

Final 2007 Formulary Guidance Changes from Draft Guidance

CMS appreciates all of the public comments received in response to the draft 2007 formulary guidelines. In order to balance different viewpoints from various stakeholders and allow drug benefit strategies that are already providing effective coverage to millions of seniors and people with a disability to the Medicare population, we have made the following modifications to the draft 2007 formulary guidance.

Drug List Review

- **CMS has included clarification of which Formulary Key Drug Types are exempt from the drug list review check.** Appendix B includes a table of Formulary Key Drug Types that are exempt from the drug list review check since these Key Drug Types are primarily covered under Part B.

Specialty Tiers

- **CMS has clarified that a specialty tier is not required on all formularies.** Formularies may choose to utilize a specialty tier within their formulary and benefit design, however, this is not a requirement.

Six Classes of Clinical Concern

- **CMS added a requirement for expedited P&T review for new drugs or newly approved uses for drugs within the six classes of clinical concern.** P&T committees are required to review new drugs or newly approved uses for drugs within the six classes that come onto the market after April 17, 2006 using an expedited review process. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement.

Formulary Submission Requirements

- **CMS added detail regarding the update of formularies prior to the beginning of 2007 marketing.** The open period for these changes will occur from August 1-7, 2006. This will be the only opportunity to update formulary files prior to the beginning of the 2007 contract year.