INCONTINENCE PRODUCTS
REVIEW AND CONTRACTING POLICIES AND PROCEDURES

This document, by the Department of Health Care Services (DHCS), Pharmacy Benefits Division, Enteral Nutrition and Medical Supplies Benefit Branch (ENMSBB), represents the review, evaluation and contracting policies and procedures used by the ENMSBB's team to make recommendations and decisions regarding addition, retention or deletion of incontinence products on the Medi-Cal Incontinence Medical Supplies Lists. Incontinence products are reviewed and evaluated for retention on, addition to, and deletion from the Medi-Cal *List of Contracted Incontinence Absorbent Products* and the *List of Contracted Incontinence Creams and Washes* in accordance to California Welfare and Institutions (W&I) Code Section 14125. The incontinence products subject to review and coverage are those that would be dispensed to Medi-Cal beneficiaries and billed by pharmacy, durable medical equipment or medical supply providers.

In accordance with W&I Code, Section 14125.2, the Department will only review incontinence products that are currently available for general retail distribution and sale to the public. When evaluating incontinence products DHCS considers five statutory criteria: safety, effectiveness, essential need, misuse potential, and cost-effectiveness. In the evaluation of the effectiveness, DHCS requires products meet certain specifications and may require manufacturer, relabeler, or distributor to submit absorbent products to testing by an independent laboratory.

California Board of Pharmacy law, which provides requirements for the dispensing of prescriptions, applies to medical supplies items dispensed by a pharmacy provider. In accordance with Pharmacy law, both inner and outer packages (when items are dispensed as a case), must be clearly labeled to avoid the potential of misuse. *Please refer to BPC § 4076 (a-e) and 16 CCR § 1707.5 (a-e) for additional information.*

A product review and cost negotiations may result in a Maximum Acquisition Cost (MAC) Agreement with DHCS for product placement on the contracted list. The contract agreement is a guarantee by the manufacturer, relabeler, or distributor that any Medi-Cal provider can purchase the product, upon request, from at least one source at or below the agreed upon MAC for dispensing to Medi-Cal beneficiaries. This is NOT a competitive bid process. The contracting process may result in multiple manufacturers, relabelers, or distributors products appearing on the contracted list. A contract agreement template for review purposes is available upon request.

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

Refer to the Medi-Cal provider manual section, *Incontinence Medical Supplies*, for the specific incontinence billing codes that are restricted to products on the contracted lists.

Manufacturers, relabelers, or 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 providers are notified by the Medi-Cal bulletins.

Products Eligible for Review

DHCS will only review an incontinence product that is currently available for general retail distribution and sale to the public. The product must be assigned a unique identifier that is a coded number registered with either Global Trade Item Number (GTIN) developed by GS1 or Health Industry Business Communications Council (HIBCC). The unique identifier, also known as a Universal Product Number (UPN), must be clearly marked on the package that would be dispensed to the recipient.

Product Category Review

DHCS conducts a Product Category Review (PCR) for incontinence supplies prior to the contract renewal process. The PCR includes a review and evaluation of all products for retention on the contracted list and may result in renegotiation and renewal of MAC agreements. DHCS notifies contractors of the PCR and the documents required for product retention on the contracted lists. Failure to respond to the notification within the allotted period may result in deletion of all the contractor's products from the list.

To ensure absorbent products retained on the *List of Contracted Incontinence Absorbent Products* meet the Product Performance Standards, DHCS reserves the right to conduct a random, periodic selection of products for testing. Products selected for testing at the request of DHCS shall be the responsibility of the contractor.

Contractors are encouraged to keep DHCS updated with names, email addresses, and phone numbers for two company representatives to ensure receipt of any notifications regarding Medi-Cal contracted incontinence products.

Individual Product Petitions

DHCS reviews and evaluates individual product petitions for addition to the contracted lists at least once during the State Fiscal Year (July 1 – June 30).

Manufacturers, relabelers, or distributors interested in adding products to the list must submit all the Product Review Required Documents **on or before June 30** of the current fiscal year to be eligible for review in the subsequent fiscal year.

Any proposed changes to products on the contracted lists that may affect the performance, use, specifications, safety, appearance, or labeling of that product must be reviewed by DHCS for product retention on the list. Contractors must notify DHCS in writing on company letterhead detailing the product changes.

At any time, a contractor may request deletion of products from the contracted list by submitting to DHCS a 90-day advance written notice on company letterhead signed by a person with legal authority. In addition, products may be deleted from the contracted list pursuant to Article VI of the contract agreement.

Product Review Required Documents

A complete individual product petition package must include all of the documents listed below. Submit the package by email to medicalsupplies@dhcs.ca.gov **OR** by mail to:

California Department of Health Care Services
Chief, Enteral Nutrition and Medical Supplies Benefit Branch

US Postal Service	UPS/FedEx
P.O. Box 997413	1501 Capitol Avenue, Suite 71.6089
MS 4604	MS 4604
Sacramento, CA 95899-7413	Sacramento, CA 95814

1. A "Letter of Intent to Contract" with DHCS for products proposed for addition to the contracted list. The letter must be on company letterhead signed by a person with legal authority.

   The following information must also be included on the letter:

   a. Company contact information
      i. Main contact person's name, title, email address and phone number.
      ii. Alternate contact person's name, title, email address and phone number.

   b. Company information
      i. Company's legal name.
      ii. Ownership – List the name and address of each person or corporation with an ownership or control interest of 5% or more in the proposed contractor 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.)
      iii. Authorized contract signer's name, title and address.
      iv. 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 name, title and email address for the following:

      - One or more individuals within the company to review contract prior to signature and receive signed contracts.
      - Authorized contract signer.

2. List of proposed products - include product description with size and package quantity, item number, Universal Product Number (UPN), UPN qualifier, HCPCS and MAC.

   Product UPN must meet one of the following:

   a. Registered GTIN (Global Trade Item Number) in 8, 12, 13, or 14 digits in length (http://www.gs1us.org/).

   b. 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

3. Signed Contractor's Certification (refer to Appendix A).

4. Prior to submission, products must be available for general retail distribution pursuant to W&I Code, Section 14125.2. Either of the following must be provided:

   - The name, location and phone number of at least one pharmacy or medical supply dealer within California, which are physical locations open to the public where proposed products are available for purchase OR

   - A state or federal listing of approved products for purchase where proposed products are included.

5. Establishment Registration and Good Manufacturing Practices.

   a. Provide proof of current annual FDA medical device establishment registration (Title 21 CFR Part 807).

   b. Provide the location of each proposed product manufacturing plant (city, state, country).

   c. For each proposed product manufacturing plant, provide a statement attesting that the plant complies with Quality System Regulation (QS)/Good Manufacturing Practices (GMP) general requirements concerning records(21 CFR 820.180) and complaint files (21 CFR 820.198).

   d. For proposed products manufactured in California, provide a copy of current 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. (California Health and Safety Code Section 111615).

6. Assurance of product safety

   - Provide a statement attesting that the proposed product components and additives are not listed on California Proposition #65 current list and in any Federal Regulatory Agency as being 'unsafe'.

7. Test reports for product types and sizes listed below. The testing and reports must meet the Absorbent Products Testing Requirements.

   - Briefs/diapers, disposable - medium and large sizes only for each product brand.

   - Protective underwear/pull-on, disposable - medium and large sizes only for each product brand.

   - Liners, shields, guards, pads, or beltless undergarments - heavy absorbency only.

- Belted undergarments.
- Disposable underpads – small and large sizes.

Refer to the Product Performance Standards for the testing parameters target values. If test results do not meet the performance parameters target values, the product brand (all sizes) may not be eligible for inclusion on the List.

8. Assurance that all products proposed meet the product specifications and performance requirements.
   - Provide a statement attesting that all the proposed products and product sizes meet the Product Performance Standards.
9. Per contract agreement, products on the List must be available from at least one source for Medi-Cal providers to purchase, upon request, at or below the agreed upon MAC for dispensing to fee-for-service Medi-Cal recipients.
   - Provide a statement acknowledging the contract agreement terms.
10. Notify DHCS of any changes to contracted products.
    - Provide a statement attesting that DHCS will be notified per contract agreement of any recall or changes to products on the List that may affect the performance, use, specifications, safety, appearance, or labeling of that product.
    - Note certain changes to a product may require re-testing by an independent laboratory.
11. Agree to provide product samples to DHCS upon request.

Negotiations

DHCS may present a price counter offer following the PCR evaluation process. The manufacturer, relabeler, or distributor may accept, reject, or present an alternative to the counter offer within the time frame requested by DHCS.

Confidentially 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 approval to add or retain products on the contract list, DHCS will send a contract to the manufacturer, relabeler, 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 List and to take action for processing provider claims for these incontinence products.

DHCS will notify the manufacturer, relabeler, or distributor of the proposed effective date the product will be added to the List. The effective date to add incontinence products is not official until published in the Medi-Cal provider bulletins. **Manufacturers, relabelers, 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

If a petition of a product has been denied, the manufacturer, relabeler, or distributor must wait until the next product category review (PCR), until they may re-petition the same product. An appeal may be made before the PCR if significant changes have been made to the product to justify a secondary review. An appeal must include specific documentation in a letter or email to the project lead requesting a new review. The project lead will determine whether the product will be considered or deferred and respond within 30 days of receipt of the appeal.

Additional Information

To learn more about the Medi-Cal Program and to view the Medi-Cal *List of Contracted Incontinence Absorbent Products* and *List of Contracted Incontinence Creams and Washes* published in the Medi-Cal Pharmacy and Allied Health Provider Manuals, please visit www.medi-cal.ca.gov.

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

PRODUCT PERFORMANCE STANDARDS

Briefs/Diapers and Protective Underwear/Pull-on, Disposable

- Closure system that is adjustable and allows for multiple fastening and unfastening or pull-on and off capabilities.
- Multi-strand, contoured elastic leg gathers.
- Elasticity performance that assures proper fit, comfort and prevention of leaks.
- Waist, hip or weight measurements appropriate for the product size must be clearly marked on all packaging to assist in determining optimal fit and reduce leakage.

Reference Sizing Chart				
	Briefs/Diapers		Protective Underwear/Pull-on	
Size	Waist Range (inches)	Weight Range (lbs.)	Waist Range (inches)	Weight Range (lbs.)
Youth	15-22	40-80	17-22	80-120
Small	20-31	80-120	22-30	110-150
Medium	32-44	100-180	28-40	140-190
Regular	40-48	130-215		
Large	44-58	140-240	34-44	180-250
Adult X-Large	58-68	210-250	42-54	240-300
Adult XX-Large	62-70	250-300	52-74	250-300

- Disposable briefs/diapers and protective underwear/pull-on must meet or exceed the target values below for all parameters. Products may be considered if only one of the parameters is no more than 15% outside of the target value.

Parameters	Brief/Diaper Target Values	Protective Underwear/Pull-on Target Values
ROA	$\leq$ 50 seconds	$\leq$ 35 seconds
Rewet Rate	$\leq$1.0 g	$\leq$ 0.5 g
Retention Capacity	$\geq$ 400 g	$\geq$ 400 g
Breathability	$\geq$ 100 cfm	$\geq$ 100 cfm

Test results are required for each product brand medium and large sizes when submitting a petition to add products.

Liners, Shields, Guards, Pads, Beltless Undergarments

- Ability to contain leakage
- Ability to contain odor
- Ability to keep the skin dry
- Ability to stay in place
- Product absorbency level must be clearly marked on the package
- Heavy absorbency level products must meet or exceed the target values below for all parameters. Products may be considered if only one of the parameters is no more than 15% outside of the target value.

Parameters	Heavy Absorbency Liner, Shield, Guard, Pad and Beltless Undergarment Target Values
ROA	≤ 50 seconds
Rewet Rate	≤ 1.0 g
Total Absorbent Capacity	≥ 1,000 g

Testing is not required for products classified as light or moderate absorbency levels.

Belted Undergarments

- Designed with soft wide elasticized waistband or reusable elastic straps designed with reinforced button holes or Velcro (minimum of one set per package).
- Designed with multi-strand, contoured elastic leg gathers.
- Elasticity performance to assure proper fit, comfort and prevention of leaks.
- Belted Undergarments must meet or exceed the target values below for all parameters. Products may be considered if only one of the parameters is no more than 15% outside of the target value.

Parameters	Belted Undergarments Target Values
ROA	≤ 50 seconds
Rewet Rate	≤1.0 g
Total Absorbent Capacity	≥ 950 g

Reusable Underwear

- Body fabric composition should be cotton or cotton/polyester blend.
- Designed with a waterproof pouch or pocket to hold a disposable pad or guard without the use of an adhesive.
- Designed with a waterproof backing and side walls to help prevent leakage.
- Waist, hip or weight measurements (refer to sizing chart) appropriate for the product size must be clearly marked all packaging to assist in determining optimal fit and reduce leakage.
- Provide durability – product must be able to withstand 52 machine washings and tumble dryings without losing its original features and functions.

Reference Sizing Chart						
Reusable Underwear						
		Small	Medium	Large	X-Large	XX-Large
Waist (inches)	Men	28-32	32-36	36-40	40-44	44-48
	Women	22-28	28-32	32-36	36-40	40-44
	Unisex	22-32	26-36	28-40	32-44	34-48
Hip (inches)		35-37	38-40	41-42	43-44	45-48

Underpads, Disposable

- Designed to help absorb leakage, help reduce odors, and help maintain dryness.
- Provides protection for beds and seating surfaces.
- Waterproof backing.
- Small size core mat area is less than 676 square inches.
- Large size core mat area must be equal to or greater than 676 square inches.
    - The size of the core mat area may vary for different products with the same overall pad dimensions due to different manufacturing. The size of a specific product's core mat area may vary slightly between lots or batches. DHCS reserves the right to determine upon review, which products meet the 'large size' underpads category for contracting purposes.
- Disposable underpads must meet or exceed the target values below for all parameters. Products may be considered if only one of the parameters is no more than 15% outside of the target value.

Parameters	Underpads, Disposable Target Values
ROA	$\leq$ 240 seconds
Rewet Rate	$\leq$15 g
Total Absorbent Capacity	$\geq$1800

Breathable Underpads, Disposable

- Designed specifically for use on low air loss or air flow beds.
- Designed to help absorb leakage, help reduce odors, and help maintain dryness.
- Designed without any plastic barriers to allow air to circulate.

Incontinence Creams

- Formulated to provide adequate protection from urine and feces.
- Skin barrier creams or ointments.
- May contain conditioning ingredients that may help soothe and moisturize the skin.
- May not contain triclosan.
- Must be labeled for incontinent care.

Incontinence Wash

- Formulated to cleanse the perineal area and gently remove urine and fecal matter.
- No rinse and non-irritating formulation.
- Formulated to help control odor.
- Must be labeled for incontinent care.

ABSORBENT PRODUCTS TESTING REQUIREMENTS

1. Manufacturers, distributors, and suppliers are responsible for product testing. Testing must be performed by an ISO 9000* compliant independent testing laboratory. DHCS does not require any specific laboratory, but it must be an analytical laboratory that is not a subsidiary of, affiliated with, or on retainer for the manufacturer, distributor or supplier.

2. Performance parameters test methods (refer to the Product Performance Standards for the specific parameters for the product type that require testing).

    a. Rate of acquisition (ROA), a measure (seconds) of the speed at which urine is wicked, or drawn away, from the skin by an absorbent product being worn, testing must be performed according to the methodology in Standard Procedure: NWSP 070.9.R1 (15) provided in the 2015 Nonwovens Standard Procedures**.

    b. Rewet rate, a measure (grams) of product's ability to withstand multiple incontinence episodes between changes, testing must be performed according to the methodology in Standard Procedure: NWSP 070.9.R1 (15) provided in the 2015 Nonwovens Standard Procedures**.

    c. Retention capacity, a measure (grams) of a product's capacity to hold fluid without leaking and rewetting the skin, testing must be performed according to the Retention Capacity Test Method.

    d. Breathability, a measure of breathable zones (air permeability) in briefs or protective underwear at a controlled differential pressure, testing must be performed according to the methodology in Standard Procedure: NWSP 070.1.R0 (15) provided in the 2015 Nonwovens Standard Procedures**.

    e. Total Absorbent Capacity testing must be performed according to the methodology in ISO Standard: ISO 11948-1:1996* for determining the absorption capacity of the absorbent core.

    The Product Performance Standards and test methods for briefs/diapers and protective underwear/pull-on are based on the National Quality Performance Standards for Disposable Adult Absorbent Products for Incontinence assembled by the National Association for Continence.

3. Five product samples for each required size of each product brand must be tested for each required performance parameter. The samples shipped to the independent laboratory for testing must be a randomly selected package available for general retail distribution.

* Available on www.iso.org (ISO, International Organization for Standardization)

**Available on both www.inda.org (INDA, Association of the Nonwoven Fabrics Industry) and www.edana.org (EDANA, International Association Serving the Nonwovens and Related Industries).

4. Provide a report of the test results that include all of the following:

    a. Test method used.

    b. The arithmetic average of the five product samples test results.

    c. Anything unusual noted during the testing.

    d. Name and address of the testing institution.

    e. Identify product samples tested by including **all** of the following:

        i. product name.

        ii. product size.

        iii. lot number.

        iv. Universal Product Number (GTIN or HIBCC).

5. Testing must be performed within 6 months of the date of submission.

6. Products that require testing and reporting:

    Petitions to add products to the List require testing and reporting for the following product types and sizes:

    - Briefs/diapers, disposable - medium and large sizes only for each product brand.
    - Protective underwear/pull-on, disposable - medium and large sizes only for each product brand.
    - Liners, shields, guards, pads, or beltless undergarments - heavy absorbency only.
    - Belted undergarments.
    - Disposable underpads – small and large sizes.

To retain products on the List, the contractor must agree to submit products to testing as required by DHCS.

DHCS may randomly select 1-5 products on the List from each contractor to submit to testing and report results. The testing requirement may not take place during any specific time and contractors may not require testing at the same time.

Testing results for the products randomly selected must be submitted within 6 months of the notice to test. Testing must be performed within 6 months of the date of submission. Testing results not received within 6 months of notice to test, may result in deletion of all the contractor's products from the List and ineligible for addition to the List for a minimum of three years. Test results must meet the parameters target values for that branded product to be retained on the List.

7. Test reports must be submitted:

   a. via email by the laboratory only to medicalsupplies@dhcs.ca.gov **OR**

   b. the original copy via mail to:

California Department of Health Care Services
Chief, Medical Supplies & Enteral Nutrition Benefits Branch

US Postal Service	UPS/FedEx
P.O. Box 997413	1501 Capitol Avenue, Suite 71.6089
MS 4604	MS 4604
Sacramento, CA 95899-7413	Sacramento, CA 95814

The *List of Contracted Incontinence Absorbent Products* testing results are available upon request. Submit request by email to medicalsupplies@dhcs.ca.gov.

Retention Capacity Test Method*

Retention Capacity: The amount of liquid (grams) retained in a product after being subjected to liquid absorption capacity test (ISO Capacity Method ISO 11948-1: 1996 (E)) then to centrifugal forces. The retention capacity equals the wet spun weight minus the dry weight.

EQUIPMENT

A. Fisher & Paykel Ecosmart Model WA37T26G washing machine or equivalent capable of a 7 minutes 15 second spin cycle at 670 rpm.

B. Weighing Tray – large enough for product being tested.

C. Lab Balance – capable of weighing to nearest gram.

PROCEDURE

1. Select 5 samples of the product for testing. The samples shall be identifiable and traceable back to the origin.
2. Weigh each dry sample and record the dry weight.
3. Perform a liquid absorption capacity test (ISO Capacity Method ISO 11948-1: 1996(E)) on the sample.
4. Upon completion of a liquid absorption capacity test, place the wet sample in the washer with the absorbent core flat facing the side of the tub. Multiple samples may be spun at the same time providing there is no overlapping of the product's core. If testing multiple samples, identify them with indelible ink for identification.
5. Push the power button on the washing machine panel. Using the arrow button, select the Spin (centrifugal) cycle under the Wash Progress display.
6. Select Medium at the Spin Speed display, and then push the Start/ Pause button. NOTE: Medium spin (centrifugal) speed is 670rpm and the complete cycle time is 7-minutes 15-seconds.
7. The machine's lid will automatically lock to prevent opening during the cycle and the spin cycle will start.
8. When the spin cycle is complete, the machine will beep and the lid will automatically unlock.
9. Remove the sample, place on a tare weighing tray and record the spun weight.
10. Calculate each sample retention capacity by: ***Spun Weight - Dry Weight (recorded prior to liquid absorbent capacity test) = Retention Capacity.***
11. Report the amount of liquid retained in grams as retention capacity for each sample.
12. Report the average retention capacity of the 5 samples tested.

*Recommended by the National Quality Performance Standards for Disposable Adult Absorbent Products for Incontinence assembled by the National Association for Continence.

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:

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, and 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)