



Billing Code 8025-01-P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Class Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notification of waiver of the Nonmanufacturer Rule for positive airway pressure devices.

SUMMARY: The U.S. Small Business Administration (SBA) is granting a class waiver of the Nonmanufacturer Rule (NMR) for Positive Airway Pressure Devices and Supplies Manufacturing. This U.S. industry comprises establishments primarily engaged in manufacturing Continuous Positive Airway Pressure (CPAP) devices, Bi-level Positive Airway Pressure (BiPAP) devices, and other products intended to treat sleep apnea by keeping a person's airways open during sleep.

DATES: This action is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Carol J. Hulme, Program Analyst, by telephone at 202-2056347; or by email at carol-ann.hulme@sba.gov.

SUPPLEMENTARY INFORMATION: Section 8(a)(17) and 46 of the Small Business Act (Act), 15 U.S.C. 637(a)(17) and 657, and SBA's implementing regulations require that recipients of Federal supply contracts (except those valued between \$10,000 and \$250,000) set aside for small business, service-disabled veteran-owned small business (SDVOSB), women-owned small business (WOSB), economically disadvantaged women-owned small business (EDWOSB), historically underutilized business zones

(HUBZones) or participants in the SBA's 8(a) Business Development (BD) program provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule (NMR). 13 CFR 121.406(b). Sections 8(a)(17)(B)(iv)(II) and 46(a)(4)(B) of the Act authorize SBA to waive the NMR for a "class of products" for which there are no small business manufacturers or processors available to participate in the Federal market.

As implemented in SBA's regulations at 13 CFR 121.1202(c), in order to be considered available to participate in the Federal market for a class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or been awarded a contract to supply the class of products within the last 24 months. The SBA defines "class of products" based on a combination of 1) the six digit North American Industry Classification System (NAICS) code, 2) the four digit Product Service Code (PSC), and 3) a description of the class of products.

On February 27, 2017, SBA received a request to waive the NMR for Positive Airway Pressure Devices and Supplies under NAICS codes 339112 (surgical and medical instrument manufacturing) and 339113 (surgical appliance and supplies manufacturing), and PSC 6515 (medical and surgical instrument, equipment and supplies). According to that request, along with supporting documentation, there were no small business manufacturers or processors of CPAP devices in the Federal market.

On September 18, 2017 (82 FR 43637), the U.S. Small Business Administration (SBA) issued a Notice of Intent to grant a class waiver for CPAP, BiPAP and other sleep apnea devices.

As revealed by the two comments submitted in response to the document, there are no small business manufacturers or processors of this product in the Federal market. The first comment, dated October 19, 2017, did not include domestic small business manufacturers capable of meeting the requirement. The second comment did not identify any manufacturers.

Therefore, in the absence of a small business manufacturer of these products, a class waiver is necessary to allow otherwise qualified regular dealers to supply the product of any manufacturer on a Federal contract set aside for small business, service-disabled veteran-owned small business (SDVOSB), women-owned small business (WOSB), economically disadvantaged women-owned small business (EDWOSB), historically underutilized business zones (HUBZones) or participants in the SBA's 8(a) Business Development (BD) program.

More information on the NMR and Class Waivers can be found at <https://www.sba.gov/contracting/contracting-officials/non-manufacturer-rule/non-manufacturer-waivers>.

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