



Memorandum

Date: April, 2009

From: Steven Stranne, M.D., J.D.

Re: Statutory Authority for CMS to Exempt Pharmacies from
DME Accreditation and DMEPOS Surety Bond
Requirements under Medicare Part B

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You asked whether statutory authority exists for the Centers for Medicare & Medicaid Services (CMS) to exempt pharmacies under Medicare Part B from the accreditation requirements for suppliers of durable medical equipment (DME) and from the surety bond requirements for suppliers of DME, orthotics, prosthetics and supplies (DMEPOS).

In particular, you asked whether CMS may exempt corporations such as pharmacies within the phrase “other persons” under Section 1834(a)(20) of the Social Security Act and within the phrase “some or all suppliers or other persons” of Section 1834(a)(16) of the Social Security Act.

Brief Summary of Our Findings

CMS has the statutory authority to determine that corporations such as pharmacies fall squarely within the statutory phrases “other persons” and “some or all suppliers or other persons.”

Part I: Exemption from Accreditation Requirements: Taken individually, each of the findings described below under Part I of this memorandum provide ample support for CMS to determine that pharmacies are “other persons” that CMS may exempt from the accreditation requirements of Section 1834(a)(20) of the Social Security Act. The following findings are discussed in greater detail below:

- The longstanding meaning of the term “persons” under the Social Security Act and Medicare includes corporations and partnerships;
- When Congress created the authority to exempt entities from the DME accreditation requirements under MIPPA in 2008, Congress did not limit the scope of the term “persons;” and

- Congress has used the term “person” throughout the Social Security Act to refer to corporate entities under Medicare.

Considered in the aggregate, these findings provide very strong support for CMS to exempt pharmacies under Section 1834(a)(20)(F) of the Social Security Act.

Part II: Exemption from Surety Bond Requirement: Similarly, taken individually, each of the findings described below under Part II of this memorandum provide ample support for CMS to determine that pharmacies are “some or all suppliers or other persons” that CMS may exempt from the surety bond requirements under Section 1834(a)(16) of the Social Security Act.

- The Social Security Act provides CMS with the discretion to apply the surety bond requirement to “some or all” suppliers or other persons who provide items or services under Medicare Part B;
- The legislative history highlights that Congress opted to provide CMS with the authority to exempt a broad range of suppliers from the surety bond requirement, such as pharmacies;
- CMS has acknowledged its authority to establish exceptions to the surety bond requirement for suppliers that are not expressly listed in the statute; and
- For all of the reasons described in Part I of this memorandum, the phrase “other persons” in the last sentence of subsection 1834(a)(16) provides CMS with the authority to exempt corporations, such as pharmacies, from the surety bond requirement.

Considered in the aggregate, these findings provide very strong support for CMS to exempt pharmacies from the surety bond requirement under Section 1834(a)(16) of the Social Security Act.

Part I: Congress Provided CMS with Ample Discretion to Exempt Pharmacies from the Accreditation Requirements for DME under Medicare Part B.

A. The Longstanding Meaning of the Term “Persons” under the Social Security Act and Medicare includes Corporations and Partnerships

The longstanding meaning of the term “persons” under the Social Security Act includes corporations and partnerships. Section 1101(a)(3) of the Social Security Act provides the following definition that applies to the Medicare program:

When used in this Act – The term “person” means an individual, a trust or estate, a partnership, or a corporation.¹

Based on the plain meaning of this statutory language, it is clear that the term “persons” is not limited to individuals and that the term “persons” includes corporate entities such as pharmacies.

¹ Title XI, Section 1101(a)(3), Social Security Act.

Corporations have been included expressly within the definition of “persons” under the Social Security Act and Medicare throughout the history of Medicare Part B. When Congress established Medicare Part B in 1965, Congress made amendments to the definitions in Section 1101 of the Social Security Act, but Congress opted against amending or otherwise narrowing the definition of “persons.” Similarly, Congress has amended other definitions under Section 1101 as part of numerous bills revising the Medicare program, but Congress has always maintained the longstanding definition of “persons” to include corporations and partnerships.

B. When Congress Created the Authority for CMS to Exempt Entities from the DME Accreditation Requirements under MIPPA in 2008, Congress Did Not Limit the Scope of the Term “Persons.”

There is nothing within the language enacted by Congress under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that would prevent corporations from qualifying as “other persons” that CMS may exempt from the accreditation requirements arising under Section 1834(a)(20) of the Social Security Act. Congress enacted the following language under MIPPA Section 154(b)(1)(A)(ii)(II):

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B), *and including such other persons*, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services ... (II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.² (emphasis added)

Although the phrase “such as orthotists and prosthetists” helps define “other persons” under this provision, the plain meaning of this phrase does not place any limits on the scope of “other persons” covered under the legislative language.

If Congress intended to exclude corporations and pharmacies from the term “other persons,” Congress had many options for limiting the exemption authority. For example, Congress could have limited the exemption to “other individuals” or could have expressly excluded “corporations” or “pharmacies.” Instead, Congress opted to use the term “other persons,” which is defined under the Social Security Act to include corporations and partnerships.

In fact, elsewhere within MIPPA, Congress expressly waived the definitions of Section 1101 and the remainder of Title XI of the Social Security Act in the establishment of a Medicare demonstration project.³ This highlights that if Congress intended to limit the scope of “other persons” to exclude corporations or pharmacies, Congress could have easily done so. Instead,

² Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Public Law 110-275.

³ MIPPA, Public Law 110-275, Section 135(b)(4).

Congress granted CMS under MIPPA the discretion to determine what individuals, corporations or partnerships to exempt from the accreditation requirements.

C. Congress Has Used the Term “Person” Throughout the Social Security Act to Refer to Corporate Entities under Medicare

Congress has affirmed or implied that a person can be a corporation or business under Medicare in other sections of the Social Security Act. A sampling of examples follows below:

- Section 1861 of the Social Security Act, which is titled “Definitions of services, institutions, etc.,” includes the following reference: “... another qualified person (including a rural health clinic)...”⁴ Since a clinic cannot be an individual, it is clear that that the term person is meant to include corporate entities.
- Elsewhere in Section 1861, Congress referred to “a facility which ... has filed an agreement ... by which it agrees not to charge any *individual or other person* for items or services ...”⁵; and “discharges the liability of such *individual or any other person* to pay for the services”⁶ (emphasis added). This distinction between “individual” and “other person” is redundant and unnecessary if the meaning of “person” is limited to individuals. This is another example in which “person” includes corporate entities.
- The fraud and abuse provisions of the Social Security Act also provide examples of the word “person” being used by Congress to refer to corporate entities. For example, Section 1128A of the Social Security Act opens as follows: “Any person (including an organization, agency, or other entity, but excluding a beneficiary...)” Similarly, Section 1129, opens with “Any person (including an organization, agency, or other entity).”

In each one of these Medicare examples, Congress could have opted to use different language, but instead, Congress used the word “person” to include various forms of corporate entities.

Part II: Congress Also Provided CMS with Ample Discretion to Exempt Pharmacies from the Surety Bond Requirements for DMEPOS Suppliers under Medicare Part B.

A. The Social Security Act Provides CMS with the Discretion to Apply the Surety Bond Requirement to “Some or All” Suppliers or Other Persons who Provide Items or Services under Medicare Part B.

CMS may opt to exclude pharmacies from the surety bond requirement because the Social Security Act provides the Secretary with significant discretion when imposing this requirement. The sentence at the end of the subsection of the Social Security Act related to the surety bond requirement (1834(a)(16)) provides:

⁴ Title XVIII, Section 1861(s)(2)(G), Social Security Act.

⁵ Title XVIII, Section 1861(aa)(2) of the Social Security Act within the definition of a “rural health clinic.”

⁶ Title XVIII, Section 1861(w)(1) of the Social Security Act within the definition of “arrangements.”

The Secretary, at the Secretary’s discretion, may impose the requirements of the first sentence with respect to ... some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C) of this title) who furnish items or services under [Medicare Part B].^{7,8}

Based on the plain meaning of the statutory language, CMS may exclude some suppliers from the surety bond requirement. The first sentence of subsection 1834(a)(16) establishes the general rule regarding requirements that must be met for the issuance or renewal of a provider number for a supplier of DMEPOS, including the surety bond requirement.⁹ The sentence at the end of this subsection (referenced above) modifies the first sentence, providing the Secretary with discretion to impose the surety bond requirement on “some or all” suppliers or other persons furnishing items or services under Medicare Part B.

Pharmacies commonly function as suppliers of DMEPOS items, and there is nothing in this provision that would prevent CMS from applying the exemption for “some or all suppliers” to pharmacies. Although subsection 1834(a)(16) includes a reference to “physicians and other practitioners,” the plain meaning of this phrase does not place any limits on the scope of “some or all suppliers” that CMS may exempt from the surety bond requirement. “Other practitioners” include physician assistants, nurse practitioners, or clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, or registered dietitians or nutrition professionals.¹⁰

Therefore, CMS has the discretion to determine whether or not to apply the surety bond requirement to pharmacies operating as DMEPOS suppliers under Medicare Part B.

B. The Legislative History Highlights that Congress Opted to Provide CMS with the Authority to Exempt a Broad Range of Suppliers from the Surety Bond Requirement, Such as Pharmacies.

Although Congress initially contemplated providing the Secretary with limited discretion to include or exclude suppliers from the surety bond requirement, the final law provides the Secretary with broad discretion to apply the requirement to “some or all” suppliers or other persons who furnish items or services under Medicare Part B. The fact that Congress intended to provide broad discretion to include or exclude various suppliers from the surety bond requirement is highlighted by the history of this provision.

⁷ Title XVIII, Section 1834(a)(16), Social Security Act.

⁸ The phrase “first sentence” refers to the first of three sentences that comprise subsection 1834(a)(16) of the Social Security Act. The first sentence of 1834(a)(16) is the only sentence that creates requirements, and as a result, this is the only logical reading of the subsection. Further, the initial version of this legislation passed by the U.S. House of Representatives referred to the “previous sentence” rather than the “first sentence” (see H.R. 2015, 105th Cong.). Before enacting the final legislation that created 1834(a)(16), Congress corrected this reference, further highlighting that the phrase “first sentence” refers to the first sentence of 1834(a)(16).

⁹ Title XVIII, Section 1834(a)(16), Social Security Act.

¹⁰ Title XVIII, Section 1842(b)(18)(C), Social Security Act.

Although the initial version of subsection 1834(a)(16) as passed by the House of Representatives limited the Secretary's discretion to certain suppliers of ambulance services and clinics, the final language enacted into law has no limitations. Initially, the House version of the bill provided that:

The Secretary, in the Secretary's discretion, may impose the requirements of the previous sentence with respect to some or all classes of suppliers of ambulance services described in section 1861(s)(7) and clinics that furnish medical and other health services (other than physicians' services) under this part.¹¹

This language was referenced in the Conference Report,¹² but Congress revised the language before passing the legislation in its final form. As noted above, the language that was signed into law provides the Secretary with unfettered flexibility to apply the requirements of 1834(a)(16) on “some or all” suppliers or other persons who furnish items or services under Medicare Part B. In accordance with this broad discretion, the Secretary could choose to exclude pharmacies from the surety bond requirement.

C. CMS has Acknowledged Its Authority to Establish Exceptions to the Surety Bond Requirement for Suppliers that Are Not Expressly Listed in the Statute.

CMS published a final rule on January 2, 2009 entitled “Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS),” to implement the surety bond requirement set forth in the Balanced Budget Act.¹³ The final rule includes exemptions from the surety bond requirement for certain orthotic and prosthetic personnel, physical therapists and occupational therapists.¹⁴ There is nothing in the statutory language that limits or otherwise makes explicit reference to these types of suppliers. The discretion for CMS to exempt these suppliers comes from the language in the last sentence of 1834(a)(16), which permits the Agency to apply the surety bond requirements to “some or all suppliers or other persons.”

D. For All of the Reasons Described in Part I of this Memorandum, the Phrase “Other Persons” in the Last Sentence of Subsection 1834(a)(16) Provides CMS with the Authority to Exempt Corporations, Such as Pharmacies, from the Surety Bond Requirement.

As discussed in detail under Part I of this memorandum, the longstanding meaning of the term “persons” under the Social Security Act and Medicare includes corporations, and Congress has used the term “person” throughout the Social Security Act to refer to corporate entities under Medicare.

¹¹ H.R. 2015, 105th Cong. (1997)(initial version that was passed by the U.S. House of Representatives).

¹² Conference Report on HR 2015, Balanced Budget Act of 1997, 143 CONG. REC. H6214 (July 29, 1997).

¹³ 74 Fed. Reg. 165 (January 2, 2009).

¹⁴ 74 Fed. Reg. at 200 (42 C.F.R. §424.57(d)(15)).

Further, there is nothing in the legislative language or history that limits the scope of the phrase “other persons” that appears in the last sentence of subsection 1834(a)(16).¹⁵

As a result, it is clear that CMS has the discretion to exclude pharmacies from the surety bond requirement as either “some or all suppliers” or as some or all “other persons” under 1834(a)(16).

Conclusion

As discussed above, there is ample support in the Social Security Act for the Secretary and CMS to exempt pharmacies from the accreditation and surety bond requirements of Medicare Part B. Please do not hesitate to contact us if you have any questions regarding this analysis. We would be pleased to provide additional information or detail.

¹⁵ Title XVIII, Section 1834(a)(16), Social Security Act.