Global Expertise
Trusted Standards
Improved Health

U.S. Pharmacopeial Convention

FOR IMMEDIATE RELEASE

CONTACT: Claudia Costabile
301-816-8314 cac@usp.org

USP Updates Medicare Model Guidelines for Part D Benefit

Public Comment Sought: October 3 – November 2, 2016

Rockville, Md., October 4, 2016 — The U.S. Pharmacopeial Convention (USP) has posted for public comment its recommended revisions to the USP Medicare Model Guidelines (USP MMG) – a classification system that supports formulary development for medications covered under Medicare Part D benefits. USP is seeking public input on the draft revisions from October 3 through November 2, 2016. The final publication of the USP MMG v7.0 is scheduled for February 1, 2017.

USP is a global health organization that aims to improve lives through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods. Under the Medicare Prescription Drug Improvement and Modernization Act (2003) Section 1860D-4(b)(3)(C)(ii), USP is charged with developing and periodically revising the Medicare Model Guidelines by request of the Centers for Medicare & Medicaid Services (CMS). The 2017 update to the model guidelines is the seventh publication since 2004, developed under a Cooperative Agreement between USP and CMS.

The USP MMG assign Categories and Classes to medicines that prescription drug plans may use when developing their own Medicare Part D formularies. The model guidelines are created through USP's transparent and independent process that utilizes scientific data, independent volunteer experts – the Healthcare Quality Expert Committee – stakeholder input and public feedback. The members of the Healthcare Quality Expert Committee are healthcare providers and practitioners, pharmacologists, clinical pharmacists, academicians, formulary specialists, and healthcare policy experts with interest in drug classification and its relevance to drug formularies.

"Since the last USP MMG revision, three years ago, there have been a record number of new drugs approved by the FDA. The expert committee has reviewed these drugs in the context of the model guidelines taxonomy and guiding principles, and proposed the USP MMG v7.0, which remains largely consistent with the previous model," said Shawn Becker, MS, BSN., Senior Director and Principal Investigator for the USP Medicare Model Guidelines. "The expert committee deliberations and reviews are conducted with a rigor grounded in science and clinical practice, which ultimately lead to Part D beneficiaries' access to safe and effective drugs."

Along with the USP MMG v7.0, USP will also publish the MMG-FRF Alignment File, an accompanying tool that maps the USP MMG v7.0 to the CMS Formulary Reference File (FRF), a list of potentially eligible Part D drugs published by CMS. This tool will assist formulary developers and others in their application of the USP MMG v7.0.

In addition to accepting written public comments to the draft USP MMG v7.0, USP will conduct informational open microphone meetings. These web meetings aim at reviewing the content and organization of the draft guidelines and require pre-registration.

Additional information can be found on the USP Medicare Model Guidelines webpage.

Media inquiries may be directed to mediarelations@usp.org.