AMCP Academy of Managed Care Pharmacy®

November 27, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-9930-P: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019

Dear Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments in response to the proposed rule Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019 (CMS-9930-P). AMCP supports comprehensive pharmacy benefits as part of the health insurance marketplaces that provide the flexibility of health plans and pharmacy benefit management (PBMs) companies to develop formularies and provide medication therapy management (MTM) services that meet the needs of the populations covered. AMCP offers comments on the following sections of the proposed rule:

- Suggestions for reducing prescription drug costs and promote drug price transparency (Preamble)
- Access to mental and behavioral health records (Part 153(g)(vi))
- Essential Health Benefits and formulary and prescription drug coverage (Part 156)
- Medical Loss Ratio (Part 156)

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.

Suggestions for Reducing Prescription Drug Costs and Promoting Drug Price Transparency (Preamble)

CMS noted in the preamble that it intends to consider future rulemaking to reduce drug costs and promote drug price transparency and seeks comments on this area.

As CMS and other agencies consider proposals to reduce prescription costs and promote transparency, it should recognize that prescription drug costs are just one element of health care and should seek to promote solutions that ensure the provision of high value care that improves outcomes rather than narrowly focus on prescription drug costs alone. AMCP encourages CMS to work with the health care professionals, including pharmacists, physicians, and nurses who are AMCP members to develop solutions that encourage market principles to promote these changes. To this end, AMCP provides the recommendations below.

Promote Value-Based Contracting (VBC)

AMCP supports the use of VBC as a tool to ensure quality outcomes and lower costs in health care and in the Medicare and Medicaid programs. In June, 2017, AMCP held a multi-stakeholder Partnership Forum, "*Advancing Value-Based Contracting*"[1] where representatives from health plans, integrated delivery systems, PBMs, data and analytics experts, and biopharmaceutical companies agreed on areas to strengthen and improve VBC, including:

- A definition of VBC for facilitating discussion with key policy makers, regulators and other stakeholders;
- Strategies for advancing development and utilization of performance benchmarks;
- Best practices in evaluating, implementing and monitoring VBCs; and
- Action plans to mitigate legal and regulatory barriers to VBCs.

AMCP encourages CMS to adopt the definition of VBC agreed to by participants as a starting point for any consideration of VBC. This definition is: "A value-based contract is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures."

CMS should begin immediate efforts to help encourage health plans and others to voluntarily enter into VBC arrangements. CMS should work in conjunction with the Center for Medicare and Medicaid Innovation and stakeholders on identifying appropriate outcomes to measure and determining how much value to assign them. To facilitate this process, AMCP is also engaged with the participants of the Forum and other stakeholders in an initiative to identify best practices to implement, monitor, and evaluate VBC and disseminate this information to stakeholders. CMS' efforts to encourage VBC should also be coordinated with the Department of Health and Human Services Office of the Inspector General to remove or waive existing regulatory barriers, including provisions under the federal Anti-Kickback Statute (42 USC § 1320a-7b(b)) that preclude full implementation of VBC.

[1]AMCP Partnership Forum: Advancing Value-Based Contracting. J Manag Care Spec Pharm, 2017 Nov;23(11):1096-1102. http://www.jmcp.org/doi/10.18553/jmcp.2017.17342**.** Accessed Nov. 25, 2017.

Support Development and Use of Outcomes-Based Quality Metrics that Include Cost Effectiveness to Enhance Decision-making

AMCP supports the use of outcomes-based quality metrics that include a cost effectiveness component. Inclusion of cost effectiveness will allow for an assessment to establish whether a treatment provides high value relative to its cost and other clinical factors. These types of measures will better allow transparency to patients and providers to select care options and will health plans and PBMs to make better determinations of plan design elements in the development of formularies. CMS should work with measure development organizations and endorsement organizations on the development and use of outcomes-based quality metrics that include cost effectiveness.

Access to mental and behavioral health records (Part 153(g)(vi))

In this section, CMS notes that health insurers and providers must obtain consent before receiving health records or assessments of patients with certain substance use disorders because of provisions contained in 42 USC 290dd-2 and in regulations promulgated by 42 CFR Part 2 that restrict direct access to this information. The provisions of this law make it difficult for providers in direct care settings to treat patients and for health plans to receive full information related to properly evaluate insurance coverage and risk adjustment for patients with substance use disorders. AMCP notes its support of changes to provisions in laws and regulations in this area to allow health plans, providers, and others to have direct access to medical records for treatment, payment, and operations without discriminating against patients with substance use disorders.[2] A change in the provisions in this law could help facilitate health plans receipt of records for appropriate risk adjustment and help to provide better insight for establishing benefits and coverage.

Essential Health Benefits (EHB) Formulary and Prescription Drug Coverage (Part 156)

Plans and PBMs Should Have Flexibility to Develop Formularies for Populations Served

CMS proposes many changes to the EHB provisions under 45 CFR §156, including prescription drug coverage. On the one hand, the proposal supports state and plan flexibility in selecting EHBs and allows plan substitution of certain EHBs except prescription drug coverage provisions. CMS is also considering adoption of a national prescription drug standard under a default federal EHB definition for a benefit year beginning after 2019. AMCP supports a comprehensive pharmacy benefit as a component of EHBs with the ability of health plans and PBMs and their clients, including individuals, employers and federal and state governments to render independent decisions regarding health benefits to meet the needs of their patient populations. This means that health plans must have the ability to create formularies and select prescription drug coverage for populations served without unnecessary mandates and restrictions.

The development of a national default standard for prescription drugs is inconsistent with the goal of providing the flexibility to health plans and PBMs to design appropriate benefits. AMCP encourages the use of managed care pharmacy tools and resources, including MTM,

[2] Partnership to Amend 42 CFR Part 2. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22755. Accessed November 25, 2017.

prior authorization, and review of current evidence[3] by individual health plans and PBMs to achieve the objectives balancing affordability and coverage as defined by the National Academy of Medicine Report: *Essential Health Benefits: Balancing Coverage and Cost*[4], AMCP recommends that CMS not consider a national standard formulary approach but rather provide more flexibility to plans to use managed care tools and compendia resources to provide affordable pharmacy benefits.

CMS Should Consider Timing of Proposed Changes and Possibly Delay Implementation Beyond 2019

AMCP is concerned that given the number of changes to the EHB provisions and in other areas, CMS should take comments on all EHB changes into account and potentially reconsider issuing the regulation for a plan year beyond 2019. This would help to ensure more continuity in the benefits that consumers in the marketplaces receive and reduce unnecessary disruption that could lead to gaps in coverage. This extension would also make sense considering submission of a benchmark change for 2019 is due by March 2018 and it is unlikely that plans will have the ability to make changes included in this proposed rule in that time frame. AMCP also recommends that CMS also consider extending the timeframe for benchmark selection for 2020 beyond July 2018.

Medical Loss Ratio (MLR) (Part 158)

AMCP provides general comments on inclusion of activities for purposes of MLR calculation. AMCP supports the inclusion of fraud prevention expenditures in incurred claims as we have previously noted in comments to CMS. Fraud, waste, and abuse are problems that plague almost every sector of health care in the United States and CMS estimates that fraud, waste, and abuse cost taxpayers billions of dollars annually within Medicare and Medicaid alone. Although the actual amount of money lost to fraud is unknown, the estimates range from as much as three percent to ten percent of all health care expenditures.[5] AMCP believes that including fraud, waste, and abuse expenses in the MLR calculation, rather than treating them as administrative costs, would encourage health plans to field more robust fraud detection programs and avoid efforts to pare back those activities.

In addition, AMCP strongly encourages CMS to include MTM programs in the MLR as quality improving activities (QIA). Medication-related problems are a significant public health issue within the healthcare system. The Food & Drug Administration's Adverse Event Reporting System estimates that more than 1.2 million prescription related-adverse events occur each year[6], resulting in $3.5 billion in medical costs annually.[7] MTM services help address the urgent public

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[3] Managed Care Pharmacy: Best Practices that Offer Quality Care and Cost Effective Coverage to Patients, Payers, Employers and Government. AMCP 2017. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22111. Accessed November 25, 2017.

[4] National Academies of Medicine, *Essential Health Benefits: Balancing Coverage and Cost*, October 2011. Accessed November 25, 2017.

[5] AMCP Where We Stand Statement: *Fraud, Waste, and Abuse in Prescription Drug Benefits, April 2015*. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=19633. Accessed November 25, 2017

[6] Food & Drug Administration's Adverse Event Reporting System Updated November 2015. http://1.usa.gov/1W3FkGL. Accessed November 25, 2017..

[7] Institute of Medicine. Committee on Identifying and Preventing Medication Errors. Preventing Medication Errors, Washington, DC: The National Academies Press 2006.

health need for the prevention of medication-related morbidity and mortality by contributing to medication error prevention, resulting in improved reliability of healthcare delivery, and enabling patients to take an active role in medication and healthcare self-management. In one significant example, a study of MTM programs in a large health system identified that 85% of patients had at least one drug therapy problem, and 29% of patients had five or more drug therapy problems.[8] A pharmacist-led MTM program in that health system saved $2,913,850 ($86 per encounter) over a ten year period. The total cost of MTM was $2,258,302 ($67 per encounter), for an estimated return on investment of $1.29 per $1.00 in MTM costs.[9] AMCP believes the inclusion of MTM programs in the MLR as a QIA would further encourage and incentivize providers to strengthen their MTM programs, resulting in increased healthcare outcomes and decreased healthcare costs.

CMS' recent proposal for 2019 changes to the Medicare Part D and Medicare Advantage programs, *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,* includes both fraud and MTM QIA activities included under MLR. AMCP supports CMS finalizing this proposal and would like to see inclusion of these activities under MLR provisions in marketplace exchanges.

AMCP appreciates your consideration of the ideas outlined above and looks forward to continuing work on these issues with CMI. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-6200 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

[8] De Oliveria D, Brummel A, Miller D. "Medication Therapy Management: 10 Years of Experience in a Large Integrated Health Care System." J Manag Care Pharm (2010): 185-95.
[9] *Ibid.*