SUBJECT: Justification for Emergency Clearance for the Paperwork Reduction Act Package for the Revision of 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

The Office of Clinical Standards and Quality (OCSQ) is requesting that the Paperwork Reduction Act (PRA) package for the revision of 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 Physician Fee Schedule be processed under 5 CFR 1320.13(a)(2) for emergency clearance. Approval of this emergency clearance process is essential because 42 C.F.R. §414.930 was revised to comply with new conflict of interest and transparency requirements for compendia issued by Congress in Section 182 (b) of the Medicare Improvements for Patients and Providers Act (MIPPA) that must be implemented on and after January 1, 2010. Although, the new conflict of interest and transparency provisions in 42 C.F.R. § 414.930 are similar to existing processes and policies compendia publishers currently have in place, the use of the emergency clearance process is necessary to guarantee compendia are compliant with theses new provisions on and after January 1, 2010 as mandated by statute.

Project Background

Section 1861(t)(2)(B)(ii)(I) of the Social Security Act lists the compendia as authoritative sources for use in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen under the fee-for service Medicare program. Due to changes in the pharmaceutical reference industry, there was only one statutorily named compendium in current publication in CY 2008. In order to revise the list , we used the authority provided to the Secretary in Section 1861(t)(2)(B) of the Act to establish an annual process to revise the list and establish a definition of “compendium” in §414.930 of the CY 2008 Physician Fee Schedule final rule following a public comment period.

Conflict of interest issues threaten the impartiality of the recommendations made by the compendia; therefore, Congress enacted MIPPA Section 182(b), which amended Section 1861(t)(2)(B) of the Act 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.’ To comply with MIPPA Section 182(b), OCSQ plans to make to following changes to 42 C.F.R. §414.930:

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.”
    - ❖ Any compendia that do not fully meet this revised definition will be removed from the list of statutorily recognized compendia.
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). The following materials 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 internal or external request for inclusion of a therapy recommendation including criteria used to evaluate the request.

- ❖ Listing of all the evidentiary materials reviewed or considered by the compendium pursuant to the request ~~for inclusion of a drug or biologic~~.
- ❖ Listing of all individuals who have substantively participated in the review and disposition of the request.
- ❖ Minutes and voting records of meetings for the review and disposition of the request.

4) The definition of a publicly transparent process for identifying potential conflicts of interest is added as a new section (a)(3). The following information is identified and made timely available in response to a public request ~~to bona fide public requestors~~ for a period of not less than 5 years, coincident with the compendium's publication of the related recommendation.
   - ❖ Direct or indirect financial relationships that exist between individuals or the spouse or minor child of ~~immediate family members of~~ individuals who have 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.
   - ❖ Ownership or investment interests between~~of~~ individuals or the spouse or minor child ~~immediate family members~~ of individuals who have substantively participated in the development of compendia recommendations and ~~the applicant(e.g.~~ the manufacturer or seller of the drug or biological being reviewed by the compendium~~)~~.

In our effort to improve conflict of interests and transparency in compendia under the authority of MIPPA 182 (b), the provisions we have outlined would ensure that the public has access to compendia deliberations regarding off-label anticancer recommendations. Below, we have included a timeline containing key dates for the PRA emergency process. We would be unable to meet the January 1, 2010 mandatory implementation of MIPPA 182(b) using the regular PRA process.

Our requested and proposed timeline

Date	Activity
10/16/09	Submit emergency justification to OMB
10/19/09	Receive approval to submit emergency package to OMB
CY 2010 Physician Fee Schedule – November 2009	Publication of Emergency Federal Register Document
10/20/09	Beginning of 30 day public comment period and concurrent OMB review of package
11/18/09	End of public comment period
11/24/09	Requested date of OMB approval

We request your support in approving our access forms under the emergency PRA procedures so we can meet the statutory deadline for implementation of the revision of 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. If you have any questions, please feel free to contact:

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