



August 28, 2009

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1413-P, Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010, Proposed Rule

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the proposed rule regarding revisions to payment policies under the physician fee schedule and other revisions to Part B for CY 2010 (proposed rule). For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. Pharmacists work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely and effectively.

Revision of Definition of Medically-Accepted Indication for Drugs; Compendia for Determination of Medically-Accepted Indication for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen

ASHP is the publisher of the American Hospital Formulary Service Drug Information (AHFS Drug Information, AHFS DI), a comprehensive, independent reference on the clinical use of medications marketed in the United States. Published continuously for 50 years, AHFS DI is recognized through federal legislation under Medicare Part B (Section 1861(t)(2)(B)(ii)(I) of the Social Security Act (the Act)), Medicaid (Section 1927(k)(6) of the Act), and Medicare Part D (Section 1860D-2(e)(1)(B) of the Act) as an official compendium for information on medically accepted uses of medications.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires a compendium that is recognized under Medicare Part B to have a publicly transparent process in place for evaluating therapies and identifying potential conflicts of interest. The Centers for Medicare and Medicaid Services (CMS) is proposing regulatory safeguards to comply with the statute and require that a compendium's publicly transparent process for evaluating therapies and identifying potential conflicts of interest

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include the disclosure of certain relevant information. While ASHP understands that CMS is creating a process to comply with the MIPPA requirements, the Society has some concerns with, and offers some clarifications to, the proposed process, and makes the following recommendations for changes to be included in the final rule.

CMS should use Food and Drug Administration (FDA) guidance as a model

ASHP strongly recommends that CMS use FDA's policies and procedures regarding conflicts of interest pertaining to FDA advisory committee members, consultants and experts as a model for its conflict of interest requirements pertaining to compendia. FDA's process is a well-established mechanism that is already known by experts likely to participate in compendial activities, and there is a close, almost identical similarity between the type of advice that is provided for drug approvals and off-label determinations.

In particular, ASHP encourages CMS to use the FDA's policy regarding the disclosure of interests by immediate family members, which references 18 U.S.C. 208, rather than the definition included in 42 CFR 411.351. 18 U.S.C. 208 includes only the spouse and minor child as family members who may present conflict of interest issues. 42 CFR 411.351 is unnecessarily broad, including husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. Furthermore, 42 CFR 411.351 relates to the prohibition of a physician making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship. This topic is unrelated to conflict of interest issues concerning advisory committee members or reviewers, and does not deal with the review of an off-label use.

Publication of applications

Under its proposed rule, CMS would require that the "application for inclusion of a therapy" be available on the compendium's Web site. However, ASHP's determination process may not originate with an application process. Instead, through its constant review and tracking of relevant literature, ASHP's compendium staff may determine whether an evaluation of a new off-label use should be performed, and an expert panel engaged. Although a formal application process may not be used, once the decision has been made to evaluate a new use, compendium staff would identify and review the evidence, provide a summary of evidence using its prespecified criteria for weighing and a listing of citations, and a ballot, to the expert panel. In addition to this information provided to the expert panel, publicly published information would include final determinations concerning medical acceptance by the expert panel for Inclusion, Exclusion, and Deletion.

Due to these processes, ASHP recommends that CMS broaden its terminology by changing the requirement that the “application for inclusion” be published, and instead require that materials provided to the expert or advisory panel by compendium staff requesting an evaluation of a new use be published, including a bibliography of any relevant studies provided to the panel, if an application is unavailable. Under this scenario, similar to that proposed when an application is available, disclosure of conflicts of interest would be triggered by the actual determination (recommendation) concerning medical acceptance (recommendation).

ASHP suggests the following regulatory language:

Publicly transparent process for evaluating therapies means that the following materials are available to the public on the compendium’s Web site coincident with the compendium’s publication of the related recommendation:

(i) The application for inclusion of a therapy including criteria used to evaluate the request or, if a compendium does not use an application process, materials provided prior to the start of the evaluation to individuals who substantively participated in the development of the compendia recommendation, including a bibliography of any relevant studies.

Transcripts of meetings

The proposed rule requires that transcripts of meetings and records of votes be published on the compendium’s Web site. However, a compendium such as AHFS may not hold face-to-face or virtual meetings, so there would be no minutes or transcripts to publish. Instead, materials provided to the advisory panel would be disclosed and published, as well as the record of the vote, which would include the number of individuals who voted “yes,” “no,” “abstain” or “recuse,” and a description of how any conflicts of interest, if present, were managed.

In lieu of actual minutes when a face-to-face or virtual meeting of an expert panel does not occur, a compendium would disclose on their Web site any relevant instructions and background material provided to the expert panel, any summary of evidence and criteria for interpretation, ballots, and other documents calling for a vote or consensus.

The proposed rule further requires that a listing of all evidentiary materials reviewed or considered by the compendium pursuant to the application be published. ASHP recommends that CMS differentiate between preliminary information that is reviewed on a regular basis by compendium staff that might lead to a decision to pursue a new use (analogous to a pre-application phase), versus information that is provided to expert panelists at the beginning of their review process. It is this latter information, including both negative and positive evidence, that is material to each specific determination concerning medical acceptance, and therefore should be disclosed. It would be unduly

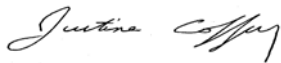
burdensome to document all information reviewed as part of a compendium's routine literature review and tracking activities, and likely not useful or relevant.

Five year retention requirement

CMS proposes that disclosures should remain publicly viewable for a reasonable period of time, defined as a period of not less than 5 years. CMS further states that a period of 5 years is a reasonable balance between the burden of maintaining this information and the public's interest in timely access to this information. ASHP recommends that disclosures should remain publicly viewable for 3 years on the Web site, and then be available for 2 more years directly from the compendium. In the context of conflict of interest disclosure, ASHP does not believe that the public's need for a prolonged 5-year period of immediate access exceeds the burden of maintaining such access. In today's environment of ongoing Web site refreshes, substantial burden and cost is borne for each page and link that needs to be maintained over time. Therefore, ASHP believes that our proposed alternative would provide a better balance.

ASHP appreciates this opportunity to present its written comments on the proposed rule. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,



Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs