

MEDICARE PRESCRIPTION DRUG BENEFIT

**SUMMARY OF USP APPROACH AND METHODOLOGY
TO THE MODEL GUIDELINES VERSION 3.0**

DRUG CATEGORIES AND CLASSES IN PART D

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Submitted by: United States Pharmacopeial Convention
CMS Cooperative Agreement No. 1C0CMS300043/02
February 5, 2007

The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The grantee assumes responsibility for the accuracy and completeness of the information in this report. CMS only funds the development of Categories and Classes and not additional materials such as the USP Drug List Table.

The Model Guidelines that result from this Cooperative Agreement, as well as the assignment of any drug to any category or class is made only for the purpose of prescription drug coverage under Part D and does not affect other activities.

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INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provided for the implementation of a prescription drug benefit to Medicare beneficiaries on January 1, 2006. In section 1860D-4(b)(3)(C)(ii), MMA states:

MODEL GUIDELINES.— The 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 additions of new covered part D drugs.

Section 1860D-4 of MMA appears under the sub-heading, “Beneficiary Protections for Qualified Prescription Drug Coverage,” indicating that the Model Guidelines are one mechanism for assuring access of Medicare beneficiaries to the prescription drugs they require. The design of categories and classes within formularies developed by prescription drugs plans that are consistent with the Model Guidelines established by the United States Pharmacopeia (USP) may not be found “likely to substantially discourage enrollment” by certain Medicare beneficiaries. (MMA, Section 1860D-11(e)(2)(D)(i) and (ii)).

Development of the Model Guidelines version 1.0 (MG 1.0) was funded through a cooperative agreement with the Centers for Medicare and Medicaid Services (CMS) and completed by USP on December 31, 2004. Information about this initial activity is available at <http://www.usp.org/healthcareInfo/mmg>.

In 2006, CMS and USP joined in a new cooperative agreement for the purpose of revising the listing of drug categories and classes for the 2008 benefit year – Model Guidelines version 3.0 (MG 3.0). The current contractual agreement required the submission of MG 3.0 by February 5, 2007.

This report provides: 1) background on USP, 2) a discussion of USP’s guiding principles for revisions to create MG 3.0 and 3) a plan for providing ongoing revisions to the listing of categories and classes over time. An attachment to this report summarizes the public comments received and USP’s responses to these comments.

USP BACKGROUND

The United States Pharmacopeial Convention (USP), established by practitioners in 1820, is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also

recognized and used in many other countries outside the United States. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years.

USP is an independent, science-based public health organization. As a self-sustaining not-for-profit, 501(c)(3) organization, USP is funded through revenues from the sale of products and services that help to ensure good pharmaceutical care. USP's contributions to public health are enriched by the participation and oversight of expert volunteers representing pharmacy, medicine, and other healthcare professions as well as academia, government, the pharmaceutical industry, health plans, and consumer organizations.

The USP Convention membership is constituted to ensure suitable representation of those sectors of the healthcare system that are impacted by, and in turn impact, USP's activities. The Convention can have more than 450 members representing:

- US colleges and schools of medicine and pharmacy.
- State medical societies and pharmacy associations.
- National and state professional and scientific organizations.
- Governmental bodies.
- Health science and other non-US organizations and pharmacopeias.
- Domestic, foreign, and international manufacturers, distributors, and trade and affiliated associations.
- Consumer organizations and persons representing the public interest.

Convention members elect the USP Convention Officers (president, treasurer, and secretary), the Board of Trustees, and the Council of Experts and vote on resolutions that determine the organization's direction and priorities

The Council of Experts is the body that makes USP's scientific and standards-setting decisions. Members of the council are elected by the USP Convention membership. Each council member serves as the chair of an Expert Committee for a 5-year term, with the members of each Expert Committee also serving a 5-year term. The Council of Experts and its Expert Committees provide the scientific foundation for USP's public health products and programs.

REVISION PROCESS

As stipulated in the MMA, USP is required to revise the Model Guidelines. Under a new cooperative agreement with CMS, USP has fulfilled this responsibility by creating MG 3.0 for use by CMS and Plans for the 2008 benefit year. USP's approach to developing

MG 3.0 is built upon the foundation that was established in the development of MG 1.0 and MG 2.0.

The elements of USP's revision process include:

- Election and meetings of the 14 Information Expert Committees (IECs).
- Meetings of the Model Guidelines Expert Committee (MGEC).
- Review of available and relevant drug information.
- Development of guiding principles for revision.
- Consideration of Part B/Part D issues.
- Performing outreach.

Each of these elements is discussed in further detail below.

Election and meetings of the USP Expert Committees

In 2006, under its rules and procedures, the USP Convention elected new members for 14 of the 16 USP Information Expert Committees for the 2005-2010 cycle. Elections for the 2 vacant Chair positions and membership for those 2 committees are in process. The chairs of USP's Information Expert Committees form the MGEC and will be in place for this 5-year term through 2010. Appendix A provides a listing of the members of the MGEC. Members of the MGEC and of all USP expert committees are selected and serve on the basis of their individual knowledge and expertise, not as representatives of any particular organization. Rules for the MGEC were established and are provided in Appendix B.

During the fourth quarter of calendar year 2006, each of the 14 IECs met to review new drugs and indications and other relevant drug information to propose revisions to the MG 2.0. The MGEC met in person 4 times between March 2006 and January 2007. These meetings were used to discuss principles, review recommendations for revisions from the IECs and to review other relevant information for potential revisions to MG 3.0. The results of the MGEC's deliberations are reflected in MG 3.0.

Review of available and relevant drug information

The information reviewed by the IECs and MGEC for consideration of development of MG 3.0 included:

- Newly approved and discontinued covered Part D drugs
- Changes in approved therapeutic uses of Part D drugs

- New information available regarding the safety and efficacy of Part D drugs
- Drug Efficacy, Study and Implementation (DESI) drugs
- The Health Plan Employer Data and Information Set (HEDIS) performance measures
- Feedback, including public comments, received since the issuance of MG 2.0
- Input from the IECs and fellow members of the MGEC.

This information came from multiple sources including CMS, the Food and Drug Administration (FDA), literature review, providers, beneficiaries, drug plans, pharmaceutical manufacturers, trade and professional associations, consumer advocacy groups, and others.

Development of guiding principles for revision

Utilizing the information described above, the MGEC used the following guiding principles in developing MG 3.0 and the Formulary Key Drug Types (FKDTs):

- The goal of the prior MGEC – to strike a balance of assuring beneficiary access to the drugs they need with the flexibility that Plans need to offer an affordable and effective benefit – remains paramount.
- The Model Guidelines are composed of two columns and carry the requirement of a minimum of two drugs. FKDTs make up a third column and are included as part of the CMS formulary review process, with a one-drug minimum.
- The therapeutic category (column 1), as before, is generally based on an FDA-approved indication.
- A pharmacologic effect generally remains the basis for class (column 2), as feasible.
- A more refined pharmacologic effect generally remains the basis for FKDTs, as feasible.
- Duplication is included if there is an attendant patient care issue.
- Categories that address combination drugs are included when an exclusive clinical benefit has been established such as when the individual components of the drug are not commercially available or when the individual components combine to form a unique chemical entity.
- Consideration, where clinically appropriate, of movement of Class elements to the FKDT column or from the FKDT to the Category or Class column.

The MGEC acknowledges that there are occasionally exceptions to these principles in MG 3.0 and the FKDTs. The fact that such exceptions exist points to certain limitations in the information that is available. For example, some classes or FKDTs may be characterized by chemical structure due to a dearth of information related to their pharmacologic effect. Despite such exceptions, MG 3.0 and the FKDTs reside upon a solid clinical foundation and lend themselves to ongoing enhancements as new information becomes available.

Consideration of Part B/Part D issues

An issue of particular importance to the MGEC was coverage determination under Medicare Part B versus Part D. The driving determination, as offered by CMS, for whether an article would be covered under Part B or D was largely based on available documentation from CMS and the concept of self-administration: items that are usually self-administered greater than 50% of the time are most likely to be covered under Part D while those that are usually not self-administered would typically fall under Part B. While there are exceptions to this concept, “self-administration” still provided a useful framework, along with available CMS documentation, to help the MGEC include those items that are most appropriate for the Part D benefit. The MGEC requests that CMS continue to work closely with Plans to ensure that no beneficiaries are discriminated against on the basis of whether a particular drug is covered under Part B or D.

Performing outreach

As with the development of MG 2.0, USP conducted an outreach program to ensure that all interested parties were given the opportunity to provide input into the deliberations of the MGEC. The following mechanisms were elements of this outreach program: the Advisory Forums, media statements and briefings, use of the USP website, and a public comment period.

USP maintained open communications via electronic and teleconference media with the members of the four Advisory Forums (representing beneficiaries, drug plans, pharmaceutical manufacturers, and providers) that were created during the development of MG 1.0. The objectives of these interactions were to provide these stakeholders with information regarding USP’s revision process, invite them to provide feedback and comments along the way, and request that they inform their members and stakeholders about USP’s process and timeline. Because the Advisory Forum members are predominantly national organizations, this proved to be an effective mechanism to help inform interested parties across the country in an efficient way.

In addition to working with the Advisory Forums, USP worked with the media to help disseminate information regarding the organization’s activities. USP staff issued multiple media statements and held media briefings to ensure that reporters understood and could accurately report on USP’s efforts to develop MG 3.0. By working with the media in this way, USP was able to reach a broad audience through the publication of articles related to the revision activity.

USP also continued to use its corporate website as a communications vehicle to inform the public about USP's revision process, timeline, next steps, and more. USP's website also included information about how interested parties could submit public comments.

This public comment period, as the name implies, provided a mechanism for any interested party to submit comments in writing to USP for consideration by the MGEC. USP posted a draft version of MG 3.0 on its website on November 10, 2006 for the specific purpose of soliciting direct feedback on the proposed revisions. In response to this effort, the comments received by USP were effectively and efficiently organized by staff to facilitate the MGEC's review and consideration for changes to the proposed revisions.

As with the public comments received during the development of MG 2.0, the comments received for this revision process tended toward some common themes, depending upon the submitter. Plans, in general, seemed to favor a reduction in categories, classes, and FKDTs.

Manufacturers, practitioners, and beneficiaries offered comments in support of a more expansive listing of categories, classes, and FKDTs. Attachment 1 includes a table of all of the comments received including the nature of the comments and the response of the MGEC.

USP also provided CMS with two opportunities to review the draft version MG 3.0 and suggest revisions to the draft. After careful consideration, the MGEC made revisions to the MG 3.0, based upon CMS' comments.

SUMMARY OF REVISIONS

To advance to MG 3.0, the MGEC revised MG 2.0 under the principles listed above – using the information also listed above – according to the following criteria:

- Expansion of category, class, or FKDT to separate pharmacologically and clinically distinct categories, classes, or FKDTs.
- Reduction of category, class, or FKDT to group clinically non-distinct categories, classes, or FKDTs.
- A clinical distinction or non-distinction refers to a consensus opinion of the MGEC taking into consideration an understanding of available comparative safety and efficacy information, clinically relevant therapeutic differences, pharmacology and medical practice.
- Exclusion of category/class/FKDT for items anticipated to be covered primarily/predominantly by Part B.

- Changes in names/titles of category, class, or FKDT for clarification purposes.

MG 3.0 reflects these changes. The table below provides a numerical comparison of MG 2.0 with its precursors.

	Version 1.0 (for 2006)	Version 2.0 (for 2007)	Version 3.0 (for 2008)
Therapeutic Categories – Total	41	49	50
Pharmacologic Classes – Total	137	117	119
Unique Categories and Classes*	146	133	138
Formulary Key Drug Types - Total	118	141	193

*Unique Categories and Classes is the sum of the number of Pharmacologic Classes and the number of Therapeutic Categories that have no associated classes.

ONGOING REVISION PROCESS

As USP has worked through this second revision of the Model Guidelines, there continues to be a number of critical needs that have been identified that will impact future revision activities. These include:

- The need for comprehensive drug information that is current, relevant, and objective to support the work of the IECs and MGEC.
- The need for an ongoing funding mechanism for USP’s work to ensure that gathering and reviewing drug information occurs without interruption.
- The need for ongoing engagement of stakeholders – through public meetings, seminars, extended comment periods, etc.
- The need to learn from the implementation of the drug benefit. CMS is poised to assess the impact of MG 3.0 on the benefit, in terms of both beneficiary access and practicality. This information is critical to assuring that the Model Guidelines evolve over time in concert with the experience of the benefit itself.

USP will continue to work closely with CMS on a rigorous ongoing revision activity, which was generally not possible in this cycle because of constrained resources and an abbreviated timeframe. The primary goal for these ongoing revisions will be for USP to continue to grow and manage a comprehensive drug information review process to revise the Model Guidelines based on “changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs.” This includes incorporating new information on existing drugs as well (e.g., safety). In order to effectively revise the Model Guidelines according to these legislative stipulations, USP will:

- Maintain and update the Model Guidelines and FKDTs based on current scientific evidence.
- Respond to inquiries and challenges from stakeholders.

In order to accomplish the objectives identified in the previous section, USP proposes to implement an approach that includes:

- The MGEC
- USP’s IECs and Advisory Panels
- USP staff
- Maintenance of a public processes to facilitate input from interested parties
- Ongoing collaboration and communication with CMS

In general, the ongoing process for revising the Model Guidelines will include:

- 1) USP staff will gather data and information regarding drugs, drug categories and drug classes. Sources for this information include FDA (e.g., new drug approvals and new indications), the medical literature, the Advisory Forums, feedback from seminars and consultations, and other resources.
- 2) USP staff will analyze and synthesize the information and provide it to the relevant Information Expert Committees for their review. These Expert Committees will put forth a recommendation as appropriate for changes to the Model Guidelines.
- 3) The MGEC will convene quarterly and review the recommendations from the Information Expert Committees and associated information and determine how best to modify the Model Guidelines.

4) USP will submit formal modifications to the Model Guidelines on an annual basis.

Each of the key aspects, resources, and components of this proposed process are described in more detail below.

The MGEC

This Committee will convene quarterly to review drug information and recommendations from USP's Information Expert Committees to determine appropriate revisions to the Model Guidelines.

USP's Information Expert Committees and Advisory Panels

Among the critical inputs to USP's process is the expertise within USP's standing Information Expert Committees. There will be 16 Information Expert Committees in the 2005-2010 cycle, comprised by volunteers possessing all of the relevant expertise required to support the MGEC (currently 14). These Information Expert Committees, defined primarily by clinical specialty, serve to review analyses and information compiled by USP staff to assess the need for changes to the Model Guidelines. Ultimately, recommendations from these Expert Committees will be reviewed and considered by the MGEC.

USP may supplement the expertise of the Information Expert Committees with advisory panels and/or advisory bodies in each of the following clinical drug information areas, including:

- Comparative efficacy and safety
- Health maintenance and the pathophysiology of disease
- Mechanism of action
- Indication/Molecular Targeting
- Clinical pharmacology

These advisory panels and/or bodies will be comprised of scientific experts in these clinical drug information areas.

USP staff

The most intensive aspect of USP's proposed approach is the use of staff to perform a perpetual and comprehensive drug information gathering, development, and review function. Staff is responsible for collecting and analyzing current scientific evidence and information to present this information in a way for various Expert Committees to expediently review and consider. Given the tremendous volume of information that is continually developed and published, this staff activity is expected to be vigorous to help

ensure that the Model Guidelines remain current in terms of assessing new FDA approved Part D eligible drugs and responding to challenges/ appeals from stakeholders.

Maintaining a public process

USP believes that the Advisory Forums are critical to ensuring that the Model Guidelines perpetually reflect consideration of input from all interested parties. In addition, USP intends to maintain an ongoing series of outreach efforts to keep the public and interested parties engaged in the process. USP and the MGEC believe that to ensure success in adjusting the Model Guidelines, substantial effort must be expended to reach out to various constituencies, through various mechanisms including a public meeting, topic-specific seminars, and consultations.

Ongoing collaboration and communication with CMS

Throughout all of the revision activities, USP will maintain close communications with CMS to ensure that proposed revisions to the Model Guidelines meet CMS's needs as the agency implements and manages the Part D benefit. CMS staff, as they have been during the development of MG 1.0, MG 2.0 and MG 3.0, will continue to be invited to attend the meetings of the MGEC, as well as all of the public meetings, seminars, consultations and other related meetings that USP conducts.

One aspect of these communications would be the creation of a feedback mechanism to enable CMS to provide USP with key findings and issues as CMS manages the implementation of the Medicare Prescription Drug Benefit. For example, information regarding the propensity of Plans to use the Model Guidelines, which categories and classes seem to be an issue for Plans and why, how effective the Model Guidelines are in assuring access and helping to manage costs – all of these and other related items of information would be very helpful for the MGEC to understand as they set about to revise the Model Guidelines.

APPENDICES

APPENDIX A

MEMBERS OF THE USP MODEL GUIDELINES EXPERT COMMITTEE 2005-2010

Members of the Model Guidelines Expert Committee are the elected chairs of the USP Information Expert Committees and are listed with the names of their respective committees.

CHAIR

Roger Williams, M.D.

Executive Vice President and
Chief Executive Officer
U.S. Pharmacopeia
Rockville, MD

SCIENTIFIC LIAISON

Deborah Perfetto, Pharm.D.

Director
Department of Information Development
U.S. Pharmacopeia
Rockville, MD

MEMBERS

Cardiology

Sarah A. Spinler, Pharm.D.

Professor of Clinical Pharmacy
Philadelphia College of Pharmacy
University of the Sciences in Philadelphia
Philadelphia, PA

Clinical Toxicology - Vacant

Dermatology

Dennis P. West, Ph.D., F.C.C.P.

Vincent W. Foglia Family Research Professor of Dermatology
Northwestern University
Feinberg School of Medicine
Department of Dermatology
Chicago, IL

Endocrinology

Karim A. Calis, Pharm.D., M.P.H.

Clinical Specialist
Endocrinology & Women's Health
National Institutes of Health
Bethesda, MD

Gastroenterology

Bruce R. Bacon, M.D.

Director, Div. of Gastroenterology and Hepatology
Saint Louis University School of Medicine
St. Louis, MO

Hematology

Patrick A. McKee, M.D.

George Lynn Cross Professor of Medicine
The University of Oklahoma Health Sciences Center
Oklahoma City, OK

Immunology

John D. Grabenstein, Ph.D.

Director of Scientific Affairs
Merck Vaccine Division
Collegeville, PA

Infectious Diseases

Douglas W. MacPherson, M.D., M.Sc., FRCPC

Consultant
Migration Health Consultants, Inc.
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Canada

Nephrology/Urology - Vacant

Neurology/Otorhinolaryngology/

Ophthalmology

Mitchell F. Brin, M.D.

Senior Vice President Development & Therapeutic Area Head
BOTOX[®] & Neurology
Allergan, LLC
Irvine, CA

Oncology

Barbara Burtness, M.D.

Fox Chase Cancer Center
Philadelphia, PA

Psychiatry

Amy H. Schwartz, Pharm.D.

Assistant Dean and Director
Cooperative Pharmacy Program
The University of Texas-Pan American
Edinburg, TX

Pulmonary Disease and Allergy

Elliot Israel, M.D.

Director, Respiratory Therapy
Brigham and Women's Hospital
Pulmonary and Critical Care Medicine
Boston, MA

Rheumatology

David H. Campen, M.D.

Medical Director
Drug Information & Technology
Kaiser Permanente
Oakland, CA

Special Populations/Clinical Pharmacology

Joseph T. Hanlon, Pharm.D.

Professor of Medicine
University of Pittsburgh
Pittsburgh, PA

Therapeutic Decision Making

Nancy Jo Braden, M.D.

Medical Director
Mercy Care Plan of Arizona
Phoenix, AZ

APPENDIX B

RULES AND PROCEDURES FOR THE 2005-2010 MEDICARE MODEL GUIDELINES EXPERT COMMITTEE

1. GENERAL.

1.01 Governance.

These Rules and Procedures for the 2005-2010 Medicare Model Guidelines Expert Committee (MGEC) represent the procedures and practices to be followed by the MGEC with respect to the revision of the Medicare Model Guidelines and related information and documents. On all matters not specifically addressed in these Rules and Procedures, the Rules and Procedures of the 2005-2010 Council of Experts (Council of Experts Rules) shall apply.

1.02 Amendments.

These Rules and Procedures may be amended from time to time by a majority vote of the MGEC. These Rules and Procedures and any modification thereto adopted by the MGEC shall be applied on a prospective basis only.

3. THE MEDICARE MODEL GUIDELINES EXPERT COMMITTEE.

3.01 Members.

The members of the MGEC shall be the Chairs of USP's Information Expert Committees, elected by USP's Convention membership as part of the Council of Experts under Section 3.02 of the Council of Experts Rules and Chapter VII, Section 1 of the Bylaws of USP.

3.02 Scope of Work.

The MGEC shall be responsible for determining and approving revisions to the Medicare Model Guidelines and related information and documents that pertain to formularies and plan designs that may be used by prescription drug plans under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Committee may also be assigned additional tasks by the Chairperson of the Council of Experts with the approval of the Executive Committee of the Council of Experts.

3.03 Chairperson.

The MGEC shall be chaired by the Chairperson of the Council of Experts (Chairperson). The Chairperson shall count towards a quorum, but shall not vote on matters before the MGEC except to break a tie.

3.04 Vice Chair.

Pursuant to Section 6.03 of the Council of Experts Rules, the MGEC shall elect a vice

chairperson, who shall serve in the temporary absence of the Chairperson.

4. ADVISORY FORUMS.

4.01 Formation.

The Chairperson shall appoint four advisory forums to the MGEC (Advisory Forums), consisting of trade associations or other organizations representing each of the following constituencies: (a) drug plans, (b) beneficiaries, (c) providers, and (d) pharmaceutical manufacturers. Additional Advisory Forums may be appointed by the Chairperson with the advice and consent of the MGEC. The MGEC shall approve those organizations invited to participate in each Advisory Forum. The purpose of the Advisory Forums shall be to provide perspective and input from each such constituency into the Medicare Model Guidelines revision process. Each Advisory Forum shall meet with USP from time to time as deemed appropriate by the Chairperson to provide such perspective and input. The Chairperson of the MGEC, with the advice and consent of the MGEC, may discharge any Advisory Forum at any time.

4.02 Conflict of Interest.

Members of an Advisory Forum shall not be subject to USP's conflict of interest policies or other standards of conduct set forth in Section 2 of the Council of Experts Rules.

4.03 Responsibility for Expenses.

USP shall not be responsible for travel or other expenses associated with participation or attendance at meetings by the members of the Advisory Forums.

5. MEETINGS.

5.01. MGEC Meetings.

Meetings of the MGEC shall be held in accordance with Section 12 of the Council of Experts Rules.

5.02. Non-Member participation in MGEC Meetings.

As set forth in Section 12.04 of the Council of Experts Rules, non-members participants must notify USP at least five days in advance of the meeting of their proposed attendance, and provide necessary background information about themselves and their affiliated organization, if any.

5.03. Confirmation.

Due to the limited space available, USP does not guarantee that all non-members that request attendance at an open meeting of the MGEC will be able to attend. USP staff will attempt to accommodate all requests for attendance in the order that the requests are received. In order to attend a MGEC meeting, non-members must receive confirmation that their request for attendance has been granted.

6. REVISION PROCESS.

6.01 Notice and Opportunity for Comment.

The MGEC shall provide the public with an opportunity to review and provide comments to revisions to the Medicare Model Guidelines and related documents. Comments received by the

public during a public comment period will not be considered confidential and will be made available to the public.

6.02 Process and Timeline for Public Comments.

During each revision process of the Medicare Model Guidelines, the MGEC will develop a process and timeline for obtaining and considering comments from the public, which shall take into account the timeline for USP's completion of the revision process under its applicable agreement with the Centers for Medicare and Medicaid Services. Such process and timeline will be made publicly available and posted on USP's website.