



MEDI-CAL CONTRACTING PROCEDURES FOR ENTERAL NUTRITION PRODUCTS

The Medical Supplies and Enteral Nutrition Benefits Branch of the Department of Health Care Services (Department) is responsible for reviewing and evaluating enteral nutrition products for retention on, addition to, or deletion from the Medi-Cal *List of Enteral Nutrition Products* (List) in accordance to California Welfare and Institutions Code (W&I Code), Section 14105.8. Enteral nutrition products subject to review and coverage are those that would be dispensed to fee-for-service Medi-Cal recipients and billed by pharmacy providers.

An enteral nutrition product may be reviewed and evaluated *either* as an Individual Product Petition (IPP) *or* as part of a Product Category Review (PCR). The Department will not begin a review unless the product is available for purchase by any Medi-Cal pharmacy provider who dispenses to fee-for-service Medi-Cal recipients. The review may result in a contract with the Department for product placement on the List.

Contracts are for Maximum Acquisition Cost (MAC) which is a guarantee by the contractor that any Medi-Cal pharmacy provider can purchase the product at or below the contracted price. A contract template for review purposes only may be requested from the project lead at any time during the review process.

The contract negotiation process may result in multiple manufacturers' and distributors' products appearing on the List. This is NOT a competitive bid process.

Confidentiality is required of all participants engaged in the contracting process. All anti-trust and collusion laws must be strictly adhered to by all during the Product Category Review and the Individual Product Petition process.

Manufacturers and distributors may discuss products that have been proposed or petitioned to the Department, but shall not reveal or actively promote that products have been or will be added to the List.

Prices proposed to the Department, counter offers from the Department, and final contracted prices shall not be shared or announced until the provider bulletins are published. Failure to comply with confidentiality requirements may result in delay of the addition of products to the List or cancellation of a signed contract.

At the conclusion of a PCR contract negotiations, but prior to the provider bulletin publishing dates, statute requires the Department to meet with representatives from the California Association of Medical Product Suppliers (CAMPS) and the California Pharmacists Association (CPhA). During this meeting, the Department will share proposed or petitioned products and broad-spectrum product pricing with stakeholders.

Product Category Review (PCR)

The PCR is initiated by the Department to determine whether products within a certain product type will be retained on, added to, or deleted from the List. It is a process by which products within a certain product type are evaluated (see Product Review Process) based on the following five criteria:

1. The safety of the product.
2. The effectiveness of the product.
3. The essential need for the product.
4. The potential for misuse of the product.
5. The immediate or long-term cost effectiveness of the product.

The Department sends a notification and invitation letter to manufacturers and distributors to participate in the PCR process. Interested manufacturers or distributors are encouraged to keep the Department updated with a contact name, address, and phone number to ensure notification of an upcoming PCR. The notification letter will provide the contact information for the project lead assigned to the PCR. The PCR may result in contracts between the Department and one or more manufacturers or distributors.

Individual Product Petition (IPP)

The IPP is a process outside of the PCR by which products with new enteral nutrition formulations or any changes to currently contracted products are reviewed and evaluated (see Product Review Process) for addition to or retention on the List based on the five criteria: safety, effectiveness, essential need, potential for misuse and cost.

Manufacturers or distributors may initiate the IPP process by sending a signed petition letter on company letterhead requesting the product(s) be added to or retained on the List. The petition letter must include a detailed description of the product and the new formulation or an explanation of the changes to the currently contracted products.

The petition letter may be submitted by mail or electronically. If submitting by mail, send to:

California Department of Health Care Services
Chief of Medical Supplies and Enteral Nutrition Benefits Branch
P.O. Box 997413, MS 4604
Sacramento, CA 95899-7413

To submit the petition letter electronically, email the project lead or medicalsupplies@dhcs.ca.gov.

Upon receipt of the petition letter, the Department will notify the company within ninety days if the review for the proposed products will begin or if the petition will be deferred to the next scheduled PCR.

PRODUCT REVIEW PROCESS

Product Presentations

The project lead will offer the manufacturer or distributor an opportunity to meet with the Department to discuss the five review criteria, the product studies and to present the business proposal (see sections below). A presentation may be required for enteral nutrition products new to the market. Typically, a meeting room is scheduled for one and one-half hours for presentations. To allow time for questions and brief discussions, a presentation of no longer than one hour is recommended. The manufacturer or distributor should notify the project lead of the individuals attending the presentation. They may include product managers, sales managers and medical experts. Presenters must provide their own audio-visual equipment.

If a meeting with the Department is not required, a document that addresses the five review criteria, product studies and the business proposal must be submitted by mail.

Product Review Criteria

The Department shall, when evaluating enteral nutrition products for retention on, addition to, or deletion from the List, consider all of the following criteria:

(1) *Safety* - the relative freedom from side effects that is determined by reviewing the contraindications, precautions, warnings and adverse effects of the enteral nutrition product. Evaluation of safety may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products, and may take into account such factors as safety of alternative methods of treatment or the relationship of safety of an enteral nutrition product to the severity of prognosis of the medical conditions for which the enteral nutrition product is indicated. Product handling requirements, packaging and form may also be consideration when evaluating safety.

(2) *Efficacy* - the extent to which an enteral nutrition product will provide needed nutrients, in a form compatible with a medical condition. Evaluation of efficacy may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products, and may take into account such factors as efficacy of alternative methods of treatment.

(3) *Essential Need* - the availability of an enteral nutrition product through the List is necessary to protect life or prevent significant disability. Evaluation of essential need may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products, and may take into account such factors as the availability of alternative methods of treatment, the incidence, severity and prognosis of the medical

conditions for which an enteral nutrition product is indicated; or whether an enteral nutrition product may provide nutrition support for a medical condition not adequately offered by any other product.

(4) *Misuse Potential* - the likelihood for unjustified, inappropriate, irresponsible or improper use of an enteral nutrition product. Evaluation of misuse potential may take into account such factors as: utilization of an enteral nutrition product where there is insufficient medical necessity for its use; continued use of an enteral nutrition product despite loss of effectiveness; and/or utilization of an enteral nutrition product where a less costly, but equally safe and efficacious alternative may be used.

(5) *Cost Effectiveness* - the immediate or long-term cost effectiveness of an enteral nutrition product. Evaluation of cost will take into account the NET COST of the product to the Department and may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products. The net cost would include any statutory mark-up or dispensing fee minus any rebate (if applicable).

As part of the cost evaluation, the Department considers data presented by the manufacturer or distributor related to the comparison of two or more treatment alternatives having identical outcomes (Cost-Minimization Analysis), the comparison of treatment alternatives which have different cost and treatment outcomes associated with them (Cost-Benefit Analysis), or the comparison of total health care system cost of treatment alternatives having similar treatment outcomes (Cost-Effectiveness Analysis).

Business Proposal

Once the review process begins, a business proposal must be submitted for the proposed product(s). The business proposal must include the documents on the Department's List of Required Documents (Appendix A) and a signed copy of the Contractor's Certifications (Appendix B).

Product Evaluation

The project lead may request additional information for considerations from the manufacturer or distributor, such as:

- Brief documentation of each of the five review criteria of safety, efficacy, essential need, misuse potential and cost effectiveness.
- Recommendations from other entities contacted for input and unsolicited input if appropriate.
- Manufacturer's product presentation.
- Pertinent medical literature or other information.

Once all requested product information and the business proposal has been received and reviewed by the project lead, the Department conducts a product evaluation meeting.

Negotiations

The Department may present a price counter offer following the product evaluation meeting. The manufacturer or distributor may accept, reject, or present an alternative to the counter offer within the time frame requested by the project lead.

Confidentiality is required of all participants engaged in the contracting process. All anti-trust and collusion laws must be strictly adhered to by all.

Decision Notification

Upon successful review and cost negotiations (if applicable) to add or retain an enteral nutrition product on the List, the Department will send a contract to the manufacturer or distributor. Once the Department receives the contract signed by the authorized representative, the Department will instruct its fiscal intermediary to inform providers of changes to the List and to take action for processing provider claims for these enteral nutrition products.

The project lead will notify the manufacturer or distributor of the proposed effective date the product will be added to the List. The effective date to add an enteral nutrition product is not official until published in the Medi-Cal provider bulletins. **Manufacturers or distributors must not announce an effective date prior to the Medi-Cal provider bulletin publications.**

If the Department decides not to contract for a product, a notification letter regarding such a decision will be sent to the manufacturer or distributor.

Appeals

When the Department decides to not contract for a product, the manufacturer or distributor of the enteral nutrition product may file an appeal within 30 calendar days of receipt of the Department's decision notification.

Additional Information

To learn more about the Medi-Cal Program and to view the *Medi-Cal List of Enteral Nutrition Products* published in the Medi-Cal Pharmacy and Allied Health Provider Manuals, please visit the [Medi-Cal website](#).

You may contact the Medi-Cal medical supply team at medicalsupplies@dhcs.ca.gov.

APPENDIX A

CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES

LIST OF REQUIRED DOCUMENTS

Business proposals to add products to the *Medi-Cal List of Enteral Nutrition Products* must include the following documents in the order listed:

1. Company information
 - a. "Letter of Intent to Contract", on company letterhead, signed by a person with legal authority, for the addition of proposed products to the *Medi-Cal List of Enteral Nutrition Products*.
 - b. Company's legal name (as it will appear on the contract).
 - c. Contract signature – name, title and address of person with legal authority to sign agreement (contract).
 - d. Contract shipment – name, title and address of person to receive by FedEx shipment the agreement (contract) if not the same as contract signee.
 - e. Ownership – List of name and address of each person or corporation or in any subcontractor in which the proposed contractor has direct or indirect ownership of 5% or more. (Subpart B (commencing with Section 455.100) of Part 455 of Subchapter C of Chapter IV of Title 42 of the Code of Federal Regulations.)
2. Signed Contractor's Certification – refer to Appendix B.
3. List of proposed products – Provide a list on an Excel spreadsheet with the following column headings for each product proposed, both as hard copy and by email.
 - a. Exact description of product.
 - b. The 11-digit billing number as it is listed in First Data Bank.
 - c. Universal Product Code (UPC) for item and case packages.
 - d. Caloric density (kcal/gram or milliliter).
 - e. Price proposal per gram or milliliter.

4. Manufacturing of proposed products.
 - a. A current GMP certificate documenting the manufacturing facility location for each product proposed.
 - b. Evidence of compliance with Good Manufacturing Practices (GMP consistent with Title 21 of the Code of Federal Regulations Chapter 1, Subchapter B, Part 110).
 - c. Evidence of compliance with the FDA Bioterrorism Act regulations.
 - d. Written verification on company letterhead signed by a person with legal authority that, upon request from DHCS, Contractor would make available copies of most recent inspection reports (FDA Form 483 or DHCS "Report of Observations") and related documents resulting from FDA or the California Department of Public Health's Food, Drug and Radiation Safety Office inspections.

5. Proposed product information.
 - a. A written product presentation for each proposed product or product types using the five criteria; safety, essential need, efficacy, potential for misuse and cost.
 - b. Product marketing materials, catalog page or package inserts describing each proposed product ingredients and indications.
 - c. Copies of all relevant published clinical studies of efficacy for each of the proposed products.

If items above are "not applicable," please explain via placeholder.

APPENDIX B

CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES

CONTRACTOR CERTIFICATIONS

I certify under penalty of perjury that I am duly authorized to legally bind the prospective Contractor to the clauses listed below. This certification is made under the laws of the State of California.

1. NON-DISCRIMINATION CLAUSE: During the performance of this Agreement, Contractor and its subcontractors and distributors shall not unlawfully discriminate, harass, or allow harassment against any employee or applicant for employment because of sex, race, color, ancestry, religious creed, national origin, physical disability (including HIV and AIDS), mental disability, medical condition (cancer), age (over 40), marital status, and denial of family care leave. Contractor and subcontractors shall insure that the evaluation and treatment of their employees and applicants for employment are free from such discrimination and harassment. Contractor and subcontractors shall comply with the provisions of the Fair Employment and Housing Act (California Government Code, Section 12990(a-f) et seq.) and the applicable regulations promulgated there under (California Code of Regulations, Title 2, Section 7285 et seq.). The applicable regulations of the Fair Employment and Housing Commission implementing Government Code, Section 12990(a-f), set forth in Chapter 5 of Division 4 of Title 2 of the California Code of Regulations, are incorporated into this Agreement by reference and made a part hereof as if set forth in full. Contractor and its subcontractors shall give written notice of their obligations under this clause to labor organizations with which they have a collective bargaining or other agreement. Contractor shall include the nondiscrimination and compliance provisions of this section in its distributor contracts.

2. CHILD SUPPORT COMPLIANCE ACT:
 - a. The contractor recognizes the importance of child and family support obligations and shall fully comply with all applicable state and federal laws relating to child and family support enforcement, including, but not limited to, disclosure of information and compliance with earnings assignment orders, as provided in Chapter 8 (commencing with section 5200) of Part 5 of Division 9 of the California Family Code; and

 - b. The contractor, to the best of its knowledge is fully complying with the earnings assignment orders of all employees and is providing the names of all new employees to the New Hire Registry maintained by the California Employment Development Department.

3. EXPATRIATE CORPORATIONS: Contractor hereby declares that it is not an expatriate corporation or subsidiary of an expatriate corporation within the meaning of California Public Contract Code Section 10286 and 10286.1, and is eligible to contract with the State of California.

4. SWEATFREE CODE OF CONDUCT:

- a. Contractor declares under penalty of perjury that no equipment, materials, or supplies furnished to the State pursuant to the contract have been laundered or produced in whole or in part by sweatshop labor, forced labor, convict labor, indentured labor under penal sanction, abusive forms of child labor or exploitation of children in sweatshop labor, or with the benefit of sweatshop labor, forced labor, convict labor, indentured labor under penal sanction, abusive forms of child labor or exploitation of children in sweatshop labor. Contractor further declares under penalty of perjury that it adheres to the Sweatfree Code of Conduct as set for on the California Department of Industrial Relations [website](#) and California Public Contract Code, Section 6108.
- b. Contractor agrees to cooperate fully in providing reasonable access to the contractor's records, documents, agents or employees, or premises if reasonably required by authorized officials of the contracting agency, the California Department of Industrial Relations, or the California Department of Justice to determine the contractor's compliance with the requirements under paragraph (a) of this section.

5. AMERICANS WITH DISABILITIES ACT: Contractor assures the State that it complies with the Americans with Disabilities Act (ADA) of 1990, which prohibits discrimination on the basis of disability, as well as all applicable regulations and guidelines issued pursuant to the ADA. (42 U.S.C. 12101 et seq.)

6. LABOR CODE/WORKERS' COMPENSATION: Contractor needs to be aware of the provisions which require every employer to be insured against liability for Worker's Compensation or to undertake self-insurance in accordance with the provisions, and Contractor affirms to comply with such provisions before commencing the performance of the work of this Agreement. (California Labor Code, Section 3700.)

7. Contractor hereby certifies under penalty of perjury that, in good faith and based on its knowledge and belief, neither it nor any person who has an ownership or controlling interest in Contractor, or is an agent or managing employee of Contractor, has been convicted of any felony or misdemeanor involving fraud or abuse in any government program, or related to neglect or abuse of a patient in connection with the delivery of a health care item or service, or in connection with the interference with or obstruction of any investigation into health care related fraud or abuse, or that has been found liable for fraud or abuse in any civil proceeding, or that has entered into a settlement in lieu of conviction for fraud or abuse in any government program, within the preceding ten (10) years.

8. Contractor certifies that the covered product(s) are in general retail distribution, sold to the general public, and comply with standards for products established by law or regulation, pursuant to California Welfare and Institutions Code, section 14125.2(a). Contractor also certifies that the covered product(s) are not manufactured, distributed, or otherwise promoted for the exclusive use of beneficiaries of the Medi-Cal program.
9. Pursuant to Section 25249.6 of the California Health and Safety Code, contractor certifies that in the course of doing business contractor will not knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10 of the California Health and Safety Code.

I further certify that the company, the proposed covered product/s, and all company representatives and practices are currently in full compliance with the requirements and provisions of the following federal codes and regulations [where applicable], and will remain so during the term of any agreement with the State of California:

Federal Codes and Regulations:
 (Found at [US Code website](#) and [Code of Federal Regulations](#))

1. **United States Code, Title 21, Section 301 et seq.** *The Federal Food, Drug, and Cosmetic Act* and the related regulations.
2. United States Code, Title 21, Section 321, subdivision (h), *definition of “medical device”*.
3. Code of Federal Regulations, Title 21, Section 807.35, *Annual Registration of Medical Device Establishment*.
4. **Code of Federal Regulations, Title 42, Section 455.104**, Disclosure by providers and fiscal agents: Information on ownership and control, **Section 455.105**, Disclosure by providers: Information related to business transactions, and, **Section 455.106**, Disclosure by providers: Information on persons convicted of crimes and the related **Section 455.102**, Determination of ownership or control percentages.

 (SIGNATURE OF LEGAL SIGNEE)

 (DATE)

 (PRINTED NAME AND TITLE OF PERSON SIGNING)

 (PRINT CONTRACTOR NAME)

 (PRINT MAILING ADDRESS, CITY, STATE, ZIP)