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Proposed Amendment To Create A Stark Exception For PAP Devices

The proposed amendment simply creates a Stark law exception for PAP devices, provided a number of conditions are satisfied, including requirements that (1) the devices be dispensed by an accredited DME supplier with whom the ordering physician has a financial relationship, (2) all Medicare coverage, billing and reimbursement criteria are satisfied, and (3) only those specific PAP devices and accessories identified by CMS are protected under the exception.

The exception for PAP devices would be within the United States Code (U.S.C.), specifically Title 42, Chapter 7 (Social Security), Subchapter XVIII (Health Insurance for Aged and Disabled), Part E, Section 1395nn, titled Limitation on certain physician referrals. Item (b) General exceptions to both ownership and compensation arrangement prohibitions is where the amendment would be incorporated. This section addresses five types of exemptions:

1. Physician services
2. In-office ancillary services
3. Prepaid plans
4. Other permissible exceptions
5. Electronic prescribing.

The exception for PAP devices would be the sixth exemption.

Sec. 1877.

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(b). *General Exceptions to Both Ownership and Compensation Arrangement Prohibitions.*—Subsection (a)(1) shall not apply in the following cases:

* * *

(6) *Positive Airway Pressure Devices and Accessories for the Treatment of Obstructive Sleep Apnea.*—

(A) *In the case of PAP Devices, provided all of the following conditions are satisfied—*

- (i) *the PAP Devices are dispensed by an Accredited DME Supplier with whom the ordering physician has a financial relationship,*
- (ii) *the PAP Devices are covered by Medicare,*
- (iii) *the PAP Devices are listed as eligible for this exception on the List of CPT/HCPCS Codes,*
- (iv) *all billing and claims submissions for the PAP Devices comply with any Federal or State law or regulation governing billing or claims submission, and*
- (v) *the arrangement for the provision PAP Devices does not violate the anti-kickback statute (section 1128B(b) of the Act).*

(B) *This exception does not apply to any financial relationships between the referring physician and any entity other than the Accredited DME Supplier that dispenses the PAP Devices.*

(C) *Definitions—*

- (i) *“Accredited DME Supplier” means a supplier of durable medical equipment that is accredited by the American Academy of Sleep Medicine, or any accrediting body approved by the Secretary.*
- (ii) *“List of CPT/HCPCS Codes” means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act, which list is updated annually by the Secretary.*
- (iii) *“PAP Devices” mean positive airway pressure devices for the treatment of obstructive sleep apnea, and related accessories, to the extent they are listed as eligible for this exception on the List of CPT/HCPCS Codes.*