

**HHS Finalizes Rule for Prescription Drug Benefit Design
under Essential Health Benefits to Implement *Affordable Care Act* Provisions and Clarifies Preventive
Coverage for Certain OTC Items**

February 21, 2013

On February 20, 2013, the Department of Health and Human Services (HHS) finalized *Affordable Care Act* (ACA) regulations related to the development of prescription drug benefits as a component of the 10 essential health benefits (EHBs) coverage requirements for qualified health plans (QHPs), individual and small group plans, and Medicaid benchmark and benchmark-equivalent plans beginning in January 2014. HHS also released “frequently asked questions” (FAQ) information on its website related to preventive services coverage of over-the-counter products dispensed by prescription.

The final rule adopts EHB standards for plan years 2014-2015 only. After 2015, HHS may reconsider its requirements for EHBs and will offer additional guidance in the future.

Now that HHS and the Obama Administration have finalized most rules related to implementation of the ACA, it will begin to issue “sub-regulatory guidance” to clarify provisions and assist in implementation. Much of the implementation efforts will now shift to the states to fill in the details and administer insurance laws. AMCP is preparing to more closely monitor state regulatory issues, including those issues related to ACA. Look for information from AMCP in the coming months.

Important Dates and Timelines for Plans Seeking to Sell Plans in Health Care Marketplaces (AKA Exchanges)

Application period for plans seeking to participate: Opens March 28, 2013 and closes April 30, 2013. The application process requires potential plans to provide information regarding benefits and costs.

HHS’ decision on qualified insurance participants will be made by July 2013. Information related to the bids will be publicly available at this time.

The HHS public media campaign will begin in June 2013.

Additional resources and background regarding AMCP’s work on EHB implementation and HHS documents are linked below.

Final Requirements for Formularies under EHBs

The final rule maintains the requirements for development of formularies as outlined in a November 20, 2012 proposed rule. These requirements are as follows:

Plans must cover “*at least the greater of*”:

- One drug in every category and class *or*
- The same number of drugs in each category and class as the benchmark plan.

Under this standard, if a benchmark plan offers more than one drug per category and class, then plans would have to offer *at least the number of drugs* in the state benchmark plan, defined as a benefits provided by a typical employer plan in the state. (A list of state benchmark plans appears in *Appendix A* of the final rule). The drug products listed must be chemically distinct. For example, if a benchmark plan offers two drugs per category or class, another plan offering two dosage forms or strengths of that same drug or a brand drug and its generic equivalent would not be chemically distinct. AMCP supports HHS' decision to not mandate that plans adopt the Medicare Part D program's mandated coverage of substantially all medications in six protected classes.

HHS will require plans to report "drug lists" (the term formulary is not used) to the entity managing the marketplace (exchange), to the state if operating outside of the exchange, or to the federal Office of Personal Management (OPM) if it is a multi-state plan.

In the December 2012 comments in response to the EHB proposal, AMCP and other commenters suggested that the formulary standard does not allow for the development of evidence-based formularies that account for the patient population served and could increase overall premium costs for employers and individuals. HHS' response to these comments in the final rule countered that its state-by-state analysis of prescription drug coverage found that the majority of the benchmark plans already meet the EHB standard or would have to add one or two additional medications for that purpose. The final rule also notes that plans may implement tiering and other utilization management tools for formularies if applied in a non-discriminatory manner. Therefore, HHS concludes that this system would have a negligible impact on premium costs

In response to comments suggesting that the proposed formulary structure provides too much flexibility to plans, HHS noted that none of the categories of EHBs, including prescription drugs, may be established in a discriminatory manner in areas such as gender, ethnicity, race, age, disability, or quality of life. States must monitor and identify discriminatory benefit designs and report this information to HHS. HHS will use complaints, appeal, and data on drug lists to refine prescription drug review in future years. Plans must also have procedures in place to ensure that individuals receive clinically appropriate medications not covered by the plan. HHS will provide sub-regulatory guidance for the exceptions process in the near future, but believes that most plans will not have to implement significant changes.

HHS Adopts the Use of USP Classification System to Report Drug Coverage

HHS adopts the use of United States Pharmacopeia's (USP) classification system as a tool to report drug coverage. In a footnote in the proposed rule, HHS indicated that the USP classification system would apply only to the submission of formulary for review and certification and that plans may use any classification system in marketing and other plan materials.

AMCP and several commenters objected to the use of a specific classification system. AMCP and others suggested that USP is an arbitrary classification system only in use today because of provisions in the *Medicare Modernization Act of 2003* mandating its use under Medicare Part D and that many other formulary classification systems exist.. In adopting the USP classification system for 2014-2015, HHS noted that the current version, USP Model Guidelines (version 5) is publicly available and is familiar to many pharmacy benefit management companies. HHS has created a [crosswalk tool](#) to count the number of drugs available in each category and class. HHS will continue to assess the need for and value of the

tool and will work with the National Association of Insurance Commissioners (NAIC) to facilitate states' use of the USP classification system.

Payment and Coverage for State-Mandated Requirements beyond EHBs

HHS adopted the proposed rule's requirements that state payment and coverage mandates enacted or implemented on or before December 11, 2011 must be covered as an EHB for plan years 2014-2015. Coverage would extend to state-required benefits for care, treatment, and service, but not to delivery method. For example if a state mandates coverage of certain prescription drugs or coverage for certain conditions, such as fertility, these will likely be incorporated as EHBs if implemented before December 31, 2011. State-specific rules related to provider types, cost-sharing, or reimbursement methods would be exempt from this requirement and therefore, the federal government would not have to cover costs associated with these requirements. Some states have already made determinations regarding the scope of EHB mandates, but the remaining states will begin to make those determinations at a rapid pace.

HHS Clarifies Scope of Coverage for Certain OTC Items for Preventive Services

HHS also released FAQs related to coverage of OTC items classified as preventive services by the United States Preventive Services Task Force (USPSTF). AMCP had requested guidance on this issue in 2011 direct correspondence to HHS. On February 20, 2013, AMCP received an email response from HHS in response to this inquiry. HHS has incorporated the question and response as a "Frequently Asked Question" (FAQ):

Q4: The USPSTF recommends the use of aspirin for certain men and women when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm. Aspirin is generally available over-the-counter (OTC) to patients. Are group health plans and health insurance issuers now required to pay for OTC methods such as aspirin?

HHS Response: Aspirin and other OTC recommended items and services must be covered without cost-sharing only when prescribed by a health care provider.

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If you have further questions regarding implementation of ACA or EHBs, please contact Mary Jo Carden, Director, Federal Regulatory Affairs by email: mcarden@amcp.org or phone: 703-683-8614 ext 603.

Resources

HHS Resources

EHB Final Rule

<https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-04084.pdf>

HHS USP Prescription Drug Coverage Crosswalk Tool

<http://cciio.cms.gov/resources/EHBBenchmark/ehb-rx-crosswalk.pdf>

HHS Resources on State Benchmark Plans

<http://cciio.cms.gov/resources/data/ehb.html>

HHS FAQ on Preventive Services and Coverage Limits

http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs12.html#coverage

AMCP Resources

AMCP Comments on Proposed EHB Rule (Submitted to HHS in December 2012)

<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15959>

AMCP Summary of EHB Proposed Rule (November 2012)

<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15857>

AMCP Comments on HHS December 2011 Bulletin (Submitted to HHS in January 2012)

<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=14617>

AMCP Comments on IoM Recommendations for EHBs (Submitted to HHS in August 2011)

<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=10748>