

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-20 One-Time Notification</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 998</b>	<b>Date: November 10, 2011</b>
	<b>Change Request 7583</b>

**SUBJECT: HIPAA 5010 Outbound File Compliance Check**

**I. SUMMARY OF CHANGES:** Contractors shall perform an analysis and confirm they are compliance checking basic syntactical integrity and specific syntax requirements on all outbound files.

**EFFECTIVE DATE: January 1, 2012 - Analysis and Design; April 1, 2012 - Implementation**

**IMPLEMENTATION DATE: January 3, 2012 - Analysis and Design; April 2, 2012 - Implementation**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**One-Time Notification**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment – One-Time Notification

Pub. 100-20	Transmittal: 998	Date: November 10, 2011	Change Request: 7583
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**SUBJECT: HIPAA 5010 Outbound File Compliance Check**

**Effective Date: January 1, 2012 - Analysis and Design; April 1, 2012 - Implementation**

**Implementation Date: January 3, 2012 - Analysis and Design; April 2, 2012 - Implementation**

## I. GENERAL INFORMATION

**A. Background:** The Centers for Medicare and Medicaid Services (CMS) is in the process of implementing the next version of the Health Insurance Portability and Accountability Act (HIPAA) transactions. The Secretary of the Department of Health and Human Services (DHHS) has adopted Accredited Standards Committee (ASC) X12 Version 5010 and the National Council for Prescription Drug Programs (NCPDP) Version D.0 as the next HIPAA transaction standards for covered entities to exchange HIPAA transactions. The final rule was published on January 16, 2009. Some of the important dates in the implementation process are:

Effective Date of the regulation: March 17, 2009

Level I compliance by: December 31, 2010

Level II Compliance by: December 31, 2011

All covered entities have to be fully compliant on: January 1, 2012

Level I compliance means “that a covered entity can demonstrate that it could create and receive compliant transactions, resulting from the compliance of all design/build activities and internal testing.”

Level II compliance means “that a covered entity has completed end-to-end testing with each of its trading partners, and is able to operate in production mode with the new versions of the standards.”

DHHS has promulgated in the Final Rules provisions which permit dual use of existing standards (ASC X12 4010A1 and NCPDP 5.1) and the new standards (5010 and D.0) from the March 17, 2009, effective date until the January 1, 2012, compliance date to facilitate testing subject to trading partner agreement.

The purpose of this change request is to instruct the A/B Medicare Administrative Contractors (MACs) to perform compliance checks on all HIPAA 5010 outbound files.

MAC estimates for this CR should include a breakdown as part of the Level of Effort (LOE) response, utilizing the following table to be included in the “Estimate-Specific Comments” portion of the LOE template, to follow the Investment Lifecycle Phases.

Investment Lifecycle Phase	Total Hours	Total Cost
*Pre-Implementation/CR Review*		
Design & Engineering Phase		
Development Phase		
Testing Phase		
Implementation Phase		

\*Note that the Pre-Implementation/CR Review costs will not be funded under the unique funding situation for the 5010/D.0 project, but instead out of the MAC’s pot of hours for Pre-Implementation/CR Review.\*



Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D / M	F / I	C / R	R / H	Shared-System Maintainers				OTHER
		M / A / C	M / A / C		R / I / E / R	I	F / I / S / S	M / C / S	V / M / S	C / W / F	
	above.										
7583.4	Contractors shall perform an analysis to confirm they are compliance checking for valid Implementation Guide specific code set values and other code sets adopted as HIPAA standards for all outbound files listed above.	X									CEDI
7583.4.1	Contractors shall make necessary changes to its COTS translators to ensure they are compliance checking for valid Implementation Guide specific code set values and other code sets adopted as HIPAA standards for all outbound files listed above.	X									CEDI
7583.5	Contractors shall perform an analysis of the Outbound File Compliance Check implementation and deliver it to the Pre-Implementation Contact by January 1, 2012.	X									CEDI

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D / M	F / I	C / R	R / H	Shared-System Maintainers				OTHER
		M / A / C	M / A / C		R / I / E / R	I	F / I / S / S	M / C / S	V / M / S	C / W / F	
	None										

### IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A**

X-Ref Requirement Number	Recommendations or other supporting information:
	None

**Section B: For all other recommendations and supporting information, use this space: N/A**

## V. CONTACTS

**Pre-Implementation Contact(s):** Angie Bartlett (410) 786-2865, [Angie.Bartlett@cms.hhs.gov](mailto:Angie.Bartlett@cms.hhs.gov)  
Jason Jackson (410) 786-6156, [Jason.Jackson3@cms.hhs.gov](mailto:Jason.Jackson3@cms.hhs.gov)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

## VI. FUNDING

**Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.