we also incorporated a number of elements into the SNF PPS, such as case-mix classification methodology, the MDS assessment schedule, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates. Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new fiscal year through the Federal Register, and to do so before the August 1 that precedes the start of the new fiscal year. Accordingly, we are not pursuing alternatives with respect to the payment methodology. Further, as discussed previously in section II.B of this notice, we are not implementing case-mix refinements at the present time, but instead are proceeding with our ongoing research in this area.

D. Conclusion

This notice does not initiate any policy changes with regard to the SNF PPS; rather, it simply provides an update to the rates for FY 2005. Therefore, for the reasons set forth in the preceding discussion, we are not preparing analyses for either the RFA or section 1102(b) of the Act, because we have determined that this notice will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Finally, in accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VIII. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register to provide a period for public comment before the provisions of a notice such as this take effect. We can waive this procedure, however, if we find good cause that notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of the finding and the reasons for it into the notice issued.

We believe it is unnecessary to undertake notice-and-comment rulemaking in this instance, as the statute requires annual updates to the SNF PPS rates, the methodologies used to update the rates have been previously subject to public comment, and this notice initiates no policy changes with regard to the SNF PPS but simply reflects the application of previously established methodologies. Therefore, we find good cause to waive notice and comment procedures.

[Catalog of Federal Domestic Assistance Program No. 93.773: Medicare-Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program]


Mark B. McClellan, Administrator, Centers for Medicare & Medicaid Services.


Tommy G. Thompson, Secretary.

[FR Doc. 04–17443 Filed 7–29–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4068–N]

Medicare Program; Open Public Meeting Regarding the Development of the Model Guidelines for Categories and Classes of Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to provide pharmaceutical benefit managers and other interested parties, an opportunity to provide individual comments on the Model Guidelines for Classes and Categories of Drugs (Model Guidelines) developed by the United States Pharmacopeia (USP). Interested parties include beneficiaries, advocacy groups, managed care organizations, trade and professional associations, prescription drug plans, healthcare practitioners, providers, pharmaceutical manufacturers, and others. USP is a nongovernmental organization, as set forth under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The MMA provides for the development of Model Guidelines by USP in consultation with pharmaceutical benefit managers and other interested parties.

DATES: The meeting is scheduled for August 27, 2004, from 9 a.m. until 4 p.m., e.d.t. This meeting is open to the public.

ADDRESSES: The meeting will be held in Baltimore, MD at the Wyndham Baltimore-Inner Harbor, 101 West Fayette Street. Phone: 410–752–1100. The meeting will be organized by the United States Pharmacopeia with support from its meeting coordinator, Conferon Inc.

FOR FURTHER INFORMATION CONTACT:
Kelly Coates, United States Pharmacopeia at 12601 Twinbrook Parkway, Rockville, MD 20852, conferences@usp.org, (301) 816–8130.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) establishes a new prescription drug benefit under Part D of the Medicare Program through competing prescription drug plans. The Secretary will approve or disapprove prescription drug plans based on various requirements in the statute, including the requirements specified in section 1866D–11(e)(2)(D)(i) and (ii) of the MMA. One of the requirements is that the Secretary does not find that the design of the plan and its benefits are likely to discourage enrollment by certain Part D eligible individuals. The Secretary may not find that the design of categories and classes within a formulary discourages enrollment if the categories and classes are consistent with Model Guidelines established by United States Pharmacopeia (USP).

In an effort to establish these guidelines, MMA requires the Secretary to request USP to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes (Model Guidelines) that may be used by prescription drug plans and to revise the classification from time to time to reflect changes in therapeutic uses of covered Part D drugs and additions of new covered Part D drugs. At the request of the Secretary and as specified in section 1866D–4(b)(3)(C)(ii) of the MMA, USP is in the process of developing the Model Guidelines that may be used by prescription drug plans and is seeking comments on the draft Model Guidelines.

II. Provisions of the Notice

The purpose of this meeting is to provide information on the draft of the Model Guidelines for Classes and Categories of Drugs to be used in Part D plan formularies and to allow for public comment.

Meeting Format: USP Staff and the USP Medicare Model Guideline Expert Committee (Expert Committee) will present a draft of the Model Guidelines and the approach and methodology of establishing the Model Guidelines. Interested persons may present data, information, or views orally or in writing, on issues directly related to the Model Guidelines.
Public Presentations: USP and the Expert Committee Members will hear oral presentations from the public. The Expert Committee may limit the number and duration of oral presentations to the time available. If you wish to make a formal oral presentation, you must contact the individual named in the FOR FURTHER INFORMATION CONTACT section of this notice and submit the following by August 20, 2004: a brief statement of the general nature of the comment, the name and address of proposed individual to present, and approximate time needed for the presentation. All presenters must submit written documentation of their oral presentation. USP will determine the time allotments for oral presentations based upon the number of presenters. If additional time is available, USP and the Expert Committee will open the floor to additional comments by attendees. An agenda for the meeting will be posted on USP’s website approximately two weeks prior to the meeting.

Public Written Comment: Comments on the draft Model Guidelines and associated documents must be mailed to Lynn Lang, United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, Maryland 20852–1790, ftc@usp.org, by September 10, 2004. Comments must clearly identify the individual or organization submitting the comment and must be clearly marked as “Comments to the Draft Model Guidelines.” Comments may be submitted either in paper or in electronic format. USP will post all comments on its Web page for public viewing.

Registration: Registration for this public meeting is required and will be on a first-come, first-served basis up to the 500-person capacity of the meeting room. There is no charge for registration. The registration deadline will be August 20, 2004. Registration may be accomplished by visiting www.usp.org/conferences or you may call United States Pharmacopeia’s meeting coordinator, Conferon Inc. at (330) 425–9330. A confirmation notice will be sent to attendees upon finalization of registration. Individuals who are not registered in advance will not be guaranteed attendance due to space limitations.

Written Requests Concerning the Public Meeting: USP will accept written questions about meeting logistics or requests for the Draft Model Guidelines before the meeting. Written submissions must be sent to: Kelly Coates, United States Pharmacopeia, at e-mail ktc@usp.org.