

50.4 – Exemptions

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

The November 7, 2005, foundation standards final rule (70 FR 67568) implemented specific exemptions for certain entities potentially involved in e-prescribing. These exemptions continue to change as improvements are realized in the e-prescribing environment. Part D sponsors should remain aware of these exemptions and work with their network pharmacies as necessary.

1. Entities may use either Health Level 7 (HL7) messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard.

This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization. For further information on the HIPAA transaction standards, refer to 45 CFR 162, or the NCPDP or ASC Web sites at www.ncdp.org or www.x12.org respectively.

2. Entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that, in turn, forwards the prescription to a dispenser, are exempt from the requirements to use the NCPDP SCRIPT Standard in transmitting such prescriptions or prescription-related information.
3. Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard in transmitting such prescriptions or prescription-related information.
4. In accordance with section 1860D-4(e)(5) of the Act, the standards specified in 42 CFR 423.160(b) supersede any State law or regulation that—
 - Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

- Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.