

## **Supporting Statement – Part A**

### **Supporting Statement For Paperwork Reduction Act Submissions**

#### **A. Background**

Section 1861(t)(2)(B)(ii)(I) establishes certain published compendia as authoritative references for determining if a substance is a drug or biological under the fee-for-service Medicare program. In the CY 2010 Physician Fee Schedule proposed rule issued on July 13, 2009, the Office of Clinical Standards and Quality (OCSQ) revised 42 C.F.R. § 414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen, which provided a definition of “compendium” and explained a process for making additions and deletions to the list to statutorily recognized compendia for this use. The revisions to 42 C.F.R. § 414.930 definition include: 1) the current definition of compendium in 42 C.F.R. § 414.930 section (a) is amended by the addition of the sentence “A compendium has publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.”; 2) the current section “(a) Definition” is renamed “(a)(1) Definitions”; 3) the definition of a publicly transparent process for evaluating therapies is added as a new section (a)(2); and 4) the definition of a publicly transparent process for identifying potential conflicts of interests is added as a new section (a)(3). In addition, the process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment in (b)(1) of 42 C.F.R. § 414.930 is amended to exclude any entity that does not fully meet this modified regulatory definition of compendium.

#### **B. Justification**

##### **1. Need and Legal Basis**

Congress enacted the Medicare Improvement of Patients and Providers Act (MIPPA). Section 182(b) of MIPPA amended Section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: ‘On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.’ We believe that the implementation of this statutory provision that compendia have a “publicly transparent process for evaluating therapies and for identifying potential conflicts of interests” is best accomplished by amending 42 C.F.R. §414.930. to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests. Therefore, we are revising 42 C.F.R. § 414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen in CY 2010 Physician Fee Schedule to comply with MIPPA Section 182 (b).

2. Information Users

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA.

3. Use of Information Technology

One-hundred percent of the compendia publishers currently post their conflict of interest disclosure policies on their website. Two of the four current statutorily recognized compendia also post the individual conflicts of interests of compendia recommendation decision makers. Since most of the provisions in our revision of §414.930 are currently being practiced by compendia publishers and posted on their website, we expect the additional burden to be minimal.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection of information does not impact small businesses or other small entities.

6. Less Frequent Collection

The collection of this data occurs each time a compendia advisory committee or experts convene to make an off-label recommendation for an anticancer drug or biologic. If the information is not collected, OCSQ cannot meet our responsibility to uphold the intent of MIPPA 182(b).

7. Special Circumstances

- ❖ The respondent (i.e. the compendia publisher) is required to make all materials mentioned under section (a)(2) 42 C.F.R. §414.930, the definition of a publicly transparent process for evaluating therapies, available to the public for a period of not less than 5 years, which includes availability on the compendium's website for a period of not less than 3 years, coincident with the compendium's publication of the related recommendation.
- ❖ The respondent (i.e. the compendia publisher) is required to make all information

mentioned under section(a)(3) of 42 C.F.R. §414.930, the definition for a publicly transparent process for identifying potential conflicts of interests, timely available in response to a public request for a period of not less than 5 years, coincident with the compendium's publication of the related recommendation.

8. Federal Register/Outside Consultation

The 30-day Emergency Federal Register notice published on November 4, 2009.

The list of requested materials and information to fulfill our conflict of interest and transparency provisions was included in the CY 2010 Physician Fee Schedule so that the public had 90-days to comment on our proposed provisions. The public comments received were from compendia publishers, public interest groups, patient advocacy groups and the private health insurance industry. The materials and information we will be collecting pertaining to an internal or external request for inclusion of a therapy in a compendium includes a listing of the criteria, evidentiary materials, individuals who have substantively participated in the review and disposition of the request, and minutes and voting records of meetings used for the review and disposition of the request. The conflict of interest information requested includes direct or indirect financial relationships between individuals or the spouse or minor child of individuals who substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium. We also requested information pertaining to the ownership or investment interests between individuals or the spouse or minor child of individuals who substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium.

9. Payments/Gifts to Respondents

No payment or gifts will be provided to respondents.

10. Confidentiality

CMS shall be assured that all applicable patient confidentiality, privacy, and other Federal laws are complied with, including the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule). In addition, the disclosure of financial conflicts of interests for individuals or the spouse or minor child of individuals with a substantive role in compendia recommendation decision making will only be timely available in response to a public request.

11. Sensitive Questions

No questions of a sensitive nature are included in this data collection.

12. **Burden Estimates (Hours & Wages)**

| CFR Section   | Information we are requesting   | Respondents (minimum – maximum) | Responses (minimum – maximum)                                     | Burden per Response (hours) | Annual Burden (hours) |
|---------------|---|---------------------------------|---|-----------------------------|-----------------------|
| §414.930      | Internal or external request for listing of therapy recommendation including criteria used to evaluate the response                                 | 10-845                          | 75-100  | 1                           | 75-100                |
| §414.930      | A listing of all evidentiary materials reviewed or considered by compendia pursuant to a response   | 10-845                          | 75-100  | 1                           | 75-100                |
| §414.930      | A listing of all respondents  | 10 -845                         | 75-100  | 1                           | 10-845                |
| §414.930      | Minutes and voting records of meetings for the review and disposition of the response   | 10-845                          | 300-400 (based on 75-100 responses requiring 4 meetings per year) | 6                           | 1800-2400             |
| §414.930      | Direct or indirect financial relationships between respondents and the manufacturer or seller of the drug or biological being reviewed by compendia | 10-845                          | 75-100  | 1                           | 10-845                |
| §414.930      | Ownership or investment relationships between respondents and the manufacturer or seller of the drug or biological being reviewed by compendia      | 10-845                          | 75-100  | 1                           | 10-845                |
| <b>Totals</b> |   | 10-845                          | 75-100  | 11                          | 1980-5135             |

In the table above, *respondents* refer to the number of individuals or the spouse or minor child of individuals who substantially participate in a compendium’s recommendations, and *responses* refer to the number of requests a compendium receives per year for inclusion of a therapy in their publication. Based on our estimate, the burden we derived for all our conflict of interest and transparency provisions above, the total burden would range from 1950 hours per compendium with 75 responses to 2600 hours per compendium with 100 responses. The variation in responses

is due to the varying size of compendia publications and different processes used by compendia publishers to generate a recommendation. In our estimate we also found that the total burden from respondents would range from 30 hours per compendium with 10 respondents to 2535 hours per compendium with 845 respondents. The variation in respondents depends on a compendium's use of internal or external staff to generate compendia recommendations. Therefore, based on these burden totals, the total burden hours per compendium to comply with our conflict of interest and transparency provisions ranges from 1980 hours (a compendium with 75 responses and 10 respondents) to 5135 hours (a compendium with 100 responses and 845 respondents). In order to capture the maximum burden for an individual compendium, we are using the highest total hour estimate, 5135 hours, per compendium to comply with our conflict of interest and transparency provisions. In addition, all these provisions could be managed by a qualified administrative assistant at an hourly rate of \$33.51 per hour based on the average salary of \$69,500 obtained from the Department of Labor.

### 13. Capital Costs

The capital costs associated with the collection of material and information is negligible for compendia publishers because they all have the existing infrastructure, currently maintained company websites, to accommodate these provisions. Any costs for compendia publishers to comply with these provisions would be captured in their general operating costs.

### 14. Cost to Federal Government

No annualized cost to the Federal government will be incurred.

### 15. Changes to Burden

The initial burden was estimated to be \$0 due to the fact that all the compendia publishers already have existing web-based conflict of interest policies in place. However, most of the public comments and OMB regarded our conflict of interest and transparency provisions as additional burden to the compendia publishers. Therefore, we have included the new collection change in burden in Section 12 of this document.

### 16. Publication/Tabulation Dates

There are no publication or tabulation dates.

### 17. Expiration Date

CMS would like an exemption from displaying the expiration date of these collection requirements for compendia publishers as outlined in 42 C.F.R. § 414.930 will be effective on and after January 1, 2010 on a continuous basis as mandated by MIPPA 182(b).