10.9 - DESI Drugs

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

For a drug to be available for reimbursement by a Part D sponsor it must meet the definition of a Part D drug. Section 1860D–2(e)(1) of the Social Security Act (the Act) generally defines a Part D drug to include those drugs that may be dispensed only upon a prescription and that meet the requirements of section 1927(k)(2) of the Act. Section 1927(k)(2) generally requires that the drug be approved by the FDA or otherwise described under sections 1927(k)(2)(A)(ii) or (A)(iii) of the Act. These provisions address those drugs affected by the Drug Amendments of 1962 (amending the Federal Food, Drug & Cosmetic Act), which require that a new drug be proven effective, as well as safe. FDA's Drug Efficacy Study Implementation (DESI) evaluates the effectiveness of those drugs that had been previously approved on safety grounds alone. FDA indicates that these drugs, and those identical, related, and similar to them, may continue to be marketed until the administrative proceedings evaluating their effectiveness have been concluded, at which point continued marketing is permitted only if a new drug application (NDA) or abbreviated new drug application (ANDA) is approved. The vast majority of the DESI proceedings have been concluded, but a few are still pending.

The definition of a Part D drug does not include less than effective (LTE) DESI drugs or those identical, related or similar drugs to the LTE DESI drug. As FDA continues to undertake reviews under the DESI program and announces results of its hearings, CMS would expect Part D sponsors to adjust their formularies accordingly, as they should with any other applicable FDA drug product announcement. If a sponsor discovers the presence of any LTE DESIs on its

formulary based on an FDA announcement or otherwise, it should remove these drugs from the formularies on accordance with section 30.3.[1]