

USP to Update Medicare Model Guidelines

November 15, 2010

The U.S. Pharmacopeia (USP) has started the process of reviewing and updating the USP Medicare Model Guidelines v5.0 (Guidelines). As part of this process, USP held public “Open Microphone Web Meetings” on November 4, 8, and 11, and will hold another meeting on November 16. In addition to these public meetings, USP is accepting written comments from interested parties. Interested parties, such as pharmaceutical manufacturers, should consider reviewing the available materials from USP and submitting written comments to the USP Model Guidelines Expert Panel (Expert Panel). **Comments must be submitted by November 30.**¹

Background

Under Section 1860D–4(b)(3)(C)(ii) of the Social Security Act, enacted by the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), USP is required to develop a list of drug classifications for use by Medicare Part D prescription drug plans. Specifically, Section 1860D–4(b)(3)(C)(ii) states that “[t]he Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs.”

It should be noted that conformance with the Guidelines is voluntary; however, conformance provides a “safe harbor” for Part D formularies. Specifically, Section 1860D–11(e)(2)(D)(ii) of the Social Security Act, enacted by the Medicare Prescription Drug Improvement and Modernization Act of 2003, states that “[t]he Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.” Therefore, if Part D formularies use the USP recommendations in developing their formularies, they could insulate themselves from charges that their formulary classifications violate the MMA by substantially discouraging enrollment of certain individuals.

¹ Information regarding the Guidelines and opportunities to comment are available at <http://www.usp.org/hqi/mmg/>.

In addition, Part D drug plan formularies typically must cover at least two drugs within each diagnostic or therapeutic class.² Because of this requirement, a balance must be struck between (1) manufacturers that want classes that are as granular as possible to encourage coverage for more drugs and (2) Part D plans that want fewer classes and fewer required covered drugs to permit more flexibility in negotiations with manufacturers.

USP utilizes the services of an Expert Panel in developing the Guidelines. The Expert Panel “is responsible for reviewing and updating the Medicare Model Guidelines,” which are “a listing of therapeutic categories and pharmacologic classes that Medicare Part D plans can utilize when developing their formularies.”³ The Expert Panel serves as an advisory body to USP’s Nomenclature, Safety, and Labeling Expert Committee, which will review and vote on the proposed Guidelines in January 2011. USP anticipates delivering the revised Guidelines to the Centers for Medicaid and Medicare Services (CMS) by the beginning of February 2011, with the Guidelines serving as a resource for Medicare Part D plans covering benefit years 2012–2014. Using the authority granted to it under the MMA, CMS has requested that USP update the Guidelines every three years.

Public Comments

As previously mentioned, USP has hosted three “Open Microphone Web Meetings” (with a fourth and final meeting to take place on November 16) to provide an opportunity for interested parties to learn about the Expert Panel’s rationale in developing the Guidelines. The meetings are designed to solicit specific feedback on the structural content and organization of the Guidelines.⁴ Participants should take note that the meetings are not designed for the discussion of specific drug products, health plan coverage, plan design, and treatment algorithms. Instead, the meetings are intended to discuss therapeutic categories and pharmacologic class designations. In addition, the meetings are intended to provide an opportunity for individuals to ask questions about and provide specific feedback on the proposed Guidelines.

USP began accepting written comments on the Guidelines on November 1. USP will accept written comments through November 30 via the USP website. Any interested party is welcome to submit written comments to the Expert Panel. In addition, USP will make submitted written comments available to the public through the USP website. Written comments should be submitted to ModelGuidelines@usp.org.

Morgan Lewis strongly encourages interested parties to submit written comments to USP and, if possible, to attend tomorrow’s Open Microphone Web Meeting. Morgan Lewis is available to assist with drafting and submitting comments to USP.

If you have any questions concerning the information in this LawFlash, please contact either of the following Morgan Lewis attorneys:

² There are exceptions to this requirement such as for classes with only one approved product or for classes that are excluded from Part D coverage.

³ Information regarding the Guidelines and opportunities to comment are available at <http://www.usp.org/hqi/mmg/>.

⁴ *Id.*

Washington, D.C.

Lee H. Rosebush
Andrew D. Ruskin

202.739.5153
202.739.5960

lrosebush@morganlewis.com
aruskin@morganlewis.com

About Morgan, Lewis & Bockius LLP

With 23 offices in the United States, Europe, and Asia, Morgan Lewis provides comprehensive transactional, litigation, labor and employment, regulatory, and intellectual property legal services to clients of all sizes—from global Fortune 100 companies to just-conceived startups—across all major industries. Our international team of attorneys, patent agents, employee benefits advisors, regulatory scientists, and other specialists—nearly 3,000 professionals total—serves clients from locations in Beijing, Boston, Brussels, Chicago, Dallas, Frankfurt, Harrisburg, Houston, Irvine, London, Los Angeles, Miami, Minneapolis, New York, Palo Alto, Paris, Philadelphia, Pittsburgh, Princeton, San Francisco, Tokyo, Washington, D.C., and Wilmington. For more information about Morgan Lewis or its practices, please visit us online at www.morganlewis.com.

This LawFlash is provided as a general informational service to clients and friends of Morgan, Lewis & Bockius LLP. It should not be construed as, and does not constitute, legal advice on any specific matter, nor does this message create an attorney-client relationship. These materials may be considered **Attorney Advertising** in some states.
Please note that the prior results discussed in the material do not guarantee similar outcomes.

© 2010 Morgan, Lewis & Bockius LLP. All Rights Reserved.