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FOR IMMEDIATE RELEASE

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USP Publishes Updated Medicare Model Guidelines for Part D Benefit

Rockville, Md., February 7, 2017 — The U.S. Pharmacopeial Convention (USP) today released USP Medicare Model Guidelines (Version 7.0) — a classification system that supports formulary development for medications covered under Medicare Part D benefits.

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 (MMG) by request of the Centers for Medicare & Medicaid Services (CMS). USP MMG v7.0 was developed under a Cooperative Agreement between USP and CMS.

The USP MMG assigns USP 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, independent process that utilizes scientific data, independent volunteer experts (the Healthcare Quality & Safety Expert Committee), stakeholder input, and public feedback. The Healthcare Quality & Safety Expert Committee members are healthcare providers, pharmacologists, clinical pharmacists, academicians, formulary specialists, and healthcare policy experts with interest in drug classification and its relevance to drug formularies.

"The updated Guidelines address evolving market and emerging public health needs — keeping pace with new FDA-approved drugs for the past three years," said Shawn Becker, MS, BSN, Senior Director and Principal Investigator for the USP Medicare Model Guidelines. "They leverage the independent and science-based process that is unique to USP and reflect thorough stakeholder and public comment."

To accommodate new drugs and therapeutic uses, a total of three new USP Classes were developed for this update including Pulmonary Fibrosis agents, and Treatment Adjuncts (in the Antineoplastics category). The USP class previously named Hepatitis C (HCV) Agents, was split into two new classes, Anti-hepatitis C (HCV) Direct Acting Agents, and Anti-hepatitis C (HCV) Agents, Other. No new drug categories were added.

Along with the USP MMG v7.0, USP also published the MMG-FRF Alignment File, an accompanying tool that maps the USP MMG v7.0 to the CMS CY16 Formulary Reference File (FRF) (v09.26.16), a list of potentially eligible Part D drugs published by CMS. This tool assists formulary developers and others in their application of the USP MMG v7.0.

For more information, visit the USP MMG v7.0 webpage or contact mediarelations@usp.org.

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The U.S. Pharmacopeial Convention (USP) is a global health organization that improves lives through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are used worldwide. For more information about USP visit http://www.usp.org.