50.1 – General Rule

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

Section 101 of the MMA added section 1860D-4(e) to the Act to require that prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically be transmitted in accordance with designated uniform standards. 42 CFR 423.160(a) requires Part D sponsors to establish and maintain an electronic prescription drug program that complies with those designated uniform standards when transmitting prescriptions and prescription-related information using electronic media.

To satisfy these requirements, CMS expects Part D sponsors to have all the necessary contracts and systems in place should prescribers desire to electronically transmit prescriptions for their Medicare eligible patients. This includes ensuring that network pharmacies can receive

electronic prescriptions (with allowance for exceptions when it is impractical or otherwise could jeopardize beneficiary access) in accordance with the adopted standards.

In order to monitor the uptake of electronic prescribing in the Part D program, CMS needs to collect prescription level data that demonstrates the frequency of electronic prescribing. CMS believes the most effective method for gathering this data is use of the Prescription Origin Code via the NCPDP 5.1 optional field 419 DJ. CMS expects to add a new optional field to the Prescription Drug Event (PDE) record that will capture the Prescription Origin Code, and CMS strongly recommends that Part D sponsors work with their network pharmacies to voluntarily begin using the 419 DJ field.

Part D plans will also be responsible for complying with future e-prescribing standards that are adopted as part of the industry standard or regulatory process. The final e-prescribing standards that have been adopted thus far establish a framework from which a robust, interoperable e-prescribing environment can develop and grow. CMS expects significant activity in this area given the rapid development of e-prescribing and its ability to improve quality of care for Part D eligible Medicare beneficiaries. Part D sponsors should familiarize themselves with the CMS e-prescribing Web site (see Appendix A) and remain current with all the e-prescribing requirements, standards and exemptions.

Except to the extent that the Drug Enforcement Agency (DEA) states otherwise, these e-prescribing rules do not apply to controlled drugs, even though such drugs may satisfy the definition of a Part D drug. Controlled drug substances remain under the jurisdiction of the DEA under the Controlled Substances Act. HHS and the DEA are working together to address the intersection of these regulations to ensure reliable standards are implemented across all prescribing environments.