STATE BOARD OF EQUALIZATION
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June 6, 2011

------ [A]
Senior Manager
--- ----, LLP
-- --- ---- -------- -----, ----- ---
--- -----, CA XXXXX

Re: Unidentified Client
Taxability of Sleep Apnea Treatment Device
Assignment No.: 11-043

Dear Mr. [A]:

This is in reply to your letter of January 26, 2011, to Robert Tucker, Tax Counsel IV with the State Board of Equalization (BOE), which has been referred to me for response. In your letter, you request, on behalf of an unnamed client (Client), a legal opinion addressing whether Client's sleep apnea treatment device is a medicine as defined in Revenue and Taxation Code section 6369.[1]

As discussed below, our conclusion is that Client's sleep apnea treatment device is a medicine and that Client is not liable for use tax on the free samples of the product and the product demonstration kits that Client provides to licensed physicians for the treatment of a human being. On the other hand, Client is liable for the use tax on the diagnostic tools it furnishes to licensed physicians, unless another exemption applies, as these tools are not medicines. Initially, however, I note that, since you have not identified your client and the specific product in question, this opinion provides only general information, and Client may not rely on it as a basis for relief from sales or use tax with respect to this product under section 6596.[2]

Nevertheless, although only general in nature, the opinions expressed in this letter are based on the facts as they have been stated in your letters of January 26, 2011, to Robert Tucker (Tucker Letter) and April 28, 2010, to the Sales and Use Tax Audit and Information Section (Audit Letter). If the actual facts differ from those stated in these letters, as summarized below, or if the assumptions we have made are incorrect, the opinions expressed herein may not apply. If the facts are not as they have been summarized or assumed to be, please feel free to write again with further clarifying information.

[1] All future statutory references are to the Revenue and Taxation Code unless indicated otherwise.
[2] See Cal. Code Regs., tit. 18, § 1705, subd. (b)(1).

BACKGROUND FACTS

In the Audit Letter, you state that Client is a medical device company that provides a product that treats the condition called obstructive sleep apnea (OSA). You state further that Client sells this product to distributors for resale to end users or patients. In addition, you state that Client provides free samples of this product to licensed physicians through its sales representatives and to distributors, who provide them for free to licensed physicians. You also state that Client provides free demonstration kits and diagnostic tools to physicians: the demonstration kit contains product samples (we are assuming only samples of the product in question here) that are used by the physician, in his or her office, to instruct patients on how to properly wear (we assume attach) the product before they go to sleep and are then discarded; the diagnostic tools enable physicians to determine if the product is helping their patients.

You describe OSA in the Audit Letter as a chronic disorder characterized by pauses in breathing or shallow breaths during sleep that affects approximately 50 million people in the United States. In the Tucker Letter, you comment further that people with OSA have been medically diagnosed with a narrower or more collapsed airway than normal at the base of the tongue and soft palate. You explain that, during sleep, the abnormal relaxation of muscles in the throat can cause the tongue and palate to fall backwards, further closing the already narrowed airway, and Client's product assists the human body by creating air pressure that keeps the airway open, assisting the patient to breathe normally. You explain further that Client's product assists and supports the muscles and other soft tissues in the patient's throat and prevents the tongue and soft palate from further closing the patient's airway.

In both letters, you note that Client's product is available only by prescription and is designed for single use only (i.e., it is disposable). You describe the product as containing a pair of special valves, each of which is separately embedded on adhesive tape and each of which is placed just inside a nostril opening and held in place by the adhesive tape, so that each nostril opening is completely covered by the valves. You state that the product is powered by the patient's own breathing through the product's valves, in that, during inhalation, the valves open completely, allowing the patient to breathe in freely, then, during exhalation, the valves close, directing the air flow (from, we assume, the patient's lungs) through two smaller air channels in the valve, which increases the air pressure in the patient's airway and helps keep the patient's airway open.

In the Tucker Letter, you note that the product is completely portable and that patients are able to move around freely while the product is attached to their nostrils.

Lastly, we assume that the "distributors" to whom Client sells the product for resale will prescribe, furnish or sell the product in accordance with the provisions of section 6369, subdivision (a), or California Code of Regulations, title 18, section (Regulation or Reg.) 1591, subdivision (b)(5) and (6), described below. We assume further that Client is a pharmaceutical manufacturer or distributor located in California and that the product in question is sold or provided for use by physicians and patients located in California.

DISCUSSION

Applicable Law

As a starting point, California imposes a sales tax measured by a retailer's gross receipts from the retail sale of tangible personal property (TPP) in this state, unless the sale is specifically exempted from taxation by statute. (§§ 6051, 6091.) The sales tax is imposed on the retailer who may collect reimbursement from its customer if the contract of sale so provides. (Civ. Code, § 1656.1; Reg. 1700.) When sales tax does not apply, use tax is imposed, measured by the sales price of TPP purchased from a retailer for the storage, use, or other consumption of TPP in California, unless specifically exempted or excluded from taxation by statute. (§§ 6201, 6401.) The use tax is imposed on the person who actually stores, uses, or otherwise consumes the TPP. (§ 6202.)

With respect to the issue presented here, section 6369 exempts from sales and use taxes the sale of "medicines," if they are dispensed or otherwise provided to the patient under certain specified circumstances.[3] (§ 6369, subd. (a).) "Medicines" includes "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease." (§ 6369, subd. (b).) "Medicines" does not include, among other things, "[a]rticles that are in the nature of . . . instruments, apparatus, contrivances, appliances, devices, or other mechanical . . . or physical equipment or article or the component parts and accessories thereof." (§ 6369, subd. (b)(2).) However, "medicines" does include certain articles, including, among others, "[p]rosthetic devices, and replacement parts for those devices, designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body . . . ." (§ 6369, subd. (c)(4).)

Regulation 1591 provides clarification regarding the application of sales and use taxes to "medicines" and medical devices. With respect to the product in question here, the term "medicines" means and includes prosthetic devices. (Reg. 1591, subd. (b)(5).) As stated, those prosthetic devices that are "designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body[] are medicines," and these devices and their replacement parts are not subject to tax as long as they are dispensed or otherwise provided to a patient under certain specified circumstances. (Reg. 1591, subd. (b)(5) & (d) [see footnote 3].) However, prosthetic devices do not have to be furnished by a pharmacist, as specified in

[3] For a sale of "medicines" to qualify for exemption from sales or use tax, it must be: "(1) Prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a registered pharmacist in accordance with law[;] (2) Furnished by a licensed physician and surgeon, dentist, or podiatrist to his or her own patient for treatment of the patient[;] (3) Furnished by a health facility for treatment of any person pursuant to the order of a licensed physician and surgeon, dentist, or podiatrist[;] (4) Sold to a licensed physician and surgeon, podiatrist, dentist, or health facility for the treatment of a human being[;] (5) Sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof[; or] (6) Furnished without charge by a pharmaceutical manufacturer or distributor to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or furnished by a pharmaceutical manufacturer or distributor without charge to an institution of higher education for instruction or research, provided that the exemption provided in this paragraph is limited to medicines of a type that can be dispensed only (A) for the treatment of a human being and (B) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided in this paragraph shall include the materials used to package, and the constituent elements and ingredients used to produce, the medicines described in this paragraph and is intended to preclude any imposition of tax pursuant to Section 6094 or 6095 with respect to those materials, elements, and ingredients." (§ 6369, subd. (a); see also Reg. 1591, subd. (d).)

subdivision (d)(1) of the regulation, to be considered dispensed on a prescription, as long as they are furnished pursuant to a written order from a physician, by, for example, a medical device retailer, clinic, or device supplier. (Reg. 1591, subd. (b)(5).)

Regulation 1591 does state that, "except as otherwise provided in subdivision (b)," articles in the nature of "instruments, apparatus, contrivances, appliances, devices or other mechanical . . . or physical equipment or article or the component parts and accessories thereof" are excluded from the definition of "medicines." (Reg. 1591, subd. (c)(2) [emphasis added].) In addition, Regulation 1591 states that "tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids," except as provided in Regulation 1591.1, subdivision (b)(4), which pertains to catheters and is not applicable here. (Reg. 1591, subd. (e)(8).)

Responses to the Questions Posed

Responses to each of the questions posed about the taxability of the product follow, in the order the questions were presented.

1. *Is the product sold by Client a "medicine" as defined in section 6369 and Regulation 1591?*

As noted above, a device that is "designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body" is a prosthetic device that is a "medicine," the sale and storage, use, or other consumption of which is exempt from sales and use tax. (§ 6369, subd. (c)(4); Reg. 1591, subd. (b)(5).) Based on the facts provided and summarized above, the product in question here is worn on a patient suffering from OSA and assists the functioning of the patient's airway, which is a natural part of the patient's body, by increasing the air pressure in the patient's airway during exhalation and keeping it open during inhalation.

You have indicated that you were advised that Client's product is not a medicine because, as stated in Sales and Use Tax Publication 45, entitled Hospitals and Other Medical Facilities, "[d]evices that only assist the patient's breathing process and, as such, do not deliver air or oxygen directly into the patient's lungs" are not "medicines."[4] (*Id.* at p. 9.) This portion of the publication explains which products are "medical oxygen delivery systems," not which products are prosthetic devices. There is nothing in the definition of "prosthetic devices" that implies that air or oxygen must be delivered directly into a patient's lungs for a device to be considered a "prosthetic device."

As noted previously, "medicines" does not include certain articles, specifically, "articles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article." (§ 6369, subd. (b)(2); Reg. 1591, subd. (c) ["medicines" also does not include such things as arch supports, cervical pillows, or hospital beds].) It is an accepted principle of statutory construction that, "when a statute contains a list or catalogue of items, a court should determine the meaning of each by reference to the others, giving preference to an

[4] Sales and Use Tax Annotation 425.0270 and the opinion letter on which this statement appears to have been based entirely on Regulation 1591, subdivision (m), concerning medical oxygen delivery systems. Subdivision (m) was deleted from Regulation 1591 effective March 10, 2000. Consequently, Annotation 425.0270 should be depublished.

interpretation that uniformly treats items similar in nature and scope." (*Moore v. California State Bd. of Accountancy* (1992) 2 Cal.4th 999, 1011-1012 [emphasis added].) Further, "a court will adopt a restrictive meaning of a listed item if acceptance of a more expansive meaning would make other items in the list unnecessary or redundant, or would otherwise make the item markedly dissimilar to the other items in the list." (*Id.* at p. 1012.) In other words, a "device," for example, as the term is used in subdivision (b)(2), should be interpreted to be similar in nature and scope to bandages, splints, or cervical pillows. In keeping with this interpretation, the term "medicines" specifically includes prosthetic devices, "notwithstanding" subdivision (b)(2), because, we may posit, they are different in nature and scope from bandages, splints, and cervical pillows – they, as relevant here, "assist the functioning of a natural part of the human body." (§ 6369, subd. (c)(4).)

Accordingly, it is our opinion that Client's product is a prosthetic device as defined in section 6369, subdivision (c)(4), and Regulation 1591, subdivision (b)(5), and is, therefore, a "medicine."

2. *When a distributor sells Client's product to medical clinics and to patients who have prescriptions, are the sales exempt from sales and use tax?*

As concluded above, yes, sales of Client's products by distributors to medical clinics and patients with prescriptions or written orders from licensed physicians are exempt from sales and use tax.

3. *When Client's sales representatives provide free samples of the product to licensed physicians, who will prescribe or furnish the sample product (pursuant to Regulation 1591, subdivision (d)(2)) to their patients, are the free samples exempt from use tax?*

Since, as concluded above, Client's product is a medicine, and assuming Client is a pharmaceutical manufacturer or distributor, Client would not be liable for the use tax that would otherwise be due, pursuant to Regulation 1670, on the free samples of the product its sales representatives provide to licensed physicians. (§ 6369, subd. (a)(6); Reg. 1591, subd. (d)(6); Reg. 1670, subd. (a).)

4. *When Client provides free samples of the product to distributors who, in turn, give them to physicians, who will prescribe or furnish the sample product (pursuant to Regulation 1591, subdivision (d)(2)) to their patients, are the free samples exempt from use tax?*

Again, since, as concluded above, Client's products are medicines, and assuming Client is a pharmaceutical manufacturer or distributor and the distributors are pharmaceutical distributors, neither Client nor the distributors would be liable for the use tax that would otherwise be due, pursuant to Regulation 1670, on the free samples of the product Client provides to the distributors and the distributors provide to licensed physicians or health facilities. (§ 6369, subd. (a)(6); Reg. 1591, subd. (d)(60; Reg. 1670, subd. (a).) On the other hand, if Client or the distributors furnish Client's product for free to someone who is not a licensed physician or surgeon or a health facility, Client or the distributors who furnish the product to such a person would be liable for the use tax. (See § 6369, subd. (a)(2) & (3).)

5. *When Client provides free demonstration kits to licensed physicians so they can instruct their patients in the use of the product, are the free demonstration kits exempt from use tax?*

If, as described in the Audit Letter, the demonstration kits include only the product in question here, along with applicable literature, then, again, since Client's product is a "medicine," Client would not be liable for the use tax that would otherwise be due on these kits, pursuant to Regulation 1670, subdivision (a). (Reg. 1591, subd. (d)(6).) However, if the demonstration kits include any other article or device besides the product in question here, the above analysis concluding that Client's product is a prosthetic device and, therefore, a "medicine," may not be applicable, and Client may be liable for use tax on the demonstration kits it provides to licensed physicians. (Reg. 1591, subd. (c)(2); Reg. 1670, subd. (a).)

6. *When Client provides free diagnostic tools to licensed physicians, are the diagnostic tools exempt from the use tax?*

No information has been provided as to the nature of the free "diagnostic tools" that Client provides to licensed physicians to determine if Client's product is helping their patients. However, it is reasonable to assume that the above analysis, concluding that Client's product is a prosthetic device and, therefore, a "medicine," would not be applicable to these diagnostic tools because they are not the product itself or replacement parts for the product. In addition, diagnostic test kits do not generally qualify as "medicines," and the sale or use of such test kits is, therefore, subject to sales or use tax. (Reg. 1591, subd. (e)(8) ["tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids"].)

Unless another exemption is applicable to these diagnostic tools, Client would be liable for the use tax on the free diagnostic tools it provides to licensed physicians. (Reg. 1670, subd. (a).)

Please let me know if you have any questions regarding the information provided here.

Sincerely,

Carolee D. Johnstone
Tax Counsel III (Specialist)

CDJ:mcb

cc: Santa Clara District Administrator (GH)
Kevin Hanks (MIC:49)
Randy Ferris (MIC:82)
Stephen Smith (MIC:82)
Robert Tucker (MIC:82)
Cary Huxsoll (MIC:82)

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September 19, 2012

----- [B]
X & X. LLP
---- and ------ --------
--- --------- -----, ---- Z
-- ----, -- XXXXX

Re: [A]
XXX XX X-XXXXX
Taxability of [ABC] Sleep Apnea Therapy
Assignment No.: 12-379

Dear Ms. [B]:

This is in response to your letter of August 21, 2012, in which you request that a legal opinion previously issued by the Board of Equalization (BOE) with respect to an unnamed taxpayer's sleep apnea treatment device, be reissued to [A] (Company), the unnamed taxpayer in the prior opinion. Following is the opinion, modified as necessary for Company, confirming that the [ABC] Sleep Apnea Therapy device (Device) is a medicine as defined in Revenue and Taxation Code section 6369.[1]

As discussed below, our conclusion is that Company's Device is a medicine and that Company is not liable for use tax on the free samples of the Device and the Device demonstration kits that Company provides to licensed physicians for the treatment of a human being. On the other hand, Company is liable for the use tax on the diagnostic tools it furnishes to licensed physicians, unless another exemption applies, as these tools are not medicines.

Initially, however, I note that the opinions expressed in this letter are based on the facts as they have been stated in your letter and Mr. ----- ----'s letters of January 26, 2011, to Robert Tucker (Tucker Letter) and April 28, 2010, to the Sales and Use Tax Audit and Information Section (Audit Letter),[2] and the assumptions stated herein. If the actual facts differ from these facts, as summarized below, or if the assumptions we have made are incorrect, the opinions expressed herein may not be reliable. Provided that the facts in this letter (both summarized and assumed) are accurate and verifiable by audit, Company may rely on this response for purposes of section 6596. (See Cal. Code Regs., tit. 18, § (Regulation or Reg.) 1705, subd. (b)(1) [explaining the circumstances under which written advice from the Board may be relied upon for the purpose of relief from liability].) If the facts are not as they have been summarized or understood or assumed to be, please feel free to write again with further clarifying information.

[1] All future statutory references are to the Revenue and Taxation Code unless indicated otherwise.
[2] Mr. VVV, Senior Manager of GHI KKK, LLP Accountants and Consultants, requested the prior opinion.

BACKGROUND FACTS

The Audit Letter states that Company is a medical device company that provides a Device that treats the condition called obstructive sleep apnea (OSA). It states further that Company sells this Device to distributors for resale to end users or patients. In addition, it states that Company provides free samples of this Device to licensed physicians through its sales representatives and to distributors, who provide them for free to licensed physicians. The Audit Letter also states that Company provides free demonstration kits and diagnostic tools to physicians: the demonstration kit contains product samples (we are assuming only samples of the product in question here) that are used by the physician, in his or her office, to instruct patients on how to properly wear (we assume attach) the Device before they go to sleep and are then discarded; the diagnostic tools enable physicians to determine if the Device is helping their patients.

The Audit Letter describes OSA as a chronic disorder characterized by pauses in breathing or shallow breaths during sleep that affects approximately 50 million people in the United States. The Tucker Letter comments further that people with OSA have been medically diagnosed with a narrower or more collapsed airway than normal at the base of the tongue and soft palate. The Tucker Letter explains that, during sleep, the abnormal relaxation of muscles in the throat can cause the tongue and palate to fall backwards, further closing the already-narrowed airway, and Company's Device assists the human body by creating air pressure that keeps the airway open, assisting the patient to breathe normally. The Tucker Letter explains further that Company's Device assists and supports the muscles and other soft tissues in the patient's throat and prevents the tongue and soft palate from further closing the patient's airway.

In both letters, it is noted that Company's Device is available only by prescription and is designed for single use only (i.e., it is disposable). They describe the Device as containing a pair of special valves, each of which is separately embedded on adhesive tape and each of which is placed just inside a nostril opening and held in place by the adhesive tape, so that each nostril opening is completely covered by the valves. The letters state that the Device is powered by the patient's own breathing through the Device's valves, in that, during inhalation, the valves open completely, allowing the patient to breathe in freely, then, during exhalation, the valves close, directing the air flow (from, we assume, the patient's lungs) through two smaller air channels in the valve, which increases the air pressure in the patient's airway and helps keep the patient's airway open.

The Tucker Letter notes that the Device is completely portable and that patients are able to move around freely while the Device is attached to their nostrils.

Lastly, we assume that the "distributors" to whom Company sells the Device for resale will prescribe, furnish, or sell the Device in accordance with the provisions of section 6369, subdivision (a), or Regulation 1591, subdivision (b)(5) and (6), described below. We assume further that Company is a pharmaceutical manufacturer or distributor and that the Device in question is sold or provided for use by physicians and patients located in California, and we understand that Company is located in --- ----, California.

DISCUSSION

Applicable Law

As a starting point, California imposes a sales tax measured by a retailer's gross receipts from the retail sale of tangible personal property (TPP) in this state, unless the sale is specifically exempted from taxation by statute. (§§ 6051, 6091.) The sales tax is imposed on the retailer who may collect reimbursement from its customer if the contract of sale so provides. (Civ. Code, § 1656.1; Reg. 1700.) When sales tax does not apply, use tax is imposed, measured by the sales price of TPP purchased from a retailer for the storage, use, or other consumption of TPP in California, unless specifically exempted or excluded from taxation by statute. (§§ 6201, 6401.) The use tax is imposed on the person who actually stores, uses, or otherwise consumes the TPP. (§ 6202.)

With respect to the issue presented here, section 6369 exempts from sales and use taxes the sale of "medicines," if they are dispensed or otherwise provided to the patient under certain specified circumstances.[3] (§ 6369, subd. (a).) "Medicines" includes "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease." (§ 6369, subd. (b).) "Medicines" does not include, among other things, "[a]rticles that are in the nature of . . . instruments, apparatus, contrivances, appliances, devices, or other mechanical . . . or physical equipment or article or the component parts and accessories thereof." (§ 6369, subd. (b)(2).) However, "medicines" does include certain articles, including, among others, "[p]rosthetic devices, and replacement parts for those devices, designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body . . . ." (§ 6369, subd. (c)(4).)

Regulation 1591 provides clarification regarding the application of sales and use taxes to "medicines" and medical devices. With respect to the Device in question here, the term "medicines" means and includes prosthetic devices. (Reg. 1591, subd. (b)(5).) As stated, those prosthetic devices that are "designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body[] are medicines," and these devices and their replacement parts are not subject to tax as long as they are dispensed or otherwise provided to a patient under certain specified circumstances. (Reg. 1591, subd. (b)(5) & (d) [see footnote 3].)

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[3] For a sale of "medicines" to qualify for exemption from sales or use tax, it must be: "(1) Prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a registered pharmacist in accordance with law[;] (2) Furnished by a licensed physician and surgeon, dentist, or podiatrist to his or her own patient for treatment of the patient[;] (3) Furnished by a health facility for treatment of any person pursuant to the order of a licensed physician and surgeon, dentist, or podiatrist[;] (4) Sold to a licensed physician and surgeon, podiatrist, dentist, or health facility for the treatment of a human being[;] (5) Sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof[; or] (6) Furnished without charge by a pharmaceutical manufacturer or distributor to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or furnished by a pharmaceutical manufacturer or distributor without charge to an institution of higher education for instruction or research, provided that the exemption provided in this paragraph is limited to medicines of a type that can be dispensed only (A) for the treatment of a human being and (B) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided in this paragraph shall include the materials used to package, and the constituent elements and ingredients used to produce, the medicines described in this paragraph and is intended to preclude any imposition of tax pursuant to Section 6094 or 6095 with respect to those materials, elements, and ingredients." (§ 6369, subd. (a); see also Reg. 1591, subd. (d).)

However, prosthetic devices do not have to be furnished by a pharmacist, as specified in subdivision (d)(1) of the regulation, to be considered dispensed on a prescription, as long as they are furnished pursuant to a written order from a physician, by, for example, a medical device retailer, clinic, or device supplier. (Reg. 1591, subd. (b)(5).)

Regulation 1591 does state that, "except as otherwise provided in subdivision (b)," articles in the nature of "instruments, apparatus, contrivances, appliances, devices or other mechanical . . . or physical equipment or article or the component parts and accessories thereof" are excluded from the definition of "medicines." (Reg. 1591, subd. (c)(2) [emphasis added].) In addition, Regulation 1591 states that "tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids," except as provided in Regulation 1591.1, subdivision (b)(4), which pertains to catheters and is not applicable here. (Reg. 1591, subd. (e)(8).)

Responses to the Questions Posed

Responses to each of the questions posed about the taxability of the Device follow, in the order the questions were presented.

1. *Is the Device sold by Company a "medicine" as defined in section 6369 and Regulation 1591?*

As noted above, a device that is "designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body" is a prosthetic device that is a "medicine," the sale and storage, use, or other consumption of which is exempt from sales and use taxes. (§ 6369, subd. (c)(4); Reg. 1591, subd. (b)(5).) Based on the facts provided and summarized above, the Device in question here is worn on a patient suffering from OSA and assists the functioning of the patient's airway, which is a natural part of the patient's body, by increasing the air pressure in the patient's airway during exhalation and keeping it open during inhalation.

It was previously indicated that Company was advised that Company's Device is not a medicine because, as stated in Sales and Use Tax Publication 45, entitled Hospitals and Other Medical Facilities, "[d]evices that only assist the patient's breathing process and, as such, do not deliver air or oxygen directly into the patient's lungs" are not "medicines."[4] (*Id.* at p. 9.) This portion of the publication explains which products are "medical oxygen delivery systems," not which products are prosthetic devices. There is nothing in the definition of "prosthetic devices" that implies that air or oxygen must be delivered directly into a patient's lungs for a device to be considered a "prosthetic device."

As noted previously, "medicines" does not include certain articles, specifically, "articles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article." (§ 6369, subd. (b)(2); Reg. 1591, subd. (c) ["medicines" also does not include such things as arch supports, cervical pillows, or hospital beds].) It is an accepted principle of statutory construction that, "when a statute contains a list or catalogue of items, a court should determine the meaning of each by reference to the others, giving preference to an

[4] See Sales and Use Tax Annotation 425.0270 on which this statement appears to have been based, concerning medical oxygen delivery systems.

interpretation that uniformly treats items similar in nature and scope." (*Moore v. California State Bd. of Accountancy* (1992) 2 Cal.4th 999, 1011-1012 [emphasis added].) Further, "a court will adopt a restrictive meaning of a listed item if acceptance of a more expansive meaning would make other items in the list unnecessary or redundant, or would otherwise make the item markedly dissimilar to the other items in the list." (*Id.* at p. 1012.) In other words, a "device," for example, as the term is used in subdivision (b)(2), should be interpreted to be similar in nature and scope to bandages, splints, or cervical pillows. In keeping with this interpretation, the term "medicines" specifically includes prosthetic devices, "notwithstanding" subdivision (b)(2), because, we may posit, they are different in nature and scope from bandages, splints, and cervical pillows – they, as relevant here, "assist the functioning of a natural part of the human body." (§ 6369, subd. (c)(4).)

Accordingly, it is our opinion that Company's Device is a prosthetic device as defined in section 6369, subdivision (c)(4), and Regulation 1591, subdivision (b)(5), and is, therefore, a "medicine."

2. *When a distributor sells Company's Device to medical clinics and to patients who have prescriptions, are the sales exempt from sales and use tax?*

As concluded above, yes, sales of Company's Devices by distributors to medical clinics and patients with prescriptions or written orders from licensed physicians are exempt from sales and use tax.

3. *When Company's sales representatives provide free samples of the Device to licensed physicians, who will prescribe or furnish the sample Device (pursuant to Regulation 1591, subdivision (d)(2)) to their patients, are the free samples exempt from use tax?*

Since, as concluded above, Company's Device is a medicine, and assuming Company is a pharmaceutical manufacturer or distributor, Company would not be liable for the use tax that would otherwise be due, pursuant to Regulation 1670, on the free samples of the Device its sales representatives provide to licensed physicians. (§ 6369, subd. (a)(6); Reg. 1591, subd. (d)(6); Reg. 1670, subd. (a).)

4. *When Company provides free samples of the Device to distributors who, in turn, give them to physicians, who will prescribe or furnish the sample Device (pursuant to Regulation 1591, subdivision (d)(2)) to their patients, are the free samples exempt from use tax?*

Again, since, as concluded above, Company's Devices are medicines, and assuming Company is a pharmaceutical manufacturer or distributor and the distributors are pharmaceutical distributors, neither Company nor the distributors would be liable for the use tax that would otherwise be due, pursuant to Regulation 1670, on the free samples of the Device Company provides to the distributors and the distributors provide to licensed physicians or health facilities. (§ 6369, subd. (a)(6); Reg. 1591, subd. (d)(60; Reg. 1670, subd. (a).) On the other hand, if Company or the distributors furnish Company's Device for free to someone who is not a licensed physician or surgeon or a health facility, Company or the distributors who furnish the Device to such a person would be liable for the use tax. (See § 6369, subd. (a)(2) & (3).)

5. *When Company provides free demonstration kits to licensed physicians so they can instruct their patients in the use of the Device, are the free demonstration kits exempt from use tax?*

If, as described in the Audit Letter, the demonstration kits include only the Device in question here, along with applicable literature, then, again, since Company's Device is a "medicine," Company would not be liable for the use tax that would otherwise be due on these kits, pursuant to Regulation 1670, subdivision (a). (Reg. 1591, subd. (d)(6).) However, if the demonstration kits include any other article or device besides the Device in question here, the above analysis concluding that Company's Device is a prosthetic device and, therefore, a "medicine," may not be applicable, and Company may be liable for use tax on the demonstration kits it provides to licensed physicians. (Reg. 1591, subd. (c)(2); Reg. 1670, subd. (a).)

6. *When Company provides free diagnostic tools to licensed physicians, are the diagnostic tools exempt from the use tax?*

No information has been provided as to the nature of the free "diagnostic tools" that Company provides to licensed physicians to determine if Company's Device is helping their patients. However, it is reasonable to assume that the above analysis, concluding that Company's Device is a prosthetic device and, therefore, a "medicine," would not be applicable to these diagnostic tools because they are not the Device itself or replacement parts for the Device. In addition, diagnostic test kits do not generally qualify as "medicines," and the sale or use of such test kits is, therefore, subject to sales or use tax. (Reg. 1591, subd. (e)(8) ["tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids"].)

Unless another exemption is applicable to these diagnostic tools, Company would be liable for the use tax on the free diagnostic tools it provides to licensed physicians. (Reg. 1670, subd. (a).)

Please let me know if you have any questions regarding the information provided here.

Sincerely,

Carolee D. Johnstone
Tax Counsel III (Specialist)

CDJ:mcb

cc: San Jose District Administrator (GH)