



**PRESENTATION TO THE SENATE COMMITTEE ON ENVIRONMENT  
AND NATURAL RESOURCES**

**SB 892**

March 14, 2019

# The Oregon Bottle Bill Excludes Every Single Health Care Product Except One

## Liquid Health Care Products not Included in the Oregon Bottle Bill:

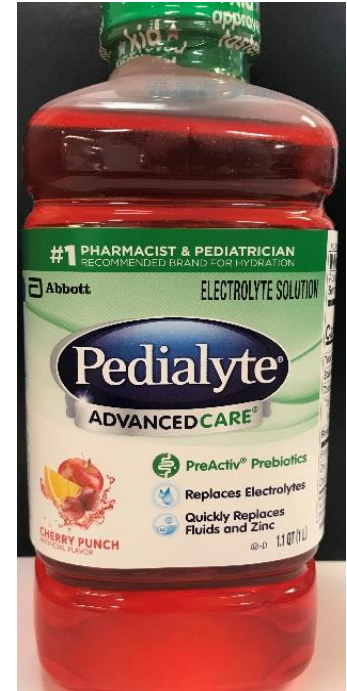
- Prescription and over the counter products such as cough syrup and antacids
- Infant Formula
- Meal Replacement Beverages

# Pedialyte® and similar products are medical food

## PEDIALYTE® CONSIDERED A MEDICAL FOOD SINCE ITS LAUNCH >50 YEARS AGO

Medical foods are regulated differently from beverages

- Section 5(b) of Orphan Drug Act (21 U.S.C. 360ee (b) (3)) defines Medical Food as:
  - “food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”



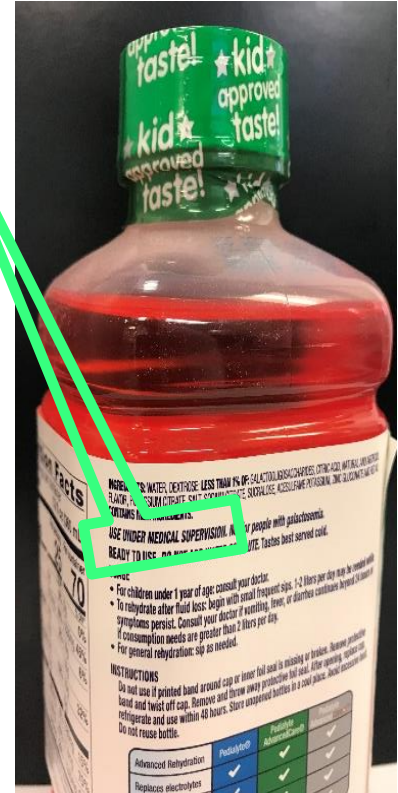
# Pedialyte® is used under medical supervision

## PEDIALYTE® NOT A SPORTS DRINK OR ENHANCED WATER

Requirement that Medical Foods are *used under medical supervision* distinguishes these products from Foods for Special Dietary Use, foods making health claims, and conventional foods

- US Food and Drug Administration (FDA) lists 4 distinct Medical Food sub-types in their Medical Foods Compliance Program Guidance Manual (dated Aug, 2006):
  1. Nutritionally complete formulas
  2. Nutritionally incomplete formulas, including individual “modular” products that may be mixed with other products before use (e.g., protein, carbohydrate or fat modulars)
  3. Formulas for metabolic (genetic) disorders in patients >12 months of age
  4. **Oral rehydration products**

Sports drinks and enhanced waters are entirely different from Pedialyte®. They have not been designed to meet the distinct nutritional requirements for dehydration associated with vomiting and diarrhea, especially in a susceptible pediatric population.



# Pedialyte<sup>®</sup> is covered under Medicaid and FSAs

## PEDIALYTE<sup>®</sup> INCLUDED IN STATE MEDICAID FORMULARIES

Oregon's Medicaid Formulary lists Pedialyte<sup>®</sup> by brand



Drug Name	Dosage Form/Strength	Drug Type
CVSTO	500 + D CR/M	Generic
CVST CAL/D	TAB 250MG	Generic
CVST CAL/D	TAB 500MG	Generic
CVST SHELL/D	TAB 250MG	Generic
CVST SHELL/D	TAB 500MG	Generic
CVST SHELL/D	TAB 500-200	Generic
CVST SHELL/D	TAB 600MG	Generic
CVST SHELL/D	TAB 500-1.25	Generic
CVST SHELL/D	TAB 500-400	Generic
<b>PEDIALYTE</b>	SOL	Brand
POT ACETATE	TAB NEUTRAL	Generic
POT ACETATE	BU 2MG/ML	Generic
POT ACETATE	BU 4MG/ML	Generic

## PEDIALYTE<sup>®</sup> REIMBURSED UNDER FLEXIBLE SPENDING ACCOUNTS (FSAs)

Pedialyte<sup>®</sup> can be reimbursed under FSAs and is frequently listed by brand; depending on the FSA plan it may require a prescription for reimbursement



### Eligible Expenses

A General Purpose Health Flexible Spending Account is the most common FSA component. PacificSource Administrators also refers to it as a Health Related Expense Account (HRE). This plan allows you to set aside pre-tax dollars to use toward reimbursable healthcare expenses. Your annual health FSA contribution will be available on the first day of your Plan Year and your Health FSA contributions will be deducted from your pay check in equal amounts throughout the year to fund the account.

- The General Purpose Health FSA allows you to pay for eligible out-of-pocket medical, dental, vision and preventative care expenses.
- You must be eligible for your employer's group sponsored medical plan to enroll in this plan, although do not need to be enrolled.
- The purchase of excessive quantities of a generally eligible expense for future use may not be reimbursable.

All expenses must be incurred for "healthcare", and not cosmetic or for general health purposes. To be considered an eligible expense, any items listed as "Potentially eligible" will require a Letter of Medical Necessity or prescription from your healthcare provider. The letter or prescription must include the item prescribed, condition being treated, and duration of treatment. For your convenience, a Letter of Medical Necessity form is available at [PacificSource.com/fsa](http://PacificSource.com/fsa) under Forms.

Expense Type	Eligibility	Comments and Special Rules (if applicable)
Prosthetics	Eligible	See also Artificial limbs and teeth.
Psychiatric care	Eligible	Example: cost of special medical care center for mentally ill dependent.
Psychoanalysis and psychologist	Potentially Eligible	Eligible if primarily for medical care. Ineligible if for general improvement of mental health or stress relief or personal enjoyment. Letter of Medical Necessity is required to prove that the services are for care.
Rehydration solution	Potentially Eligible	Example: Pedialyte. Athlete rehydration fluids are generally ineligible. A Letter of Medical Necessity is required.

# Pedialyte® is included in medical protocols

## PEDIALYTE® OFTEN 1<sup>ST</sup> LINE THERAPY TO MANAGE MILD TO MODERATE DEHYDRATION

Initially designed to manage mild to moderate dehydration due to acute gastroenteritis (diarrhea/vomiting) in infants and children

Often stocked by pharmacies

- #1 pharmacist and pediatrician recommended brand of oral rehydration solutions



The screenshot shows the Siskiyou Pediatric Clinic L.L.P. website. The header features the clinic's logo with a sun, mountains, and a family silhouette. A navigation bar includes links for Home, Our Providers, Services, Contact, Policies, FAQs, and a phone number (541.955.LOVE (5683)). A left sidebar lists menu items: Our Providers, Services, Forms, Policies, Advice, Testimonials, Resources, SPC Newsletter, and Contact. The main content area is titled "Vomiting" and includes a definition, cause, and expected course. Under "Home Care", it lists instructions for newborns, two-month-olds, and older children. A "Clear liquids" section provides a protocol: "Give one teaspoon of a clear liquid (preferably an electrolyte solution such as **PEDIALYTE**, TREN, KAOELECTROLYTE or RICELYTE) every 10 minutes for one hour. Do not use water."

# The Federal Food and Drug Administration Tightly Regulates Medical Foods

## From the FDA's "Frequently Asked Questions About Medical Foods", Guidance for Industry:

- "FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food (21 CFR 101.9(j)(8)) ... Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who requires use of the product as a major component of a disease or condition's specific dietary management."
- "Any facility engaged in manufacturing, processing, packing, or holding medical foods for consumption in the United States must register with FDA."

## From The FDA's Compliance Program Guidance Manual for Medical Foods:

- "Medical Foods can be classified into the following categories: a) Nutritionally complete formulas; b) Nutritionally incomplete formulas, including individual "modular" type products that may be mixed with other products before use (e.g., protein, carbohydrate, or fat modulars); c) Formulas for metabolic (genetic) disorders in patients over 12 months of age; or d) Oral rehydration products."

# The Federal Food and Drug Administration Tightly Regulates Medical Foods

## FDA Compliance Program Guidance Manual (Continued):

- “Because of the susceptible population for which medical foods are intended, the agency is committed to assuring their continued safety and integrity through annual inspections of all medical foods manufacturers in the U.S. and foreign countries.”

## Examples of FDA Enforcement Actions Against Mislabeled Medical Food Products:

- “Your...products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C § 343(a)(1)] because the product labeling is false and misleading in that the products are labeled and marketed as medical foods but do not meet the definition of a medical food in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the criteria set forth in Title 21 Code of Federal Regulations section 101.9(j)(8) [21 C.F.R. 101.9(j)(8)]...You should take prompt action to correct the violations noted in this letter. Failure to do so may result in regulatory action by FDA without further notice, including, without limitation, seizure and injunction.”



# No Other State Includes Medical Food in Their Bottle Bill Programs

## Examples of exemptions:

- **Hawaii:** “The term "deposit beverage" excludes the following:
  - (2) A liquid that is a drug, **medical food**, or infant formula as defined by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.);
- **California:** “Chapter 2. §14504. (b) "Beverage" does not include any of the following: ...
  - (b)(3) Milk, **medical food**, or infant formula...
  - (c)(2)(A) "**Medical food**" means a food or beverage that is formulated to be consumed, or administered enterally under the supervision of a physician, and that is intended for specific scientific principles, are established by medical evaluation...Chapter 2, §14504.
  - (c)(2)(C) ) "**Medical food**" includes any product that meets the definition of "medical food" in the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360ee (b)(3)).

# SB 892 creates a narrow exemption for rehydration products that qualify as medical foods

- **ORAL REHYDRATION PRODUCTS COVERED UNDER MEDICAL FOODS EXEMPTION:**
  - Pedialyte®, Enfalyte®, store branded oral rehydration products
- **The -1 amendment gives consumers and recyclers an additional 91 days after passage before implementation**





**Abbott**