

**SEC. 3109. EXEMPTION OF CERTAIN PHARMACIES FROM ACCREDITATION REQUIREMENTS.**

(a) IN GENERAL.—Section 1834(a)(20) of the Social Security Act (42 U.S.C. 1395m(a)(20)), as added by section 154(b)(1)(A) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 100–275), is amended—

(1) in subparagraph (F)(i)—

(A) by inserting “and subparagraph (G)” after “clause (ii)”; and

(B) by inserting “, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011” before the semicolon at the end; and

(2) by adding at the end the following new subparagraph:

“(G) APPLICATION OF ACCREDITATION REQUIREMENT TO CERTAIN PHARMACIES.—

“(i) IN GENERAL.—With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

“(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

“(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

“(ii) PHARMACIES DESCRIBED.—A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

“(I) The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as deter-

mined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

“(II) The pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

“(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18, United States Code.

“(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence 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, as requested by the Secretary.”.

(b) ADMINISTRATION.—Notwithstanding any other provision of law, the Secretary may implement the amendments made by subsection (a) by program instruction or otherwise.

(c) RULE OF CONSTRUCTION.—Nothing in the provisions of or amendments made by this section shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w-3).