20.1 – General Rule

(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Each Part D plan sponsor must establish quality assurance (QA) measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The Part D sponsor's comprehensive quality assurances system will ensure enrollees receive access to high quality prescription drug coverage. As a result, the Part D sponsor's QA measures and systems minimally include:

1. Representation that the Part D sponsor requires network providers to comply with minimum standards for pharmacy practice as established by the States.

2. Concurrent drug utilization review (DUR) systems, policies and procedures.

3. Retrospective DUR systems, policies and procedures.

4. Internal medication error identification and reduction systems.

5. Provision of information to CMS regarding the plan sponsor's QA measures and systems, according to CMS-specified guidelines.

Furthermore, Part D sponsors must establish and maintain an electronic prescription drug program that is consistent with uniform e-prescribing standards that are adopted under 1860D-4(e)(3) of the Act (see section 50 of this manual chapter for a description of the current e-prescribing standards). Prescribers, dispensers and plans must utilize the final e-prescribing standards when transmitting prescription and prescription-related information using electronic media for Part D covered drugs for Part D eligible individuals. While e-prescribing is voluntary for physicians (and other prescribers) and pharmacies (and other dispensers), if these persons or entities e-prescribe covered Part D drugs for Part D eligible individuals, they must comply with the adopted standards.

E-prescribing (addressed in section 50 of this chapter), although not required as an element of the sponsor's quality assurance system, has demonstrated value in preventing medication errors by permitting each prescription to be checked electronically for dosage, interactions with other medications, and therapeutic duplication at the point-of-care, thereby improving overall medication use. Therefore, CMS recommends Part D sponsors incorporate their electronic prescription drug program within their quality assurance system.