

File and Use Certification --Process

Effective June 7, 2005, as part of the CMS streamlined marketing review process, both Medicare Advantage (MA) and the Medicare Prescription Drug Benefit Program (Part D) require File and Use Certification for CY 2006 marketing materials, unless the organization requests a waiver. Attachment 2 crosswalks the organization through the various review options and the Attachment 3 indicates which materials are available for File & Use Certification and list the various marketing materials by review categories.

Qualification for the 2006 Marketing Materials File and Use Certification Process

The signed File and Use Certification form must be submitted to the CMS via HPMS by July 1, 2005 and prior to submitting eligible materials. The Certification form must be signed by the organization's CEO or CFO and will remain in effect until further notice from CMS. CMS will provide a model attestation/certification form in Chapter 3.

MA organizations requesting a waiver must submit the request to Regional Office by July 1, 2005. The waiver request must include the H#, reason for the waiver, and contact information.

File and Use Certification Policies and Procedures

Each organization must provide CMS with a File and Use Certificate prior to submitting materials under the File and Use Certification process.

The File and Use Certificate certifies that the organization is ensuring the accuracy and veracity of its marketing materials and that the materials are not misleading and adhere to CMS' marketing guidelines - Chapter 3 of the Medicare Managed Care Manual. Under the File and Use certification process the organization must submit marketing material to CMS at least 5 calendar days prior to their use.

Marketing materials may be used after 5 calendar days but not before any date CMS may have established for the use of any particular material(s). For example, MA organizations may began to market October 1, 2006, however if an organization submits materials in August, they cannot use them after 5 days but must instead wait until October 1.

- **Eligible Material:** Materials that are eligible for the File and Use Certification process consist of: (1) all advertisement materials, (2) provider/pharmacy directories, and (3) certain CMS model letters without modifications (e.g., enrollment/disenrollment, claims, organization determinations, appeals, grievances model letters). See Attachment 3.
- **Non-Eligible Material:** Materials that are not eligible for File and Use Certification are those that CMS considers as being a possible risk to a Medicare beneficiary if found to be inaccurate in any way. These documents are Summary of Benefits, Evidence of

Coverage, Member Handbook, Annual Notice of Change, Mid-Year Benefit Enhancement Notices, Enrollment and Disenrollment forms.

Note: A complete list of eligible materials is provided in Chapter 3 of the Marketing Manual and in Attachment 3.

Retrospective Review

All materials submitted through the File and Use Certification process will be subject to a retrospective review. The Regional Office will conduct semi-annual reviews of a random sample of the marketing materials that each organization has submitted. CMS will investigate all marketing complaints. CMS may require an organization to issue an addendum or re-issue marketing materials at no expense to the Government if the material does not conform to CMS' marketing requirements.

Failure to comply with marketing policies may result in a corrective action to protect Medicare beneficiaries.

Loss of File and Use Certification Privileges

An organization may lose File and Use Certification privileges if it uses materials that do not meet the requirements of Chapter 3 of the Medicare Managed Care Manual. The RO will notify the organization in writing that its File and Use Certification privilege is being revoked.