed rule includes a Request for Information (RFI) soliciting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale.

AMCP Comments: AMCP recommends that CMS work with stakeholders to review the recommendations from the RFI to understand their implications prior to proposing any formal changes.

Any Willing Provider Standards

CMS Proposal: CMS clarifies that sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. CMS proposes to redefine "retail pharmacy" and "mail order pharmacy." CMS notes that it does not support the use of sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations. CMS also notes that it would not expect sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so. CMS also proposes to establish deadlines by which sponsors must furnish their standard terms and conditions to requesting pharmacies.

AMCP Comments: AMCP opposes the any willing provider provisions. AMCP supports the ability of plan sponsors to selectively contract with only those pharmacies necessary to enable the organization to provide beneficiaries with adequate access to pharmacy services, and quality, cost-effective health care. Plan sponsors build networks of pharmacies who demonstrate they can deliver high-quality, affordable health services to beneficiaries.[7] By selectively contracting with pharmacies, plan sponsors assure that beneficiaries can receive the best care, have adequate access to the pharmacies they need, and reduce the likelihood that valuable health care resources will be wasted through inappropriate use.

The any willing provider provisions of the proposed rule, by contrast, would require plan sponsors to contract with any pharmacy who agrees to meet the terms and conditions of the organization, whether or not it can be demonstrated that the pharmacy meets both the quality standards, and the geographic access needs of the plan sponsor. Proponents argue that these mandates assure that beneficiaries can choose among pharmacies for receiving their health services. However, plan sponsors must compete against each other for beneficiaries, whether through employer-sponsored programs, the individual market, or exchanges and this competition motivates plan sponsors to provide access to a broad number of pharmacies. In fact, many beneficiaries select a health plan based on its ability to provide broad access for all beneficiaries by having pharmacy networks in place across many geographic areas.

AMCP also believes that beneficiaries are able to exercise freedom of choice without any willing provider mandates. Plan sponsors go to great lengths to assure they have enough qualified pharmacies in their networks so patients have adequate access to needed medical services. Before or while enrolling, prospective beneficiaries can verify pharmacy participation in a specific plan by utilizing online resources, thereby making an informed decision. If a beneficiary has not developed a pharmacy relationship, they can then choose from among a broad array of individual pharmacies within the plan's network.

Additionally, AMCP opposes the any willing provider provisions on the following grounds:

- Any willing provider provisions result in increased costs to the health system. For example, some health plans achieve economies of scale by owning or operating their own in-house pharmacies, opting not to contract with outside pharmacies. Other health plans achieve cost-savings by selectively contracting with certain pharmacies, offering increased volume of business in exchange for reductions in pharmacy charges. Health plans also minimize administrative costs by maintaining a select pharmacy network. The any willing provider provisions, therefore, would undermine the ability of plan sponsors to achieve these savings, and pass those savings onto purchasers and beneficiaries. An economic analysis of states with any willing provider requirements for pharmacies found that there is an association between any willing

[7] C. Durrance, The Impact of Pharmacy-Specific Any-Willing-Provider Legislation on Prescription Drug Expenditures, Atl Econ J, 2009; 37: 409-423

provider provisions and an increase in both overall per-patient health expenditures and an increase in per-patient pharmaceutical spending.[8]

- Any willing provider provisions that do not require the pharmacy to meet the terms and conditions of the plan sponsor's contract undermine the ability to control the quality of clinical services provided to its beneficiaries. Plan sponsors rely on utilization review and other quality assurance programs to ensure that beneficiaries receive high-quality, cost-effective care. Such programs are effective only if plan sponsors can selectively contract with those pharmacies who satisfy the plan's quality requirements, and whose performance can be regularly monitored by the plan.

- The any willing provider provisions could potentially increase the likelihood of prescription drug fraud. Prescription drug fraud may take several forms, including the distribution of counterfeit drugs and patients presenting forged prescriptions to legitimate pharmacies. Another disturbing trend is the practice of opening a pharmacy that is fraudulent itself. In this scenario, the pharmacy owners are able to bill payers for phantom prescriptions that are never filled, accept payment and then close their doors before they are audited. Because they would not be able to exclude any pharmacy from their network, any willing provider provisions could make it difficult, if not impossible, for a plan sponsor to not include a pharmacy suspected of fraud in their network. A plausible link between any willing provider provisions and increased fraud has been acknowledged by the Government Accountability Office (GAO), which has suggested that allowing the Medicare program to establish a preferred provider network and to negotiate with select providers would be acceptable strategies to help curb fraud, waste and abuse in the program.[9]

- The any willing provider provisions undermine competition in the marketplace. The Federal Trade Commission has held that any willing provider provisions discourage competition in the health care marketplace for both pharmaceutical services and managed care programs, restricting beneficiary access to affordable health care, and limiting beneficiary choice to enroll in the health benefit program that best suits their needs. AMCP agrees with this position and believes that competitive market forces dictate that prepaid health plans make sure they have sufficient numbers of pharmacies in their networks to provide adequate access to health care services to their beneficiaries.

AMCP is also concerned that the deadlines by which sponsors must furnish their standard terms and conditions to requesting pharmacies is not realistic and that a 7-10 day timeframe would be more feasible for plan sponsors.

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[8] *Id.*

[9] GAO, Medicare: Modern Management Strategies Could Curb Fraud, Waste and Abuse (GAO/T-HEHS-95-227, July 31, 1995), available online at http://archive.gao.gov/t2pbat1/154851.pdf.

Therefore, AMCP recommends that CMS abandon the any willing provider provisions and maintain the status quo. In addition, CMS should modify the timeframe for furnishing standard terms and conditions to a requesting pharmacy from 2 days to at least 7-10 days.

D. Health Information Technology & Data Interoperability

NCPDP Script Standard

CMS Proposal: CMS proposes to adopt the NDPDP SCRIPT Standard Version 2017071, and retire the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting prescriptions and prescription-related information.

AMCP Comments: AMCP supports adoption of the updated NCPDP SCRIPT standard for e-prescribing. However, CMS's proposal does not require use of the NCPDP electronic prior authorization (ePA) standard. AMCP supports the adoption of the ePA standard approved by NCPDP to improve efficiencies in the prior authorization process, improve patient outcomes, reduce POS rejections, and improve the Medicare Part D member experience. Therefore, AMCP recommends that CMS also adopt the NCPDP ePA standard.

Disclosure Requirements

CMS Proposal: CMS proposes to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC) to alleviate plan burden related to printing and mailing

AMCP Comments: AMCP supports the electronic delivery of documents required under Medicare as it alleviates plan burden, decreases administrative costs on the healthcare system, and also reduces the number of paper documents that beneficiaries receive from plans.

E. Fraud, Waste, and Abuse

Quality Improving Activities

CMS Proposal: CMS proposes to remove the current exclusion of fraud prevention activities from Quality Improving Activities (QIA) and to expand the definition of QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. CMS proposes to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses.

AMCP Comments: AMCP strongly supports the inclusion of fraud prevention expenditures in incurred claims for Medical Loss Ratio (MLR) reporting purposes. AMCP believes that including fraud, waste, and abuse

expenses in the MLR calculation, rather than treating them as administrative costs, will encourage health plans to field more robust fraud detection programs and avoid efforts to pare back those activities.

Days' Supply Requirements

CMS Proposal: CMS proposes to change the transition supply requirements for long-term care patients from 91 – 98 days to 30 days due to concerns with waste and costs. CMS clarifies the transition supply requirements for outpatient is one month and not necessarily 30 days to account for medications that are packaged as 28 day supplies

AMCP Comments: AMCP supports a decrease in the transition supply requirements to help address waste and decrease overall costs for beneficiaries.

F. Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. 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