MEDI-CAL CONTRACTING PROCEDURES FOR INCONTINENCE SUPPLIES

The Medical Supplies and Enteral Nutrition Benefits Branch of the Department of Health Care Services (Department) is responsible for reviewing and evaluating incontinence supplies for retention on, addition to, or deletion from the Medi-Cal *List of Incontinence Supplies* (List) in accordance to California Welfare and Institutions Code (W&I Code), Section 14125. The incontinence supplies subject to review and coverage are those that would be dispensed to fee-for-service Medi-Cal recipients and billed by pharmacy or durable medical equipment (DME) providers.

An incontinence supply product may be reviewed and evaluated *either* as an Individual Product Petition (IPP) *or* as part of a Product Category Review (PCR). In accordance with W&I Code, Section 14125.2, the Department will only review an incontinence supply product that is currently available for general retail distribution and sale to the general public, not manufactured, distributed or promoted for the exclusive use by Medi-Cal recipients. The review and cost negotiations may result in a contract with the Department for product placement on the List. This is NOT a competitive bid process.

Contracts are for Maximum Acquisition Cost (MAC) which is a guarantee by the contractor that any Medi-Cal provider can purchase the product at or below the contracted price. The contract negotiation process may result in multiple manufacturers and distributors' products appearing on the List. A contract template for review purposes only may be requested from the project lead at any time during the review 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 until the provider bulletins are published.

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 incontinence supply technology and any proposed 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 be added to or retained on the List. The petition letter must include a detailed description of the product and the new technology 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). 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 incontinence experts. Presenters must provide their own audio-visual equipment.

If a meeting with the Department is not desired, 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 incontinence supplies for retention on, addition to, or deletion from the List, consider all of the following criteria:

(1) *Safety* - the relative freedom from side effects as determined by reviewing the contraindications, precautions, warnings, and adverse effects of the incontinence supply. Evaluation of safety may involve a single incontinence supply or comparisons between two or more incontinence supplies, and may take into account such factors as safety of alternative methods of treatment.

(2) *Efficacy* - the speed, duration, and extent to which an incontinence supply will alleviate or control the medical condition of incontinence. Evaluation of efficacy may involve a single incontinence supply or comparisons between two or more incontinence supplies, and may take into account such factors as efficacy of alternative methods of treatment.

(3) *Essential Need* - the incidence, severity and prognosis of the medical conditions for which an incontinence supply is indicated. Evaluation of essential need may involve a single incontinence supply or comparisons between two or more incontinence supplies, and may take into account such factors as the availability of alternative methods of treatment, whether an incontinence supply is curative agent or palliative in effect, or whether an incontinence supply may provide treatment for a medical condition not adequately treated by any other incontinence supply.

(4) *Misuse Potential* - the opportunity for unjustified, inappropriate, irresponsible, or improper use of an incontinence supply. Evaluation of misuse potential may take into account such factors as: utilization of incontinence supplies where there is insufficient medical necessity for its use; continued use of an incontinence supply despite loss of

effectiveness; and/or utilization of an incontinence supply where a less costly but equally safe and efficacious alternative may be used.

(5) *Cost Effectiveness* - the immediate or long-term cost effectiveness of the product. Evaluation of cost takes into account the NET COST of the product to the Department. The net cost would include any statutory mark-up or dispensing fee.

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.
- Company's product presentation.
- Pertinent medical literature or other information.
- Analysis of testing results (if applicable).

In the evaluation of the effectiveness of a product, the Department may require the manufacturer or distributor to submit its products to testing by an independent laboratory. For the purposes of this section, "independent laboratory" means an analytical laboratory that is not a subsidiary of, affiliated with, or on retainer for the manufacturer or distributor.

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 incontinence supply product(s) 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 incontinence supplies.

The project lead will notify the manufacturer or distributor of the proposed effective date the product(s) will be added to the List. The effective date to add an incontinence supply product(s) 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 incontinence supply 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 Incontinence Supplies* 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 Incontinence Supply 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 Incontinence Supply 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. **Current Annual Registration of Device Establishment** - A copy of the electronically confirmed Initial or Annual FDA Registration of Device Establishment. (Title 21 of the Code of Federal Regulations Chapter 1 Subchapter H Part 807)

4. **List of proposed products** – Provide a list on an Excel spreadsheet with the following column headings for each product proposed, both as a hard copy and by email.

    a. Exact description of product (include size if applicable).

    b. Package quantity.

    c. Universal Product Number (UPN) for all package sizes.

d. UPN qualifier.

(1) The UPN must meet one of the following:

(a) Registered GTIN (Global Trade Item Number) in 8, 12, 13, or 14 digits in length.

(b) Registered HIBCC (Health Industry Business Communications Council) alpha/numeric.

(c) UPN qualifiers.

i. UK – GTIN 14 digits

ii. UP – GTIN 12 digits

iii. HI – HIBCC

iv. EN – GTIN 13 digits

v. EO – GTIN 8 digits

e. HCPCS.

f. Catalog item number.

g. Price proposal.

5. **General Retail Distribution (W&I Code, Section 14125.2)** – Letter of attestation on company letterhead, signed by person with legal authority that the proposed products are available for general purchase in the marketplace.

6. **Manufacturing information of proposed products.**

a. Location of each proposed product manufacturing plant (city, state, country).

(1) Proposed products manufactured in California, provide a copy of each most recent valid medical device manufacturing license or renewal issued by the California Department of Public Health's Food, Drug and Radiation Safety Office. A separate license is required for each place of manufacture.

b. A letter of attestation on company letterhead, signed by person with legal authority that the manufacturing plant complies with Quality System Regulation (QS)/Good Manufacturing Practices (GMP) general requirements concerning records and complaint files consistent with Title 21 of the Code of Federal Regulations Chapter 1 Subchapter H Part 820.180 and Part 820.198. NOTE: Class I devices are exempt from the GMP regulation, except for general requirements concerning records (21CFR 820.180) and complaint

files (21 CFR 820.198), as long as the device is not labeled or otherwise represented as sterile.

c. Letter of attestation on company letterhead, signed by person with legal authority that upon request from the Department, Contractor will 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.

d. Product Safety – Letter of attestation on company letterhead, signed by person with legal authority that all components and additives in the proposed incontinence absorbent products to retain or add on the List are considered safe and are not listed on California Proposition #65 current list and in any Federal Regulatory Agency as being "unsafe". The letter should also include upon request from the Department, the Contractor will make available a list of all the proposed products components and additives.

7. **Product Specifications** – Proposed products must meet certain product specifications.

   a. Letter of attestation on company letterhead, signed by person with legal authority that the proposed products meet Medi-Cal absorbent products specifications.

   b. Provide marketing materials, catalog pages, or written document describing each proposed product attributes or specifications.

8. **Product Testing Standards** – proposed products must meet Medi-Cal absorbent products testing standards.

   a. Testing Requirements.

      (1) An original copy of test results from an independent laboratory (analytical laboratory that is not a subsidiary of, affiliated with, or on retainer for, the manufacturer or distributor) must be submitted for all products proposed (each product brand in each size).

      (2) The independent laboratory should receive products shipped for testing in the original retail package.

      (3) The report must show testing performed within 6 months of the date of submission.

      (4) In addition to the test results, the report must include the following information:
      (a) Name and address of testing institution.

      (b) Reference the test method used.

(c) Complete identification of all materials tested including product name and size, item number or UPN.

b. NOTE: Contact the lead consultant or email medicalsupplies@dhcs.ca.gov to request the Medi-Cal Absorbent Products Specifications and Testing Standards.

c. 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)