



Academy of
Managed Care
Pharmacy®

April 21, 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: CMS-9949-P. *Patient Protection and Affordable Care Act*; Exchange and Insurance Market Standards for 2015 and Beyond

Dear Administrator Tavenner:

The Academy of Managed Care Pharmacy (AMCP) writes today to encourage the Department of Health and Human Services (HHS) and the Center for Consumer Information and Insurance Oversight (CCIIO) to not implement a regulatory mandate requiring an expedited exceptions process for certain medications as proposed in 45 CFR §156.122 (Prescription Drug Benefits) contained in the *Patient Protection and Affordable Care Act (ACA)*; Exchange and Insurance Market Standards for 2015 and Beyond. The ACA implemented a competitive marketplace approach to the provision of health insurance with the goal of ensuring appropriate patient access while balancing costs consistent with the 2011 Institute of Medicine Report (IOM) *Essential Health Benefits: Balancing Coverage and Costs*¹. The use of formularies developed by pharmacy and therapeutics committees (P&T) that include pharmacists, physicians, and other health care providers, and managed care tools, including prior authorization and step therapy help to meet these goals by ensuring patient access to safe and effective medications while managing costs.

Qualified health plans (QHPs) in the marketplace have an obligation to ensure that individuals receive access to the appropriate medications, including those not included on the formulary when clinically appropriate. Regulatory requirements would only add an administrative, costly burden that would not allow plans and health care providers to work with patients to ensure appropriate access to safe and effective medication at affordable prices.

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 believes that managed care organizations and their clients, including individuals, employers and federal and state governments, must be able to render independent decisions using the most current evidence-based standards for patient care. P&T committees work diligently to use evidence-based scientific and clinical evidence to select medications for formulary placement.

100 North Pitt Street | Suite 400
Alexandria, VA 22314
800 827 2627 | 703 683 8416
Fax 703 683 8417
www.amcp.org

Medications excluded from formularies often do not demonstrate the necessary effectiveness and safety of other medications in a category, class or indication. However, if an individual demonstrates a clinical need for a certain medication, QHPs have established processes in place for individuals to request and plans to grant exceptions to formularies. Regulatory mandates are not only disruptive to health plans' ability to implement effective formularies and work directly with individuals to ensure appropriate medication therapy, but rules may be duplicative of individual state insurance department requirements requiring an expedited process for certain emergency medications. CMS should not add to this regulatory burden, but rather allow plans to continue to work with health care providers and individuals to determine whether an exception should be granted.

Conclusion

Flexibility in the provision of prescription drug coverage decisions and in using prescription drug management practices allow QHPs to incorporate evidence-based best practices to optimize clinical outcomes for patients while maintaining benefit affordability. AMCP urges CMS to provide flexibility to QHPs to work together with plans, health care providers, and individuals to provide appropriate medication therapy without adding new, unnecessary government mandates.

Thank you again for the opportunity to comment on this proposed rule. 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

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- ¹ Institute of Medicine. Essential Health Benefits: Balancing Coverage and Costs. (October 6, 2011). <http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx> (accessed April 16, 2014).
- ² AMCP. Comments to HHS on Patient Protection and Affordable Care Act; Standards Related to EHBs, Actuarial Value, and Accreditation; Proposed Rule (45 CFR Parts 147, 155, and 156). December 20, 2012. <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15959>. (accessed April 16, 2014). *See also* AMCP. Comments to HHS on EHBs. CMS Bulletin. December 16, 2011. <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=14617> (accessed April 16, 2014).

