

10.7 - *Drugs* Purchased in Another Country

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors must exclude Part D drugs from qualified prescription drug coverage if they are not sold in the United States. In addition, Part D sponsors may only pay for drugs that satisfy the definition of Part D drug. In general, such definition requires FDA approval for sale in the United States. Therefore, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved.

In the event of a drug shortage, in order to ensure access to critically needed drugs in conjunction with the actions taken by the FDA, CMS will accept PDE submissions with national drug codes for foreign versions of Part D drugs, imported under the FDA's exercise of its enforcement discretion. PDE allowances will be limited to the specific drug product(s), conditions, and the duration of the shortage as specified by the FDA. Such products cannot be discounted under the Medicare Coverage Gap Discount Program.

