
The Department of Health and Human Services (HHS) is issuing this information bulletin to inform our stakeholders of the January 24, 2020, Federal Register publication of the final rule CMS-0055-F. This final rule makes a regulatory change under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), modifying the requirements for use of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version D, Release 0, August 2007, by requiring the use of the Quantity Prescribed (460-ET) field to identify partial fills for Schedule II drugs.

Background

HIPAA requires the Secretary of HHS to adopt standards for electronic health care administrative transactions conducted between health care providers that conduct electronic transactions, health plans, and health care clearinghouses.

Section 1174 of the Social Security Act authorizes the Secretary of HHS to adopt modifications to adopted standards through the use of the rule making process that is required in order to conduct this action. The August 2000 “Health Insurance Reform: Standards for Electronic Transactions” final rule (65 FR 50312, 50322), defined the term “modification” as a change that is substantial enough to justify publication of a new implementation specification for a published version of the standard, and mandated that the Secretary of HHS must make such changes through regulation.

The Comprehensive Addiction and Recovery Act (CARA) of 2016 expanded the circumstances in which a pharmacist may dispense less than the full prescribed amount of Schedule II drugs. A technical issue with version D.0 necessitated a modification of the requirements for the use of that standard to accurately reflect this provision of CARA. In January 2019 (84 FR 633), the Secretary published a proposed rule titled “Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard”. This Final rule adopts this change as proposed.

What this Final Rule Will Do
This modification enables covered entities to clearly distinguish in a HIPAA retail pharmacy transaction if a prescription is a “partial fill” where less than the full amount prescribed is dispensed under the CARA provision. This is a modification to ensure information is available to help prevent impermissible refills of Schedule II drugs and to yield better data for researchers to enhance understanding of prescribing trends. We believe this modification will assist with addressing the public health concerns associated with prescription drug abuse in the United States.

If you have questions about this Information Bulletin, or other topics related to the adopted standards or operating rules, please send them to administrativesimplification@cms.hhs.gov.

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