



News Flash – The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) encourage public comment on two regulations issued on 12/30/2009 that lay a foundation for improving quality, efficiency and safety through meaningful use of certified electronic health record (EHR) technology. CMS and ONC worked closely to develop the two rules and received input from hundreds of technical subject matters experts, health care providers, and other key stakeholders. The CMS proposed rule and related fact sheets may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Legislation/Recovery/index.html> on the CMS website. The ONC's interim final rule may be viewed at <http://healthit.hhs.gov/standardsandcertification> on the Internet.

MLN Matters® Number: MM6806 **Revised**

Related Change Request (CR) #: 6806

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Effective Date: January 1, 2010

Related CR Transmittal #: R120BP

Implementation Date: March 1, 2010

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

Note: This article was updated on November 23, 2012, to reflect current Web addresses. This article was previously revised on February 17, 2010, to include Web links to additional information regarding this issue. All other information remains unchanged.

Provider Types Affected

This article is for physicians, other providers, and suppliers submitting claims to Medicare contractors (carriers, Fiscal Intermediaries (FI), Part A/B Medicare Administrative Contractors (A/B MAC), or DME Medicare Administrative Contractors (DME MAC)) for services provided to Medicare beneficiaries.

What You Need to Know

CR 6806, from which this article is taken, 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

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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. Please see the Background section, below, for details.

Background

A compendium is defined “as a comprehensive listing of FDA-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, recognizes three compendia: 1) American Medical Association Drug Evaluations (AMA-DE); 2) United States Pharmacopoeia-Drug Information (USP-DI) or its successor publication, and 3) American Hospital Formulary Service-Drug Information (AHFS-DI). To date, AHFS-DI, plus other authoritative compendia (found at <http://www.cms.gov/Medicare/Coverage/CoverageGenInfo/index.html>) that the Secretary of Health and Human Services identifies, serve as sources for you 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, and 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 (MIPPA) 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.”

CR 6806, from which this article is taken, announces that effective January 1, 2010, 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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In this revised definition, a compendium:

1. 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;
2. Is indexed by drug or biological; and
3. *Has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.*

Additional Information

You can find more information about the revised definition of “compendium” by going to CR 6806, located at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R120BP.pdf> on the CMS website.

For more detailed information about the revised definition of “compendium” and the incorporation of MIPPA section 182 (b) into the compendia review process for current and future statutorily recognized compendia based on this provision, see 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 released in the November 25, 2009 Federal Register, which you can find at <http://www.gpo.gov/fdsys/pkg/FR-2009-11-25/pdf/E9-26502.pdf> on the Internet.

You will find this revised compendium definition in the updated *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) as an attachment to that CR.

You might also want to read the MLN Matters® article titled 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, released on October 24, 2008, which you can find at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6191.pdf> on the CMS website.

If you have any questions, please contact your carrier at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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