CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 346	Date: June 25, 2010
	Change Request 7021

SUBJECT: Guidance on Implementing Section 3109 (a) of the Patient Protection and Affordable Care Act (PPACA)

I. SUMMARY OF CHANGES: Section 3109 (a) of the PPACA amends subparagraph (F)(i), of section 154(b)(1)(A), of the Medicare Improvements for Patients and Providers Act of 2008, by not requiring a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011.

EFFECTIVE DATE: January 1, 2011
IMPLEMENTATION DATE: January 3, 2011

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/Table of Contents
N	15/38.6.1/Compliance Standards for Pharmacy Accreditation

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
Not Applicable.

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:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 346	Date: June 25, 2010	Change Request: 7021

SUBJECT: Guidance on Implementing Section 3109 of the Patient Protection and Affordable Care Act (PPACA)

EFFECTIVE DATE: JANUARY 1, 2011
IMPLEMENTATION DATE: JANUARY 3, 2011

I. GENERAL INFORMATION

A. Background: Section 302 of the Medicare Modernization Act of 2003 (MMA) added a new paragraph 1834(a)(20) to the Social Security Act (the Act). This paragraph required the Secretary to establish and implement quality standards for suppliers of DMEPOS. All DMEPOS suppliers that furnish such items or services set out at subparagraph 1834(a)(20)(D) as the Secretary determines appropriate must comply with the quality standards in order to receive Medicare Part B payments and to retain Medicare billing privileges. Pursuant to subparagraph 1834(a)(20)(D) of the Act, the covered items and services are defined in section 1834(a)(13), section 1834(h)(4) and section 1842(s)(2) of the Act. The covered items include:

- DME;
- Medical supplies;
- Home dialysis supplies and equipment;
- Therapeutic shoes;
- Parenteral and enteral nutrient, equipment and supplies;
- Transfusion medicine; and
- Prosthetic devices, prosthetics, and orthotics.

Section 154(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added a new subparagraph (F) to section 1834(a)(20) of the Act. In implementing quality standards under this paragraph the Secretary shall require suppliers furnishing items and service on or after October 1, 2009 directly or as a subcontractor for another entity, to have submitted evidence of accreditation by an accreditation organization designated by the Secretary. This subparagraph states that eligible professionals and other persons (defined below) are exempt from meeting the September 30, 2009, accreditation deadline unless CMS determines that the quality standards are specifically designed to apply to such professionals and persons. Section 1834(a)(20)(F)(i) was further amended by Public Law 111-72, which delayed the date to January 1, 2010, on which the accreditation requirement applied to pharmacies.

Section 3109 (a) of the Patient Protection and Affordable Care Act (PPACA) amends subparagraph (F)(i) of section 154(b)(1)(A) of the Medicare Improvements for Patients and Providers Act of 2008 by not requiring a pharmacy to submit to the Secretary such evidence of accreditation prior to January 1, 2011. Also, with respect to items and services furnished on or after January 1, 2011, section 3109 (a) provides that the quality standards and accreditation requirements set forth in section 1834(a)(20)(F) shall not apply to such pharmacies if the pharmacy meets ***each*** of the following: the total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales for the previous 3 calendar years, 3 fiscal years or other yearly period specified by the Secretary; the pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics and supplies, has been issued a provider number for at least 5 years ; no final adverse action (as defined in section 424.579a) of title 42, Code of Federal Regulations) has been imposed in the past 5 years; the pharmacy submits an attestation that the pharmacy meet the first three

criteria listed above and; the pharmacy agrees to submit materials as requested during the course of an audit conducted on a random sample of pharmacies selected annually.

B. Policy: Section 3109 (a) of the PPACA.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7021.1	The National Supplier Clearinghouse (NSC) shall not require that a pharmacy submit proof of accreditation as a condition of enrollment before January 1, 2011.										NSC-MAC
7021.2	The NSC-MAC shall determine which enrolled suppliers are pharmacies that are not accredited.										NSC-MAC
7021.3	The NSC-MAC shall make a list of enrolled pharmacies which are not accredited, who will be enrolled for 5 calendar years prior to January first of the next calendar year.										NSC-MAC
7021.3.1	The NSC-MAC shall prepare the list by September 30, 2010, and base it upon individually enrolled practice locations. New locations of enrolled chain pharmacies shall not be considered to have been enrolled for 5 calendar years.										NSC-MAC
7021.4	The NSC-MAC shall prepare a letter which enables all individually enrolled practice locations of pharmacies, who have been enrolled for 5 calendar years prior to January 1, 2011, to attest that they are exempt from the requirement to be accredited because their total DMEPOS billings subject to accreditation are less than 5 percent of their total pharmacy sales as determined based upon the total pharmacy sales of the pharmacy for the previous 3 calendar or fiscal years.										NSC-MAC
7021.4.1	The NSC-MAC shall cite in the letter that the attestation requires the signature of the authorized or delegated official of the entity. The authorized and delegated officials are defined in Section 15 of the Medicare Enrollment Application (CMS-855S) and as described in the internet enrollment application version										NSC-MAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	of the Provider Enrollment, Chain and Ownership System (PECOS).										
7021.5	The NSC-MAC shall obtain NSC project officer approval of the letter shown in Business Requirement (BR) 7021.4.										NSC-MAC
7021.6	The NSC-MAC shall send a notice of revocation by January 10, 2011 to all enrolled pharmacies who are not accredited and who will not be enrolled for 5 calendar years as of January 1, 2011.										NSC-MAC
7021.7	The NSC-MAC shall mail the letters required in BR 7021.4 during the period of October 1 2010 – October 31, 2010.										NSC-MAC
7021.7.1	The NSC-MAC shall ensure that the mailing be in the form of an endorsement letter with an enclosed stamped self addressed envelope.										NSC-MAC
7021.7.2	For pharmacies with more than one practice location, the NSC-MAC shall cite, in the letter, the need to attest for each individually enrolled practice location.										NSC-MAC
7021.7.3	The NSC-MAC shall ensure that pharmacies that have had a change of ownership in the prior 5 years which resulted in a change in their legal business entity including a change in their tax identification number (TIN) shall not qualify for an attestation accreditation exemption and therefore shall be excluded from the attestation letter.										NSC-MAC
7021.8	The NSC-MAC shall review the submissions received from suppliers who received the attestation letter.										NSC-MAC
7021.9	The NSC-MAC shall ensure that pharmacies that properly signed the attestation letter be given an accreditation status of exempt.										NSC-MAC
7021.10	The NSC-MAC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their attestations.										NSC-MAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7021.11	The NSC-MAC shall send a notice of revocation by January 10, 2011, to all enrolled pharmacies who were sent an attestation letter and have not properly completed it as of the date of the notice of revocation.										NSC-MAC
7021.11.1	The NSC-MAC shall cite in the notice of revocation that the revocation is for a lack of required accreditation.										NSC-MAC
7021.12	Between April 1, 2011 and April 30, 2011, the NSC-MAC shall compile a sample listing of at least 10 percent of the pharmacies that have submitted an NSC accepted attestation exempting them from accreditation.										NSC-MAC
7021.12.1	The NSC-MAC shall include in the listing all who submitted accepted attestations who have a high fraud level indicator as well as at least some other pharmacy attesters.										NSC-MAC
7021.13	The NSC-MAC shall develop a letter to be sent to pharmacies that will be audited to determine if their accreditation exemption attestations are correct.										NSC-MAC
7021.13.1	The NSC-MAC shall request, in the letter, submission of evidence substantiating the pharmacy supplier's attestation was correct. Requested materials for this evidence shall include as a minimum a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods.										NSC-MAC
7021.14	The NSC-MAC shall obtain NSC project officer approval of the letter shown in BR 7021.13.										NSC-MAC
7021.15	Within 45 days after project officer approval of the letters described in BR 7021.13, the NSC-MAC shall mail a copy of the letter to the sample of pharmacy exemption attesters determined in BR 7021.12.										NSC-MAC
7021.16	The NSC-MAC shall determine the acceptability of the replies received in response to the audit verification										NSC-MAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	random sample mailing described in BR 7021.15.										
7021.16.1	The NSC-MAC shall use DMEPOS billing data, for only products and services requiring accreditation, to assist in the determination.										NSC-MAC
7021.17	The NSC-MAC shall make attempts to assist and follow-up with pharmacy supplies that have not submitted or properly completed their audit verifications.										NSC-MAC
7021.18	The NSC-MAC shall consult with the NSC project officer in cases where they are uncertain as to the acceptability of the supplier's response to the audit request.										NSC-MAC
7021.19	By June 30, 2011, the NSC-MAC shall send a notice of revocation to all enrolled pharmacies that were sent an audit verification letter who did not submit satisfactory evidence that they were in compliance with the requirements to obtain an accreditation exemption. The notice of revocation shall cite that the revocation is for a lack of required accreditation.										NSC-MAC
7021.20	The NSC-MAC shall follow the procedures shown in the BR's above concerning issuance of attestation letters and audit survey letters for all succeeding years after they have been performed for the first time.										NSC-MAC

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7021.21	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"										NSC-MAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	listserv. Contractors shall post this article, or a direct link to this 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

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

V. CONTACTS

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VI. FUNDING

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

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.

Medicare Program Integrity Manual
Chapter 15 - Medicare Provider/Supplier Enrollment

Table of Contents
(Rev. 346, 06-25-10)

15.38.6.1 – Compliance Standards for Pharmacy Accreditation

(Rev. 346, Issued: 06-25-10, Effective: 01-01-11, Implementation: 01-03-11)

The National Supplier Clearinghouse (NSC) shall not require that a pharmacy be accredited as a condition of enrollment before January 1, 2011.

The NSC-MAC shall determine which enrolled suppliers are pharmacies that are not accredited and who will be enrolled for 5 calendar years prior to January 1 of the next calendar year. The NSC-MAC shall then send a notice of revocation by January 10, 2011, to all enrolled pharmacies who are not accredited and who will not be enrolled for 5 calendar years as of January 1, 2011.

The NSC-MAC shall prepare a letter which enables all individually enrolled practice locations of pharmacies who have been enrolled for 5 calendar years prior to January 1, 2011, to attest that they are exempt from the requirement to be accredited because their total durable medical equipment, prosthetics orthotics and supplies (DMEPOS) billings subject to accreditation are less than 5 percent of their total pharmacy sales, as determined based upon the total pharmacy sales of the pharmacy for the previous 3 calendar or fiscal years. The letter shall cite that the attestation requires the signature of the authorized or delegated official of the entity. The authorized and delegated officials are defined in Section 15, of the Medicare Enrollment Application (CMS-855S), and as described in the internet enrollment application version of the Provider Enrollment, Chain and Ownership System (PECOS). Before mailing the letters, the NSC-MAC shall obtain NSC project officer approval of the letter. The mailing shall be in the form of an endorsement letter with an enclosed stamped self addressed envelope. The mailing should be performed between October 1, 2010 and October 31, 2010. For pharmacies with more than one practice location, the letters shall cite the need for each individually enrolled practice location to attest that they are exempt from the accreditation requirements. New locations of enrolled chain pharmacies shall not be considered to have been enrolled for 5 calendar years. Pharmacies that have had a change of ownership in the prior 5 years which resulted in a change in their legal business entity, including a change in their tax identification number (TIN), shall not qualify for an attestation accreditation exemption and therefore shall not be sent the attestation letter.

The NSC-MAC shall review the attestations received from pharmacies. Pharmacies that properly signed the attestation letter shall be given an accreditation status of exempt. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their attestations. The NSC-MAC shall send a notice of revocation by January 10, 2011, to all enrolled pharmacies who were sent an attestation letter and have not properly completed it as of the date of the notice of revocation. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

Between April 1, 2011 and April 30, 2011, the NSC-MAC shall compile a sample listing of at least 10 percent of the pharmacies that have submitted an NSC accepted attestation exempting them from accreditation. The NSC-MAC shall develop a letter to be sent to pharmacies that will be audited to determine if their accreditation exemption attestations are correct. The letter shall request submission of evidence substantiating that the validity of the pharmacy supplier's attestation. At a minimum, requested materials for this evidence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods. The NSC-MAC shall obtain NSC project officer approval of the letter. Within 45 days after project officer approval of the letter the NSC-MAC shall mail a copy of the letter to the random sample of pharmacies which claimed exemption through an attestation. The NSC-MAC shall determine the acceptability of the replies received in response to the audit verification random sample mailing. The NSC shall use DMEPOS billing data for only products and services requiring accreditation to assist in the determination. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their audit verifications. The NSC-MAC shall consult with the NSC project officer in cases where they are uncertain as to the acceptability of the supplier's response to the audit request. By June 30, 2011, the NSC-MAC shall send a notice of revocation to all enrolled pharmacies that were sent an audit verification letter who did not submit satisfactory evidence that they were in compliance with the requirements to obtain an accreditation exemption. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

The NSC-MAC shall follow the procedures shown above concerning issuance of attestation letters and audit survey letters for all succeeding years after they have been performed for the first time.