



Guidance on Implementing Section 3109 of the Patient Protection and Affordable Care Act (ACA) – JA7021

Related CR Release Date: June 25, 2010

Date Job Aid Revised: July 2, 2010

Effective Date: January 1, 2011

Implementation Date: January 3, 2011

Key Words	MM7021, CR7021, R346PI, ACA
Contractors Affected	Durable Medical Equipment Medicare Administrative Contractors (DME MACs)
Provider Types Affected	Provider types affected are DME Prosthetics and Orthotics Suppliers (DMEPOS).



- Change Request (CR) 7021 revises the *Medicare Program Integrity Manual* (Chapter 15 (Medicare Provider/Supplier Enrollment)) to include Section 38.6.1 (Compliance Standards for Pharmacy Accreditation).
- It explains the revised requirements for pharmacies as a result of Section 3109 (a) of the ACA.
- That section states that certain pharmacies are not required to have submitted evidence of accreditation to the Secretary of Health and Human services prior to January 1, 2011.

Provider Needs to Know...

- The ACA, Section 3109 (a) amends the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (subparagraph (F)(i) of Section 154(b)(1)(A)) by **not** requiring a pharmacy to submit to the Centers for Medicare & Medicaid Services (CMS) such evidence of accreditation prior to January 1, 2011.
- Also, with respect to items and services furnished on or after January 1, 2011, the ACA (Section 3109 (a)) provides that the quality standards and accreditation requirements set forth in MIPPA (Section 1834(a)(20)(F)) will 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 CMS;

- The pharmacy has been enrolled under Section 1866(j) of the Social Security Act as a supplier of DMEPOS and 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 meets 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.
 - The National Supplier Clearinghouse (NSC) will **not** require that a pharmacy be accredited as a condition of enrollment before January 1, 2011.
 - The NSC-MAC will 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 will then send a notice of revocation by January 10, 2011, to all enrolled pharmacies who are not accredited or who are not exempt from the accreditation requirements.
 - The NSC-MAC will prepare a letter which enables all individually enrolled practice locations of pharmacies, who have been enrolled for five 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.
 - The letter will 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.
 - The letters should be mailed between October 1, 2010, and October 31, 2010.
 - For pharmacies with more than one practice location, the letters will 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 will not be considered to have been enrolled for five calendar years.
 - Pharmacies that have had a change of ownership in the prior five years, which resulted in a change in their legal business entity, including a change in their tax identification number, will not qualify for an attestation accreditation exemption.
 - The NSC-MAC will review the attestations received from pharmacies.
 - Pharmacies that properly signed the attestation letter will be given an accreditation
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status of exempt.

- The NSC will make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their attestations.
- The NSC-MAC will 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 will cite that the revocation is for a lack of required accreditation.
- Between April 1, 2011, and April 30, 2011, the NSC-MAC will 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 will develop a letter to be sent to pharmacies that will be audited to determine if their accreditation exemption attestations are correct.
- The letter will request submission of evidence substantiating the validity of the pharmacy supplier's attestation.
- At a minimum, requested materials for this evidence will 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 will determine the acceptability of the replies received in response to the audit verification random sample mailing.
- The NSC will use DMEPOS billing data for only products and services requiring accreditation to assist in the determination.
- The NSC will make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their audit verifications.
- By June 30, 2011, the NSC-MAC will 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 will cite that the revocation is for a lack of required accreditation.

Background

- The Medicare Modernization Act of 2003 (MMA; Section 302) added a new paragraph 1834(a)(20) to the Social Security Act (see http://www.ssa.gov/OP_Home/ssact/title18/1834.htm on the Internet) that required CMS to establish and implement quality standards for suppliers of DMEPOS.
 - All DMEPOS suppliers that furnish such items or services identified in Section 1834(a)(20)(D) of the Social Security Act (as CMS determines appropriate) must comply with the quality standards in order to receive Medicare Part B payments and to retain
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Medicare billing privileges.

- MIPPA (Section 154(b) <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:SN0310>) added a new subparagraph (F) to Section 1834(a)(20) of the Social Security Act. In implementing quality standards under this paragraph, CMS required suppliers furnishing items and service on or after October 1, 2009, to have submitted evidence of accreditation by an accreditation organization designated by CMS.

Operational Impact	N/A
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Reference Materials	
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The related MLN Matters® article can be found at <http://www.cms.gov/MLN MattersArticles/downloads/MM7021.pdf> on the CMS website.

The official instruction (CR7021) issued regarding this change may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R346PI.pdf> on the CMS website.
