

This draft is provided for discussion purposes only to determine what topics a possible proposed rule might address. This discussion draft is under no circumstances to be used to determine a tax liability and/or eligibility for tax exemptions.

12/16/2013 draft

WAC 458-20-18801 ~~Prescription drugs, prosthetic and orthotic devices, ostomic items, and medically prescribed oxygen.~~ Medical substances, devices, and supplies for humans; drugs prescribed for human use; medically prescribed oxygen; prosthetic devices; mobility enhancing equipment; and durable medical equipment.

~~(1) Definitions. As used in this section:~~

~~(a) "Prescription drugs" are medicines, drugs, prescription lenses, or other substances, other than food for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other ailment in humans ordered by (i) the written prescription to a pharmacist by a practitioner authorized by the laws of this state or laws of another jurisdiction to issue prescriptions, or (ii) an oral prescription of such practitioner which is reduced promptly to writing and filled by a duly licensed pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is promptly reduced to writing and filled by the pharmacist, or (iv) physicians or optometrists by way of written directions and specifications for the preparation, grinding, and fabrication of lenses intended to aid or correct visual defects or anomalies of humans.~~

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~~(b) "Prescription" means a formula or recipe or an order written by a medical practitioner for the composition, preparation and use of a healing, curative or diagnostic substance, and also includes written directions and specifications by physicians or optometrists for the preparation, grinding, and fabrication of lenses intended to aid or correct visual defects or anomalies of humans.~~

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~~(c) "Other substances" means products such as catalytics, hormones, vitamins, and steroids, but the term generally does not include devices, instruments, equipment, and similar articles. However, "other substances" does include the needles, tubing, and the bag which are part of an intravenous set for delivery of prescription drugs. It also includes infusion pumps and catheters when used to deliver prescription drugs to a specific patient. These items are not conceptually distinct from the prescription drug solution. This same rationale applies to tubing and needles which are used in placing prescribed nutritional products in the patient's system. The stand which holds the intravenous set is not included nor are plain glass slides, plain specimen collection devices, and similar items which are used in the laboratory. This term does include diagnostic substances and reagents, including prepared slides, tubes and collection specimens devices~~

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~~which contain diagnostic substances and reagents at the time of purchase by a laboratory.~~

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~~(d) "Medical practitioner" means a person within the scope of RCW 18.64.011(9) who is authorized to prescribe drugs, but excluding veterinarians, and for the purposes of this rule includes also persons licensed by chapter 18.53 RCW to issue prescriptions for lenses.~~

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~~(e) "Licensed dispensary" means a drug store, pharmacy, or dispensary licensed by chapter 18.64 RCW or a dispensing optician licensed by chapter 18.34 RCW.~~

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~~(f) "Prosthetic devices" are artificial substitutes which generally replace missing parts of the human body, such as a limb, bone, joint, eye, tooth, or other organ or part thereof, and materials which become ingredients or components of prostheses.~~

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~~(g) "Orthotic devices" are apparatus designed to activate or supplement a weakened or atrophied limb or function. They include braces, collars, casts, splints, and other similar apparatus as well as parts thereof. Orthotic devices do not include durable medical equipment such as wheelchairs, crutches, walkers, and canes nor consumable sup-~~

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~~plies such as embolism stockings, arch pads, belts, supports, bandages, and the like, whether prescribed or not.~~

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~~(h) "Ostomic items" are medical supplies used by colostomy, ileostomy, and urostomy patients. These include bags, tapes, tubes, adhesives, deodorants, soaps, jellies, creams, germicides, and sundry related supplies.~~

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~~(i) "Medically prescribed oxygen" means oxygen prescribed for the use in the treatment of a medical condition. For periods after July 27, 1991, this term shall include, but is not limited to, the sale or rental of oxygen concentrator systems, oxygen enricher systems, liquid oxygen systems, and gaseous, bottled oxygen systems for use by an individual under a prescription. (See RCW 82.08.0283.)~~

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~~(j) "Legend drugs" are those drugs which may not be legally dispensed without a prescription. These drugs are listed in the official United States pharmacopeia or similar source. (See RCW 69.41.010(8).) WAC 246-865-010(5) requires legend drugs to have a label stating that federal law prohibits dispensing without a prescription. Also refer to RCW 69.41.010(9).~~

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~~(k) "Nutrition products" are prescribed dietary substances formulated to provide balanced nutrition as a sole source of nourishment.~~

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~~(2) **Business and occupation tax.** The business and occupation tax applies to the gross proceeds from sales of drugs, medicines, prescription lenses, or other substances used for diagnosis, cure, mitigation, treatment, or prevention of disease or other ailments in humans. Sales of these items to persons for resale are taxable under the wholesaling classification. Sales to consumers are taxable under the retailing classification. Persons who provide medical services to patients are taxable under the service and other business activities classification on the gross charge to the patient, notwithstanding that some prescription drugs may be separately charged to the patient. Persons who provide medical services should refer to WAC 458-20-151 and 458-20-168 for additional tax reporting information.~~

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~~(3) **Deductions.** The following may be deducted from gross proceeds for computing business and occupation tax:~~

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~~(a) Sales of prescription drugs and other medical and healing supplies furnished as an integral part of services rendered by a publicly operated or nonprofit hospital, nonprofit kidney dialysis facil-~~

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~~ity, nursing home, or home for unwed mothers operated as a religious or charitable organization which meets all the conditions for exemption for services generally under RCW 82.04.4288 or 82.04.4289 (see WAC 458-20-168).~~

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~~(4) **Retail sales tax.** The retail sales tax applies upon all retail sales of tangible personal property unless expressly exempted by law.~~

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~~(5) **Exemptions.** The following exemptions apply from the retail sales tax and use tax.~~

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~~(a) Legend drugs are exempt from retail sales tax or use tax when sold for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other ailments of humans. This exemption applies to all levels of sales and distribution of legend drugs, including legend drugs given away as samples. Legend drugs are exempt from sales tax when sold to hospitals, doctors, dentists, or any other medical practitioner, as well as to patients. Sellers of legend drugs are not required to retain a resale certificate or other exemption documentation from the legend drug purchaser. The exemption applies at the time of purchase even if the hospital or medical practitioner who makes such~~

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~~purchases will not resell the legend drug as a separate line item charge to its patient.~~

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~~(b) The retail sales tax does not apply to sales of nonlegend drugs, nutrition products including dietary supplements or dietary adjuncts, medicines, prescription lenses, or other substances, but only when~~

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~~(i) Dispensed by a licensed dispensary~~

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~~(ii) Pursuant to a written prescription~~

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~~(iii) Issued by a medical practitioner~~

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~~(iv) For diagnosis, cure, mitigation, treatment, or prevention of disease or other ailment in humans. (See RCW 82.08.0281.)~~

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~~(c) Laboratory reagents and other diagnostic substances are exempt from retail sales tax when used as part of a test prescribed to diagnose disease in humans. These items include, among others, reagents, calibrators, chemicals, gases, vacutainers with heparin or other chemicals or medicines, and prepared media. Control reagents are~~

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~~exempt, but only when the control reagents are used in performing tests prescribed for a patient. Reagents which are used to merely calibrate equipment and are not related to a test prescribed for a specific patient are not exempt.~~

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~~(d) The retail sales tax exemption applies also to intravenous sets, including the needles and tubing, when used for the administration of drugs prescribed to a patient. This also includes catheters, infusion pumps, syringes, and similar items when used for the delivery of prescription drugs. Medical gas delivery system components, including tubes, nebulizers, ventilators, masks, cannulae and similar items, are not conceptually distinct from the prescribed gases they deliver and are exempt from retail sales or use tax. The medical delivery system includes airway devices (tubes) which are prescribed to keep a patient's airways open and to deliver medical gases.~~

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~~(e) The retail sales tax does not apply to sales of prosthetic devices, orthotic devices prescribed by physicians, osteopaths, or chiropractors, nor to sales of ostomic items. (See RCW 92.08.0283.) Sutures, pacemakers, hearing aids, and kidney dialysis machines are examples of prosthetic devices. Drainage devices which are particular~~

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~~ly prescribed for use on or in a specific patient are exempt from sales or use taxes as prostheses because they either replace missing body parts or assist dysfunctional ones, either on a temporary or permanent basis. A prosthetic device can include a device that is implanted for cosmetic reasons. Hearing aids are also exempt when dispensed or fitted by a person licensed under chapter 18.35 RCW. A heart-lung machine used by a hospital in its surgical department is not an exempt prosthetic device.~~

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~~(f) The sale of medically prescribed oxygen is not subject to retail sales or use tax when sold to an individual having a prescription issued by a person licensed under chapter 18.57 or 18.71 RCW for use in the medical treatment of that individual.~~

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~~(g) The retail sales tax does not apply to the purchase of anesthesia gases, medical gases, contrast media, or irrigation solutions when these items are used under a physician's order as part of a medical treatment for a specific patient.~~

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~~(6) **Proof of exemption.** Persons selling legend drugs need only to substantiate that the drugs meet the definition of legend drugs and are for use in the diagnosis, cure, mitigation, treatment, prevention~~

~~of disease or other ailments in humans. Resale certificates or other exemption certificates are not required for these sales. For sales to consumers of nonlegend drugs, sellers must retain in their files the written prescription bearing the signature of the medical practitioner who issued the prescription and the name of the patient for whom prescribed. See also WAC 458-20-150 Optometrists, ophthalmologists, and oculists; 458-20-151 Dentists, dental laboratories and physicians; and 458-20-168 Hospitals.~~

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~~(a) Hospitals and physicians who purchase drugs for use in providing medical services to patients may purchase the drugs without payment of retail sales tax if the drugs will only be dispensed under a physician's order. It is not required that the hospital or physician make a specific charge to the patient for drugs dispensed under a physician's order for the drug purchase to be exempt from retail sales or use tax. This also includes the purchases of intravenous sets, catheters, infusion pumps, syringes, and similar items which will be used for delivery of prescription drugs. The hospital or physician may give the nonlegend drug supplier an exemption certificate. The certificate should be retained by the seller for a period of five years after the last sale covered by the certificate. Certificates should not be sent~~

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~~to the department of revenue. The certificate should be in the following form:~~

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~~Prescription drug exemption certificate~~

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~~(name of purchaser)~~

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~~(address of purchaser)~~

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~~I hereby certify: That I am a registered Washing-  
ton taxpayer. I may legally prescribe or dispense drugs or  
other substances. I further certify that the drugs and other  
substances listed below purchased from . . . . . (name of  
vendor) will be prescribed and used for the treatment of  
illness or ailments of human beings. I shall maintain invoice  
es and prescriptions or such other records as are necessary  
to account for the disposition of the drugs or other substance  
es for which I have not paid retail sales tax. In the event that  
any such drug or substance is used without a prescription  
being issued, it is understood that I am required to report  
and pay use tax measured by its purchase price. If I have  
indicated that this is a blanket certificate, this certificate  
shall be considered part of each order which I may hereafter  
give to you, unless otherwise specified, and shall be valid  
for a period of four years or until revoked by me in writing.  
Description of drugs and other substances to be purchased:~~

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**DRAFT**

\_\_\_\_\_

\_\_\_\_\_

Dated: \_\_\_\_\_

Single Purchase . . . . . Blanket Certificate \_\_\_\_\_

(indicate by check mark if certificate is for a single  
purchase or continuing purchases)

\_\_\_\_\_

(signature of purchaser or authorized agent)

(title)

\_\_\_\_\_

(Revenue registration number of buyer)

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~~(b) A blanket exemption certificate may be given if there will be continuing purchases from a particular supplier. Blanket exemption certificates should be renewed at intervals not to exceed four years. The purchaser should indicate by an appropriate check mark on the certificate whether the certificate is being used for a single purchase or will be for continuing purchases. It is unnecessary to list each and every drug on the exemption certificate if all drugs purchased from a particular supplier are exempt.~~

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~~(7) **Use tax.** The use tax does not apply to the use of articles and products which are exempt from sales tax as specified herein. (See RCW 82.12.0277.) This includes legend drugs which are given away as samples.~~

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~~(8) **Examples.** The following examples identify a number of facts and then state a conclusion. These examples should be used only as a general guide. The tax status of each situation must be determined after a review of all of the facts and circumstances.~~

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~~(a) ABC Hospital purchases both legend and nonlegend drugs. These drugs are held in inventory and dispensed to patients only under the written order of the patient's physician. These drugs are not billed~~

~~specifically to the patient, but the cost is recovered through a general floor charge to the patient. ABC Hospital may purchase these drugs without payment of sales or use tax.~~

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~~(b) ABC Hospital purchases reagents for use in its laboratory which are nonlegend drugs. Laboratory reagents are chemical compounds used to promote reactions in the laboratory to aid in determining disease pathology and are not administered directly to the patient. These reagents are used for three purposes consisting of tests on the tissue from a specific patient, a control reagent which is not applied to the tissue from the patient but is used to measure or control the reaction, and a reagent used to calibrate equipment. The reagents used for the first two purposes may be purchased without payment of sales or use tax. The reagents for the calibration of equipment are also exempt if the equipment is calibrated as part of tests for a specific patient. Reagents used to calibrate equipment that is not part of a prescribed test for a patient are taxable.~~

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~~(c) XY Blood Bank purchases reagents which are nonlegend drugs. These reagents are used in determining the blood type and presence of disease. The blood is sold to local hospitals. The purchase of these~~

~~reagents is taxable since they are not used to provide treatment for a specific patient.~~

## **Part 1. INTRODUCTION**

(101) **Introduction.** This rule provides tax-reporting information for persons making sales of medical products. It also provides information about the retail sales tax and use tax exemptions available for the sale and use of certain medical products for humans.

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(102) **How is this rule organized?** This rule is divided into five parts as follows:

(a) **Part 1. Introduction.** Part 1 provides information relating to the purpose of the rule, how the rule is organized, and provides a listing of additional rules that may be helpful to the reader in determining taxability related to medical products.

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(b) **Part 2. Medical Products.** Part 2 of this rule identifies what "medical products" include for purposes of this rule. "Medical products" is not a statutory term, but instead, is a term used simply to collectively describe the medical items addressed by this rule.

(c) **Part 3. Applicable Taxes.** Part 3 of this rule provides information on the taxes that apply to the sale, use, purchase, or manufacture of medical products.

(d) **Part 4. Common Exemptions.** Part 4 of this rule provides information on common retail sales tax and use tax exemptions related to medical products.

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(e) **Part 5. Bundled transactions.** Part 5 of this rule addresses the treatment of bundled transactions involving medical products.

(103) **How are examples included in this rule to be used?** This rule contains examples which identify a number of facts and then state a conclusion. The examples should be used only as a general guide. The tax results of other situations must be determined after a review of all of the facts and circumstances.



(104) What are some other department of revenue rules that address medical or health related providers that might apply? The department of revenue (department) has adopted other rules addressing the taxability of various activities related to the providing of health care. Readers may want to refer to the department's web site at dor.wa.gov and or the following rules for additional information:

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(a) WAC 458-20-150 Optometrists, ophthalmologists, and opticians;

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(b) WAC 458-20-151 Dentists and other health care providers, dental laboratories and dental technicians;

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(c) WAC 458-20-168 Hospitals, medical care facilities, and adult family homes.

## Part 2. MEDICAL PRODUCTS

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(201) What are medical products for purposes of this rule? Medical products include durable medical equipment, drugs, mobility enhancing equipment, over-the-counter drugs, and prosthetic devices as defined by Washington statute. Medical products also include other tangible personal property used for medical purposes, not covered by one of the statutory definitions. The remainder of Part 2 of this rule describes these medical products.

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(202) What is durable medical equipment? Durable medical equipment is equipment, including repair and replacement parts for durable medical equipment that:

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(a) Can withstand repeated use;

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(b) Is primarily and customarily used to serve a medical purpose;

(c) Generally is not useful to a person in the absence of illness or injury; and

(d) Is not worn in or on the body. See RCW 82.08.0283. Also, see subsection (206) (b) of this rule for an explanation of what is considered "worn in or on the body."

Table 1 below provides a non-exclusive list of durable medical equipment product examples.

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**Table 1**

**Durable Medical Equipment Examples**

<ul style="list-style-type: none"><li><u>Anesthesia machine and ventilator</u></li><li><u>Atomizers (medical)</u></li><li><u>Apnea monitors</u></li><li><u>Diagnostic equipment</u></li><li><u>Beds, bags, trays, bedpans, commodes, pads, pillows, crash carts, lamps, bulbs, and tables (medical)</u></li><li><u>Blood parameter and blood gas analyzer</u></li><li><u>Bone growth stimulator (not worn on the body)</u></li><li><u>Bovie (cauterization)</u></li><li><u>Cardiopulmonary bypass machine</u></li><li><u>Continuous positive airway pressure (CPAP &amp; BI-PAP) machine (not worn on the body).</u></li></ul>	<ul style="list-style-type: none"><li><u>Cofflator</u></li><li><u>Continuous passive motion devices</u></li><li><u>Electronic speech aids (not worn on the body)</u></li><li><u>Endoscopes</u></li><li><u>Enteral feeding bags, tubing, and connectors</u></li><li><u>Feeding plugs</u></li><li><u>Glucose meters</u></li><li><u>Instruments, e.g., clamps, drills, forceps, retractors, scalpels, reamers, scissors</u></li><li><u>Intravenous (IV) stands and poles</u></li><li><u>Kidney dialysis devices</u></li><li><u>Lasers</u></li><li><u>Lithotripters</u></li><li><u>Reusable needles or reusable staplers</u></li></ul>	<ul style="list-style-type: none"><li><u>Nebulizers</u></li><li><u>Respiratory humidifier</u></li><li><u>Sling scales</u></li><li><u>Stapler (must be empty as staples are not durable medical equipment.)</u></li><li><u>Stethoscopes, stirrups, and stretchers (medical)</u></li><li><u>Suction regulators</u></li><li><u>T.E.N.S units (not worn on the body)</u></li><li><u>Tourniquets</u></li><li><u>Ultrasound probes, transducers, and mini dopplers</u></li><li><u>Whirlpools (medical)</u></li><li><u>X-ray equipment</u></li></ul>
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(203)(a) What is a drug? A "drug" is a compound, substance, or preparation, and any component of a compound, substance, or preparation, other than food and food ingredients, dietary supplements, or alcoholic beverages:

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(i) Recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; or

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(ii) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or

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(iii) Intended to affect the structure or any function of the body.

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See RCW 82.08.0281.

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Table 2 below provides a non-exclusive list of drug product examples.

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**Table 2**

**Drug Examples**

- | <b>Drug Examples</b>   |
|--|
| <ul style="list-style-type: none"><li>• <u>Dermal fillers - injectable</u></li><li>• <u>Federal prescription (RX) drugs, including biologicals</u></li><li>• <u>Implanted radioactive isotopes</u></li><li>• <u>Gases - medical grade (nitrous oxide, oxygen, carbon dioxide, helium)</u></li><li>• <u>Insulin</u></li><li>• <u>Kidney dialysis solution</u></li><li>• <u>Prescription medicated cotton swabs and gauze wraps</u></li><li>• <u>Parenteral nutrition formulas</u></li><li>• <u>Sterile water - solutions for adding to mixtures, and irrigation</u></li><li>• <u>Vaccines</u></li></ul> |

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(b) Substances that are necessary to the performance of durable medical equipment are not drugs. A compound, substance, or preparation that is necessary for durable medical equipment to perform its function is not a drug, even when it otherwise meets the definition of drug in this subsection.

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(c) Examples of compounds, substances, preparations that are necessary in order for the durable medical equipment to perform its function.

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**Example 1.** A Coulter Blood Cell Counter uses an electrolytic solution to perform its function. The solution is entirely contained within the device and does not physically interact with the patient's tissue (blood) apart from the device. The device cannot perform its function without the electrolytic solution. The solution is an integral part of the Coulter Blood Cell Counter and is not a drug even though the device is used to diagnose disease and the test it performs is conducted pursuant to a prescription.

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**Example 2.** A cryoablation device uses extremely cold, thermally conductive solution inside a hollow probe or needle to freeze and remove diseased or malfunctioning cells within a patient's body. The solution is entirely contained within the device and does not physically interact with the patient's tissue apart from the device. The device cannot perform its function without the solution. The solution is an integral part of the device and is not a drug even though the device is used in the cure, mitigation, and treatment of disease as part of a prescribed procedure.

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**Example 3.** A specialized medical laser uses certain gases (e.g. argon, helium) to determine the wavelength of the light emitted. This allows the laser to identify specific cells or substance types. The gas is entirely contained within the laser and does not physically interact with the patient's tissue apart from the device. The device cannot perform its function without the gas. The gas is an integral part of the device and is not a drug even though the gas is consumed and the laser is used in the cure, mitigation, and treatment of disease as part of a prescribed procedure.

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(204) **What is mobility enhancing equipment?** Mobility enhancing equipment is equipment, including repair and replacement parts for mobility enhancing equipment that:

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(a) Is primarily and customarily used to provide or increase the ability to move from one place to another and is appropriate for use either in a home or a motor vehicle;

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(b) Is not generally used by persons with normal mobility; and

(c) Does not include any motor vehicle or equipment on a motor vehicle normally provided by a motor vehicle manufacturer. See RCW 82.08.0283.

Table 3 below provides a non-exclusive list of mobility enhancing equipment products.

**Table 3**

**Mobility Enhancing Equipment Examples**

- Bath aids - raised toilet seat, tub and shower
- Bed pull-up T
- Car seats (mobility enhancing)
- Canes
- Crutches
- Handrails and grab bars to assist in rising from commode, tub, or shower.
- Lift chairs and replacement parts
- Lifts (hydraulic or electric) used to raise or transfer patients from bed to chair, commode, or bath
- Scooters and transporters
- Swivel seats enabling the disabled to rotate in order to rise from a chair
- Wheelchairs adapted for specific uses or functions, e.g., all terrain wheelchairs
- Transfer belts to assist in the transfer of patients
- Walkers
- Wheelchairs

(205) **Over-the-counter drugs.** An over-the-counter drug is a drug that contains a label that identifies the product as a drug required by 21 C.F.R. Sec. 201.66, as amended or renumbered on January 1, 2003. The label includes:

(a) A "drug facts" panel; or

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(b) A statement of the "active ingredient(s)" with a list of those ingredients contained in the compound, substance, or preparation. See RCW 82.08.0281.

Table 4 below provides a non-exclusive list of over-the-counter drug products.

**Table 4**

**Over-the-Counter Drug Examples**

- Antihistamines
- Anti-inflammatory
- Analgesic
- Contact lenses solution
- Eternal nutrition formulas with drug facts box
- Hydrogen peroxide
- Medicated cotton swabs and gauze wraps (non-legend)
- Povidone Iodine
- Rubbing alcohol

(206) (a) **What is a prosthetic device?** A prosthetic device is a replacement, corrective, or supportive device, including repair and replacement parts for a prosthetic device, worn on or in the body to:

- (i) Artificially replace a missing portion of the body;
- (ii) Prevent or correct a physical deformity or malfunction; or
- (iii) Support a weak or deformed portion of the body. See RCW

82.08.0283.

Table 5 below provides a non-exclusive list of prosthetic device products.

**Table 5**

**Prosthetic Device Examples**

• <u>Abdominal belts, binders, and supports</u>	• <u>Ear, nose, and throat implants</u>	• <u>Shoulder and elbow implants</u>
• <u>Acetabular cups</u>	• <u>Foley catheter</u>	• <u>Skin implants</u>
• <u>Ankle brace</u>	• <u>Gastric bands and balloons</u>	• <u>Speech aids (electronic) worn on the body</u>
• <u>Anti-embolism</u>	• <u>Hand and feet</u>	

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<p><u>stocking</u></p> <ul style="list-style-type: none"> <li>• <u>Artificial eyes, heart valves, larynx, limbs</u></li> <li>• <u>Back braces</u></li> <li>• <u>Bone cement and wax</u></li> <li>• <u>Bone pins, plates, nails, screws</u></li> <li>• <u>Braces to align the skeletal or muscular system</u></li> <li>• <u>Breast implants and external prosthesis</u></li> <li>• <u>Cervical collars</u></li> <li>• <u>Cochlear implant</u></li> <li>• <u>Corrective eye glasses</u></li> <li>• <u>Continuous positive airway pressure (CPAP) machines which are specifically designed to be wholly worn on the body and portable</u></li> <li>• <u>Dental prostheses, including but not limited to full and partial dentures, crowns, inlays, fillings, braces, and retainers</u></li> <li>• <u>Drainage devices for single patient use because they serve the same drainage functions as the body's natural systems</u></li> <li>• <u>Eye glass frames and lenses</u></li> </ul>	<p><u>implants</u></p> <ul style="list-style-type: none"> <li>• <u>Head halters</u></li> <li>• <u>Hearing aids</u></li> <li>• <u>Insulin pumps</u></li> <li>• <u>Knee immobilizers</u></li> <li>• <u>Implanted pacemakers</u></li> <li>• <u>Mastectomy surgical bras</u></li> <li>• <u>Maxillofacial devices implanted</u></li> <li>• <u>Membrane implants (neutron, spinal, joint)</u></li> <li>• <u>Contact lenses</u></li> <li>• <u>Orthobiologics implants</u></li> <li>• <u>Orthopedic shoes, shoe lifts, inserts, arch supports, heel protectors</u></li> <li>• <u>Edema gloves,</u></li> <li>• <u>mast pants, burn garments</u></li> <li>• <u>Salem sump with anti-reflux valve</u></li> </ul>	<ul style="list-style-type: none"> <li>• <u>Ocular implants</u></li> <li>• <u>Slings</u></li> <li>• <u>Sphincters</u></li> <li>• <u>Splints and splint materials</u></li> <li>• <u>Slings, braces, collars, casts, splints, embolism stockings, arch pads, pelvic traction belts, traction pulley clamp assemblies and cords, supports, post-operation shoes, cast shoes, specialized orthotic shoes, diabetic shoes and inserts, and other similar apparatus</u></li> <li>• <u>Stents (coronary and urinary)</u></li> <li>• <u>Stents implants through endoscopy</u></li> <li>• <u>Sutures, staples, and skin glue for closing wounds along with disposable needles</u></li> <li>• <u>Stockings - compression</u></li> <li>• <u>Tendon implants</u></li> <li>• <u>T.E.N.S. units worn on the body</u></li> <li>• <u>Testicular and penile implants</u></li> <li>• <u>Trachea tubes</u></li> <li>• <u>Trusses</u></li> </ul>
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• <u>Hearing instruments</u>		
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(b) When is a device not worn on or in the body? For the purpose of this exemption, "worn on the body" means the entire device is something a person puts on or has on their person, to be carried with and habitually becomes part of the person as a whole, much in the sense that a person wears clothing or other personal items. Such devices are designed to be wholly worn on the body and portable. A device is not "worn on or in the body" simply because part of it is attached to the body in some way for a period of time. These devices cannot be partially floor-standing, plugged into an outlet, or moved by virtue of dragging, wheels, or with the assistance of a separate device (e.g. a cart or intravenous stand).

(c) Examples of items that are not prosthetic devices worn on or in the body. The following are examples of items not considered prosthetic devices worn on or in the body.

Example 4. Continuous positive airway pressure (CPAP) machines are commonly used by patients with sleep apnea disorders to facilitate normal breathing. Patients using a CPAP machine are normally hooked up to the machine via tubing and individually tailored masks. Even though the mask is normally "worn" for significant periods of time each night, the mask by itself can not accomplish the intended purpose. The machine performing the function is not worn on the body as a complete system. Neither the mask separately, nor the machine as a whole system, is a prosthetic device.

Example 5. Heart-lung machines generally replace the function of the heart and lungs during surgery, as well as regulating body temperature and providing an avenue of introduction for anesthetics or other medications directly into a patient's bloodstream. While a heart-lung machine is attached to the patient, it is commonly a floor-standing or wheeled unit and is not a prosthetic device.

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**Part 3. APPLICABLE TAXES**

(301) What basic tax information do I need to be aware of when selling, purchasing, using or manufacturing medical products? This subsection provides general tax-reporting information for persons who sell, purchase, use, or manufacture, medical products.

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(302) How are medical products taxed? In general, sales of medical products are taxable. Sales of medical products to consumers such as doctors, hospitals, or patients are subject to retailing business and occupation (B&O) tax and the retail sales tax. These taxes apply to the sale of medical products as follows:

(a) Retail sales tax. Retail sales tax applies to the sale of medical products to a consumer unless a specific exemption applies. RCW 82.04.050 and 82.08.020. Specific exemptions are discussed below in Part 4 of this rule.

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(b) Retailing B&O tax. There is no general B&O tax exemption for sales of medical products. Even if a sale of a medical product is exempt from retail sales tax, the gross proceeds from the sale of the medical product to a consumer is subject to the retailing B&O tax.

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(c) Wholesaling B&O tax. Sales to persons who resell the medical products (e.g., pharmacies) are subject to the wholesaling B&O tax. Persons making wholesale sales should refer to WAC 458-20-102 for information regarding their responsibility to obtain a reseller permit.

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(d) Manufacturing B&O tax. Persons who manufacture products, including medical products, in this state are subject to the manufacturing B&O tax upon the value of these products. Manufacturers selling the products at retail or wholesale in this state are also subject to either the retailing or wholesaling B&O tax, as the case may be. In

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such cases, the manufacturer must report under both the "production" (manufacturing) and "selling" (wholesaling or retailing) classifications of the B&O tax, and claim a Multiple Activities Tax Credit (MATC). Refer to WAC 458-20-19301 for a more detailed explanation of the MATC.

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Persons who manufacture molds or other products that they use in a manufacturing process are subject to the manufacturing B&O tax upon the value of the product manufactured. (See also WAC 458-20-112 and 458-20-134 regarding "value of products" and "commercial or industrial use", respectively.) Such persons also incur a use tax liability with respect to their use of the molds or products, unless a specific exemption applies. For example, RCW 82.12.02565 provides a use tax exemption for the use of certain molds in a manufacturing operation. (Refer to WAC 458-20-13601 for additional information regarding the manufacturers machinery and equipment sales tax and use tax exemptions.)

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(e) Use tax or deferred retail sales tax. Purchases of medical products at retail are subject to retail sales tax unless a specific exemption exists in the law. If the seller does not collect retail sales tax, a buyer who is not reselling the products must pay the retail sales tax (commonly referred to as the "deferred retail sales tax") or use tax directly to the department, unless the specific items purchased are exempt under the law. See WAC 458-20-178 (Use tax) for additional information on use tax.

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(303) Retail sales tax should be paid by the consumer based on the principal use of the product. Some medical products can be put to both an exempt and taxable use. At the time of purchase a buyer may not know exactly how the item or items will be used. In such cases, retail sales tax must be paid to the seller at the time of purchase when the buyer expects to principally (i.e. more than fifty percent of

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the time) put the item to a taxable use in the normal course of business. However, if the buyer expects to principally put the item to use in an exempt manner, the buyer may provide the seller with an appropriately completed exemption certificate that lists the retail sales tax exempt item or types of items included in the purchase. See subsection 304 of this rule for more information on exemption certificates. When a seller receives an appropriately completed exemption certificate, that seller is relieved of the responsibility to collect the retail sales tax for those specific items or types of items identified on the certificate and sold in that transaction.

**(a) Items put to taxable use where tax was not paid.** If the buyer doesn't pay sales tax on an item, and later puts that item to use in a manner that is not exempt of sales tax, the buyer must pay deferred sales or use tax to the department. The deferred sales tax liability should be reported by the buyer on the use tax lines of the excise tax return (including both state and local portions of the tax). The tax should be reported based on the location and sales tax rate which is in effect where the buyer took possession of the item.

**(b) Items put to exempt use where tax was paid.** If the buyer does not give an exemption certificate to the seller indicating a certain item is exempt of retail sales tax, the seller must collect the tax at the time of purchase on that item. If the buyer later puts that item to first use in an exempt manner, the buyer may take a deduction on the excise tax return equal to the value of the item. This deduction should be claimed in the deduction column of the retail sales tax line, and should be identified as a "taxable amount for tax paid at source" deduction on the deduction detail worksheet. When completing the local sales tax section of the tax return, the value of the item must be credited using the seller's tax location code (assuming the buyer took possession of the item at the seller's location) and computed at the local sales tax rate paid to the seller.

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(c) Examples.

**Example 6. Purchase of items which are principally exempt.** ABC Medical Center (ABC) purchases a case of sterile silicon tubing. One case contains twenty units of sterile tubing in individually sealed sterile packaging. The tubing purchased by ABC is either used to deliver medically prescribed oxygen from tanks to a patient (an exempt use), or used by ABC's laboratory to conduct certain tests (not an exempt use). At the time of purchase, ABC does not know how many of the twenty packages in the case will be used for oxygen tank systems versus how many will be drawn out of inventory by the lab. However, according to ABC's inventory records from past periods, the tubing will principally be used as part of the medically prescribed oxygen systems. ABC provides the seller of the tubing with a properly completed exemption certificate (in this case, the "Sales Tax Exemption Certificate for Health Care Providers"). The seller is not required to collect retail sales tax on the case of sterile tubing. As ABC puts the tubing to use, it must keep track of when a package of tubing is used by the laboratory. Deferred sales tax is due and should be reported on and remitted with the excise tax return for the period in which ABC used the tubing.

**Example 7. Purchase of items which are principally taxable.** Assume the same items and situation as in Example 6, except that for this example, according to ABC's inventory records from past periods, the tubing will be principally used for retail sales taxable purposes in the laboratory. ABC cannot provide an exemption certificate for purchase of the tubing and must pay retail sales tax to the seller. As ABC puts the tubing to use, it may keep track of when a package of tubing is put to exempt use with a medically prescribed oxygen system. ABC may then take on its excise tax return a tax paid at source deduction for the value of the package used.

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(304) Sellers must obtain an exemption certificate on any retail sales exempted from the retail sales tax. Unless otherwise provided in this rule, sellers making retail sales to medical practitioners, nursing homes, and hospitals must obtain an exemption certificate to document any tax-exempt sales of the products discussed in this rule when those businesses are the consumers. Information about exemption certificates may be obtained by:

- (a) Using the department's web site at dor.wa.gov/; or
- (b) Calling the department's telephone information center at 1-800-647-7706.

**Part 4. COMMON RETAIL SALES TAX AND USE TAX EXEMPTIONS**

(401) What common retail sales tax and use tax exemptions apply to the sale of medical products? This part of the rule provides a non-exhaustive list of retail sales tax and use tax exemptions available with respect to various medical products.

(402) Sales of medical products pursuant to a prescription. Most retail sales tax exemptions available for sales of medical products require that the item is purchased under authority of a prescription.

(a) What is a prescription? A "prescription" is an order, formula, or recipe issued in any form of oral, written, electronic, or other means of transmission by a duly licensed practitioner authorized by the laws of this state to prescribe. See RCW 82.08.0281. The specific requirements for a prescription may differ depending on the item exempted and the RCW chapter under which the person issuing the prescription is licensed. Close attention must be paid to the details given for each specific exemption explained in the following subsections of this rule.

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(b) **No automatic exemption.** A prescription does not automatically qualify a sale of a medical product for a sales tax or use tax exemption. Unless a specific exemption exists in statute for the sale or use of the item in question the item is not exempt, even with a prescription. For example, if a physician prescribes a regimen of exercise at the local fitness club, the mere issuance of the prescription does not qualify the sales of that service for a retail sales tax exemption because no such exemption exists in statute.

(c) **When medical procedures are prescribed.** When a medical procedure is prescribed by a duly licensed practitioner authorized to prescribe the same, that overall prescription fulfills the prescription requirement (if any) for each eligible exempt item used in the procedure. For example, an orthopedic surgeon conducts joint replacement surgery for a patient's diseased joint. As part of that surgical procedure, prescription drugs and other eligible exempt items are used. The surgeon does not specifically issue a separate written prescription for each eligible exempt item. The surgeon's order for the surgical procedure and the oral directions provided by the surgeon during the procedure fulfill any prescription requirement for each eligible item used in an exempt manner during that procedure.

(d) **Dispensed pursuant to a prescription.** The purchase of drugs to be dispensed in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body, by hospitals or other persons licensed to prescribe such drugs, are considered dispensed pursuant to a prescription and therefore exempt, providing the buyer gives the seller an exemption certificate as discussed in Part 3 of this rule.

(403) **Sales tax and use tax exemptions available with respect to various medical products.**

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(a) Sales to a free hospital are exempt from sales tax and use tax.

RCW 82.08.02795 and 82.12.02745 provide retail sales tax and use tax exemptions for items sold to and used by a "free hospital" when those items are reasonably necessary for the operation of, and provision of health care by a free hospital. For the purpose of these exemptions, "free hospital" is a hospital that does not charge patients for health care provided by the hospital.

(b) Sales of drugs for human use can be exempt from retail sales tax and use tax when sold under the authority of a prescription. RCW

82.08.0281 and 82.12.0275 provide retail sales tax and use tax exemptions for drugs for human use dispensed or to be dispensed to patients, pursuant to a prescription. These exemptions apply to the distribution of "sample" prescription drugs provided free of charge to duly licensed practitioners authorized by the laws of this state to prescribe. For the exemptions to apply, the drug involved must be intended to interact with a specific patient through direct contact with that patient, whether applied internally or externally to the patient's body, or as part of a test conducted on a tissue sample taken from that patient. A seller is not required to collect sales tax when it obtains a properly completed exemption certificate indicating prescription drugs, intended for human use sold to medical practitioners, nursing homes, and hospitals, will be put to an exempt use under the authority of a prescription. Otherwise, the retail sales tax must be collected. See Part 3 of this rule for information about exemption certificates.

(c) Sales of disposable devices used to deliver prescription drugs for human use. RCW 82.08.935 and 82.12.935 provide retail sales tax and use tax exemptions for disposable devices used to deliver drugs for human use, pursuant to a prescription.

(i) What are disposable devices used to deliver drugs? "Disposable devices used to deliver drugs" include single-use items such as a sin-

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gle-use syringe, I.V. tubing, and I.V. catheters. A stand or device that holds the tubing or catheter is not a disposable device used to deliver drugs.

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(ii) **Example - disposable devices.** A nursing home purchases single-use syringes, tubing used to deliver drugs, and stands used to hold the intravenous (IV) fluid containers. If the nursing home provides the seller with a completed "Sales Tax Exemption Certificate for Health Care Providers," retail sales tax does not apply to the purchase of single-use syringes and tubing. However, retail sales tax applies to the IV stands because the stands are "durable medical equipment," not disposable or single-use, and no specific exemption for them exists in the law. For information about durable medical equipment, see Part 2 of this rule.

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(d) **Sales of "over-the-counter" drugs with a prescription are exempt from retail sales tax and use tax.** RCW 82.08.940 and 82.12.940 provide retail sales tax and use tax exemptions for "over-the-counter" drugs sold for human use, pursuant to a prescription. See Section (205) for the definition of over-the-counter drug.

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(i) **Example.** A patient's medical practitioner prescribes over-the-counter pain relief medication. The patient takes the prescription to a pharmacy. The sale of the over-the-counter drug is exempt from retail sales tax. In contrast, if the patient's medical practitioner simply recommends that the patient use an over-the-counter pain relief medication, without completing a prescription for the medication, the sale of the over-the-counter drug is subject to retail sales tax.

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(ii) **Example.** A hospital makes bulk purchases of various over-the-counter drugs to dispense to patients pursuant to a doctor's prescription. The hospital's purchases of such drugs are exempt from retail sales tax providing the hospital gives the seller an exemption certificate as discussed in Part 3 of this rule.

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(iii) **Example.** An employer purchases drug test kits from a local drug store and administers them to current and prospective employees as a



condition of employment. The employer's purchase of the drug tests is subject to retail sales tax because the tests are not prescribed by a licensed physician for the employees or prospective employees.

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(e) Dietary supplements (also known as nutrition products) with a prescription are exempt from retail sales and use taxes. Sales of dietary supplements not covered by either of the retail sales tax or use tax exemptions for "food and food ingredients" are generally subject to retail sales tax or use tax. See RCW 82.08.0293 and 82.12.0293. However, RCW 82.08.925 and 82.12.925 provide specific retail sales tax and use tax exemptions for sales of "dietary supplements" for human use, pursuant to a prescription. A "dietary supplement" is any product, other than tobacco, intended to supplement the diet, and that satisfies all three of the criteria listed below in (i) through (iii).

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(i) Contains one or more of the following dietary ingredients:

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(A) A vitamin;

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(B) A mineral;

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(C) An herb or other botanical;

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(D) An amino acid;

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(E) A dietary substance for use by humans to supplement the diet

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by increasing the total dietary intake; or

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(F) A concentrate, metabolite, constituent, extract, or combination

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of any ingredient described in this subsection; and

(ii) Is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or if not intended for ingestion in such form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet; and

(iii) Is required to be labeled as a dietary supplement, identifiable by the "supplement facts" box found on the label as required pursuant to 21 C.F.R. Sec. 101.36, as amended or renumbered as of January 1, 2003. See RCW 82.08.0293.

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(f) Licensed naturopaths have their own retail sales tax and use tax exemptions available. The sale or use of medicines of mineral, animal, and botanical origin which are prescribed, administered, dispensed, or used by a licensed naturopath in the treatment of a human patient are exempt from retail sales and use taxes. See RCW 82.08.0283 and 82.12.0277.

"Naturopathic medicines" are vitamins; minerals; botanical medicines; homeopathic medicines; hormones; and those legend drugs and controlled substances consistent with naturopathic medical practice in accordance with rules established by the secretary of health. Controlled substances are limited to codeine and testosterone products that are contained in Schedules III, IV, and V in chapter 69.50 RCW. See RCW 18.36A.020.

(g) Drugs and devices used for family planning may be exempt. RCW 82.08.0281 and 82.12.0275 provide sales tax and use tax exemptions for drugs and devices sold or used under certain conditions for family planning purposes. Family planning purposes include promoting, inhibiting, preventing, and determining of conception. This includes all single-patient use items, whether ingested, attached, or applied to persons for family planning purposes. Persons making tax-exempt sales of these drugs and devices to medical practitioners, clinics, or hospitals must obtain an exemption certificate to substantiate the exempt nature of any sale, as discussed in Part 3 of this rule.

The purchase, sale, or use qualifies for exemption when either one of the following conditions exists:

- The drug or device is supplied by a family planning clinic that is under contract with the Washington State department of health to provide family planning services; or

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- The family planning items are or will be dispensed to patients, pursuant to a prescription. Persons dispensing these items are required to obtain and maintain files of prescriptions to document the exempt nature of such sales.

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(h) **Medically prescribed oxygen is exempt from retail sales tax and use tax.** RCW 82.08.0283 provides a retail sales tax exemption for sales of medically prescribed oxygen for an individual prescribed by a person licensed under chapters 18.57 RCW (Osteopathy -- Osteopathic medicine and surgery) or 18.71 RCW (Physicians) for use in the medical treatment of that individual. A complimentary use tax exemption is provided in RCW 82.12.0277. Persons making tax-exempt sales of these items must obtain an exemption certificate to substantiate the exempt nature of any sale as discussed in Part 3 of this rule.

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(i) **What is medically prescribed oxygen?** The exemption for "medically prescribed oxygen" is not limited to gaseous or liquid oxygen (chemical designation O<sup>2</sup>). "Medically prescribed oxygen" is defined by RCW 82.08.0283 to include, among other things, oxygen concentrator systems, oxygen enricher systems, liquid oxygen systems, and gaseous, bottled oxygen systems. The primary use of the equipment must be for the generation or storage of medically prescribed oxygen (O<sup>2</sup>). These systems include regulators, cannulae, masks, and similar items used to deliver the oxygen to the individual from the tax-exempt oxygen generation or storage device.

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(ii) **Accessories may not be exempt.** Exempt medical oxygen systems are sometimes connected to the patient through taxable systems. The exemption for medically prescribed oxygen only applies to items up to the point the exempt oxygen system is connected to the taxable system. From that point of connection forward to the patient, masks, tubing, or other similar items remain part of the taxable system and are subject to retail sales tax.

(iii) **Examples.**

(A) **Example.** A physician prescribes oxygen for a patient. The patient rents an oxygen concentrator system and a separate cart to transport the system. The prescribed oxygen concentrator system can be rented exempt of sales tax. However, the exemption for "medically prescribed oxygen" does not include a separate cart used to transport a tax-exempt system. For information about durable medical equipment, see Part 2 of this rule. If the oxygen concentrator system and cart are rented for one, nonitemized price the rental may be a bundled transaction. See Part 5 of this rule for information on how tax applies to a bundled transaction.

(B) **Example.** A physician prescribes a "continuous positive airway pressure" (CPAP) system for a patient diagnosed with a sleep apnea disorder. The CPAP system primarily supplies room air, under pressure, to keep the patient's airway passages open and thereby prevent obstruction of airflow in and out of the lungs. As a result, the sale of the CPAP system is subject to retail sales tax because it is not a system that satisfies the statutory definition of "medically prescribed oxygen." (Note: certain CPAP systems, when designed to be entirely worn on the body, can qualify for exemption from retail sales tax as prosthetic devices. See Part 2 of this rule for more information.)

(C) **Example.** Assume the same facts for a CPAP system as provided in the previous example (B). In addition, the physician prescribes an oxygen trickle by which medical oxygen is provided to the patient from an oxygen tank through a tube attached to the mask of the CPAP system. The addition of an oxygen trickle does not change the purpose or taxability of any part of the CPAP system. The CPAP system does not generate or store oxygen and is not eligible for the exemption provided for medically prescribed oxygen. The oxygen, oxygen tank, and any tubing used to convey the oxygen is covered by the exemption for medi-

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cally prescribed oxygen, but only up to the point that it attaches to the taxable CPAP system.

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(i) Insulin has its own specific exemption from retail sales tax and use tax - no prescription is required. RCW 82.08.985 and 82.12.985 provide specific sales tax and use tax exemptions for insulin for human use. A prescription is not required for the sale of insulin to be exempt from tax.

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(j) Sales of laboratory reagents and other diagnostic substances may be exempt from retail sales and use taxes, under the right circumstances. The definition of drug includes compounds, substances, or preparations (e.g., laboratory reagents and other diagnostic substances) used for the diagnosis of disease. Thus, sales of laboratory reagents and other diagnostic substances are not subject to retail sales tax when prescribed for an individual by a duly licensed practitioner and used to diagnose, cure, mitigate, treat, or prevent disease in humans. RCW 82.08.0281. A comparable use tax exemption is provided in RCW 82.12.0275. Laboratory reagents and diagnostic substances must physically interact with a specific patient's specimen to qualify for exemption. Persons making tax-exempt sales of these items must obtain an exemption certificate to substantiate the exempt nature of any sale as discussed in Part 3 of this rule.

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(i) What are laboratory reagents and other diagnostic substances? "Laboratory reagents and other diagnostic substances" are substances employed to produce a chemical reaction in order to detect, measure, or produce, other substances. To be a diagnostic substance, the application of the substance to a patient's specimen must result in identification of the characteristics of a particular disease.

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(ii) Laboratory reagents, other diagnostic substances or prepared

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media when sold in a container. Reagents, diagnostic substances, and prepared media often come prepared in a container (test tube, vial, cylinder, Petri dish, etc.), ready for use. It makes no difference to the taxability of the substance if it is sold with or without a container. The function of the substance determines its taxability. The term "prepared media" includes transport media if the resulting culture grown on the medium is used in performing diagnostic tests for specific patients.

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(iii) Examples - laboratory reagents and other diagnostic substances. This subsection provides examples of laboratory reagents and other diagnostic substances that may qualify for sales and use tax exemptions under RCW 82.08.0281 and 82.12.0275, provided all requirements for the exemptions are met. The following items are reagents or other diagnostic substances:

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(A) Stains, dyes, and decolorizers that react with and cause a change in a cellular tissue. The substances are used to stain the cell tissues in a manner that will mark or highlight certain portions of cells;

(B) Decalcifying solution, dehydrating solution, and clearing agents that chemically react with the patient's specimen; and

(C) Test strips impregnated with a reagent, which when, applied to a patient's specimen, test for indicators of a disease.

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(iv) What substances are not reagents? Some substances are used solely for purposes of preparing specimens for examination and diagnosis or to facilitate examination of a specimen. Such substances do not themselves produce a chemical reaction resulting in the detection, measurement, or production of another substance. They merely facilitate or enable specimen testing and are not exempt under RCW 82.08.0281 or 82.12.0275. The following lists examples of substances and items which are not reagents:

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(A) Paraffin that is extracted from a tissue specimen without having chemically altered the cells;

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(B) Gelatin that is extracted out of the specimen before staining and leaves the cell structures unaffected;

(C) Electrodes;

(D) Tissue cassettes;

(E) Freezing medium;

(F) Liquid agar when used to gel patient specimens;

(G) Test tubes or cylinders that do not contain a reagent;

(H) Plain slides and cover slips that are not coated with a reagent;

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(I) Mounting medium to adhere the cover slip to the slide; and

(J) Acids and other solutions when used for cleaning purposes.

(v) What about reagents and diagnostic substances that can be used in more than one way (multiple use substances)? Some reagents or other diagnostic substances have multiple uses, some of which may qualify for a sales or use tax exemption. Such substances are exempt only to the extent they are used as part of a test prescribed to diagnose disease in humans. For example, alcohol can be used either as a reagent (e.g. to react with a cellular tissue) or to clean counters, furniture etc. Alcohol used as a cleaning agent is subject to retail sales or use tax. See Part 3 of this rule for guidance on when to apply retail sales tax to products with multiple uses, with both retail sales taxable and exempt uses being possible.

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(k) Sales of controls, calibrators, and standards used with laboratory test equipment are not exempt from retail sales and use taxes. The sales tax and use tax exemptions provided by RCW 82.08.0281 and 82.12.0275 do not apply to drugs (compounds, substances, or preparations) used as a control, calibrator or standard in conjunction with the test of patient specimens in a medical laboratory.

(i) What are controls? A "control" is a material, solution, lyophilized (freeze-dried) preparation or pool of collected serum designed to be used in the process of quality control. Controls do not physically interact with a specific patient's specimen. The concentrations of the substances of interest in the control are known within limits determined during its preparation or before routine use. Controls are generally used with each test of patient specimens to validate the accuracy of that particular test.

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(ii) What are calibrators? A "calibrator" is a material, solution, or lyophilized (freeze-dried) preparation designed to be used in calibration of medical laboratory machines. The values or concentrations of substances of interest in the calibration material are known within limits determined during its preparation or before use. Calibrators are generally used at specified intervals such as every eight hours, at midnight, or at shift changes, in accordance with the machine manufacturer's requirements or the requirements of administering agencies to verify the accuracy of the machine.

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Calibrators are subject to retail sales tax or use tax because they are used to diagnose problems with machines and they do not physically interact with a patient's specimen to diagnose disease.

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(iii) What are standards? A "standard" is a reference material of fixed and known chemical composition capable of being prepared in an essentially pure form. "Standard" also includes any certified reference material generally accepted or officially recognized as the unique standard used to test and calibrate medical lab equipment. Standards are often used in the original setup of medical lab equipment.

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A standard is subject to retail sales tax and use tax because it is used to test and calibrate equipment and does not physically interact with a patient's specimen.

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(l) Sales of human blood, tissue, organs, or body parts may be exempt from retail sales and use taxes - no prescription or exemption certificate is required.

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RCW 82.08.02806 provides a retail sales tax exemption for human blood, tissue, organs, bodies or body parts when used for medical research or quality control testing purposes. RCW 82.12.02748 provides a comparable use tax exemption.

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(i) Definitions of human blood, tissue, organs, or body parts. For the purposes of this exemption the following definitions apply:

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(A) "Blood" means human whole blood, plasma, blood derivatives, and related products (e.g. bone marrow).

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(B) "Tissue" includes human musculoskeletal tissue, musculoskeletal tissue derivatives, ligament tissue, skin tissue, heart valve tissue, human bone, and human eye tissue.

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(C) "Organs" or "body parts" means a part of a human body having a special function.

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(ii) Materials consisting of both human and animal components.

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Materials consisting of both human and animal components are not "human blood, tissue, organs, or body parts" and do not qualify for this exemption.

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(iii) Sales of spermatozoa. These retail sales tax and use tax exemptions do not apply to sales or purchases of spermatozoa (male reproductive cell).

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(m) Durable medical and mobility enhancing equipment. - Retail sales tax or use tax applies in most cases. Retail sales tax or use tax applies to the sale or use of durable medical equipment and mobility en-

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hancing equipment, unless a specific exemption applies. See subsections (202) and (204) for the definition of durable medical and mobility enhancing equipment.

(n) Sales of prosthetic devices may be exempt of retail sales and use taxes. RCW 82.08.0283 provides a retail sales tax exemption for sales of prosthetic devices prescribed, fitted, or furnished for an individual by a person licensed under the laws of this state to prescribe, fit, or furnish prosthetic devices. The exemption includes repair and replacement parts, as well as labor and services rendered in respect to repairing, cleaning, altering, or improving prosthetic devices. RCW 82.12.0277 provides a corresponding use tax exemption. Persons making tax-exempt sales of these prosthetic devices to medical practitioners, nursing homes, and hospitals, must obtain an exemption certificate to substantiate the exempt nature of any sale as described in Part 3 of this rule. See subsection (206) for the definition of prosthetic device.

(o) Kidney dialysis devices are exempt of retail sales and use taxes with a prescription. RCW 82.08.945 provides a retail sales tax exemption for sales of kidney dialysis devices for human use pursuant to a prescription. The exemption also includes repair and replacement parts, as well as labor and services rendered in respect to repairing, cleaning, altering, or improving kidney dialysis devices. RCW 82.12.945 provides a comparable use tax exemption. For the purpose of this exemption, a "kidney dialysis device" is a device which physically performs the dialyzing or separating process on blood. "Kidney dialysis device" does not include other equipment or tools used in conjunction with a kidney dialysis device.

**Example.** A kidney dialysis device is wired to a dedicated backup generator that exists only to service the dialysis device when the main source of power is interrupted or is unavailable. Under those condi-

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tions the dialysis process cannot be performed without the use of the generator to power the dialysis device. Even so, the generator does not perform the actual dialysis process on the patient's blood and is not a kidney dialysis device.

(p) Nebulizers are exempt of retail sales and use taxes with a prescription. RCW 82.08.803 and 82.12.803 provide sales tax and use tax exemptions in the form of a refund for the sale or use of a nebulizer for human use pursuant to a prescription. A nebulizer is "a device, and not a building fixture, that converts a liquid medication into a mist so that it can be inhaled." The exemptions include repair and replacement parts, as well as labor and services rendered in respect to repairing, cleaning, altering, or improving a nebulizer.

Under these exemptions, sellers must collect the tax on sales subject to these exemptions. To obtain a refund of tax paid, buyers must apply for a refund directly from the department by submitting a completed refund application form to the department and including the original sales receipt. Any buyer submitting an application for refund should refer to WAC 458-20-229 or use the department's web site at [dor.wa.gov/content/ContactUs](http://dor.wa.gov/content/ContactUs).

(q) Ostomic items are exempt of retail sales and use taxes - no prescription is required. RCW 82.08.804 and 82.12.804 provide specific sales tax and use tax exemptions for ostomic items for colostomy, ileostomy, or urostomy patients. "Ostomic items" are disposable medical supplies used by colostomy, ileostomy, and urostomy patients and include bags, belts to hold up bags, tapes, tubes, adhesives, deodorants, soaps, jellies, creams, germicides, and related supplies. "Ostomic items" do not include undergarments, pads and shields to protect undergarments, sponges, or rubber sheets. A prescription is not required for the sale of ostomic items to be exempt from tax.

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**Part 5. BUNDLED TRANSACTIONS**

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(501) What is a bundled transaction? A "bundled transaction" is the retail sale of two or more products, except real property and services to real property, where:

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- the products are otherwise distinct and identifiable; and
- the products are sold for one nonitemized price.

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A bundled transaction does not include the sale of any products in which the sales price varies, or is negotiable, based on the selection by the buyer of the products included in the transaction.

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(a) How are bundled transactions generally taxed for retail sales tax purposes? A transaction is generally considered a bundled transaction subject to retail sales tax if more than ten percent of the purchase price or sales price is attributable to retail sales taxable products. RCW 82.08.190 and 82.08.195.

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(b) Exception. A transaction which otherwise meets the definition of a "bundled transaction" is not a bundled transaction when both of the following are true:

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(i) The transaction includes food and food ingredients, drugs, durable medical equipment, mobility enhancing equipment, over-the-counter drugs, prosthetic devices, or medical supplies; and

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(ii) The seller's purchase price or sales price of the taxable tangible personal property is fifty percent or less of the total purchase price or sales price of the bundled tangible personal

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property. Sellers may not use a combination of the purchase price and sales price of the tangible personal property when making the fifty percent determination for a transaction.

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(502) How are kits (or trays) used for medical procedures taxed if they contain a combination of individually taxable and nontaxable items? Medical procedure kits are often purchased as a plastic-wrapped package that includes the various items needed to perform a particular medical procedure. A procedure kit can combine items that are either subject to retail sales tax or exempt from retail sales tax if sold separate from a kit or tray, as individual items. However, when a kit involves a bundled transaction sold for one nonitemized price, the sale of the entire kit is either subject to retail sales tax or exempt. This subsection explains how to determine whether a particular medical procedure kit is subject to or exempt from retail sales tax. Persons making a tax-exempt sale of a kit must obtain an exemption certificate from the buyer that lists the general item types within the kit that are exempt as discussed in Part 3 of this rule. If a particular item within a kit is only exempt pursuant to a prescription, the item (or the procedure in which the item is used) must be prescribed by a duly licensed practitioner authorized by the laws of this state to prescribe the same.

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**Example.** A glucose testing kit is prescribed for a human patient. The kit includes a glucose meter, five sample test reagent strips, and a lancet. The glucose meter is durable medical equipment, has a purchase price of \$40.00, and is subject to retail sales tax when sold separately. (See Part 2 of this rule for more information concerning durable medical equipment.) The lancet is a single-use tool not covered by any exemption, has a purchase price of \$40.00, and is subject to retail sales tax when sold separately. In this case, the test reagent strips qualify as disposable drug delivery devices, have a purchase price of \$20.00, and are exempt from retail sales tax when sold

separately pursuant to a prescription. The total purchase price of the kit is \$100.00.

To determine if the full purchase price of the kit is subject to retail sales tax, the purchase (or sales) price of the taxable components should be compared to the total purchase (or sales) price of the kit. If the taxable components exceed fifty percent of the price, the entire kit is subject to retail sales tax. In this case, the purchase price for both the glucose meter and lancet (\$40.00 + \$40.00 = \$80) are more than fifty percent of the total kit purchase price of \$100.00. Therefore, retail sales tax is due on the sale of the kit. But if the taxable components were fifty percent or less of the total kit purchase price, sales tax would not be due on the kit.

[Statutory Authority: RCW 82.32.300. WSR 92-05-065, § 458-20-18801, filed 2/18/92, effective 3/20/92; WSR 87-05-042 (Order 87-1), § 458-20-18801, filed 2/18/87; WSR 83-07-032 (Order ET 83-15), § 458-20-18801, filed 3/15/83. Statutory Authority: RCW 82.01.060(2) and 82.32.300. WSR 78-07-045 (Order ET 78-4), § 458-20-18801 (Rule 188), filed 6/27/78; Order 74-2, § 458-20-188 (codified as WAC 458-20-18801), filed 6/24/74.]

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