

## Response to Comments: Attendance Guide for Open Meetings

This document summarizes the comments we received regarding Draft Attendance Guide for Open Meetings. Thank you for the comments.

### Comment 1

After reviewing the draft Attendance Guide for Open Meetings, I would like to respectfully ask if you would please confirm as to whether these new guidelines will prohibit the brief conversations that have traditionally taken place at the conclusion of the open meetings between the in-person meeting attendees and WPS staff members? I am asking for clarification based upon the last sentence in the 2<sup>nd</sup> paragraph: *“All communications the day of the open meeting should occur within the bounds of the Meeting Agenda, and in accordance with the open meeting process described by the meeting Chair, including any special considerations shared verbally the day of the meeting.”*

As someone who has attended a number of WPS Open Meetings in the past, I have always appreciated the opportunity to meet and speak with WPS staff member at the conclusion of the Open Meeting. These brief introductions and/or discussions often have no relation to the draft policies/topics specifically outlined in the Open Meetings’ agenda. However, I find them to be very valuable and sincerely appreciate WPS staff members’ professionalism; willingness to share their knowledge; and the time they often take to thoroughly answer any questions that may arise out of these discussions. I sincerely hope that these new meeting guidelines will not prohibit these types of interactions in the future.

Andrea Warren-Smith, National Account Executive – Medicare, Bristol Myers Squibb™

### Response 1

Thank you for the comment, we have updated the guide to state “WPS personnel will be available to discuss matters unrelated to the LCDs. However, these discussions may occur only after the Open Meeting agenda has been completed, in the room established for convening the Open Meeting, and during the time allotted for the Open Meeting that remains on completion of the agenda.”

### Comment 2

The following comments are provided on the WPS Draft Attendance Guide for Open Meetings which was developed to provide guidance to all attending stakeholders on professional conduct.

#### Key Points of Discussion within the Draft Attendance Guide

**Paragraph 2:** *“One way we ensure we can meet this aim is by sharing the expectations a participant should have for the open meeting, and by discouraging ex parte communications the day of the meeting... The LCD process offers alternative opportunities for engagement (for example, the informal meeting request) for stakeholders who wish to have a discussion with WPS on a particular topic, including a topic potentially discussed at an open meeting. All communications the day of the open meeting should occur within the bounds of the Meeting Agenda, ...”*

**Stakeholder guidance in item number 3.** states: *“In order to provide equal access, stakeholders should only expect to speak with WPS staff during the designated public comments timeframes.”*

**Stakeholder guidance in item number 5.** states: *“Participants will conduct themselves in a professional and civil manner that encourages transparency (e.g., by not initiating ex parte discussions outside of the meeting). Ex parte discussions disadvantage all meeting participants who may benefit from the equal sharing of information and complicate the inclusion of these comments into the deliberations on the policy under discussion. Individuals who seek to initiate discussion outside of the meeting will be reminded of the alternative venues within the LCD process for providing information.”*

**Comments:** We understand that the Open meetings and policy staff have limited time to allow for presentations and comments on the related draft LCDs on the agenda. Often when all information has been discussed relevant to the agenda topics, stakeholders have been able to briefly discuss developing or published evidence pertaining to a specific medical technology, pharmaceutical or diagnostic product with the policy staff after the meeting has finished. This brief dialogue expedites the process by guiding the stakeholder to submit the information in either a coverage or reconsideration letter. Limiting dialogue between medical products stakeholders or providers to only discuss agenda topics at these meetings will increase the time required to conduct informal meetings should the stakeholder desire to request a meeting rather than a brief discussion regarding the new evidence.

Stakeholders who have interest or comment/present on an agenda topic at the meeting are also limited to conduct their comments only during their comments allotted time. Any discussions after the meeting to clarify any information presented (even by the policy staff) are now also forbidden. All stakeholders are guided to send their verbal comments in writing to WPS after the meeting for inclusion in the draft LCD review, so limiting any post meeting discussion is also counterproductive.

**Recommendations:**

1. Allow stakeholders who presented or gave comments to have discussions with policy staff after the meeting to answer any questions, clarify any statements and then follow-up with their comments in writing.
2. Allow stakeholders who have questions for policy staff outside of the agenda topics to briefly (no more than 4-5 minutes) and professionally discuss their concerns regarding a particular policy or medical product (after the Open meeting comments/presentations are concluded) and receive guidance as how best to proceed with their question or follow-up action. This may be in the form of a request for coverage, reconsideration, request for an informal meeting or simply a request for clarification from the WPS medical policy staff.
  - a. By affording the brief discussions at the end of the Open meeting, this will help to limit informal meeting requests which take additional time and administration, and which may have been handled more efficiently in the course of a brief conversation at the end of an Open meeting.
3. Limit discussions not related to the agenda topics to occur only after the meeting concludes.
4. Limit all post meeting discussions between policy staff and stakeholders to less than 5 minutes to respect other attendees who would also like to speak w/policy staff members.

Scott Blackman, CMBS, National Director, Payer Policy and Reimbursement

**Response 2**

Thank you for the comment, please see Response 1.

### **Comment 3**

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am filing the following comments on the WPS Draft Attendance Guide for Open Meetings which was developed to provide guidance to all attending stakeholders on professional conduct. MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

We understand that the open meetings and policy staff have limited time to allow for presentations and comments on the related draft LCDs on the agenda. However, should this Guide go forward as is, it may curtail access to Medicare Administrative Contractor (MAC) policy staff and the opportunity to engage them on discussions relevant to individual technologies, developing evidence, provider challenges and more. It is critical for stakeholders to interact with MACs to further enhance innovation and continue to provide novel treatments to patients in a timely manner.

Open meetings play a critical role in the fulfillment of your obligation to ensure Medicare beneficiaries in the regions for which WPS GHA acts as the MAC have access to reasonable and necessary medical services as promised under the Social Security Act. The goal of these meetings, and of the entire LCD development process<sup>1</sup>, should be to gather all information relevant to a final determination. Any policy that could hinder the free flow of such information should be closely scrutinized.

We believe that the restrictions described in the Draft Attendance Policy—in particular the restrictions on ex parte communications and the potential imposition of sanctions against stakeholders for conduct that is intended to assist WPS by providing relevant information to support a final determination—have the potential to impede beneficiary access to beneficial new medical technologies and therapies by unnecessarily limiting the information available to WPS to develop appropriate LCDs.

Restrictions on ex parte communications are typically imposed in adjudicatory proceedings where there is a need to maintain judicial impartiality and fairness between adversarial parties, who have primary responsibility for introducing evidence supporting their position and rebutting evidence from the other side. Such restrictions prioritize the interest of each party to know about and challenge information submitted by the other over the interest of the decision maker having access to all relevant information. However, the process for developing LCDs is not intended to be an adversarial process. It is intended to serve Medicare beneficiaries by facilitating, to the fullest extent possible, coverage determinations that are grounded on a full and complete examination of all relevant evidence.

While we understand your interest in ensuring that open meetings are conducted in an efficient manner, we do not believe a prohibition on ex parte communications, enforced by the threat of sanctions against stakeholders, is appropriate in this context. To the extent that information is provided to WPS outside of the official open meeting session, WPS has many opportunities to review and consider its accuracy, relevance, and applicability to the final determination. Creating barriers to the review and consideration of such information is not the right answer.

We believe that the alternatives to ex parte communications suggested by WPS, including submitting written comments or requesting a separate meeting, would actually decrease the efficiency of the overall LCD process. Drafting written comments or scheduling additional

meetings would be overly burdensome in the many cases where a brief post-meeting conversation could resolve questions raised during the open meeting. And for more complex questions or the discussion of matters that are unrelated to the open meeting agenda, rather than adopting the Draft Attendance Policy, WPS should consider other mechanisms to improve efficiency, such as establishing “office hours” or another regular forum for stakeholders to interact with WPS medical directors, policy analysts, and other staff.

MDMA appreciates this opportunity to comment on the WPS Attendance Guide for Open Meetings. We all share an interest in ensuring that LCDs are firmly grounded in the best available evidence, so that beneficiaries have access to the full range of reasonable and necessary medical services. MDMA stands ready and looks forward to working with you on ways to enhance the exchange of important information and asks that WPS not to proceed with implementing the Draft Attendance Policy absent a robust replacement mechanism for meaningful interactions between WPS staff and stakeholders.

Mark Leahey President and CEO, Medical Device Manufacturers Association

**Response 3**

Thank you for the comment, please see Response 1.

**Comment 4**

Will the Draft LCD Open Meeting Attendance Guide prohibit informal brief conversations on topics unrelated to the Draft LCDs, like those we have had in the past after the formal meeting time ends?

Understanding the intent of the Guide will help in evaluating the need for formal comment.

Lisa Dunn, Senior Regional Account Executive, AMGEN

**Response 4**

Thank you for the comment, please see Response 1.