The Department of Health Care Services (DHCS) reviews and evaluates products for retention on, addition to, and deletion from the Medi-Cal List of Contracted Incontinence Absorbent Products (List) in accordance to California Welfare and Institutions (W&I) Code Section 14125. The incontinence absorbent products 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 providers. DHCS will only review an incontinence absorbent product that is currently available for general retail distribution and sale to the general public.

When evaluating incontinence products for addition to, retention on, or deletion from the List, DHCS considers five statutory criteria; safety, effectiveness, essential need, misuse potential, and cost-effectiveness. In the evaluation of the effectiveness of a product, DHCS may require manufacturers, distributors, or suppliers to submit products to testing by an independent laboratory.

A product review may result in a maximum acquisition cost (MAC) contract agreement with DHCS for product placement on the List. The contract agreement is a guarantee by the manufacturer, distributor, or supplier 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 fee-for-service Medi-Cal recipients. A contract agreement template for review purposes is available upon request.

The MAC would remain the same throughout the three year contract agreement. During the contract renewal process, DHCS may negotiate new MACs with manufacturers, distributors, and suppliers.

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.

Certain Medi-Cal incontinence billing (HCPCS) codes are contracted. For the contracted billing codes, only products on the List are eligible for Medi-Cal reimbursement. Refer to the Medi-Cal provider manual section, *Incontinence Medical Supplies* for the contracted billing codes.

**Product Addition to the List**

After July 1, 2016, incontinence products petitioned and/or added to the List must meet the new performance standards. DHCS will conduct a review of incontinence products petitioned for addition to the List that meet the new performance standards once per State Fiscal Year (July 1 – June 30). Manufacturers, distributors, and suppliers must submit a petition and the product review required documents prior to the start of the fiscal year, no later than June 30, to be eligible for the annual review.
Note: Petitions with all the product review required documents submitted by June 30, 2017 will be eligible for the upcoming annual review for fiscal year 2017-2018.

Upon review, products approved for addition to the List with signed contract agreements will be added as soon as administratively possible. The administrative process to add products to the List will take place only once per year.

Manufacturers, distributors, and suppliers may discuss products that have been proposed or petitioned to DHCS, but shall not reveal or actively promote specific products that have been or will be added to the List until the provider bulletins are published.

**Product Retention on the List**

Effective April 1, 2018, currently contracted products must meet DHCS new performance standards to be retained on the List. Contract agreements must be renewed prior to expiration to retain products on the List.

Products on the List with any changes that may affect the performance, use, specifications, safety, appearance, or labeling of that product must be reviewed for product retention on the List. Manufacturers, distributors, and suppliers must notify DHCS by submitting a letter outlining the changes.

DHCS will notify manufacturers, distributors, and suppliers of the contract renewal process to retain products on the List prior to expiration of the contract agreement. Failure to respond to the notification within the allotted time frame may result in the deletion of all contracted products by the manufacturer, distributor, or supplier from the List.

To renew contracts, manufacturers, distributors, and suppliers will be required to update certain documents and certify that contracted products will continue to meet or exceed DHCS performance standards for the term of the contract agreement. Test results will not be required for the contract renewal process.

To ensure products retained on the List meet the product performance standards, DHCS reserves the right to conduct a random, periodic selection of products that must be tested for retention on the List. Testing requirements at the request of DHCS shall be the responsibility of the manufacturer, distributor, or supplier.

Manufacturers, distributors, and suppliers are encouraged to keep DHCS updated with a contact name, email address, and phone number to ensure notification of an upcoming contract renewal process.

**Product Deletion from the List**

At any time, a manufacturer, distributor, or supplier may request deletion of one or more products from the 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 List pursuant to Article VI of the contract agreement.
Product Review Required Documents

Below is a list of documents that DHCS require for review of incontinence products petitioned for addition to the List of Contracted Incontinence Absorbent Products.

All statements must be on company letterhead signed by person with legal authority.

Proposals may be submitted by email to medicalsupplies@dhcs.ca.gov OR by mail to:

California Department of Health Care Services  
Chief, Medical Supplies & Enteral Nutrition Benefits Branch  
US Postal Service  
P.O. Box 997413  
Sacramento, CA 95899-7413
MS 4604  
Sacramento, CA 95814

1. 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](https://en.wikipedia.org/wiki/GTIN)) in 8, 12, 13, or 14 digits in length
b. Registered HIBCC ([Health Industry Business Communications Council](https://www.hibcc.org)) alpha/numeric

**UPN qualifiers**

- UK – GTIN 14 digits
- UP – GTIN 12 digits
- HI – HIBCC
- EN – GTIN 13 digits
- EO – GTIN 8 digits

2. Your company information

   a. Company’s legal name
   b. Contract signature - name, title and address of person with legal authority to sign agreement (contract)
   c. Contract shipment – name, title and address of person to receive by FedEx shipment the agreement (contract)
   d. 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.)
3. Signed Contractor’s Certification (refer to Appendix A)
4. Products must be available for general retail distribution (W&I Code, Section 14125.2).
   • Provide a statement attesting that the proposed products are available for general purchase in the marketplace at the time of submission.
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. Product testing should be performed and reported for the following product types and sizes. Testing requirements must be met for each reported test results.
   • 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
   NOTE: If the test results for the medium or large size briefs/diapers or protective underwear/pull-on do not meet the performance parameters target values, all sizes within that branded product 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 performance standards.
Note: Any size brief/diaper or protective underwear/pull-on may be randomly selected for testing for retention on the List.

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: Products may require re-testing by an independent laboratory if the UPN changes or there’s a change that can reasonably affect a product’s performance.

11. Agree to provide product samples to DHCS upon request.
Testing Requirements

1. Manufacturers, distributors, and suppliers are responsible for the 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 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 methodology in Appendix B.

   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 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 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 [ISO, International Organization for Standardization](https://www.iso.org) website

**Available on both [INDA, Association of the Nonwoven Fabrics Industry](https://www.inda.org) and [EDANA, International Association Serving the Nonwovens and Related Industries](https://www.edana.net) websites
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
   a. Name and address of the testing institution
   b. 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

   **NOTE:** If the test results for medium or large size briefs/diapers or protective underwear/pull-on do not meet the performance parameters target values, all sizes within that branded product may not be eligible for inclusion on the List.

   **To retain products on the List, the manufacturer, distributor, or supplier must agree to submit products to testing as required by DHCS.**

   During the three year contract agreement, DHCS may randomly select 1-5 products on the List from each manufacturer, distributor, and supplier to submit to testing and be reported. The testing requirement should not be expected to take place during any specific time period, nor should it be expected that all products and/or manufacturers, distributors, or suppliers will 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 manufacturer, distributor or supplier contracted 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.

   **Note:** Any size disposable brief/diaper or protective underwear/pull-on may be randomly selected for testing.

   **Manufacturers, distributors, and suppliers are encouraged to keep DHCS updated with a contact name, email address, and phone number to ensure notification of required product testing.**
7. Test reports must be submitted:
   a. via email by the laboratory only to medicalsupplies@dhcs.ca.gov OR
   b. via mail (the original copy) 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 71.5131
   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
Performance Standards

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

Product specifications requirements

- 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 should be clearly marked on the package to assist in determining optimal fit and reduce leakage

Reference Sizing Chart

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

Product performance requirements

Products must meet or exceed the target values below for any three of the four parameters. No more than one of the four parameters may fall more than 15% outside of the target value. Test results are required only for medium and large sizes when submitting a petition to add products to the List.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Brief/Diaper Target Values</th>
<th>Protective Underwear/Pull-on Target Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROA</td>
<td>≤ 50 seconds</td>
<td>≤ 35 seconds</td>
</tr>
<tr>
<td>Rewet Rate</td>
<td>≤ 1.0 g</td>
<td>≤ 0.5 g</td>
</tr>
<tr>
<td>Retention Capacity</td>
<td>≥ 400 g</td>
<td>≥ 400 g</td>
</tr>
<tr>
<td>Breathability</td>
<td>≥ 100 cfm</td>
<td>≥ 100 cfm</td>
</tr>
</tbody>
</table>
Liners, Shields, Guards, Pads, Beltless Undergarments

Product specifications requirements for all absorbency levels

- Ability to contain leakage
- Ability to contain odor
- Ability to keep the skin dry
- Ability to stay in place

Product performance requirements for heavy absorbency

Testing requirements must be met and test results must meet or exceed the target values below for any two of the three testing parameters and be within 15% of the target value for the third parameter.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Heavy Absorbency Liner, Shield, Guard, Pad and Beltless Undergarment Target Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROA</td>
<td>≤ 50 seconds</td>
</tr>
<tr>
<td>Rewet Rate</td>
<td>≤ 1.0 g</td>
</tr>
<tr>
<td>Total Absorbent Capacity</td>
<td>≥ 1,000 g</td>
</tr>
</tbody>
</table>

Belted Undergarments

Product specifications requirements

- 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

Product performance requirements

Testing requirements must be met and test results must meet or exceed the target values below for any two of the three testing parameters and be within 15% of the target value for the third parameter.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Belted Undergarments Target Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROA</td>
<td>≤ 50 seconds</td>
</tr>
<tr>
<td>Rewet Rate</td>
<td>≤ 1.0 g</td>
</tr>
<tr>
<td>Total Absorbent Capacity</td>
<td>≥ 950 g</td>
</tr>
</tbody>
</table>
Reusable Underwear

Product specifications requirements

- 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 should be clearly marked on the package to assist in determining optimal fit and reduce leakage

Product performance requirements

- Provide durability – product must be able to withstand 52 machine washings and tumble dryings without losing its original features and functions

Reference Sizing Chart

<table>
<thead>
<tr>
<th>Reusable Underwear</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
<th>X-Large</th>
<th>XX-Large</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waist (inches)</td>
<td>Men</td>
<td>28-32</td>
<td>32-36</td>
<td>36-40</td>
<td>40-44</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>22-28</td>
<td>28-32</td>
<td>32-36</td>
<td>36-40</td>
</tr>
<tr>
<td></td>
<td>Unisex</td>
<td>22-32</td>
<td>26-36</td>
<td>28-40</td>
<td>32-44</td>
</tr>
<tr>
<td>Hip (inches)</td>
<td></td>
<td>35-37</td>
<td>38-40</td>
<td>41-42</td>
<td>43-44</td>
</tr>
</tbody>
</table>
Underpads, Disposable

Product specifications requirements
- 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 a lot and/or batch. DHCS reserves the right to determine upon review, which products meet the ‘large size’ underpad category for contracting purposes.

Product performance requirements
Testing requirements must be met and test results must meet or exceed the target values below for any two of the three testing parameters and be within 15% of the target value for the third parameter.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Underpads, Disposable Target Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROA</td>
<td>≤ 240 seconds</td>
</tr>
<tr>
<td>Rewet Rate</td>
<td>≤ 15 g</td>
</tr>
<tr>
<td>Total Absorbent Capacity</td>
<td>≥ 1800</td>
</tr>
</tbody>
</table>

Breathable Underpads, Disposable

Product specifications requirements
- 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
APPENDIX A

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:


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, CITY, STATE, ZIP)
APPENDIX B

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.
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.
   Note: 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.