March 7, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments to Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule (42 CFR Parts 409, 417, 422, et al)

Dear Ms. Tavenner:

The Academy of Managed Care Pharmacy (AMCP) respectfully submits comments in response to Medicare Program; Contract Year 2015 *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule* (42 CFR Parts 409, 417, 422, et al.) January 10, 2014 (Part D proposed rule.) AMCP is a national professional association of pharmacists, physicians, nurses, and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

AMCP members employed by health plans, pharmacy benefit management companies (PBMs), and other managed care organizations have been actively involved in the operation of the Medicare Part D program since its creation under the *Medicare Modernization Act of 2003* (MMA) and its full implementation in 2006. AMCP members are proud of the accomplishments of the Medicare program that has consistently provided beneficiaries with access to affordable medications at budgeted costs to the government substantially lower than originally projected by the Congressional Budget Office.[1] These cost savings are also coupled with tremendous approval among Medicare beneficiaries based on surveys that show 90% consumer satisfaction rates – among those who received medicines through their prescription drug plans, 97% were satisfied.[2]

Beneficiaries are also given a wide choice of plans in each region. These choices allow beneficiaries to select among a variety of plans in their region that suits their individual needs by cost, access to pharmacies, and availability of prescription delivery methods, including retail and mail order. Beneficiaries have readily transparent plan choices that are easily reviewable on the online Medicare Plan Finder or by phone at 800-MEDICARE.[3]

Many factors contribute to the success of the Medicare Part D program, but one area where AMCP members have direct involvement on a daily basis is the implementation of managed care

tools to ensure access to safe and cost effective medications. One key managed care tool AMCP members use to deliver safe and appropriate medications is *formularies*, established by pharmacy and therapeutics (P&T) committees. P&T committees are comprised of pharmacists and physicians who critically review evidence-based literature on medications in each category and classes covered by Medicare Part D and select those medications that are the safest and most effective for that population for formulary placement. P&T decisions then help plans negotiate with pharmaceutical companies for lower costs for medications with better safety and effectiveness profiles. Beneficiaries then pay lower cost-sharing amounts for medications selected for preferred formulary status.[4] In the proposed rule's analysis of suggested changes for the clinical classes of concern, CMS cites the important contributions of P&T committees in ensuring beneficiary access to safe and effective medications.[5]

The Medicare program savings are attributable to a number of factors associated with the unique market-based design of the Medicare Part D program that allows beneficiaries to have access to a variety of options to access affordable medications in a manner that is convenient to them, including through mail order and community retail pharmacies.[6] These plan choices also offer Medicare beneficiaries variation in the amounts they will spend in premiums and prescription medications. Another managed care tool that contributes to the success of the Part D program is *preferred pharmacy networks*. In 2014, 70% of Medicare beneficiaries chose Part D plans that included a preferred network of pharmacies.[7] Preferred pharmacy networks allow Medicare beneficiaries to pay lower premiums and pay lower medication prices at certain pharmacies. Beneficiaries who prefer access to a greater number of pharmacies in a region currently have a robust number of plans available; moreover, beneficiaries may choose lower-cost preferred networks or may choose to pay slightly higher, yet affordable premiums to have access to a wider variety of pharmacies. These choices are the backbone of the Medicare program and contributors to its success.

AMCP is concerned that the proposed rule may undermine the success of the program by:

- Limiting current beneficiary choices by restricting specific plans to only two per region;[8]
- Limiting beneficiary access to preferred networks;[9]
- Eroding the market success of the program by introducing unnecessary government intrusion into negotiations between plans and pharmacies;[10] and
- Expanding the medication therapy management (MTM) program to 55% of beneficiaries in a way that expands access, but unnecessarily stretches resources in a manner that does not effectively ensure access to pharmacists' services to those beneficiaries who really need it.[11]

AMCP comments will specifically consider some of the concerns raised above in more depth below. We would like to emphasize that in February, AMCP joined more than 200 other diverse organizations representing health plans, PBMs, insurance companies, patient advocacy groups, consumer groups, physicians, business groups, pharmaceutical and biotechnology companies, charitable organizations and others to request that the proposed rule be rescinded.[12] AMCP stands by this request and urges CMS to not finalize the provisions of the proposed rule because of the restrictions on access to plans by beneficiaries and the potential to increase costs to both beneficiaries and the government.[13]

While AMCP generally opposes most provisions of the rule, one positive provision that may save the program and beneficiary costs as well as improve safety is the proposal to allow Part D plans to manage medications in three of the six classes of clinical concern (protected classes). Namely, this provision allows plans to manage through evidence-based formularies for medications in the antidepressant, antipsychotic, and immunosuppressant classes of medications. AMCP supports CMS' analysis that requiring plans to cover all or substantially all of these products may increase overall program costs and may pose dangers for some seniors who use them. AMCP encourages CMS to finalize this provision through an interim final rule process to begin in 2015.

AMCP's comments will focus on the following specific areas of concern with the rule:

- The true impact of the MTM expansion to nearly 55% of beneficiaries will likely target beneficiaries who may not necessarily need or want MTM services and thus may result in a diminished impact for the potential of MTM to improve health outcomes and reduce health care costs. Rather that proposing an expansion, CMS should allow plans to focus MTM on beneficiaries *at greatest risk of hospitalization or rehospitalization*, such as individuals who are transitioning from one health setting to another. CMS should also recognize the growing importance of pharmacists' medication management services in accountable care organizations (ACOs), patient-centered medical homes, and other integrated delivery system models that seek to improve health outcomes while lowering costs. AMCP believes that integrated delivery models, such as ACOs, are more appropriate for the provision of medication management services and that health plans should be able to target beneficiaries who require MTM. Furthermore, until managed care pharmacy and other pharmacy stakeholders develop health information technology (HIT) standards to improve the delivery of MTM, the expansion will cause more chaos in the market and not improve meaningful access.
- Impact on market competition in the Medicare Part D program if CMS proceeds with its proposed interpretation of the non-interference clause. AMCP is concerned that this provision exceeds CMS' regulatory authority established by the MMA and will serve to reduce competition, limit plan choices, and increase premiums and medication costs for beneficiaries and the government.
- Changes in the structure and administration of preferred pharmacy networks and requirements to include "any willing pharmacy" in networks will result in increases in premium and medication costs to beneficiaries and additional costs to taxpayers. The proposal also suggests that future efforts to implement performance-based service contracts for pharmacies could be prohibited – which is antithetical to the Medicare program's other goals of implementing new care delivery models that focus on collaboration among health care providers and entities to improve health care outcomes and lower costs.
- Generic drug prices could increase if proposed maximum allowable cost (MAC) price reporting and contractual requirements are implemented.
- CMS' mandated operational requirements for mail order pharmacies constitute inappropriate government interference with business and implements unnecessary mandates on all plans because of the specific actions of a small number of plans.

AMCP Supports Proposed Changes to Permit Formulary Management in Three of the Six Clinical Classes of Clinical Concern (Protected Classes) and To Allow Point of Sale Safety Edits (§423.120(b)(2)(v) and (vi)

AMCP Recommendation and Position: Allow Part D Plans to Manage Medications in Three of the Six Protected Classes

CMS should implement its proposal to eliminate restrictions to plan management in the antidepressant, antipsychotic, and immunosuppressant classes of clinical concern based on its objective test described in the proposal. AMCP agrees with CMS' analysis that the restrictions on formulary management in these classes increase costs to the Medicare Part D program and also may harm beneficiaries, as is the case with inappropriate use of antipsychotics for agitation associated with dementia in older adults. A change to allow for plan management would not result in beneficiary harm or limited access to medications in these classes, because as CMS correctly cites in its analysis, P&T committee determinations along with CMS' reviews relating to nondiscrimination and transition supplies requirements ensure appropriate access to all medications covered by Medicare Part D.

AMCP has long supported the ability of plans to manage medications in all categories and classes. In the proposed rule, CMS correctly indicates that the protected classes raise costs associated with the Medicare program, citing a 2008 study commissioned by AMCP and conducted by Milliman that showed that medication spending in the protected classes disproportionately account for 16.8% to 33% of medication spending in these classes. Further, these protections reduce the ability of plans to negotiate lower prices for these medications, thereby increasing costs to beneficiaries and the government.[14]

Requirements to include all or substantially all medications on a formulary in the protected classes also result in potential safety concerns, because plans have limited ability to use standard utilization management tools to discourage use of inappropriate medications. Furthermore, formulary placement determinations related to cost sharing also relate to the P&T committee's evaluation of the safety profile of medications. Often, newer medications with less reliable safety and efficacy data in comparison to other medications are placed on higher formulary tiers which require beneficiaries to pay additional costs and are designed to encourage use of safer medications. If a beneficiary requires a non-formulary covered medication, plans are required to have a formulary exceptions process in place to ensure the beneficiary can access the medication. Given these protections and CMS' formulary review process, continued restrictions on plan management of agents in these three classes are unnecessary. Beneficiaries can access necessary medications even if not covered under the formulary by using the exceptions process required by Medicare.

AMCP Recommendation and Position: Allow Part D Plan Management of Antipsychotics to Begin in 2015 and Do Not Delay until 2016

AMCP recommends that given the body of evidence suggesting that the use of antipsychotics in Medicare beneficiaries has been associated with a slightly elevated risk of morbidity and mortality, CMS proceed with allowing plans to begin managing medications in this class in 2015, and not wait until 2016 as proposed. As CMS suggests in the proposed rule, Part D plans' formulary management process, including required transition supplies is sufficient to ensure that

beneficiaries receive access to appropriate medications in this class. Continued protection of this class would place beneficiaries at risk of harm for an additional year. Furthermore, regardless of when the change is implemented, plans would work with beneficiaries, prescribers, and pharmacists to ensure that medications are discontinued or changed safely.

Part D plans, CMS, and the Department of Health and Human Services Office of Inspector General (HHS-OIG) have identified that inappropriate utilization of antipsychotics in older adults with dementia – based on off-label use of these medications, particularly for nursing home residents – creates a dangerous situation associated with a substantial risk of morbidity and mortality.[15] A 2011 HHS-OIG study examined Medicare Part B and D claims data from January 1-June 30, 2007, to determine the level of use and prescribing of antipsychotics for off-label indications, such as depression, obsessive compulsive disorder, and agitation in dementia, and prescribing that is counter to a black-box warning of the risks of morbidity and mortality associated with use in dementia-related psychosis.[16] Overall, the study found that nursing home residents received 20% of all antipsychotic medications prescribed to Medicare beneficiaries. Eighty-eight percent of claims were prescribed for the condition contraindicated by the black-box warning and 83% of these claims were for off-label indications. This amounted to nearly 1.4 million inappropriate claims for the medications and a total of $116 million paid in erroneous claims.[17] The HHS-OIG review did not specifically examine formulary requirements for antipsychotics but noted that without a requirement for a diagnosis code, pharmacies have difficulty determining the indication. However, if plans were permitted to implement standard formulary management tools, including prior authorization, then more clinical information could be collected to determine whether the medication is appropriate.

A 2007 Agency for Health Care Quality Research (AHRQ) systematic review of use of atypical antipsychotics for off-label indications found that little evidence exists for use of these medications for off-label indications.[18] In fact, this study found that use of these agents for off-label indications is associated with a slightly elevated risk of morbidity and mortality.[19] Given the questionable safety and efficacy profile on the use of antipsychotics in Medicare beneficiaries, there does not seem to be a justifiable rationale to continue with the policy of open access until 2016.

AMCP Recommendation and Position: Allow for Certain Patient Safety Edits at the Point of Sale
AMCP supports CMS' proposal to allow point of sale utilization safety edits based on Food and Drug Administration (FDA) maximum daily dosing and black-box warnings for medications in the protected classes. As CMS correctly indicates, this is consistent with plan responsibilities to ensure safe use of medications. AMCP also supports CMS' continued exception allowing plans not to cover all medications identified as therapeutic alternatives by the FDA *Orange Book.*

AMCP Opposes the Proposed MTM Expansion Outlined in the Proposed Rule
(§ 423.153(d))

AMCP Recommendations and Position: CMS should withdraw the proposed MTM expansion
The proposed expansion reduces the number of chronic conditions and medications for eligibility and reduces targeted spending levels to $620 per year. CMS estimates that this change will expand eligibility to 55% of Medicare beneficiaries. AMCP supports the provision of MTM by

pharmacists but does not believe that the current infrastructure, which is little more than a regulatory unfunded mandate, provides a solid foundation for a practice model to truly provide the level of services necessary to improve outcomes. CMS' own study conducted by Acumen[20] and a literature review performed by AHRQ[21] suggest that the current MTM program does not effectively reduce overall costs, health outcomes, or reduce hospitalizations. AMCP agrees with these findings and is actively engaged in efforts with its members, CMS, hospitals and other health systems, and other health care providers and stakeholders to seek MTM solutions that actually improve health care outcomes, reduce hospitalizations and readmissions, and help to lower spending. CMS should also focus efforts on MTM interventions that close gaps in therapy and those included in ACOs and other integrated delivery models.

MTM programs should be designed based, not on arbitrary mandates, but on the needs of identified enrollees in a plan, utilizing appropriate patient selection criteria and interventions to meet the needs of individual members. MTM programs should identify appropriate outcomes and design measurements to assess the outcomes while maintaining appropriate documentation and results. This position is supported by organizations including AARP, AMCP, and the American Pharmacists Association, and the National Association of Chain Drug Stores consensus document *Sound Medication Management Principles, version 2.0.*[22] This document established a set of criteria for patient identification and recruitment into MTM program through enrollment criteria involving patients at risk for adverse events and those likely to be at risk for chronic diseases or other health problems. Lists of eligible patients should be updated frequently. Patients at risk could include those who:

- Overutilize or underutilize medications;
- Visit multiple physicians;
- Routinely are not adherent to or persistent with medication regimens;
- Do not understand how to use their medications and do not have a support system/network in place to guide their utilization;
- Have financial barriers to obtaining their prescriptions, including those who use very expensive medications or have very high total drug expenses; and
- Need multiple medications to treat complex comorbidities.[23]

Eligibility should not be based on an arbitrary dollar threshold increase not supported by MTM research.

As stated above, AMCP does not believe that CMS' proposed MTM expansion will meet the goals of improving the provision of MTM and improving health outcomes. AMCP is concerned that these provisions would actually dilute the value of MTM by expending scarce resources, particularly on completion of CMRs, which are time consuming because of the lack of HIT standards. Furthermore, the CMRs do not necessarily provide beneficial medication information in a useable format.

CMS' estimates that the program could expand to 55% of beneficiaries, but the reality could be much greater. For example, according to 2006 data from the Kaiser Family Foundation, in 2006, 64% of Medicare beneficiaries had high blood pressure, while an additional 42% had a reported "heart condition."[24] This is in addition to the reduction in the number of medications required to be eligible for coverage and the drastic targeted spending reductions that CMS' own estimates finds is based on fills of two generic prescriptions per month[25]

AMCP Recommendations and Position: CMS Should Refine the CMR and TMR Process by Enhancing HIT Capabilities

Plan responsibilities for MTM continue to grow each year with no funding from CMS. Plans must currently perform a comprehensive medication review (CMR) on each MTM-eligible beneficiary and then perform targeted medication reviews (TMRs) on a quarterly basis. CMS actuaries have estimated the costs for the completion of the CMR alone to be $111 million,[26] a fraction of the true amount that many AMCP members consider to be within the actual range to provide CMRs for 18 million Medicare beneficiaries. Furthermore, CMS' *Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter* (2015 draft call letter) includes ways that CMS suggests for improving MTM and CMRs and TMRs by implementing HIT standards for MTM. AMCP will provide separate comments on the call letter which will emphasize our goal of implementing an HIT industry-driven standard to facilitate and improve the provision of MTM.

AMCP members consistently report that the calculations used by CMS to determine CMR utilization do not nearly cover the actual costs associated with completion and mailing. CMS estimates that the time to complete a CMR is approximately 35 minutes. This figure greatly underestimates the completion time. The initial contact with beneficiaries through plan pharmacists is often 35 minutes and then after the initial discussion is completed, additional work is necessary to compile the information and then mail the forms, for a total of about 2 hours' time. In addition, CMS greatly underestimates the labor costs associated with CMS completion. Given the level of training for pharmacists and others involved with CMR completion, the labor costs are much greater than the $70 estimates.

AMCP Recommendations and Position: MTM Should Not Be Limited to Face-to-Face Interactions

AMCP also encourages CMS to revise its goals to encourage MTM in ways other than face-to-face. Given the number or requirements on plans to conduct MTM, CMS must recognize that plans often rely on telephonic communications to reach beneficiaries. As other forms of technology continue to be accepted in the provision of health care, beneficiaries could be reached in other ways and should be considered by CMS as legitimate means to perform MTM.

AMCP is concerned that the MTM expansion assumes that community retail pharmacies would handle the additional service levels necessary to provide MTM. AMCP members consistently report difficulties in receiving participation in MTM programs at the current level from community retail pharmacies. This expansion could place an additional unnecessary burden on plans when trying to actively engage community retail pharmacies to perform these services.

Until AMCP and other industry stakeholders develop an HIT solution for MTM and provide more data to effectively provide MTM in a manner that improves outcomes and lowers costs, CMS should not make any additional changes to MTM eligibility criteria. As suggested in the proposed rule, these solutions could also help to improve access to MTM services for minorities and other special populations.

CMS Should Rescind Its Proposed Interpretation of the Non-Interference Clause that Will Result in Unnecessary Government Intervention in Medicare Operations Between Plans and Pharmacy Networks (§423.10)

AMCP Recommendation: *CMS Should Rescind Its Proposed Interpretation or Seek a Change to the Statute*

Given the Congressional intent of the non-interference clause, the history of CMS' interpretation that it will not intervene with operations between and among plans and pharmacy networks, and the negative impact such interference would have in the operation of Medicare Part D, CMS should rescind its interpretation of the non-interference clause.

As a regulatory agency, CMS may only interpret the meaning of a statute when the provision is unclear or ambiguous.[27] Here, CMS is interpreting a provision of the MMA that not only is unambiguous, but CMS itself has a history of interpreting it in a manner inconsistent with the proposed re-interpretation.

The following is the clause at issue for purposes of this section: "Non-interference.—In order to promote competition under this part and in carrying out this part, the Secretary—may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."[28] CMS' current interpretation that it may oversee contract negotiations with plans and pharmacy networks is incorrect. The clause does not limit itself to negotiations for price or formulary, but rather negotiations in general. The MMA created a competitive market consisting of plans and pharmacy networks to establish the Medicare Part D program. Given this goal, if Congress had intended for CMS to interfere with negotiations with plans and pharmacy networks, then this intent would be available either in the plain meaning of the statute or the legislative history. Neither of these conditions applies and evidence to the contrary exists based on the examples given below:

Sections from the first Part D final regulation issued in 2005 included the following explanations and statements related to the non-interference clause:[29]

- "As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans."
- "We do not believe the MMA provides us with the authority to establish fee schedules or interfere with the contracts between plans and providers."

Then in 2010, the Medicare Part D final rule[30] included the following statement in the preamble:

- The non-interference provision at section 1860D–11(i) of the Act explicitly provides that "the Secretary may not interfere with the negotiations between pharmacies and PDP sponsors, which would include payment negotiations between the Part D sponsors and pharmacies for MTM services."

As listed above, until now, CMS has historically maintained a precedent of not interfering with negotiations between plans and pharmacies consistent with statutory intent. Given this precedent, CMS must either rescind its statement or seek an amendment to the statute through Congressional authority.

CMS Should Maintain the Preferred Pharmacy Network Structure and Allow Plans to Negotiate with Pharmacies to Ensure Access Prescription Drugs at Affordable Prices and Ensure Network Quality (§423.100 and §423.120 and §324.120(a)(8))

AMCP Recommendations and Position: Preferred Pharmacy Networks Save Beneficiary and Medicare Program Costs and Should be Allowed to Continue

AMCP supports the use of preferred pharmacy networks as a tool that Part D plans may utilize in their Medicare Part D plan offerings. Plans with preferred networks contribute to the robust plan choices available to beneficiaries in the 34 Medicare Part D regions. Recent study findings suggest that preferred pharmacy networks save Medicare beneficiaries money by providing them the opportunity to pay lower premiums and receive medications at lower negotiated prices at network pharmacies. Therefore, beneficiaries should have access to plans with preferred networks as part of a variety of choices available.

Provisions in the 2015 draft call letter indicate that CMS will conduct a study on the impact of preferred cost sharing. AMCP will submit a separate comment on the 2015 draft call letter, but urges CMS to include plans with preferred networks in the study. Further, AMCP urges CMS not to finalize the proposed rule provisions or make any changes to the preferred pharmacy structure until the findings of the study are analyzed and subject to public review and comment.

Preferred networks represent a win-win for Medicare Part D beneficiaries and for the government by lowering prescription drug costs. Under preferred pharmacy network arrangements, plans negotiate reduced prices with certain retail pharmacies for Medicare Part D drugs. In exchange for beneficiaries' utilization of these pharmacies, they receive reduced monthly premiums, and co-payments and co-insurance is generally reduced—thus creating a win for the government and for beneficiaries. *Consumer Reports Magazine* recently recommended preferred pharmacy networks as one way for consumers to save money on prescription drug costs.[31] In 2014, more than 70% of all Medicare beneficiaries enrolled in PDPs chose plans with preferred networks[32] and nearly 85% of 400 beneficiaries recently surveyed are satisfied with these plans.[33]

Recent analyses suggest the following advantages when using preferred pharmacy networks:

- Plan offerings with the lowest monthly premiums for Medicare Part D include preferred pharmacy networks. Seven of the top 10 plans with the lowest monthly premiums include preferred pharmacy networks.[34]
- Preferred network plans may lower premiums substantially, thus lowering costs for both beneficiaries and for the government, particularly in payments for low-income subsidies.[35] Preferred pharmacy networks have contributed to year-to-year premium reductions since introduced in 2011.[36]

AMCP Recommendations and Position: Preferred Pharmacy Networks Leveraged to Help Improve Outcomes and Quality Measures

AMCP supports the use of preferred pharmacy networks as a tool to ensure quality of care and access to pharmacies that may influence health outcomes and lower costs as part of integrated

delivery models, ACOs, and other emerging payment models. AMCP is concerned that restrictions in the proposed rule could make integration of pharmacies as full participants in ACOs and other models difficult in the future and therefore CMS should re-consider these provisions.

Preferred pharmacy networks may be leveraged to help improve overall outcomes and quality measures. First, risk-sharing arrangements with pharmacy networks and incentives to increase generic utilization rates increases pharmacist and pharmacy participation in patient health care management and may help to improve medication adherence and utilization by ensuring that patients receive the appropriate medications at a reasonable cost. Second, preferred pharmacy networks may also incorporate pharmacists patient care services and interventions into accountable care arrangements and other integrated care delivery to achieve better health outcomes at a lower cost. Pharmacies and pharmacy chains that help to achieve better health outcomes should receive incentives to continue these practices through preferred network arrangements.

The Center for Medicare and Medicaid Innovation (CMMI) issued a Request for Information (RFI) in December 2013 to consider integration of Medicare Part D into ACOs,[37] including information related to Medicare Part D integration into ACOs and the possibility of enhanced risk sharing by ACO participants. In comments responding to the RFI, AMCP supported integration of Part D into ACOs so long as certain conditions were met, including the ability of pharmacies to participate in risk sharing. AMCP is concerned that CMS' current Part D proposal would undermine the ability for pharmacies to ever fully participate in ACOs as full partners because of restrictions on the ability to enter into insurance risk contracts. CMS should rescind this short-sighted proposal to ensure that pharmacies are not restricted from full participation in ACOs and other emerging delivery models in the future.

AMCP Recommendations and Position: "Any Willing Pharmacy" Provisions Do Not Save Cost but Rather Increase Costs Because Lack of Negotiation

"Any willing pharmacy" provisions that require plans to offer terms and conditions to any pharmacy willing to accept the terms only serve to increase prices to consumers because of limitations on the ability of plans to negotiate with pharmacies. AMCP supports market-based competition that occurs when plans and pharmacies negotiate aggressively for prices and services. CMS should not change this structure that has worked to allow the success of the program.

CMS' proposed changes to "any willing pharmacy provisions" are short-sighted because this would impose barriers on plans' ability to negotiate competitively in the 34 regions. In fact, they've been shown to harm consumers by increasing prices. This premise is supported by analyses conducted by both the Department of Justice and the Federal Trade Commission.[38] CMS should also heed these analyses before requiring "any willing pharmacy" provisions.

Generic Drug Prices Could increase if Proposed MAC Price Disclosure and Reporting Requirements are Implemented and Therefore CMS Should Rescind These Provisions
(§ 423.505(b)(21))

AMCP Recommendation and Position: CMS Should Rescind the MAC Pricing Provisions
CMS should rescind the current proposal that changes requirements for MAC pricing and requires plans to include contractual terms with MAC prices and requires notification to pharmacies prior to changes. AMCP supports the use of MAC pricing as a managed care tool to encourage the dispensing of cost-saving generic drugs, which benefits the overall health care system. AMCP opposes the proposed MAC pricing changes on the following grounds:

- MAC lists are proprietary calculations that include methodologies used to pay pharmacies, and therefore, government intrusion into this is an inappropriate direct interference into a negotiation between plans and pharmacies; and
- Requirements establishing that MAC lists must be updated every 7 days and that pharmacies must be notified in advance of any changes are also inappropriate government interference with business practices. [39]

Part D plans operate in a highly competitive environment; therefore, it is essential to ensure that their contracted pharmacies compete with each other to obtain the lowest price possible for beneficiaries. If MAC price information is publicly disclosed, it would have an anticompetitive effect on health plans, employers and other payers. Competing health plans would have access to others' pricing information and competing pharmacies would have access to others' MAC reimbursement calculations, allowing both the potential opportunity to price fix. This may increase drug prices for health plans, employers, other payers and consumers.

AMCP supports, as a best practice, payers providing a fair and timely MAC appeals process related to a contracted pharmacy's MAC pricing inquiries or disputes. AMCP recognizes that instances exist when the MAC pricing must be revised based on certain environmental factors, e.g., the supply of available products is diminished or limited. Examples of where MAC pricing may be suspended include when raw ingredient availability reduces the number of trade available products on the market and when litigation or the threat of litigation lead to an injunction or concern within the marketplace, thereby limiting the number of manufacturers who offer a product. Plans need the flexibility to adjust for these market circumstances. AMCP also supports as a best practice, payers including a provision in the contract that provides for notification of updates to the MAC list within a specified time period. However, AMCP does not support a government-mandated turnaround time.

AMCP believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care benefits. Competitive negotiations between parties are more likely to provide fair and equitable reimbursement on drugs dispensed. The government intervention proposed by CMS removes the incentive for a pharmacy to make wise purchasing decisions. The payers and consumers will not benefit from a system of government-mandated payments to a private entity; rather it will decrease competition and further drive up the cost of the prescription drug benefit.

AMCP is not aware of any other instance where federal or state laws require private companies to disclose their proprietary pricing methodology to a purchaser. Imposing government price controls on one market segment for the purpose of financially benefiting another segment is not an appropriate role for CMS under its regulatory authority.

CMS' Proposed Establishment of Mail Order Operational Requirements for Plans Is Inappropriate Government Intervention and Punishes All Plans Because of the Actions of a Few and Should Be Rescinded (§423.120)

AMCP Recommendations and Position: CMS Should Not Impose Operational Requirements for Mail Order on Plans

CMS' proposed requirements for mail order procedures constitute inappropriate government intervention into plan operations and punish all plans for the actions of a few. AMCP believes that Part D plans must have the flexibility to use mail service delivery of prescription drugs as a component of their prescription drug benefit. Mail order pharmacies are a valuable tool used by Part D plans to increase patient safety, offer patient convenience, and maintain the affordability of the prescription drug benefit as a whole. In addition, Part D plans should have the ability to set patient cost-sharing levels for prescription orders filled through mail order pharmacies different from the patient cost-sharing levels for prescription orders filled through retail community pharmacies unless retail community pharmacies are willing to accept the terms and conditions of the mail order pharmacy.[40]

Conclusion

AMCP again urges CMS to rescind its proposed rule because of the impact that limiting choice of pharmacies and number of plans and other provisions could have on beneficiaries' access to affordable, high quality medications. AMCP believes that several measures included in the proposal, namely changes to preferred networks and the MTM expansion, could result in additional, unnecessary costs to the program without providing better access to medications or delivering better care to beneficiaries. For these reasons, AMCP believes that the best course of action is to rescind the proposed rule. AMCP will continue to work with CMS and Congress to ensure that the harmful provisions of this proposed rule are not implemented. Thank you for the opportunity to submit comments. If you have questions, please contact me at 703-683-8416 or erosato@amcp.org.

Sincerely,

Edith A. Rosato, RPh, IOM
Chief Executive Officer

[1] Hoadley J. Medicare Part D Spending Trends: Understanding Key Drivers and Role of Competition. Kaiser Family Foundation Medicare Policy Issue Brief. March 2012. http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8308.pdf. Accessed March 1, 2014.
[2] Medicare Today. *Seniors' Opinions about Medicare Prescription Drug Coverage: 8th Year* Update. September 2013, p. 13. http://www.medicaretoday.org/MT2013/KRC%20Survey%20of%20Seniors%20for%20Medicare%20Today%20%20FINAL.pdf. Accessed March 1, 2014.
[3] Medicare Plan Finder. https://www.medicare.gov/find-a-plan/questions/home.aspx. Accessed March 1, 2104.
[4] AMCP Position on Formularies. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=14350.Accessed March 1, 2014.
[5] Medicare Program; Contract Year 2015 *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule* (42 CFR Parts 409, 417, 422, et al. January 10, 2014. §423.120(b)(2)(v) and (vi). Drug Categories or Classes of Clinical Concern and Exceptions.
[6] Hoadley at 1.
[7] Drug Channels Institute. *Medicare Part D PDPs with Preferred Pharmacy Networks 2014* October 15, 2013.
[8] *Ibid.* §423.265. Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region.
[9] *Ibid* at 5. §423.100 and §423.120. Preferred Cost Sharing.
[10] *Ibid* at 5. §423.10 Interpreting the non-Interference Provision.
[11] *Ibid*. at 5.§423.153(d). Medication Therapy Management Program under Medicare Part D.
[12] Letter to CMS Administrator Marilyn Tavenner Urging Rescission of the Medicare Part D Proposed Rule. February 18, 2014. http://www.amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-_docs/2014/CMS%20-%20Rescind%20Part%20D%20Proposed%20Rule%202.18.14.pdf. Accessed March 1, 2014.
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