AMCP Academy of Managed Care Pharmacy®

November 4, 2011

Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Subject: Essential Benefits – Prescription Drugs

Dear Secretary Sebelius:

The Academy of Managed Care Pharmacy (AMCP) offers comments to the Department of Health and Human Services (HHS) on the Affordable Care Act (ACA) requirement to include prescription drugs as an essential benefit.

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 6,000 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.

Based on provisions contained in the ACA, by 2016, an estimated 30 million individuals are expected to obtain health insurance through private health insurance markets, primarily through state insurance exchanges, and state expansion of Medicaid programs. These programs are to include a federally-determined essential health benefits (EHB) package. The ACA essential health benefits provision includes prescription drugs as one of ten required categories of the benefit package.

As the national association representing health care professionals with experience in managing prescription drug benefits, the Academy is offering recommendations on how the prescription drug benefit should be designed.

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The Academy applauds the classification of a prescription drug benefit as one the essential health benefits as identified in the ACA.[1] AMCP believes that access to drugs and management of medication therapies should be included under the "prescription drugs" category of the benefit package. AMCP proposes that health plans should maintain autonomy over the design of the prescription drug benefit and determination of the specific drugs needed to be covered in order to meet patient needs and to be deemed essential. This would allow a health plan to have the flexibility necessary to meet the needs of the population it serves while ensuring high quality and keeping the benefit affordable.

Access to drugs may be defined as drugs, devices (e.g. nebulizers) or medical supplies (e.g. insulin syringes) that are regulated by legislation to require a prescription from a legitimate provider before they can be obtained. Access to and proper management of medications has been shown to reduce the morbidity and mortality associated with many common diseases and conditions.[2,3,4] Management of drugs may include such practices as formulary management; medication therapy management (MTM); utilization management (UM)/drug utilization reviews (DUR); tiered copayments or co-insurance; adherence programs; health information technology; and access to risk evaluation and minimization strategies (REMS) management. These terms are explained in explained in the attachment to this letter.

Regulators should not define or require specific drugs or drug categories for inclusion or exclusion under the essential health benefits provision; instead, health plans should be allowed flexibility in determining appropriate coverage. The Institute of Medicine report *Essential Health Benefits: Balancing Coverage and Costs* indicated that the design and administration of health benefits rather than the scope of benefits themselves are what appear to differentiate small employer plans from each other and from large employer plans.[5] Examples of coverage decisions which should be made at the health plan level include over-the-counter (OTC) products; prescription categories that have an OTC option available (e.g., antihistamines, proton pump inhibitors); vitamins; and products that are generally used for cosmetic purposes (e.g., wrinkles, skin discoloration). All formulary decisions should be made at the health plan level.

The medications and related products listed on a formulary are determined by a pharmacy and therapeutics (P&T) committee or an equivalent entity. Due to the multiplicity of medications on the market, the continuous introduction of new medications, and the discovery of clinical misadventures once a product has been in use, a formulary must be a dynamic and continually revised listing. In order to keep a formulary current, the P&T committee meets regularly to review newly released drugs and to assess analyses of drugs already in the marketplace. Formulary changes must occur on a regular basis as the Food and Drug Administration approves new medications and new uses for existing medications. P&T committees must consider formulary changes as new evidence becomes available on medications which would change previous decisions on the effectiveness or safety of medications. Health plans and insurers must be able to make formulary changes to provide the most appropriate, cost-effective care to their members.

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[1] "Subject to paragraph (2), the Secretary shall define the essential health benefits, except that such benefits shall include at least the following general categories and the items and services covered within the categories: (A) Ambulatory patient services. (B) Emergency services. (C) Hospitalization. (D) Maternity and newborn care. (E) Mental health and substance use disorder services, including behavioral health treatment. (F) Prescription drugs. (G) Rehabilitative and habilitative services and devices. (H) Laboratory services. (I) Preventive and wellness services and chronic disease management. (J) Pediatric services, including oral and vision care." *Patient Protection and Affordable Care Act* (P.L. 111-148), Section 1302.

[2] Smith M, Giuliano MR, Starkowski MP. In Connecticut: Improving patient medication management in primary care. *Health Aff. 2011; 30:646-54.*

[3] Chisholm-Burns MA, Zivin JSG, Lee JK et al. Economic effects of pharmacists on health outcomes in the United States: a systematic review. *AJHP*. 2010; 67:1624-34.

[4] Isetts BJ, Schondelmeyer SW. Clinical and economic outcomes of medication therapy management services: The Minnesota experience. J Am Pharm Assoc. 2008;48:203-11.

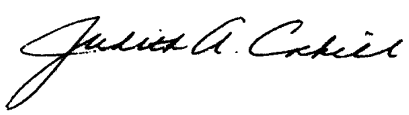
[5] Institute of Medicine. *Essential Health Benefits: Balancing Coverage and Costs*, prepublication version, p. xii. (October 6, 2011). http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx (accessed November 2, 2011).

Flexibility in making prescription drug coverage decisions and in using prescription drug management practices will allow health plans to incorporate managed care best practices and optimize clinical outcomes while maintaining benefit affordability.

The Academy encourages HHS to use this framework in defining a prescription drug benefit to be offered through qualified health plans and state expansion of Medicaid programs. AMCP would be pleased to provide additional guidance to HHS as the essential benefit is developed.

If we can answer any questions or provide additional information, please contact me at (703) 683-8416 x603 or jcahill@amcp.org.

Sincerely,



Judith A. Cahill
Chief Executive Officer

cc: Steve Larsen,
Director, Center for Consumer Information and Insurance Oversight

Attachment

Formulary management – Formulary management is an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes. A drug formulary, or preferred drug list, is a continually updated list of medications and related products supported by current evidence-based medicine, judgment of physicians, pharmacists and other experts in the diagnosis and treatment of disease and preservation of health. The primary purpose of the formulary is to encourage the use of safe, effective and most affordable medications.

A formulary system is much more than a list of medications approved for use by a managed health care organization. A formulary system includes the methodology an organization uses to evaluate clinical and medical literature and the approach for selecting medications for different diseases, conditions and patients. Policies and procedures for the procuring, dispensing, administering and appropriate utilization of medications are also included in the system. Formulary systems often contain additional prescribing guidelines and clinical information which assist health care professionals to promote high quality, affordable care for patients. Finally, for quality assurance purposes, managed health care systems that use formularies have policies in place to give physicians and patients access to non-formulary drugs where medically necessary.[6]

Medication therapy management (MTM) – MTM programs are offered by health plans to optimize therapeutic outcomes by improving the use of medications by patients with chronic conditions and multiple medications and to avoid adverse drug events and unnecessary costs. MTM programs are designed to improve collaboration among pharmacists, physicians, and other health care professionals; enhance communication between patients and their health care team; and optimize medication use for improved patient outcomes. MTM services empower patients to take an active role in managing their medications. The services are dependent upon pharmacists working collaboratively with physicians and other healthcare professionals to optimize medication use in accordance with evidence-based guidelines. MTM services are distinct from medication dispensing and focus on a patient-centered, rather than an individual product-centered, process of care. These services encompass the assessment and evaluation of the patient's complete medication therapy regimen, rather than focusing on an individual medication product. MTM services help address the urgent public health need for the prevention of medication-related morbidity and mortality. MTM services contribute to medication error prevention, result in improved reliability of healthcare delivery, and enable patients to take an active role in medication and healthcare self-management.[7]

Utilization management (UM)/drug utilization reviews (DUR) - Drug utilization review (DUR) is defined as an authorized, structured, ongoing review of prescribing, dispensing and use of medication. DUR encompasses a drug review against predetermined criteria that results in changes to drug therapy when these criteria are not met. It involves a comprehensive review of patients' prescription and medication data before, during and after dispensing to ensure appropriate medication decision-making and positive patient outcomes. As a quality assurance measure, DUR programs provide corrective action, prescriber feedback and further evaluations.

DUR is classified in three categories:

- *Prospective* - evaluation of a patient's drug therapy before medication is dispensed
- *Concurrent* - ongoing monitoring of drug therapy during the course of treatment

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[6] Academy of Managed Care Pharmacy (AMCP), *Concept Series Paper on Formulary Management*. 2009. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (accessed November 2, 2011)

[7] American Pharmacists Association and National Association of Chain Drug Stores Foundation, *Medication Management in Pharmacy Practice: Core Elements of an MTM Service Model*, Version 2.0., 2008. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=10354 (accessed November 2, 2011)

- *Retrospective* - review of drug therapy after the patient has received the medication

DUR programs play a key role in helping managed health care systems understand, interpret, evaluate and improve the prescribing, administration and use of medications. Employers and health plans find DUR programs valuable since the results are used to foster more efficient use of scarce health care resources.[8]

Tiered copayments or co-insurance – Many managed care organizations use a "tiered" pharmacy benefit design. All medications and related products subject to clinical review are assigned to a formulary "tier." The tier represents the level of coverage the health plan will provide. The most cost-effective agents (often generics) are usually assigned to the most preferred tier and have the lowest patient out-of-pocket costs. The least cost-effective agents are usually assigned to the least preferred tier and have the highest patient out-of-pocket costs or offer no coverage. The preferred tier(s) are commonly referred to as "formulary" and non-preferred tier(s) as "non-formulary." In other cases, non-formulary drugs are not assigned a tier and are not listed on the formulary.[9]

Adherence programs – Studies have shown that 20 to 30 percent of medication prescriptions are never filled and that up to 50 percent are not taken as prescribed. Medication nonadherence tends to occur with greater frequency when the medications are used to treat asymptomatic, chronic conditions such as hypertension and hypercholesterolemia. The literature suggests that 20 to 75 percent of patients who are prescribed medications for these conditions are not adhering to the regimen. This lack of adherence to medical advice has been estimated to cause approximately 125,000 deaths, at least 10 percent of hospital admissions, and substantial worsening of morbidity and mortality. Interventions used to improve medication adherence have been developed that address individual or system factors.[10]

Health information technology - Electronic health records and electronic prescribing provide a means to improve access, safety, quality and cost-effectiveness of medication use which is clearly a cornerstone to successful treatment of both acute and chronic health conditions and the ultimate health of a health plan's members. Effective electronic prescribing and electronic medical records are essential components of medication reconciliation. Medication reconciliation is the comprehensive evaluation of a patient's medication regimen anytime there is a change in therapy in an effort to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions as well as to observe compliance and adherence patterns.

Risk evaluation and minimization strategies (REMS) management - A risk evaluation and mitigation strategy (REMS) is a strategy to manage a known or potential serious risk associated with a drug or biological product. A REMS is required if FDA finds that a REMS is necessary to ensure that the benefits of the drug or biological product outweigh the risks of the product, and FDA notifies the sponsor. A REMS can include a medication guide, patient package insert, a communication plan, elements to assure safe use, and an implementation system.[11]

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[8] AMCP, *Concept Series Paper on Drug Utilization Review*. 2009. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9296 (accessed November 2, 2011)

[9] AMCP, *Concept Series Paper on Formulary Management.*

[10] Agency for Healthcare Quality and Research, "Closing the Quality Gap Series: Comparative Effectiveness of Medication Adherence Interventions; Research Protocol." August 18, 2011. http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=764 (accessed November 2, 2011)

[11] FDA, Questions and Answers on the Federal Register Notice on Drugs and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies. http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm095439.htm (accessed October 25, 2011)

The Food and Drug Administration Amendments Act of 2007 (FDAAA) authorizes FDA to require pharmaceutical manufacturers to submit a proposed REMS as part of an application if the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug. FDA is also authorized to require pharmaceutical manufacturers to submit a proposed REMS if the FDA becomes aware of new safety information and determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.[12]

[12] FDA, *Guidance for Industry Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications.* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM184128.pdf (accessed October 25, 2011).