

**United States Small Business Administration
Office of Hearings and Appeals**

NAICS APPEAL OF:

First Nation Group, LLC,

Appellant,

Solicitation No. 36C10G24R0014

U.S. Department of Veterans Affairs

SBA No. NAICS-6270

Decided: March 7, 2024

APPEARANCES

Jonathan T. Williams, Esq., Meghan F. Leemon, Esq., Kelly A. Kirchgasser, Esq., PilieroMazza, PLLC, Washington D.C., for Appellant, First Nation Group, Inc.

Brian C. Love, Contracting Officer, for U.S. Department of Veterans Affairs, Fredericksburg, Virginia

Julie M. Nichols, Esq., Roeder, Cochran and Phillips, PLLC, McLean, Virginia, for MedEquip Supply Corp.

DECISION

I. Introduction and Jurisdiction

On January 16, 2024, the U.S. Small Business Administration (SBA) Office of Hearings and Appeals (OHA) received the above-captioned appeal from First Nation Group, LLC, (Appellant). The appeal challenges the North American Industry Classification System (NAICS) code assigned to Solicitation No. 36C10G24R0014 (Solicitation). Pursuant to the Solicitation, the procuring agency, the U.S. Department of Veterans Affairs (VA), intends to procure Medical Emergency Alert Devices (MEAD) for its Prosthetics Sensory Aid Service (PSAS).

In its appeal, Appellant maintains that the Contracting Officer (CO) clearly erred in assigning NAICS code 334220, Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, to the Solicitation. Appellant contends that the appropriate NAICS code for this order is 334510, Electromedical and Electrotherapeutic Apparatus Manufacturing. For the reasons discussed *infra*, the appeal is DENIED.

OHA decides appeals of NAICS code designations under the Small Business Act of 1958, 15 U.S.C. § 631 *et seq.*, and 13 C.F.R. parts 121 and 134. Appellant filed the instant appeal within 10 calendar days after issuance of the RFQ, so the appeal is timely. 13 C.F.R. §§

121.1103(b)(1), 134.304(b); Federal Acquisition Regulation (FAR) 19.103(a)(1). Accordingly, this matter is properly before OHA for decision.

II. Background

A. The Solicitation

On January 4, 2024, VA issued Solicitation No. 36C10G24R0014. The Solicitation seeks to procure MEADs for the VA's PSAS. The procurement is a 100% small business set aside, and the designated NAICS code is 334220, Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, with a corresponding 1,250 employee size standard. The procurement's objective is to ensure the availability of and consistency of the device nationwide and to obtain volume-based standardized pricing by establishing an enterprise-wide Indefinite Delivery Indefinite Quantity (IDIQ) contract. (Solicitation, at 7.) The Solicitation requires an offeror to provide an uninterrupted supply of products and delivery of MEADs. The offeror is to provide both, a neck pendant device and a wristband device, and an instruction manual in English and Spanish for each device. The device is to meet safety requirements, such as not having pinch points or sharp edges when wearing it and being latex-free or made of hyposensitive material. (*Id.*)

The devices must also meet minimum technical requirements (MTRs). These include availability in 4G mobile functionality across the U.S., a push button connection feature, auto-fall detection capability, 911 call functionality, structured provisions to address false alarms or user cancellation to agent prior to escalation to 911, ability of user to enter a minimum of 3 additional contacts exclusive of 911, GPS functionality, a built in speaker and microphone, unlimited minutes, wearing accessories, water-resistant, 7-day minimum battery life, charging accessories, AC port and adaptor, written set up instructions in English and Spanish, an 800 customer service number, and a minimal IP67 standard rating. (*Id.*, at 7-8.) The MEADs will be delivered directly to the veteran once the prescribing practitioner has evaluated the veteran and determined that he or she needs the device. (*Id.*, at 9.)

In reviewing offers, the VA technical panel will review product literature to determine whether the proffered devices meet the MTRs. The technical panel will review the product for safety, determining whether there are any pinch points or sharp edges when wearing, handling, opening or closing the devices, and whether there are any limitations to detachability for the devices when pulled or snatched. The technical panel will also evaluate the following for ease of performance: push button connection features, auto fall detection, responsiveness to being exposed to water, and responsiveness of the call center to provide a physical location of the device using the GPS feature. In addition, the technical panel will evaluate for usability the accuracy of the fall detection feature, the speed of the call center response, clarity of communication of the speakers and microphone, and whether components will break if bent or dropped. (*Id.*, at 62.)

B. The Appeal

On January 16, 2024, Appellant filed the instant appeal. Appellant argues that the appropriate NAICS code for this procurement is 334510, Electromedical and Electrotherapeutic Apparatus Manufacturing, with a corresponding 1,250 employee size standard. Appellant maintains that it is an interested party because while both NAICS codes have the same size standard, Appellant does not qualify as a small business under NAICS code 334220, but it would qualify as a small business under NAICS code 334510, based on the nonmanufacturer rule. Whether Appellant qualifies as a small business for this procurement depends upon whether it satisfies the nonmanufacturer rule. (Appeal at 2, citing 13 C.F.R. §§ 121.402(b)(2), 121.406(a).) Appellant would supply a product manufactured by a large business, but there is no contract-specific waiver of the nonmanufacturer rule for this RFP, nor is there a class waiver of the nonmanufacturer rule under NAICS code 334220. Appellant therefore cannot qualify as a small business under the nonmanufacturer rule for this procurement if the designated NAICS code is 334220. (*Id.*, at 3.)

Appellant maintains it could, however, qualify as a nonmanufacturer if the designated NAICS code were 334510. This is because there is a class waiver of the nonmanufacturer rule under NAICS code 334510 for:

Electromedical and Electrotherapeutic Apparatus Manufacturing, diagnostic equipment, MRI (Magnetic Resonance Imaging) manufacturing; MRI medical diagnostic equipment manufacturing, medical ultrasound equipment manufacturing, patient monitoring equipment (e.g., intensive care coronary unit) manufacturing, positron emission equipment tomography (PET) scanners manufacturing.

(*Id.*, at 3, citing 72 Fed. Reg. 72433 (Dec. 12, 2007).)

Appellant maintains the MEAD is covered by the existing class waiver under NAICS code 334520 because it is an “electromedical apparatus” and it is also a diagnostic and patient monitoring device. Appellant asserts it would be considered an eligible small business nonmanufacturer if NAICS code 334510 was the designated NAICS code and the class waiver was incorporated into the RFP pursuant to 13 C.F.R. § 121.1206(a). (*Id.*)

Appellant argues NAICS code 334510 best describes the principal purpose of the MEAD because it is a medical device. The first two words of its title are “medical emergency.” NAICS code 334510 covers medical devices, while NAICS code 334220 does not. It covers communications devices, and the MEAD is not principally a communications device, but a medical device. (*Id.*, at 10.)

Appellant explains, the MEAD is being acquired for VA's PSAS, which provides medical equipment and support services to veterans. It will be prescribed to veterans by a clinician. Communication devices such as cellphones or GPS devices are not medical equipment and would not be prescribed by a doctor. This demonstrates that the MEAD is fundamentally a medical device, not a wireless communications device. (*Id.*, citing RFP at 7, 9.)

Appellant further maintains the MTRs and VA's planned technical evaluation confirm the MEAD's principal purpose falls within NAICS code 334510. While several of the MTRs address functionalities analogous to products which fall under NAICS code 334220, like 4G mobile, GPS, and built-in speaker, the fact the MEAD has some wireless communications features does not make it a wireless communications device. The MEAD is by name and intended use a diagnostic medical device. Other medical products such as the pacemaker and cardiograph have wireless communications functions, but their fundamental characteristic is as electromedical devices. (*Id.*, at 11.)

In Appellant's view, the most important function of the MEAD is patient monitoring for medical purposes, reflected in the auto-fall detection capability. This is a critical component which differentiates it from the broadcasting and wireless communications products that fall under NAICS code 334220, such as cellphones and GPS devices. The primary purpose of a MEAD is to serve as a patient monitoring device by automatically detecting falls and alerting family members or medical providers. (*Id.*, at 11.) It is for that primary medical purpose that the MEAD is prescribed by VA clinicians to veterans. It includes the option for the wearer to manually push a button to call family or medical providers in the event of a medical emergency. The MEAD's principal purpose is not to serve as a communications device, but to detect and be utilized in the event of a medical emergency. (*Id.*)

Appellant points to how the VA will evaluate MEADs to support its argument. The VA technical panel will focus its evaluation on a few key characteristics of an offeror's MEAD that includes reviewing the performance and accuracy of the auto-fall detection feature. The panel will also evaluate how quickly the call center responds. The VA evaluation will emphasize patient monitoring and medical alert components of the MEAD, as compared to wireless communication. (*Id.*, at 11-12, citing RFP at 62.)

Finally, Appellant notes that it has reviewed 386 prior VA acquisitions of MEADs, and none were under NAICS code 334220. (*Id.*)

D. CO's Response

On February 1, 2024, the CO responded to the instant appeal, arguing that NAICS code 334220 is the correct code. The CO affirms the Solicitation seeks to establish a source of supply for MEADs. The purpose of the MEADs is to connect the monitored patient with help in the event of a fall or other emergency. VA is specifically seeking a telecommunications device with Global Position System (GPS) capability. GPS is a satellite-based radio navigation system that provides geolocation and time information to a GPS receiver. (Response, at 3.)

The CO explains the VA is seeking both neck pendants and wristband devices to be worn on the outside of the patient/end user. The solicitation's MTRs describe a radio, telephonic, or wireless communication-type device, with the GPS capability. The MTRs also include the following telecommunications type functions: 4G mobile, 911 functionality, push button connection, allow the user to enter contacts, GPS functionality, speaker and microphone, unlimited minutes. (*Id.*)

The CO maintains that none of the references found in the description for NAICS code 334510 regarding invasive medical devices, imaging, therapeutic, or diagnostic equipment, are applicable to the stated MTRs of the solicitation. VA asserts it made the determination that the principal purpose of the MEADs is more in line with wireless communications than ultrasound or imaging equipment. While they are used in medical emergencies, they do not have any therapeutic or imaging capability, as described in NAICS code 344510. They are not implanted for and do not provide therapeutic benefit. They do not perform diagnostic functions but are solely for monitoring and connecting the patient via wireless communication with medical support services in the event of an emergency. (*Id.*, at 4.)

The CO also points to its rule that MEADs are not medical devices for purpose of the VA authorization to provide prosthetics benefits to veterans. (*Id.* at 5, citing 85 Fed. Reg. 84245 (Dec. 28, 2020).)

E. MES' Response

On February 1, 2024, MedEquip Supply Corp. (MES), as an interested party, responded to the appeal. MES first argues that Appellant does not have standing to bring this appeal. Appellant is advocating for a NAICS code with the same size standard as the NAICS code the CO has designated. When the size standard is the same for both challenged and the desired NAICS code, an appellant cannot be adversely affected and has no right to appeal. (MES Response at 2-3, citing *NAICS Appeal of X-Ray Associates, LLC*, SBA No. NAICS-4728 (2005).) MES asserts there is no precedent supporting Appellant's argument that it has standing because it could qualify as a small business under its desired NAICS code because it could meet the requirements of the non-manufacturer rule under that code, but not the other. Appellant must show it will be a potential bidder under the new code to have standing. (*Id.*, citing *NAICS Appeal of Credence Management Solutions*, SBA No. NAICS-5914 (2018).) MES argues Appellant could only have standing if OHA agrees its desired code better describes the products sought.

MES further argues that NAICS code 334220 better describes the principal purpose of the items sought. MEADs connect the user with help in the event of a fall or other emergency, they are a type of radio device worn by the user. All of the MTRs describe a radio-telephonic or wireless communication type device. In describing the devices, MTRs use words such as 4G mobile functionality, 911 call functionality, push button connections, GPS functionality, speaker and microphone, and unlimited minutes. The MTRs do not describe invasive medical devices, imaging, therapeutic, or diagnostic equipment, as expressed in NAICS code 334510 and the waiver to the NMR. (*Id.*, at 4.)

MES emphasizes that NAICS code 334220 describes wireless communication equipment, such as GPS equipment, pagers, and cellular phones. On the other hand, NAICS code 334510 covers electromedical and electrotherapeutic apparatus. Further, the NMR waiver Appellant relies upon reflects the same NAICS code 334510. (*Id.*, citing 72 Fed. Reg. 72433 (Dec. 20, 2007).)

Contrary to Appellant's assertions, MES argues that MEADs are much more in line with wireless communication than ultrasound or imaging equipment. While they are used in medical emergencies, they do not have therapeutic or imaging capacity, as described for NAICS code 344510. They are not implanted for therapeutic benefit like pacemakers, do not provide therapeutic benefit like hearing aids, and do not perform diagnostic functions. MEADs have no medical capability beyond connecting the user via wireless telecommunication with support on the other end. (*Id.*, at 5.)

Furthermore, MES maintains the VA recently agreed with this distinction for its Federal Supply Schedule (FSS) program. In the VA's MES solicitation and Amendment 1, it is stated that no type of personal alert/monitoring devices fall within the scope of the schedule, but under GSA Schedule 70, SIN 132-8. The schedule only covers medical IT products where the purpose is diagnosis or treatment. It does not cover products of a general IT nature. VA has promulgated a rule that MEADs are not medical devices for purpose of the VA authorization to provide prosthetics benefits to veterans. (*Id.* at 5-6, citing 85 Fed. Reg. 84245 (Dec. 28, 2020).)

MES thus maintains NAICS code 334220 is the appropriate choice.

F. Appellant's Reply

On February 6, 2024, Appellant filed a Motion for Leave to Reply to the Responses, together with the Reply. Appellant argues it is responding to new assertions raised by MES about Appellant's status as an interested party, misguided reliance by VA and MES on a 2020 Rulemaking and mischaracterizations of the contemplated products.¹

First Appellant reasserts its claim of standing under 13 C.F.R. § 134.302(b). Appellant states it is a nonmanufacturer and must comply with 13 C.F.R. § 121.406(b) to qualify as a small business for this procurement. Appellant intends to supply a product made by a large business and cannot qualify unless NAICS code 334510 is the designated code, because there is a class waiver of the nonmanufacturer rule for this code, but not for NAICS code 334220. (Reply, at 2.) *6 In response to MES's citing of *NAICS Appeal of X-Ray Associates, LLC*, SBA No. NAICS-4278 (2005), Appellant argues the regulation does not state explicitly that an appellant cannot meet the “adversely affected” size standard if the size standard is the same between the NAICS code designated by the CO and an appellant's preferred code. Determining whether a concern is adversely affected is a fact-specific inquiry based upon the particular circumstances. Appellant points to *NAICS Appeal of Nat'l Electric Coil*, SBA No. NAICS-5666 (2015) where OHA found standing in an unrestricted procurement where the challenged code would prevent that appellant from receiving a HUBZone price evaluation preference. Appellant points out that a concern

¹ On the same day, the CO objected to Appellant's Motion on the grounds that 13 C.F.R. § 134.309(d) does not permit reply to a response. The VA views that in accordance with 13 C.F.R. § 134.314, the burden of proof is on the appellant who filed the original appeal and as such, no reply to response should be considered. As 13 C.F.R. § 134.309(d) permits a reply when “the Judge directs otherwise,” in the interest of a more complete record and discussion of the issues hereinafter, I ADMIT Appellant's Reply into the record and OVERRULE the CO's objection.

small under the challenged standard has standing to appeal advocating a lower size standard, because it is adversely affected by having to compete with larger firms. (*Id.*, at 2-3, citing *NAICS Appeal of SAC Cleaners, Inc.*, SBA No. NAICS-5468 (2013).) Appellant distinguishes *X-Ray Associates*, because that appellant failed to explain why it was adversely affected by the NAICS code designation at issue. (*Id.*)

Appellant further asserts that the VA rule cited by VA and MES in fact supports its argument that VA cannot acquire the MEADs for PSAS if they are a purely communication device that falls under NAICS code 334220. There, VA concluded that its statutory authority under 38 U.S.C. §§ 1701(6)(f) and 1710 to provide prosthetic and rehabilitative items to veterans does not include a MEAD that is purely a communications device. (*Id.* at 6, citing 85 Fed. Reg, at 84246.) Appellant asserts VA noted that prescribed medical use of MEADs, where some patients need to be safe in their homes due to their medical conditions, it may be possible for a clinician to determine that a MEAD is the appropriate item to directly and actively contribute to the treatment of that medical condition. VA thus removed a proposed restriction on MEADs from the definition of “home medical equipment” at 38 C.F.R. § 17.3210. (*Id.*, at 7.)

Appellant argues that removing a restriction on MEADs from the definition of home medical device means that they may be considered medical devices depending upon their functionality and the purpose for which they are prescribed. (*Id.*, at 7-8.) Appellant argues the final rule supports its position. The RFP does not seek a MEAD that is purely a communication device. This acquisition is for PSAS, which does not have statutory authority to provides MEADs which are purely communication devices. The MEAD sought by this RFP is more than a pure communication device because of auto-fall detection capability and it will be prescribed by VA clinicians based upon determination of a medical need. Appellant points to the RFP at 7, 9, and 62, detailing an auto-fall detection MTR, and the necessity of prescription before an individual receives the MEAD. (*Id.*, at 8.)

Appellant further argues that VA and MES ignore the patient monitoring and diagnostic products that fall under NAICS code 334510 and asserts it is only for invasive or implanted devices that have therapeutic or imaging capability. However, NAICS code 334510 covers more than just imaging and therapeutic devices, it is for “electromedical and electrotherapeutic devices,” and is not limited to invasive or implanted devices. Hearing aids and cardiophones fall under NAICS code 334510 but are not invasive or implanted. (*Id.* at 8-9.)

The MEADs sought here are not invasive or implanted but their salient functions are patient monitoring and diagnostic, which make NAICS code 334510 the best fit. VA admits the monitoring is part of the MEADs functions. (*Id.*, at 9, citing VA Response at 4.) The VA's Response admits the devices are used in medical emergencies (at 4). Further, the name of the product, its intended functionality, the fact a VA clinician must prescribe them based upon determination of medical need, and how VA will evaluate the product according to the RFP all support a NAICS code 334510 designation. (*Id.* at 9.)

Appellant argues the prescription of MEADs based upon medical need is a key point. Appellant points to the RFP: “[t]he goal is to have the medical alert devices delivered directly to the Veteran once the prescribing practitioner has assessed, evaluated and made a determination

that the veteran needs the device.” (*Id.*, citing RFP at 9.) Appellant asserts PSAS has no authority to provide MEAD to veterans unless it is prescribed by a clinician to “actively or directly treat or rehabilitate a veterans' health condition or limitation.” (*Id.* 9, citing 85 Fed. Reg. at 84246-47.) The MEAD must meet the characteristics of an electromedical device under NAICS code 334510 that is prescribed for patient monitoring, diagnostic, or therapeutic functions. Otherwise PSAS lacks authority to provide it to veterans. (*Id.* at 9-10.)

G. MES' Sur-Reply

On February 23, 2024, MES filed a Motion for Leave to Sur-Reply to Appellant's Reply, together with a proposed Sur-Reply. In its Motion, MES explains that it objected to this leave when Appellant asked and its response was directly made to the arguments raised in the appeal petition, for which Appellant had the burden of proof in its initial filing. As such, any reply would give Appellant a second bite of the apple and unnecessarily delay a decision in this matter and the entire procurement. As the Judge has not directed a reply from Appellant, MES continues to oppose to Appellant's Motion and Reply. (MES' Motion.)

In its Sur-Reply, MES claims that Appellant has not shown any reason why OHA should consider its arguments in the proposed reply post close of the record. 13 C.F.R. § 134.309(b). Appellant has the burden of setting forth its entire argument in its appeal. 13 C.F.R. § 134.305(a)(3). *See also NAICS Appeal of PrimeTech International Inc.*, SBA No. NAICS-6014 (2019) (denying a reply where the Appellant expanded its argument beyond its initial appeal). (MES' Sur-Reply, at 1.)

MES highlights that on Appellant's Reply, Appellant acknowledged the size standard was the same for both NAICS codes, but conveniently did not address the OHA case law indicating it could not be adversely affected. Instead, it only focused on its argument that it was “adversely affected” because it cannot comply with the NMR non-waiver for NAICS code 334220. (*Id.*, at 1-2.) However, now Appellant wishes to address the case law contrary to its position which MES argues that it should have addressed in its appeal and further argues that the regulations in question should be narrowly construed is just for Appellant's own benefit. Appellant offers no reason based in law why OHA should allow this after the close of the record. Thus, OHA must reject this.

Next, MES alleges that Appellant did not offer any argument in its appeal as to why the VA's final rule regarding medical alert devices supports its position. While MES' response offered a statement that the VA held medical alert devices are not medical devices for purposes of the VA's authorization to provide prosthetics benefits to veterans and provided a link to the final rule, Appellant has used that as a jumping off point to make an entirely new argument in its proposed reply and thus, OHA must reject this too. MES adds that the new final rule does not support the use of NAICS code 334510 because the MEADs are simply communication devices. MES cites to the final rule:

[W]hen such devices and bracelets are purely communication devices that do not actively or directly treat or rehabilitate a veteran's health condition or limitation,

they do not meet the direct and active component standard as described in the proposed rule.

(*Id.*, at 2.)

MES asserts that communication is precisely the principal purpose of the MEADs, procured by the VA, because MEADs are purely communication devices and do not provide any therapeutic benefit. (*Id.*)

MES revisits its own response when it made clear distinctions between the definitions of NAICS code 334220 and 334510, as already defined. However, in its proposed reply, Appellant attempts to provide arguments enlarging its position, which it did not state in its initial appeal. (*Id.*) Finally, Appellant's proposed reply failed to address the fact that the Federal Supply Schedule (FSS) program administered by the VA has stated that medical alert systems are not medical devices, which MES argued in its response and Appellant does not address it because it hurts its position. For these reasons, OHA should deny Appellant's Motion to Reply in its entirety and repudiate the arguments advanced in its proposed reply.² (*Id.*, at 2-3.)

III. NAICS Manual³

The CO's designated NAICS code, 334220, Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, covers:

[E]stablishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.

NAICS Manual, at 264.

Appellant's preferred NAICS code, 334510, Electromedical and Electrotherapeutic Apparatus Manufacturing covers:

² As earlier ruled, in the interest of a complete record and discussion of the issues hereinafter, I ADMIT MES' Sur-Reply and OVERRULE MES' objection to Appellant's Motion for Leave to File a Reply.

³ Executive Office of the President, Office of Management and Budget, *North American Industry Classification System-United States (2022)*, available at <http://www.census.gov>. SBA has instructed that, for purposes of SBA programs, the 2022 edition of the *NAICS Manual* is utilized effective October 1, 2022, “the beginning of the new fiscal year following the effective date of the OMB's release of the NAICS 2022 revision.” See 87 Fed. Reg. 59,240 (Sept. 29, 2022).

[E]stablishments primarily engaged in manufacturing electromedical and electrotherapeutic apparatus, such as magnetic resonance imaging equipment, medical ultrasound equipment, pacemakers, hearing aids, electrocardiographs, and electromedical endoscopic equipment.

NAICS Manual, at 268.

IV. Discussion

A. Standard of Review

Appellant has the burden of proving, by a preponderance of the evidence, all elements of its appeal. Specifically, Appellant must show that the CO's NAICS code designation is based upon a clear error of fact or law. 13 C.F.R. § 134.314; *NAICS Appeal of Durodyne, Inc.*, SBA No. NAICS-4536, at 4 (2003). SBA regulations do not require the CO to select the perfect NAICS code. *NAICS Appeal of Evanhoe & Assocs., LLC*, SBA No. NAICS-5505, at 14 (2013). Rather, the CO must assign the NAICS code that best describes the principal purpose of the product or service being acquired in light of the industry descriptions in the *NAICS Manual*, the description in the solicitation, the relative value and importance of the components of the procurement making up the end item being procured, and the function of the goods or services being acquired. FAR 19.303(a)(2); 13 C.F.R. § 121.402(b). A procurement is usually classified according to the component that accounts for the greatest percentage of contract value. *Id.* OHA will not reverse a NAICS code designation “merely because OHA would have selected a different code.” *NAICS Appeal of Eagle Home Med. Corp.*, SBA No. NAICS-5099, at 3 (2009).⁴

B. Analysis

The threshold issue is Appellant's standing to challenge the instant NAICS code designation, whether it is a concern adversely affected by that designation. 13 C.F.R. § 134.302(b). The two codes have the same size standard, and OHA has in the past dismissed appeals where the preferred code had the same size standard as the challenged one. *NAICS Appeal of X-Ray Associates, LLC*, SBA No. NAICS-4728 (2005). However, OHA has not ruled that there can be no NAICS code appeal when the preferred code has the same size standard as that designated. The question is whether Appellant has been adversely affected by the designation. As MES notes, in *X-Ray Associates*, an appellant failed to explain how it was adversely affected by the NAICS code designation. Here, Appellant maintains that it cannot compete for this procurement under the designated code, but it can under its preferred code, because this code has a class waiver of the nonmanufacturer rule. Accordingly, I conclude that Appellant is adversely affected by this NAICS code designation and has standing to bring this appeal.

⁴ The standard of review for NAICS code cases being well established, I shall not address MES's argument concerning the VA regulations. The question of whether the appropriate code has been chosen is determined by the contents of the solicitation and the descriptions in the *NAICS Manual*.

In reviewing the CO's designated NAICS code 334220, which covers broadcast and wireless communications equipment, I find the MEADs clearly perform a telecommunications function. As already discussed, they are worn by the patient, and the patient uses them to send an electronic signal to medical personnel in the event of a medical emergency. The device can also notify the medical personnel if the patient falls. The MTRs emphasize the electronic and telecommunications features of the MEADs. The MTRs use such terms as 4G mobile functionality, 911 call functionality, GPS functionality, speaker and microphone. Aligned with its communication functionality, the technical panel evaluating the proffered MEADs will consider telecommunication factors, such as push-button connection features, auto fall detection, responsiveness if exposed to water, responsiveness and speed of call center response, and clarity of communication. Section II.A, *supra*.

The Solicitation clearly identifies the MEADs are for communication, and unlike hearing aids, pacemakers, or other electronic medical devices, they do not perform medical or therapeutic functions. *Id.* They do not deliver medication, provide therapeutic electronic stimulus, or enhance any of the patient's senses. Rather, they communicate with medical assistance when the patient is in distress. The devices appear to perform the same function that a telephone would, summoning assistance for a distressed patient, but faster, more efficiently — communicating immediately with medical assistance and available on the patient's person.

While the MEAD must be prescribed for the patient, the requirement of a prescription is not mentioned as one of the characteristics of NAICS code 334510, nor is it one excluded from NAICS 334220. Section III, *supra*. The MEAD does alert medical personnel when the patient suffers a fall, but this is not the diagnosis of a medical condition, but an alert to an event befalling the patient. Section II.A, *supra*. On its face, these characteristics do not mandate a characterization of the MEAD as a medical device, rather than a communication device.⁵

Accordingly, I conclude that the CO's designation of NAICS code 334220 for this procurement is correct. Appellant has failed to establish that this designation is based upon any error of fact or law.

Appellant has not demonstrated that the CO's designation of NAICS code 334220 is procurement is clearly erroneous. Therefore, I need not consider the NAICS code Appellant advocates, or other alternative codes. It is well settled that “OHA will not assign a different

⁵ 85 Fed. Reg. 84245 (Dec. 28, 2020) appears to exclude communicative devices from medical devices on Prosthetic and Rehabilitative Items and Services, when the rules clearly revise “the definition of the term home medical equipment in § 17.3210 as proposed to remove the restriction on medical alert devices, and [] further delete the proposed definition of medical alert device as it will no longer be needed.” *Id.*, at 84246. Indeed, the VA distinguishes between “monitoring or preventive function,” to “actively and directly contributing to treatment” and carves out the possibility for a prescribing clinician “to assess clinical needs on a case by case basis” to patients who would need a communicative device for treatment or rehabilitative purposes. *Id.* However, the VA's ruling and changes are not in the context of NAICS codes, so they are not pertinent or controlling when the NAICS Manual and RFP contain enough information to make my findings.

NAICS code to a procurement unless the CO's choice of NAICS code is shown to be clearly erroneous.” *NAICS Appeal of Elevated Technologies, Inc.*, SBA No. NAICS-6264 (2024).

V. Conclusion

For the above reasons, I DENY the instant appeal. The CO appropriately selected NAICS code 334220, Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, with a corresponding 1,250 employee size standard for this instant procurement.

This is the final decision of the U.S. Small Business Administration. *See* 13 C.F.R. § 134.316(d); FAR 19.103(a)(7).

CHRISTOPHER HOLLEMAN
Administrative Judge