



MEDICAL SUPPLY PRODUCTS REVIEW AND CONTRACTING POLICIES AND PROCEDURES

This document, by the Department of Health Care Services (DHCS), Pharmacy Benefits Division, represents the review, evaluation and contracting policies and procedures for disposable medical supply products covered under the outpatient medical supply benefit.

Medical supply products are reviewed and evaluated for retention on, addition to, or deletion from the *List of Medical Supply Products* (List) in accordance to California Welfare and Institutions Code (W&I Code), Section 14105.47. Medical supply products subject to review and coverage are those administered through the fee-for-service (FFS) outpatient delivery system by durable medical equipment and pharmacy providers.

A medical supply product may be reviewed and evaluated *either* as an Individual Product Petition (IPP), *or* as part of a Product Category Review (PCR). DHCS will not begin a review unless the product has received appropriate marketing approval and is currently available on the market.

A product review and cost negotiations may result in a contract with DHCS for product placement on the contracted product list. Not all covered products or product types are contracted. Refer to the List in the Medi-Cal Allied Health and Pharmacy Provider Manuals for the specific product categories and medical supply billing codes that are restricted to contracted products. The product categories and medical supply billing codes may be restricted to one type of agreement (contract) or both agreement types:

- Maximum Acquisition Cost (MAC) Agreement guarantees an acquisition cost as the maximum selling price to all providers.
- Maximum Acquisition Cost (MAC) and Rebate Agreement guarantees both a MAC to all providers and a net cost to DHCS through a rebate (percentage of the MAC per unit).

The contract negotiation process may result in multiple manufacturers and distributors products appearing on the contracted product 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 DHCS, but shall not reveal or actively promote that products have been or will be added to the List until the provider bulletins are published.

DHCS reviews and evaluates medical supply products for retention on, addition to, or deletion from the List either as an Individual Product Petition (IPP) or as part of a Product Category Review (PCR) 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

Product Category Review (PCR)

The PCR is initiated by DHCS to determine whether products within a certain medical supply category will be retained on, added to, or deleted from the List. DHCS sends a notification and invitation letter to manufacturers and distributors to participate in the PCR process. Interested manufacturers or distributors are encouraged to keep DHCS updated with a contact name, email 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 submission requirements and due dates to be eligible for participation. During the PCR process, companies will have an opportunity to meet with DHCS to discuss the proposed products, present the five review criteria, product studies and required documents. The PCR process may result in contract negotiations with DHCS for product placement on the List.

Individual Product Petition (IPP)

The IPP is a process outside of the PCR by which products with new medical supply technology and any proposed changes to currently contracted products are reviewed and evaluated for addition to or retention on the List based on the five review criteria.

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(s) and the new technology or an explanation of the changes to the currently contracted products.

Submit petition letters and required documents electronically to medicalsupplies@dhcs.ca.gov or by mail to:

California Department of Health Care Services
Pharmacy Benefits Division
Chief of Medical Supplies and Enteral Nutrition Benefits Branch

US Postal Service
P.O. Box 997413
MS 4604
Sacramento, CA 95899-7413

UPS/FedEx
1501 Capitol Avenue, Suite 71.6089
MS 4604
Sacramento, CA 95814

Upon receipt of the petition letter, DHCS will notify the company within ninety days if the review for the proposed products has been initiated or if the petition will be deferred to the next scheduled PCR. IPPs may be deferred until the next PCR if the proposed products do not offer any significant clinical benefit over products currently on the List.

Product Review Criteria

When evaluating medical supplies for retention on, addition to, or deletion from the List of Medical Supply Products, DHCS considers 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 medical supply.

Evaluation of safety may involve a single medical supply or comparisons between two or more medical supplies, and may take into account such factors as safety of alternative methods of treatment or the relationship of safety of a medical supply to the severity and prognosis of the medical conditions for which the medical supply is indicated.

2. *Efficacy* - the speed, duration and extent to which a medical supply will alleviate, control or cure the medical condition for which the medical supply is indicated. Evaluation of efficacy may involve a single medical supply or comparisons between two or more medical 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 condition for which a medical supply is indicated. Evaluation of essential need may involve a single medical supply or comparisons between two or more medical supplies. It may take into account such factors as the availability of alternative methods of treatment, whether a medical supply is curative or palliative in effect or whether a medical supply may provide treatment for a medical condition not adequately treated by any other medical supply.
4. *Misuse Potential* - the likelihood for unjustified, inappropriate, irresponsible or improper use of a medical supply. Evaluation of misuse potential may take into account such factors as: utilization of a medical supply where there is insufficient medical necessity for its use; continued use of a medical supply despite loss of effectiveness; and/or utilization of a medical 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 a medical supply product. Evaluation of cost effectiveness takes into account the NET COST of the product to DHCS. The net cost would include any statutory mark-up or dispensing fee minus any rebate (if applicable).

As part of the cost evaluation, DHCS 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).

PRODUCT EVALUATION

DHCS will conduct an internal meeting to evaluate the product following receipt of all the required documents. The project lead may request additional information for considerations from the manufacturer or distributor, such as:

- Recommendations by other entities contacted for input and unsolicited input if appropriate
- Company's product presentation
- Pertinent medical literature or other information

LIST OF REQUIRED DOCUMENTS

All of the following documents are required to evaluate proposed products for addition to the contracted list.

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 contracted product list.
- 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. Specify preferred method to receive and sign contract documents

FedEx Shipment – provide name, title and address of person to receive by FedEx shipment the contract documents.

Or

Electronically via *DocuSign* – provide email address of person with legal authority to sign contract electronically. Include name, title and email address of other individuals within the company to receive and review the contract via *DocuSign*.

- 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 A.
 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 by email to medicalsupplies@dhcs.ca.gov .
 - a. Exact description of product (include size if applicable)
 - b. Package quantity
 - c. Universal Product Number (UPN) for all package sizes
 - d. UPN qualifier
 - i. The UPN must meet one of the following:
 - Registered GTIN (Global Trade Item Number) in 8, 12, 13, or 14 digits in length (<http://www.gs1us.org/>)
 - Registered HIBCC (Health Industry Business Communications Council) alpha/numeric (<http://www.hibcc.org/>)
 - **UPN qualifiers**

UK – GTIN 14 digits	EN – GTIN 13 digits
UP – GTIN 12 digits	EO – GTIN 8 digits
HI – HIBCC	
 - ii. For products billed by pharmacy providers only, the 11-digit NDC-like product number as listed in DHCS primary price reference source, currently First Data Bank (FDB). To be eligible for review, the product 11-digit NDC-like number must be active and updated in FDB.
 - e. HCPCS
 - f. Catalog item number
 - g. Price proposal
5. Manufacturing information of proposed products
 - a. Location of each proposed product manufacturing plant (city, state, country)
 - i. 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. 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 DHCS, the company 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.

6. Proposed product information

- a. A written presentation for proposed product 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 specifications or characteristics.
- c. If applicable, copies of the 510(k) or pre-market approval letter(s) documenting marketing clearance or approval of the proposed medical supply product(s) manufactured.

NEGOTIATIONS

DHCS 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.

Prices proposed to DHCS, counter offers from DHCS, and final contracted prices shall not be shared or announced until the provider bulletins are published. Rebates for individual products, when applicable, will not be shared with anyone at any time. Failure to comply with confidentiality requirements may result in delay of the addition of products to the contracted product 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 DHCS to meet with representatives from the California Association of Medical Product Suppliers (CAMPS) and the California Pharmacists Association (CPhA). During this meeting, DHCS will share proposed or petitioned products and broad-spectrum product pricing with stakeholders.

DECISION NOTIFICATION

Upon successful review and cost negotiations to add or retain a medical supply product on the contracted list, DHCS will send a contract to the manufacturer or distributor. Once DHCS receives the contract signed by the authorized representative, DHCS will instruct its fiscal intermediary to inform providers of changes to the contracted list and to take action for processing provider claims for these medical supplies.

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

APPEALS

When DHCS decides to not contract for a product, the manufacturer or distributor of the medical supply product may file an appeal within 30 calendar days of receipt of the DHCS decision notification.

ADDITIONAL INFORMATION

To learn more about the Medi-Cal Program and to view the *Medi-Cal List of Medical Supplies* published in the Medi-Cal Pharmacy and Allied Health Provider Manuals, please visit www.medi-cal.ca.gov.

To contact the DHCS medical supply team, please email medicalsupplies@dhcs.ca.gov

APPENDIX A

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 located at www.dir.ca.gov, 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 <http://uscode.house.gov/> and www.gpoaccess.gov/cfr/index.html)

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)

(PRINTED NAME AND TITLE OF PERSON SIGNING)

(DATE)

(PRINT CONTRACTOR NAME)

(PRINT MAILING ADDRESS)

(PRINT MAILING CITY, STATE, ZIP)