

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850



## **CENTER FOR BENEFICIARY CHOICES**

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**TO:** Medicare Part D Sponsors

**FROM:** Cynthia G. Tudor, Ph.D.  
Acting Director, Medicare Drug Benefit Group

**DATE:** June 23, 2006

**RE:** Compliance with HIPAA Administrative Simplification Provisions

Recently, a number of pharmacies have notified CMS that several pharmacy benefit managers (PBMs) that have contracted with Part D sponsors (both stand-alone Prescription Drug Plan Sponsors and Medicare Advantage Organizations offering Part D (MA-PDs)) are not complying with the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In particular, these PBMs are not issuing payment and remittance notices consistent with the HIPAA-adopted ACS X12N 835, Version 4010/4010A1: Health Care Claim Payment and Remittance Advice Implementation Guide (“835”).

HIPAA requires the Department of Health and Human Services (HHS) to adopt standards for electronic transactions and implementation specifications for those transactions, and standard codes to be used in the transactions. In implementing the statute, HHS adopted the ASC X12N 835 standard for health care payment and remittance advice. All covered entities under HIPAA are required to use the 835 standards for their electronic payment/ remittance advice transactions.

Part D Sponsors that are “covered entities” under HIPAA are required to comply with all the applicable requirements of that statute. Also, the Part D regulations at 42 CFR § 423.505(h)(2) specifically require Part D Sponsors to comply with the HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164. Your organization is accountable for your PBM’s compliance with these rules consistent with the regulations at 42 CFR § 423.505(i).

CMS advises Part D Sponsors to ensure that your organization and/or your PBM contractors are processing electronic remittances to pharmacies consistent with the 835 standard. Part D Sponsors that do not employ the 835 standard in their processing of pharmacy remittances risk CMS sanction based on their non-compliance with their Part D contract. Also, your organization and/or your PBM may be subject to investigation and enforcement action by the CMS’ Office of E-Health Standards and Services should a pharmacy make a formal HIPAA complaint related to the 835 standards or other HIPAA-related matters.

Please contact your Part D Account Manager with any questions. Thank you.