CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 331	Date: APRIL 11, 2008
	Change Request 5987

SUBJECT: Clinical Laboratory Fee Schedule - Implementation of Section 113 of the Medicare, Medicaid and State Children's Health Insurance Program (MMSCHIP) Extension Act of 2007

I. SUMMARY OF CHANGES: This One-Time Notification provides specific instructions concerning the implementation of Section 113 of the MMSCHIP legislation for clinical diagnostic laboratories.

New / Revised Material
Effective Date: April 1, 2008
Implementation Date: May 12, 2008

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.*

R/N/D	Chapter / Section / Subsection / Title
N/A	N/A

III. FUNDING:
SECTION A: For Fiscal Intermediaries and 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):
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

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SUBJECT: Clinical Laboratory Fee Schedule - Implementation of Section 113 of the Medicare, Medicaid and State Children's Health Insurance Program (MMSCHIP) Extension Act of 2007

Effective Date: April 1, 2008

Implementation Date: May 12, 2008

I.   GENERAL INFORMATION

Background: This One-Time Notification provides instructions for implementing Section 113 of the Medicare, Medicaid and State Children's Health Insurance Program (MMSCHIP) Extension Act of 2007.

For Calendar Year (CY) 2006, the Current Procedural Terminology (CPT) established the new code 83037 ("Hemoglobin; glycosylated (A1c)" by device cleared by the Food and Drug Administration (FDA) for home use"). The CPT code 83036 ("Hemoglobin; glycosylated (A1c)") already existed on the clinical laboratory fee schedule.

For calendar year 2006, CMS determined that code 83037 should be paid via carrier gapfilling. For calendar year 2007 and future years, CMS set payment for code 83037 by crosswalking it to a similar test code, 82985 ("Glycated protein").

Policy: The MMSCHIP Extension Act of 2007, which passed in December 2007, included Section 113. Section 113 of the legislation set the price for any diagnostic test for HbA1C that is labeled by the FDA for home use equal to the payment rate for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)). The new law is effective for tests furnished on or after April 1, 2008.

II.   BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	D M E MAC	F I	C A R R I E R	R H H I	FISS	MCS	VMS	CWF	OTHER
5987.1	Effective for dates of service on or after April 1, 2008, claims for codes 83037 and 83037QW are priced by crosswalking to code 83036.	X		X	X						

Number	Requirement	A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5987.2	Carriers shall retrieve the updated 2008 Clinical Laboratory Fee Schedule file (filename: MU00.@BF12394.CLAB.CY08.V0205B) from the CMS mainframe on or after March 10, 2008. Carriers shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., carrier name and number). Please note that the new MAC configuration, effective April 1, 2008, is reflected in this file.	X			X						
5987.3	Intermediaries shall retrieve the updated 2008 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY08.V0205B.FI) from the CMS mainframe on or after March 10, 2008. Intermediaries shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., intermediary name and number). Please note that the new MAC configuration, effective April 1, 2008, is reflected in this file.	X		X							
5987.4	For claims with dates of service on or after April 1, 2008, contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X		X	X						

III.   PROVIDER EDUCATION TABLE

Number	Requirement	A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5987.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	D M E MAC	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV.   SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	N/A

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk at glenn.mcguirk@cms.hhs.gov

Post-Implementation Contact(s): Glenn McGuirk at glenn.mcguirk@cms.hhs.gov

VI. FUNDING

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

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)*:

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.