AMCP Academy of Managed Care Pharmacy®

February 28, 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

Dr. Patrick Conway, MD
Deputy Administrator, Innovation & Quality and CMS Chief Medical Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Request for Information: *Evolution of ACO Initiatives at CMS;* Section II.B, Integration of Part D Benefits

Dear Administrator Tavenner and Dr. Conway:

The Academy of Managed Care Pharmacy (AMCP) writes today in response to the Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) Request for Information (RFI): *Evolution of ACO Initiatives at CMS* released in December 2013. Specially, AMCP comments focus on the Section II.B. Integrating Accountability for Medicare Part D Expenditures. AMCP supports integration of both Medicare Part D plans into accountable care organizations (ACOs) and the use of pharmacists' medication management as an essential component of team-based care in ACOs.

Appropriate medication use is an important component of health care, and Medicare beneficiaries with chronic conditions fill approximately 50 prescriptions per year, account for more than three-quarters of all hospitalizations and are 100 times more likely than individuals without a chronic illness to be re-hospitalized.[1] These statistics demonstrate the important role of medications in the care of chronically ill Medicare beneficiaries, but also demonstrates the need for better integration among Medicare Part D plans and the pharmacists and pharmacies that help deliver medication management to ensure safe and appropriate use. Yet, neither Medicare Part D plans nor pharmacists' services are fully integrated in Medicare's ACO model, but should be, considering their critical and growing role in managing patient care.

However, full integration of Part D into ACOs requires CMS and CMMI and other stakeholders to take the following important and necessary steps:

- Recognize pharmacists and pharmacies as providers under the Medicare program to help improve health care outcomes and reduce costs;
- Incorporate pharmacists, pharmacies, and pharmacy benefit management companies (PBMs) in waivers from federal fraud and abuse laws for ACOs under the Medicare Shared Savings Programs to ensure that these entities and individuals may fully participate;
- Allow pharmacies to enter into risk-based contracts for services; and,
- Include pharmacists, pharmacies, and PBMs as full users of electronic health records (EHRs).

AMCP also encourages CMS and CMMI to examine the Medicare Advantage-Prescription Drug (MA-PD) program as examples of the successful integration of medications into a risk based model.

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.

Each of AMCP's recommendations will be examined below in greater depth.

Recognize Pharmacists and Pharmacies as Providers under Part B of the *Social Security Act* (SSA) or Support Recognition in ACO Section of SSA

AMCP Recommendation: CMS and CMMI should encourage Congress to recognize pharmacists and pharmacies under Medicare Part B of the SSA or as providers in ACOs to encourage their full participation and benefit from the important medication management services they provide.

AMCP Comments: Lack of recognition of pharmacists and pharmacies as Medicare providers presents an enormous challenge to full integration of Medicare Part D into ACOs, because these providers do not have the ability to receive payment under the Medicare program and more importantly, cannot fully participate in ACOs as currently adopted. The SSA[i] defines "physicians" under the Medicare program, as including doctors of medicine and osteopathy, doctors of dental surgery and dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors, but not pharmacists and pharmacies. This omission means that pharmacists and pharmacies currently may only receive payment based on dispensing medications and, in limited circumstances, may receive payment when performing under the direct supervision of a physician or other Medicare-authorized provider. AMCP continues to support the objective of achieving Medicare Part B provider status for pharmacists and urges CMS and CMMI to work with Congress to take action in this direction.

AMCP recognizes that full Medicare Part B recognition might not be attainable in the timeframe necessary to ensure that pharmacists make meaningful contributions to ACOs and other integrated delivery models. Therefore, AMCP urges Congress to consider the inclusion of pharmacists as providers in ACOs under Section 1899 of the SSA. In December 2013, AMCP joined other pharmacy organizations in support of an amendment to the 2013 *Sustainable Growth Rate* (SGR) legislation to incorporate pharmacists as health care providers in ACOs.[ii] While the amendment was not offered because of time constraints during debate, the amendment had support in the Senate Finance Committee and among other pharmacy groups. AMCP urges CMS and CMMI to encourage Congress to reconsider

adoption of this amendment under SGR or other legislation to expedite inclusion of pharmacists and pharmacies as providers in ACOs.

Pharmacists work in organizations across diverse care settings to provide medication management. The goal of medication management is to ensure safe, effective, appropriate, and economical use of prescription medications for patients using a patient-centered interdisciplinary, evidence-based approach.[iii] Examples of where ACOs could incorporate pharmacists' medication management services include:

- Medication reconciliation where pharmacists utilize clinical interventions and health information technology (HIT) solutions to establish complete, accurate, and updated medication records, particularly during transitions of care from one health setting to others. A 2013 systematic review of the use of medication reconciliation to reduce hospital readmissions showed that pharmacists' involvement in medication reconciliation plays a "major role" in successful interventions.[iv] Medication reconciliation is a critical component of ACOs' ability to achieve the necessary outcomes to reduce hospital readmissions, and therefore could benefit greatly from the inclusion of pharmacists.
- Medication therapy management clinics for anticoagulation; transplant programs; HIV; hepatitis; psychiatric and lipid management. Patients with chronic diseases requiring multiple medications are at high risk for hospitalization and could benefit from pharmacists' interventions that help to ensure safe, effective, and affordable medication use, while reducing and managing medication-related problems.

The pharmacists' services described above are targeted at many of the domains CMS has identified for improving outcomes in ACOs, including: care coordination/ patient safety with a measure using medication reconciliation after discharge from an inpatient facility; and better health for populations, including improving care for patients with diabetes, ischemic vascular disease, heart failure, and coronary artery disease.[v] AMCP's 2012 white paper, *Pharmacists as Vital Members of ACOs: Illustrating the Important Role Pharmacists Play on Health Care Teams*,[vi] provides specific examples of models that include pharmacists used by existing health systems. CMS and CMMI should consult this white paper as a resource for programs that incorporate pharmacists.

Incorporate Pharmacists, Pharmacies, and PBMs in Waivers from Federal Fraud and Abuse Laws for ACOs under the Medicare Shared Savings Programs

AMCP Recommendation: Amend or clarify federal fraud and abuse regulations to allow pharmacists, pharmacies, and PBMs to actively participate in ACOs by incorporating them into waivers that allow them to share directly in cost savings.

AMCP Comment: The *Affordable Care Act* implemented several waivers to laws related to civil monetary penalties (CMPs) for gainsharing, beneficiary inducement, and the federal Anti-Kickback statute[vii] that allows for certain health care providers and suppliers to share savings under ACO arrangements and other Medicare shared savings programs. To integrate Medicare Part D into ACOs, PBMs, pharmacists, and pharmacies would have to be full participants in the gainsharing waiver and other waivers afforded to certain health care providers and entities allowing them to share cost savings.

Allow Pharmacies to Enter into Risk Based Contracts for Services under Medicare Part D

AMCP Recommendation: Revise provisions in the Medicare Part D proposed rule[viii] that imply risk based contracting with pharmacies would be prohibited and that contract terms between Part D plans and pharmacies be limited to costs of drugs and dispensing.

AMCP Comment: AMCP's comments to the Medicare Part D proposed rule released in January 2014 will include an extensive analysis of this issue related to CMS' interpretation of the non-interference clause; preferred network prohibitions; and any willing provider provisions. AMCP believes that the provisions, as drafted, could limit future opportunities for Part D plans to engage pharmacies in ACO models by prohibiting risk-based payments or limiting contracts to payments for drugs and dispensing only. In light of CMS' proposed prohibition on engaging pharmacies in insurance risk contracts, the CMS Part D rule seems to contradict the overall goal of ACOs and other initiatives to lower costs and improve outcomes through performance-based services. CMS and CMMIs' consideration of this issue is particularly important as it evaluates the questions posed under Section II.A.1: Transition to greater insurance risk.

Including Pharmacies, Pharmacists, and PBMs as Full Users of EHRs

AMCP Recommendation: CMS and CMMI should work with the Office of the National Coordinator, the Department of Health and Human Services, Congress, and pharmacy and managed care pharmacy stakeholders to ensure that pharmacists, pharmacies, and PBMs have the ability to fully utilize EHRs to share and access medication records and comprehensive patient information.

AMCP Comment: The *American Recovery and Reinvestment Act of 2009* included provisions and resources to develop bi-directional EHRs for certain eligible providers, including physicians and hospitals, but not pharmacists and pharmacies.[ix] As a result, pharmacists do not have the ability to read full EHRs containing a patient's comprehensive information, add recommendations or other notations to EHRs, or fully share prescription records and other prescription information among and between eligible entities. This situation is a significant barrier to integration of Medicare Part D into ACOs, because proper health information technology infrastructure is a key to success.

Conclusion

AMCP thanks CMS and CMMI for considering public comments regarding potential integration of Medicare Part D into ACOs. AMCP believes that this step could help improve the goals of the program—improving patient outcomes while lowering costs—but certain critical steps must be taken before fully realizing that objective. AMCP looks forward to working with CMS and CMMI in moving this initiative forward. If we can answer any questions or provide additional information, please contact me at (703) 683-8416 x645 or erosato@amcp.org.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

[i] Section 1861(r) of the *Social Security Act.*

[ii] AMCP Letter to Senate Finance Committee Supporting Amendment to SGR to incorporate pharmacists as health care providers in ACOs. December 11, 2013. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=17437. Accessed February 27, 2014.

[iii] Pharmacists as Vital Members of Accountable Care Organizations: Illustrating the Important Role that Pharmacists Can Play on the Health Care Team. Academy of Managed Care Pharmacy; March 2012. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9728. Accessed February 27, 2014.

[iv] Kwan JL, Lisha L, Sampson M. et al. *Ann Intern Med.* 2013;158(5_Part_2):397-403. doi:10.7326/0003-4819-158-5-201303051-00006.

[v] Improving Quality of Care for Medicare Patients: ACOs; Fact Sheet. CMS; November 2012. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Quality_Factsheet_ICN907407.pdf. Accessed February 27, 2014.

[vi] *Ibid.* at 6.

[vii] 42 USC §1320a-7a(b) "Gainsharing civil monetary penalty"; 42 USC 1320a-7b(b)(1) &(2) "Beneficiary inducement civil monetary penalty"; and 42 USC 1320a-7b(b)(1), (2), and (5) Anti-Kickback Statute.

[viii] 42 CFR Parts 409, 417, 422, et al. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule. January 10, 2014.

[ix] Spiro S. The impact of EHRs on pharmacy practice. *Drug Topics*; April 2012. http://www.pharmacyhit.org/pdfs/Article.pdf. Accessed February 27, 2104.