



## Revision of Definition of Compendia as Authoritative Source for Use in the Determination of a Medically-Accepted Indication of Drugs/Biologicals Used Off-label in Anti-Cancer Chemotherapeutic Regimens – JA6806

**Note:** MLN Matters® article MM6806 was revised to include Web links for additional information, which have been added in the Reference Materials section below. An additional link to other authoritative compendia was also added on page 2 below.

Related CR Release Date: January 29, 2010 **Revised**

Date Job Aid Revised: February 26, 2010

Effective Date: January 1, 2010

Implementation Date: March 1, 2010

**Key Words** MM6806, CR6806, R120BP, Compendia, Anti-Cancer, Chemotherapeutic, Regimens

**Contractors Affected**

- Medicare Carriers
- Part A/B Medicare Administrative Contractors (A/B MACs)
- Fiscal Intermediaries (FIs),
- DME MACs (DME MACs)
- Regional Home Health Intermediaries (RHHIs)

**Provider Types Affected**

Physicians, other providers, and suppliers submitting claims to Medicare Carriers, FIs, Part A/B MACs, or DME MACs for services provided to Medicare beneficiaries



- Change Request (CR) 6806 announces that effective January 1, 2010, the Centers for Medicare & Medicaid Services (CMS) is revising the definition of “compendium” in the *Medicare Benefit Policy Manual*, Chapter 15, (Covered Medical and Other Health Services), Section 50.4.5 (Process for Amending the List of Compendia for Determinations of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).
- This revision requires a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.

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### Revised Definition of Compendium

#### Provider Needs to Know...

- Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases;
  - Is indexed by drug or biological; and
  - Has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.
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#### Background

- A compendium is defined “as a comprehensive listing of the Food and Drug Administration-approved drugs and biologicals (or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium - for example, a compendium of anti-cancer treatment).”
  - Section 1861(t)(2)(B)(ii)(I) of the Social Security Act (the Act), as amended by Section 6001(f)(1) of the Deficit Reduction Act of 2005, Pub. Law 109-171, recognized three compendia:
    - 1) American Medical Association Drug Evaluations;
    - 2) United States Pharmacopoeia-Drug Information or its successor publication; and
    - 3) American Hospital Formulary Service-Drug Information (AHFS-DI).
  - To date, AHFS-DI, plus other authoritative compendia ([http://www.cms.hhs.gov/CoverageGenInfo/02\\_compendia.asp#TopOfPage](http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp#TopOfPage)) that the Secretary of Health and Human Services identifies, serve as sources for providers to use in determining the “medically-accepted indication” of drugs and biologicals that are used off-label in an anti-cancer chemotherapeutic regimen (**unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia**).
  - In the Medicare Physician Fee Schedule final rule for calendar year 2008, CMS established a process for revising the list of compendia. CMS also increased the transparency of the process by incorporating a list of desirable compendium characteristics outlined by the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on March 30, 2006, as criteria for decision-making.
  - Although the MEDCAC desirable characteristics for compendia included reference to conflict of interest and transparency, Section 182(b) of the Medicare Improvements for Patients and Providers Act amended Section 1861(t)(2)(B) of the Act by adding 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.”
  - CMS is revising the definition of “compendium” in the *Medicare Benefit Policy Manual*, Chapter 15, Section 50.4.5, to include this public transparency requirement.
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Operational Impact	N/A
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Reference Materials	
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The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6806.pdf> on the CMS website.

The official instruction (CR6806) regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R120BP.pdf> on the CMS website. The revised compendium definition in the updated *Medicare Benefit Policy Manual* is an attachment to that CR.

For more detailed information about the revised definition of "compendium" and the incorporation of the Medicare Improvements for Patients and Providers Act Section 182 (b) into the compendia review process for current and future statutorily recognized compendia based on this provision, providers may review Issues Related to MIPPA Number 13. Section 182(b) (*Revision of Definition of Medically-Accepted Indication for Drugs; Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen*), which was released in the November 25, 2009, Federal Register at <http://www.gpo.gov/fdsys/pkg/FR-2009-11-25/pdf/E9-26502.pdf> on the Internet.

Providers may also want to review MLN Matters® article MM6191 (*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*), which was released on October 24, 2008, and may be viewed at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6191.pdf> on the CMS website.

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