AMCP Academy of Managed Care Pharmacy®

December 19, 2014

The Honorable Sylvia Mathews Burwell
Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Academy of Managed Care Pharmacy Comments: *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Proposed Rule* (45 CFR Parts 144, 145, 147, 148, 153, 154, 155, 156, and 158)

Dear Secretary Burwell:

The Academy of Managed Care Pharmacy (AMCP) is pleased to submit comments in response to the *Patient Protection and Affordable Care Act (ACA); HHS Notice of Benefit and Payment Parameters for 2016; Proposed Rule.* AMCP's comments focus on the Prescription Drug Benefits in 45 CFR §156.122, Mandatory Access to Retail Pharmacies in 45 CFR§156.122(e)), Specialty Pharmacies and Specialty Drugs (45 CFR §156.122(e) (i) and (ii)), and the Quality Improvement Strategy in 45 CFR §156.1130. AMCP thanks the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS) for the opportunity to provide these comments and looks forward to continuing to work to improve the provision of pharmacy benefits for individuals in qualified health plans (QHPs) and other types of prescription dru coverage.

AMCP is a national professional association of pharmacists 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.

Formulary Drug List Development (54 CFR §156.122(a))

AMCP Comments: Use of Pharmacy & Therapeutics Committees (P&T) as the Primary Means to Develop Formularies

AMCP is pleased that HHS recognizes the important role that P&T committees have as the most effective way to develop a formulary. AMCP encourages HHS to adopt the use of standards established by the Medicare Part D program that have been effective in ensuring sound formularies with clinically appropriate selection of medications. AMCP supports the adoption of the P&T committee as the primary means to develop formularies and not require the use of a drug count system or the use of any specific formulary, including the United States Pharmacopeia (USP)

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model classification system or the American Hospital Formulary Service (AHFS). In addition, the use of a single classification should not be mandatory. An approach that relies on P&T committee expertise to develop formularies would permit the voluntarily use of a drug classification system, if appropriate, to ensure robust formulary development.

P&T committees include health care professionals who have a proven process for evaluating medications for formulary placement. The P&T review process uses the most updated clinical and scientific data to make determinations; whereas standards may be outdated. As noted by HHS in the preamble, P&T's committees' evaluation allows for the selection of appropriate medication for the individuals served by a plan. The proposed approach to use the P&T committee is also consistent with the manner that typical employer plans develop formularies. Thus the use of P&T committees would be consistent with requirements established by §1302 of the ACA that essential health benefits (EHB) in QHPs be based upon the typical employer plan.

AMCP further notes that the Medicare Part D classification system allows plans to use either the USP or the AHFS as a safe harbor to approve the formulary classification systems.[1] Medicare Part D standards provide specific requirements for P&T committees including: member disclosure to HHS; conflicts of interest, formulary management, the inclusion of specialists in certain areas (consistent with HHS' proposal for QHPs) and the role of the P&T committee. Standard P&T requirements for both QHPs and Medicare Part D would allow for administrative efficiencies and reduce confusion.

> *AMCP Recommendations*: HHS should adopt the proposed provision that allows for the use of P&T committees as the primary means to develop formularies and not require any specific classification system, including USP or AHFS. P&T committee standards should be consistent with those for Medicare Part D and therefore new requirements are not necessary.

AMCP Comments: Use a Standard Drug Count System, Such as USP, only if Necessary to Replace the Existing Variability among the Selection of Multiple State Benchmark Plans

While AMCP does not specifically endorse the use of a drug count system, such an approach reduces the variability and administrative efficiencies that occur with the variability associated with using multiple state benchmark plans' formulary systems. The current requirements to meet the state benchmark plan and use USP drug counts causes confusion and difficulty in making appropriate coverage determinations.

> *AMCP Recommendations*: HHS should adopt a drug count system only as a means to replace the confusion and administrative burdens associated with the need to meet multiple requirements, including USP drug counts and state benchmark drug counts. However, as stated above, AMCP reiterates its positon that P&T committees primarily develop formularies.

AMCP Comments on Definition of "Practicing" Providers for Inclusion on the P&T Committee

[1] Medicare Prescription Drug Benefit Manual, Chapter 6, §30.2.1.

AMCP supports the Medicare Part D standard that requires the use of practicing physicians, pharmacists, and other health care providers as members of the P&T committee, but would like HHS to clarify that this does not necessarily require the individuals to be practicing full time. Often, healthcare providers practice but also engage in clinical research, serve as faculty professors. In some cases, physicians, pharmacists, and other health care providers may serve as consultants to health plans as subject matter experts in a specific disease state. Many of these individuals also engage in practice. Individuals who serve dual roles should not be excluded from serving on P&T committees.

> *AMCP Recommendation*: HHS' final rule should clarify that members of P&T committees need not practice full time to qualify for membership.

AMCP Comments on Whether P&T Committees Should Include only "Prescribers"

In the preamble, HHS seeks comment on whether P&T committees should include only health care providers who prescribe. Pharmacists do not regularly prescribe but as noted above, are required under Medicare Part D standards to be included in P&T committees. Pharmacists are also the health care provider with the most expertise and knowledge about medication therapy and therefore, their inclusion on P&T committees is necessary to ensure the most comprehensive and balanced expertise.

> *AMCP Recommendation*: HHS' final rule should not specify that only health care providers who prescribe be included on P&T committees. Pharmacists represent one example of health care providers who do not regularly prescribe but have been recognized by Medicare Part D as necessary on P&T committees, thus HHS should be consistent with standards across programs.

AMCP Encourages HHS to Permit P&T Committees to Consider Pharmacoeconomic Data

P&T committees for Medicare Part D plans are permitted to use pharamcoeconomic studies in making formulary determinations[2] as long as these studies are with other information that ensures safe and effective medication therapy selection. Pharmacoeconomic decisions when used in conjunction with other clinical decision-making tools would allow QHPs to ensure access to robust and cost effective formularies that helps to improve access to benefits and reduce overall costs to consumers and to federal, state, and local governments.

Mandatory Access to Retail Pharmacies (45 CFR§156.122(e))

AMCP Comments: Postpone Consideration of Access and Network Adequacy Requirements, Including Mail-Order Restrictions, until the National Association of Insurance Commissioners (NAIC) Completes its Model Legislation and Permit Individuals to Use Mail-Order as an Option

NAIC is currently seeking input on its model legislative language for network adequacy requirements, with comments due in January 2015. The NAIC process will include a variety of stakeholders, including health plan issuers, employers, consumers, and providers. This

[2] Medicare Prescription Drug Benefit Manual, Chapter 6, §30.1.5.

comprehensive approach will allow a broad perspective regarding the development of network adequacy standards.

AMCP is also concerned that the HHS proposal would interfere with the ability of state legislatures and insurance departments to regulate provider networks, a key tenet of the ACA to regulate the administration of benefits.[3] The use of mail-order pharmacy is not a benefit, but a network option to provide a convenient, lower cost manner to receive medications.

These lower costs have been demonstrated by studies, including a 2013 study conducted for the United States Department of Defense's TRICARE program that showed a 16.7% lower cost for prescriptions obtained through mail-order rather than retail pharmacy.[4] Other studies have shown that mail-order pharmacies also improve medication adherence. One recent study showed that individuals with diabetes who received medications for multiple chronic conditions through mail-order were less likely to visit the emergency room in comparison to individuals who received prescriptions from a retail pharmacy.[5] Therefore, these findings suggest that CMS should re-consider its restrictions on mail-order.

> *AMCP Recommendation*: HHS should not usurp the authority of states to develop laws and regulations related to insurance laws. In this spirit, HHS should not consider making any changes to the mail-order requirements or make any other changes to network adequacy requirements until NAIC completes its comprehensive draft model legislation. Furthermore, CMS should examine more closely the value and convenience that mail-order provides to certain individuals before limiting access.

Specialty Pharmacies and Specialty Drugs (45 CFR §156.122(e) (i) and (ii))

AMCP Comments: HHS Should Continue to Recognize the Need for Specialty Medications to be Dispensed and Distributed Through Specialty Pharmacies and Not the Retail Pharmacy Network

HHS' proposal seems to suggest that specialty medications, except those that specifically have special handling requirements in the label or are subject to a Food and Drug Administration Risk Evaluation and Mitigation Strategy should be made available through the retail pharmacy network. This proposal is short-sighted and fails to recognize the special services and care management required for dispensing these products to individuals with chronic conditions such as cancer, hepatitis, and rheumatoid arthritis. Specialty medications, which include a growing number of expensive biologic agents and newer, more expensive small molecule agents for chronic conditions, require specialty pharmacies with specially trained staff to manage patients and be available 24 hours a day 7 days a week.

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[3] Mach AL, Fernandez B. *Private Health Insurance Reforms in the ACA*. Cong. Research Service. July 24, 2013.
[4] U.S. Department of Defense, Inspector General. *The TRICARE Mail or Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place*. July 24, 2103. http://www.dodig.mil/pubs/documents/DODIG-2013-108. Accessed December 16, 2014.
[5] Safety and Effectiveness of Mail-Order Pharmacy Use in Diabetes. *Am. J. Manag. Care*, 2013; 19(11):882-887http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n11. Accessed December 16, 2014.

First, with regard to the need for helping an individual manage medication administration, these products are often injectable agents that require unique supplies, such as syringes to properly administer. These supplies may not always be readily available in a retail pharmacy. In addition, individuals who use specialty medications must often adhere to strict medication administration regimens that require vigilance by a specialty pharmacy. Specialty pharmacies have trained staff, including pharmacists, nurses, and case managers, who specifically understand the additional supplies necessary to properly administer these medications and to provide regular consultation with individuals to ensure proper adherence and use. Specialty pharmacies that are able to perform these functions are often accredited by URAC or another recognized accreditation body. These accreditation standards allows individuals and health care providers to have confidence that the specialty pharmacy meets the needs of the beneficiary.

In addition to complex care considerations associated with specialty medications, the cost of these products is skyrocketing and expected to account for more than one-half of pharmacy spending by the year 2018.[6] Therefore, QHPs and other payers must be mindful of the costs associated with the distribution of these products. Specialty pharmacies are often better equipped to manage costs associated with these medications, and thus should be encouraged as the health care system aims to improve access and lower costs. Specialty pharmacies may also use the trained professional staff to work in conjunction with prescribers to evaluate all clinical options available to individuals and determine the best course of therapy, which may include beginning with other treatments that have been shown to be as effective as the more expensive regimens.[7] If an individual does require the use of specialty medications, specialty pharmacies have often shown better capabilities to manage these conditions in comparison to retail pharmacies.[8] While in some cases a retail pharmacy may be able to manage these individuals, it is less likely given the number of professional staff and time necessary to handle individuals who require specialty medications.

AMCP is also concerned that HHS' inclusion of specialty pharmacy as a component of the retail mail-order benefit is flawed. For the reasons described above, specialty medications must be treated differently from other medications and should not be considered in the same manner as older medications or many existing small molecule agents.

> *AMCP Recommendations:* HHS should consider specialty medication distribution issues as separate from retail mail-order pharmacy and thus not proceed with actions that could merge the two areas as suggested in the proposed rule. Like the issue of retail pharmacy networks, the use of specialty pharmacy networks and retail pharmacy networks will likely be considered in the NAIC model legislation and therefore, HHS should not finalize any changes until this work is complete. Finally, as noted in the mail-order pharmacy analysis of these comments, the use of specialty pharmacy networks is not an

[6] Lotvin AM. Shrank WH, Singh SC, et al. *Specialty Medications: Traditional and Novel Tools Can Address Rising Spending on These Costly Drugs.* Health Affairs, 33, no.10 (2014):1736-1744. http://content.healthaffairs.org/content/33/10/1736.full.pdf+html?sid=41e3a11e-90dc-465a-934b-36f4687d4df3. Accessed December 16, 2014.

[7] *Ibid.*

[8] Understanding and Improving Adherence for Specialty Products. IMS Health 2010. http://adhereforhealth.org/wp-content/uploads/pdf/Understanding_Improving_Adherence_Specialty_Products_IMS_Health.pdf. Accessed December 16, 2014.

EHB but rather a network issue and thus is in the purview of state laws and regulations and insurance commission directives.

Quality Improvement Strategy (QIS) (45 CFR §156.1130)

AMCP Comments. AMCP appreciates the flexibility that HHS has provided to QHPs to develop a transparent QIS based on the needs of individuals enrolled in the plans and that currently, HHS will not require specific measures to be adopted. AMCP also supports alignment of measures across programs as suggested by the National Quality Strategy and the Physician Quality Reporting System under Medicare. AMCP also supports the goals of the development of the QIS: improvements in quality; reductions in hospital readmission; improvements in safety; a reduction of medical errors; and reduce health disparities. Medication quality issues and the pharmacists who manage these issues play an integral role in ensuring a robust QIS. AMCP members have been involved with the Medicare Star Ratings program for Medicare Part D and have significant experience with understanding successful measures and those that have been challenging to implement and therefore their expertise should be leveraged.

AMCP Recommendations: HHS should encourage QHPs to leverage the experience of managed care pharmacists in developing and implementing the Medicare Star Ratings program to develop a robust and effective QIS. HHS should also ensure that communications about the development of the QIS are as transparent as possible and made available on a public website.

AMCP thanks HHS for the opportunity to comment on this proposed rule and looks forward to continuing to work to improve access to safe and affordable medications offered through QHPs in the federally-facilitated marketplaces and to all individuals in the United States covered by a managed pharmacy benefit. If you have any questions regarding these comments, please contact me by phone at 703-683-8416 or by email: erosato@amcp.org.

Sincerely,

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