10.1 - General

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

Subject to the exclusions specified in section 20 of this chapter, a Part D drug means *the following*, *if* used for a medically-accepted indication as defined by section 1927(k)(6) of the Act:

- A drug *that may be dispensed only upon a prescription* that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;
- A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;
- Insulin described in section 1927(k)(2)(C) of the Act;
- Medical supplies associated with the delivery of insulin;
- A vaccine licensed under section 351 of the Public Health Service Act and its administration.

*The Centers for Medicare & Medicaid Services (*CMS*)* considers it best practice for Part D sponsors to consider the proper listing of a drug product with the *Food and Drug Administration (*FDA*)* as a prerequisite for making a Part D drug coverage determination. The FDA is unable to provide regulatory status determinations through their regular processes if a drug product is not properly listed. Therefore, Part D sponsors should begin the drug coverage determination process by confirming that a prescription drug product national drug code (NDC) is properly listed with the FDA. *The FDA's Comprehensive NDC Structured Product Labeling Data Elements file (NSDE) is used as a source of NDC information for Medicare Part D Formulary Reference File and prescription drug event (PDE) editing. The NSDE file can be found at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm*

CMS interprets "dispensed only upon a prescription" as meaning a drug that is recognized by the *FDA* as a prescribed drug requiring "Rx only" on its label per section 503(b)(4) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Additionally, Part D sponsors must recognize a physician's authority to delegate prescribing where authorized by State law. Generally, in retail pharmacy, standing orders and protocols are methods used by physicians to delegate and define their prescribing authority to non-physician providers such as pharmacists. Standing orders are typically pre-approved documents for a specific drug or vaccine, contain a set of required clinical criteria and permit administration of

the drug without physician examination, as long as the required clinical criteria are met. A protocol is similar to a standing order but is generally broader in scope and may include multiple drugs and extensive clinical criteria. *A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription, as required by §423.104(h).*