Supporting Statement – Part A

Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen (CMS-10302)

A. Background

This is reinstatement package. In general, compendia are published by various institutions and traditional reference book publishing houses to provide information on drugs, their effectiveness, safety, toxicity, and dosing. Compendia are frequently used to determine whether a medication has a role in the treatment of a particular disease; these roles include both therapeutic uses approved by the U.S. Food and Drug Administration (FDA) and off-label indications. Section 1861(t)(2)(B)(ii)(I) of the Social Security Act establishes a list of certain published compendia as authoritative references for use in determining medically-accepted indications for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen under the fee-for-service Medicare program. This provision also provides the Secretary the authority to revise the list of statutorily recognized compendia.

Consequently, in the CY2008 Physician Fee Schedule (PFS) final rule issued on November 27, 2007, CMS established a definition of a "compendium" and an annual process to revise the statutorily recognized list via 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 the CY 2010 PFS final rule issued on November 25, 2009, we again revised 42 C.F.R. § 414.930 to specify that a compendium must have publicly transparent processes for identifying potential conflicts of interests and for evaluating the off-label use of anti-cancer drug therapies. In addition, we amended the C.F.R. to exclude any entity that does not fully meet the modified regulatory definition of compendium.

This change was approved under the PRA in 2010 and this request does not change the existing information collection. There is no collection instrument.

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 interest." Implementation of this statutory provision was accomplished by amending 42 C.F.R. §414.930 via the CY 2010 PFS 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.

Currently, no other changes to the statute or C.F.R. have occurred since then.

2. Information Users

On and after January 1, 2010, all currently listed compendia are required to comply with these provisions 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. Subscriptions to the various compendia are available to the public and can be used by health care providers to help determine whether an off-label use of an anti-cancer drug therapy could be considered medically acceptable.

3. Use of Information Technology

Each compendium publisher must maintain a standard of transparency by posting their conflict of interest policies and process for evaluating the off-label uses of anti-cancer drugs on their website. One-hundred percent of the currently recognized compendia publishers post their conflict of interest policies and their process for evaluating off-label chemotherapeutic therapies done on or after January 1, 2010 on their website. Since all of the provisions in our revision of §414.930 are currently being practiced by compendia publishers and posted on their website, we expect the burden to maintain compliance 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, CCSQ 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 retain 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 Web site for a period of not less than 3 years.

- ❖ The respondent (i.e. the compendia publisher) is required to retain 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 interest, available to a bona fide member of the public for a period of not less than 5 years.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on June 10, 2026 (91 FR 35215). Two comments addressing this continuation and updated estimates were received. We summarized and responded to these comments in the "response to comments" document associated with this supporting statement. To resolve these comments, we explained that one commenter's suggested burden estimate was consistent with our full burden estimates in this supporting statement. For the other comment, we explained that we disagree that the information collection and burden estimates require significant changes and reevaluation at this time because CMS has not received information to support or justify changes to the estimates and no statutory or regulatory changes have occurred.

The 30-day Federal Register notice published on November 5, 2026 (91 FR 69848).

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 with a substantive role in compendia recommendation decision making and their immediate family members will only be available to bona fide members of the public by 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 of respondents and the manufacturer or seller of the				

	drug or biological being reviewed by compendia	10-845	75-100	1	10-845
Totals		10-845	75-100	11	1980-5135

In the table above, *respondents* refers to the number of those who substantially participate in a compendium's recommendations and their immediate family members, and *responses* refers 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 an executive administrative assistant at an hourly rate of $51.78 per hour or annual salary of $107,710 based on the 90th percentile national wage estimate obtained from the Department of Labor's Bureau of Labor Statistics May 2024 report (https://www.bls.gov/oes/current/oes436011.htm); plus 100% for fringe benefits and overhead to total $103.56 per hour or $215,420 annual salary. Therefore, the cost of the maximum burden for an individual compendium could be $531,780.60 ($103.56 per hour at 5135 hours), per compendium to comply with our conflict of interest and transparency provisions.

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

We estimate that a GS 14 Step 1 federal employee will spend 40 hours annually overseeing this program. The locality adjusted 2026 hourly wage for a CMS employee located in the Central Office in Baltimore at that Grade and Step is $68.96. Thus, the annual cost to the federal government is $2,758 ($68.96 x 40).

15. Changes to Burden

The change in burden estimates is due to updating the estimates from May 2021 wages to May 2024 wages. The cost has increased from $485,258 to $531,781. Otherwise, there are no program changes or adjustments to the collection.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS will display the expiration date on https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/compendia.html.

18. Certification Statement

There are no exceptions to the certification statement.