

# V.A.C.<sup>®</sup> THERAPY

## PATIENT INFORMATION GUIDE

PROVEN THERAPIES. HEALING AT HOME WITH KCI.



Acelity™



ACCREDITED

If you have questions about KCI V.A.C.<sup>®</sup> Therapy, please call 1-800-275-4524.





<b>IMPORTANT INFORMATION</b>	
<b>Please READ and KEEP this information posted in a handy place.</b>	
<b>YOUR CONTACT INFORMATION</b>	
Your Nurse's Name:	
Your Nurse's Phone Number:	
Your Home Health Agency (HHA) or Wound Care Center:	
Your Doctor's Name:	
Your Doctor's Phone Number:	
<b>KCI CUSTOMER SUPPORT</b>	<b>Call 1-800-275-4524.</b>
<b>In case of emergency:</b>	<ul style="list-style-type: none"><li>• <b>FIRST</b> call 9-1-1 (or your local emergency number).</li><li>• <b>THEN</b> call your doctor or nurse.</li></ul>
<b>INFORMATION FOR YOU TO KNOW</b>	
Your V.A.C.® Therapy Unit model:	
Where can you find information about your specific V.A.C.® Therapy Unit?	Refer to the documents that came with your therapy unit for instructions on how to use it. <b>If you did not receive these items, call KCI at 1-800-275-4524.</b>
Issues with the V.A.C.® Therapy Unit?	<b>Do not attempt to fix the therapy unit.</b> If you have any problems with the unit, call KCI right away at 1-800-275-4524.
Keep your V.A.C.® Therapy Unit <b>ON</b> .	<b>If therapy is off/interrupted for more than two hours, your dressing will need to be changed!</b>
Dressings:	<b>Remember dressings are for single use only!</b> The used dressing must be thrown away after each dressing change.
Who changes the dressings?	Your doctor will decide how and when your dressings will be changed. It could be in the doctor's office, by a home health agency or at a wound care clinic. In some cases, a caregiver, family member or friend may be trained. <b>ONLY THOSE WHO HAVE BEEN PROPERLY TRAINED SHOULD CHANGE THE DRESSINGS.</b>
Ordering Supplies:	Call KCI at 1-800-275-4524.



<b>WHEN TO CALL YOUR DOCTOR OR NURSE</b>	
<b>BLEEDING:</b>	<p>If you see a sudden increase or large amount of blood from your wound in the tubing or canister:</p> <ol style="list-style-type: none"><li>1. <b>TURN OFF</b> the therapy unit right away.</li><li>2. <b>APPLY</b> pressure over the area.</li><li>3. <b>DO NOT</b> remove your dressing.</li><li>4. <b>CALL 9-1-1</b> (or your local emergency number) and <b>THEN</b> call your doctor or nurse.</li></ol>
<b>DIFFICULTY BREATHING:</b>	<p>If you have <b>DIFFICULTY BREATHING, CALL 9-1-1</b> (or your local emergency number).</p>
Other Concerns:	<p>Talk with your doctor or nurse if you have any concerns about:</p> <ul style="list-style-type: none"><li>• Wound Infection</li><li>• Other Serious Infections</li><li>• Allergic Reactions</li></ul> <p>See page 16 of this Patient Information Guide for more safety information.</p>

## How To Use This Book

**This Patient Information Guide is designed to be an all in one resource for KCI V.A.C.® Therapy. Please save this guide and all the documents that came with your therapy unit. You may be asked to refer to these items during a KCI service call.**

Read and follow all instructions in this guide. Your safety is our first concern. For important safety information, see page 16. Please read this information carefully.

For a description of how V.A.C.® Therapy works and what to expect while you are using it, see page 9.

For information about your benefits and the terms and conditions of use, see page 20. Please read this information carefully. Your signature on the Proof of Home Delivery/Assignment of Benefits (POD/AOB) form is your agreement to these important terms and conditions. This section also includes information about privacy practices and your rights and responsibilities as a patient.

For information specific to the state where you live, see page 37. Check this section to see if your state is included.

### **Important Safety Information Comes With Your V.A.C.® Therapy Unit**

Your therapy unit comes with several documents that include important warnings for your safety. Before using your therapy unit:

- Review the user manual with your doctor or nurse.
- Review the quick reference guide (if your therapy unit includes one). Keep this guide with your therapy unit at all times.
- Review the safety information sheet (SIS) with your doctor or nurse. Keep this SIS with your therapy unit at all times.
- If there are questions or this information is missing, contact KCI right away at 1-800-275-4524.



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# What is V.A.C.® Therapy?

## Introduction

**This Patient Information Guide provides important information about your treatment with KCI's V.A.C.® Therapy System. If you have questions or need further information call your doctor or nurse, or call KCI at 1-800-275-4524.**

## Wound healing is a process

Proper wound care management is needed to heal your wound. Your doctor has prescribed a V.A.C.® Therapy System for your care. A doctor or nurse is responsible for directing the use of the system, including therapy application and dressing changes.

## How long will it take to heal my wound?

The length of time to heal a wound is different for every patient. General conditions, size and location of the wound, and nutritional status can affect the time it takes for a wound to heal. Your doctor or nurse will discuss when and why V.A.C.® Therapy may end.

## Why V.A.C.® Therapy?

V.A.C.® Negative Pressure Wound Therapy has helped to promote wound healing for millions of patients worldwide. Doctors, nurses, and hospitals all rely on V.A.C.® Therapy as an advanced wound therapy to help their patients heal.

## What is V.A.C.® Therapy?

The V.A.C.® Therapy System is a medical device system that helps wounds heal by delivering negative pressure (a vacuum) to the wound through a special dressing and therapy unit. This creates an environment that promotes the wound healing process. This negative pressure helps:

- Draw wound edges together
- Remove wound fluids and infections materials
- Promote granulation tissue formation (the connective tissue in healing wounds)

Unlike gauze bandages that merely cover a wound, V.A.C.® Therapy actively works to help the wound healing process.

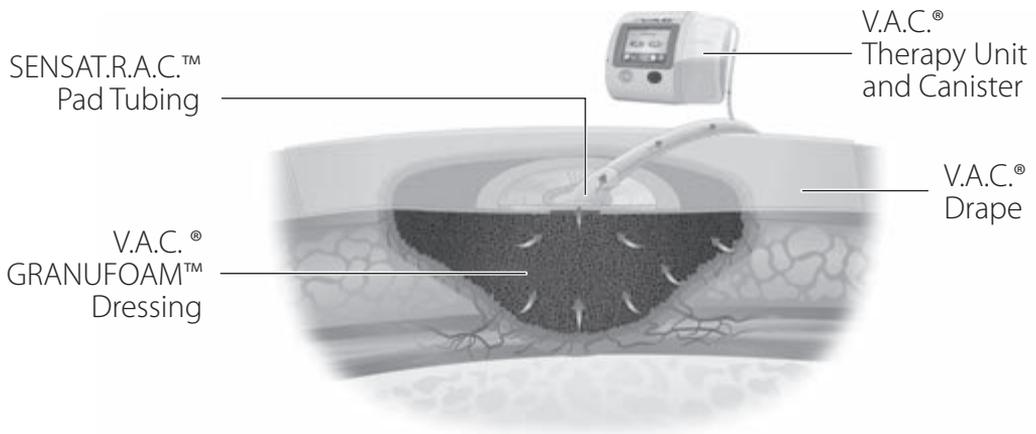
The V.A.C.® Therapy System also helps:

- Provide a moist wound healing environment
- Reduce wound odor
- Reduce the need for daily dressing changes

## The V.A.C.® Therapy System

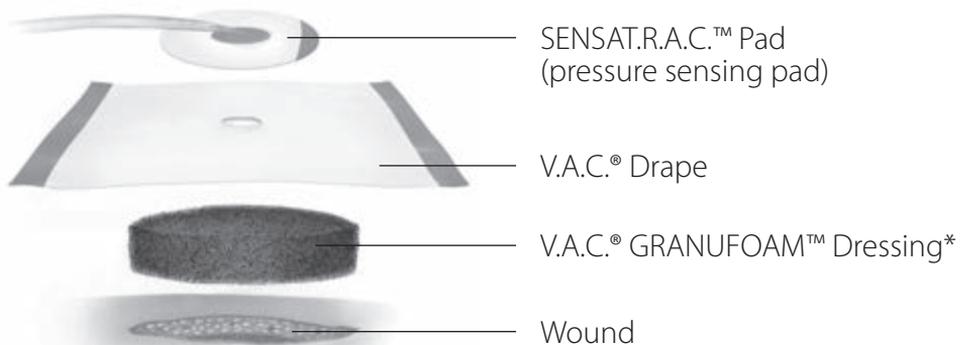
### The V.A.C.® Therapy System includes:

- The V.A.C.® Therapy Unit that delivers negative pressure
- A specially designed disposable canister to manage wound fluid
- Sterile tubing with a pressure sensing system that connects the therapy unit to the dressing
- Special foam dressings that are placed in the wound
- A clear drape with adhesive that covers the foam dressing



### V.A.C.® Dressing Placement

The V.A.C.® Dressing goes inside the wound. The wound area is sealed with the clear V.A.C.® Drape that helps maintain negative pressure over the wound. One end of the tubing connects to the dressing, the other end connects to the canister that fits into the V.A.C.® Therapy Unit.



\*If used, V.A.C. WHITEFOAM™ is typically recommended for placement under V.A.C.® GRANUFOAM™ Dressing.

## V.A.C.® Dressing Changes

The V.A.C.® Therapy System uses special foam dressings with the therapy unit. Only V.A.C.® Dressings are to be used with V.A.C.® Therapy Units. Wounds treated with the V.A.C.® Therapy System should be checked on a regular basis by your doctor or nurse who is responsible for treatment.

- For a non-infected wound: KCI recommends the dressings be changed every 48 to 72 hours, but no less than 3 times per week.
- For infected wounds: These wounds must be checked often and very closely. Infected wounds dressings may need to be changed more often than 48 to 72 hours. Dressing change intervals should be based on continuing evaluation of your wound condition by your doctor or nurse.

## V.A.C.® Therapy Units



V.A.C.® Therapy Units are lightweight portable devices designed for patients who enjoy the freedom of being mobile. Refer to the documents that came with your therapy unit for specific instructions on how to use it.

Do not attempt to service or repair the V.A.C.® Therapy Unit. If you have any problems with the unit, call KCI right away at 1-800-275-4524.



## V.A.C.® Therapy Use

**Keep V.A.C.® Therapy on (off for no more than two hours).**

- If therapy is turned off for more than two hours, the V.A.C.® Dressing must be removed and replaced. Call your doctor or nurse for more information.

- If the unit is off for more than 15 minutes and the power to the unit is on, an alarm will sound. Refer to the documents that came with your therapy unit for instructions on how to manage this alarm.
- The clear V.A.C.® Drape is waterproof. You can wash or shower with the dressings in place and with the tube clamped (closed off). Turn off the unit and unplug it from the electrical outlet. **Warning: do not take the therapy unit into the bathtub or shower.**

### V.A.C.® Therapy Settings

Patient compliance with V.A.C.® Therapy is important for proper healing. Your doctor will determine the negative pressure settings for your unit. **Please do not change any of the settings on the V.A.C.® Therapy System or remove the dressing unless told to do so by your doctor or nurse.**

### Ordering Additional Supplies

- When you are down to one case of dressings OR five canisters, it is time to order new supplies.
- To order new supplies, call KCI at 1-800-275-4524. Please allow at least 3-5 business days for delivery.

#### **IMPORTANT: DISPOSABLE ITEM RETURN INFORMATION**

KCI only accepts the return of unopened and/or unused V.A.C.® Therapy disposables if:

- the product is identified as substandard (defective and less than full quality for the particular item)
- the product is identified as unsuitable (inappropriate for the customer at the time it was sold)
- the product was shipped in error by KCI, in accordance with the Centers for Medicare & Medicaid Services (CMS), Durable Medical Equipment (DME) Prosthetics, Orthotics and Supplies (POS) Supplier Standards

### Hospital Admission

Please notify KCI if you are admitted to a hospital or inpatient facility. Call KCI at 1-800-275-4524 to arrange for the return of your V.A.C.® Therapy System. This call stops the billing process and you will not be charged.

Also call your doctor or nurse to arrange a visit to ensure the V.A.C.® Therapy Unit has been properly removed and all necessary precautions are in place to ensure your safe transfer.

## Questions and Answers

1. How does V.A.C.® Therapy feel?

Most patients describe V.A.C.® Therapy as a non-painful, mild pulling sensation that, in most cases, is not noticeable after a few minutes. Wound comfort may vary by individual person. The wound may become tender or itch as it heals; this is usually a good sign. If itching or discomfort persists, please call your doctor.

2. Can you move around while on V.A.C.® Therapy?

Yes. The V.A.C.® Therapy System is lightweight and was specifically designed to provide flexibility and freedom of mobility. Your ability to move around depends on your condition, the wound location and the treatment your doctor has prescribed. **The V.A.C.® Therapy System may be disconnected so you can take a shower. Therapy may not be off any longer than two hours per day. If therapy is off/interrupted for more than two hours, your dressing will need to be changed.**

3. What does the foam dressing look like when V.A.C.® Therapy is on?

Your doctor may prescribe a V.A.C.® GRANUFOAM™ or V.A.C. WHITEFOAM™ Dressing for your wound type. The V.A.C.® GRANUFOAM™ Dressing will shrink down and wrinkle like a raisin when V.A.C.® Therapy is working. The V.A.C. WHITEFOAM™ Dressing may only have a few wrinkles.

4. Does changing the V.A.C.® Dressing hurt?

Some people do experience discomfort during dressing changes depending on the wound type, location and patient condition. The discomfort is similar to other dressings and wound care treatments for the same wound type. Your doctor or nurse can give you advice about pain relief.

## 5. Who should change my dressing, and how?

Usually a nurse from your doctor's office, home health agency or wound care clinic trained in V.A.C.® Therapy will change your dressing. If approved by your doctor or nurse, a caregiver, family member or friend may change the dressing **if they have been properly trained.**

The following steps should be followed by you and your caregiver to reduce the risk of infection and the spread of germs:

- Cover your mouth and nose with a tissue when you cough or sneeze or cough or sneeze into your upper sleeve, not your hands. Put your used tissue in a waste basket.
- Caregiver should wash hands with soap and warm water for 20 seconds or clean hands with an alcohol-based hand cleaner, before and after each patient contact or procedure.
- Caregiver should always wear gloves and protective clothing and eyewear when handling blood or body fluid, or when in contact with mucous membranes or open cuts.
- Any caregiver with an open cut or skin condition should not care for the patient until the condition has been cleared.
- Caregiver should dispose of soiled dressing according to hospital or institution protocols. **Do not reuse dressing.**
- Caregiver should always count the total number of foam pieces put into the wound. They should record this number and the dressing change date on the drape or Foam Quantity Label (if supplied) and in your chart.
- Refer to application instructions provided with the dressing for more information.

## 6. What if my V.A.C.® Therapy Unit alarms?

Refer to the documents that came with your therapy unit for information on alerts and alarms. If needed, call your doctor, nurse or KCI for assistance.



You can call KCI at 1-800-4524 to troubleshoot in real time over the phone, 24 hours a day. To help in troubleshooting your therapy unit, please keep handy the small white tubing cap that comes on the end of the canister tubing.

7. Who do I call in case of an emergency?

- First, call your local emergency number (i.e., 911).
- After you call local emergency, call your doctor or nurse.
- For all other medical concerns, refer to the Patient Safety Information section of this guide.

8. How can my caregiver be helpful?

A family caregiver or friend can help you by reminding you how important it is to keep your V.A.C.® Therapy Unit on. Also, when directed by your doctor or nurse and only after proper training, your caregiver can assist in:

- changing dressings and canisters
- responding to therapy unit alarms
- monitoring the therapy

9. How do I order supplies?

When you are down to **one case of dressings OR five canisters**, call KCI at 1-800- 275-4524 to order more. Please allow at least 3-5 business days for delivery.

10. What do I do when my V.A.C.® Therapy is completed?

Call KCI at 1-800-275-4524 to arrange for the return of your V.A.C.® Therapy System. This call stops the billing process and you will not be charged.

## Patient Safety Information

**At KCI, your safety is our first concern. If you have questions or concerns about product delivery, set up or any related issues, call KCI at 1-800-275-4524.**

- Most issues can be resolved over the phone.
- If the issue cannot be resolved over the phone, KCI can provide additional assistance.



Important

For operating instructions and additional safety information, please see the documents included with your therapy unit.

Your doctor or nurse has more information about your wound. Ask your doctor or nurse for any additional information you may need before using this product.

Do not change the settings on the therapy unit without your doctor or nurse giving you specific direction.

If approved by your nurse or doctor, a caregiver, family member or friend may change the dressing **if they have been trained by a doctor or nurse.**



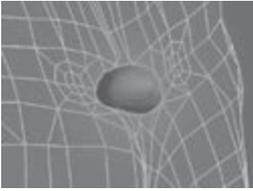
Bleeding

### Warning – Some Patients May Have A Risk Of Bleeding

If you have recently had heart surgery, or surgery on blood vessels, or are on blood thinners, you may have a higher risk of bleeding, whether you are using V.A.C.® Therapy or not.

**If you see a sudden increase or a large amount of blood from your wound in the tubing or canister:**

- **Turn OFF the therapy unit right away.**
- **Apply pressure over the area.**
- **Do not remove your dressing.**
- **Call 9-1-1 (or local emergency number) FIRST.**
- **Then call your doctor or nurse.**



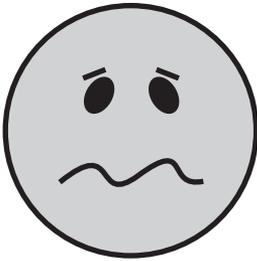
Wound Infections

### Wound Infection

If you have an infected wound, your doctor or nurse will decide the right treatment for you. Your dressing should be changed more frequently.

Call your doctor or nurse right away if you think your wound is infected or if the following symptoms develop or worsen:

- You have a fever
- Your wound is sore, red or swollen
- Your skin itches or you have a rash or redness around the wound
- The area in or around the wound feels very warm
- You have pus or a bad smell coming from the wound



Serious Infections

### Serious Infection

Sometimes a wound infection can spread throughout the rest of the body. Call your doctor or nurse right away if you have any of the following symptoms:

- You are sick to your stomach or throwing up
- You are dizzy or feel faint when you stand up
- You have diarrhea
- You have a headache
- Your throat is sore
- You have a rash
- You feel confused
- You have a fever over 102°F



V.A.C.<sup>®</sup>  
Disposables

### Allergic Reactions

V.A.C.<sup>®</sup> Dressings, V.A.C.<sup>®</sup> Drape and V.A.C.<sup>®</sup> Canisters are delivered sterile and do not contain latex. Use items only from unopened packages, use them only once and then throw them away. The V.A.C.<sup>®</sup> Drape (dressing cover) has a coating that may cause an allergic reaction if you are allergic or sensitive to some glues. Call your doctor or nurse right away if you have any of the following symptoms:

- Redness
- Rash or hives
- Swelling
- Severe itching

If you have difficulty breathing, seek immediate emergency medical assistance or call 9-1-1 (or local emergency number).



V.A.C.® Therapy Unit

**Keep Therapy On (Off For No More Than Two Hours)**

If therapy is interrupted or turned off for more than two hours, call your nurse or doctor right away. The old dressing will need to be removed and the wound irrigated. Never leave a V.A.C.® Dressing in place without active V.A.C.® Therapy for more than two hours.

A new V.A.C.® Dressing from an unopened sterile package should be applied and V.A.C.® Therapy restarted. Or, an alternate dressing should be applied at the direction of the treating nurse or doctor. Call your nurse or doctor to have this done.



V.A.C.® Simplace™ Dressing

**Count Foam Dressing Pieces**

Your doctor, nurse, or trained caregiver should always count the total number of foam pieces put into your wound. They should record this number and the dressing change date on the drape or Foam Quantity Label (if supplied) and in your chart. Make sure that the same number of foam pieces is removed during your dressing change.

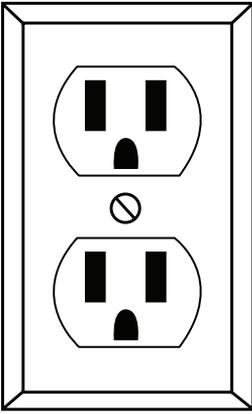
**Cover Your Cough**

Cover your mouth and nose with a tissue when you cough or sneeze, or cough or sneeze into your upper sleeve, not into your hands. Put your used tissue in the waste basket.

Clean your hands after coughing or sneezing. Wash hands with soap and warm water for 20 seconds, or clean with alcohol-based cleaner.

**In Case of Evacuation or Immediate Departure**

Please call KCI at 1-800- 275-4524 if you are evacuated due to natural disaster or choose to evacuate or immediately depart from your current address. We will need your new or temporary address so we can best support your needs.



### Electrical Requirements

A three-pronged electrical outlet is recommended for use with this product. If you do not have a three-pronged outlet, use a three-pronged adapter. For safe use of the adapter, secure the ground wire to the center screw of the outlet cover plate.

- Extension cords are not recommended for use with this product.
- Do not overload your electrical outlets.
- Keep electrical cords out of traffic areas.
- Do not spill liquids on the V.A.C.® Therapy Unit; it must remain dry.

### Fall Prevention Tips

Follow these safety tips to help prevent slips or falls while using the V.A.C.® Therapy System:

- Know your surroundings. Avoid possible tripping hazards, such as throw rugs, extension cords, and uneven floors.
- Place the V.A.C.® Therapy Unit power cord so that it is not a tripping hazard. When not using the power cord (therapy unit is off or in battery mode) make sure the cord is unplugged and put away.
- Safely store and secure any excess power cord and tubing to prevent tripping. See the therapy unit user manual for how to properly secure tubing.
- Be cautious of door knobs and other household objects that could catch exposed tubing.
- Be careful when getting into and out of bed. When practical, have a caregiver or a capable family member present to help you.
- Use nightlights during the night to light any areas where you walk.
- For hospital bed use: if there is a hospital bed in your home, consult the bed manufacturer's instructions for use. Talk to your doctor or nurse about keeping the bed in the lowest practical position. If your doctor has ordered the use of hospital bed rails in your home, it is recommended they be fully raised when a nurse or family caregiver is not present.

# Patient Financial Responsibility

## Assignment of Benefits (AOB)

**The following is a copy of the Assignment of Benefits (AOB) you received with your V.A.C.® Therapy Unit. This form allows KCI to work directly with your insurance company, eliminating any inconveniences. Without a signed AOB, KCI cannot bill your insurance company, which may result in direct patient billing.**

I give KCI USA, Inc. ("KCI") the right to bill for and receive insurance payments for my medical care and I direct my insurance company, Medicare, Medicaid, and any other entity paying for my medical care ("my insurer") to pay KCI directly for the equipment and supplies provided to me.

1. I understand that ownership of the equipment shall at all times remain the property of KCI USA, Inc, unless I qualify for and agree to purchase the equipment. KCI shall have the right to inspect the equipment wherever the same may be and that I may be responsible for the replacement value of the KCI rental product in the event it is lost, damaged, or stolen while in my possession or control.
2. I understand that my insurer may need information about my medical condition to make a decision about making payments to KCI. This information may be maintained by my physician, home healthcare agency, medical facility, employer, or other entities. I authorize any holder of medical information about conditions for which I am being treated to release that information to KCI and insurer.
3. I understand that I am responsible for reading, signing, and returning the Assignment of Benefits form to KCI USA, Inc.; if not returned, I assume full responsibility of all financial charges associated to my therapy treatment provided by KCI USA, Inc.

4. I understand that KCI, my insurer, healthcare provider and other entities involved in my medical care may need certain individually identifiable financial or health information to assist in my care. I agree that such information may be used and disclosed by KCI, my insurer, healthcare providers, and other entities for purposes of treatment, payment, healthcare operations or as otherwise permitted by law. I understand that additional information on types of uses and disclosures that may be made are contained in KCI's Notice of Privacy Practices. I understand that I may revoke my consent at any time if I do so in writing, except to the extent such consent has already been relied upon.
5. For Medicare/Medicaid Beneficiaries: I understand that I am responsible for any and all deductibles or co-payments established by Medicare or Medicaid. This information has been explained to me.
6. For all other insurance coverage: I understand that I am responsible for all deductibles, co-payments, or other amounts established by my insurance company, as well as all charges for non-covered services provided to me by KCI. This information has been explained to me.
7. I have received a copy of the Patient Information Guide (which includes KCI's Notice of Privacy Practices, Supplier Standards [for Medicare] and product information and instructions).
8. I understand the care and utilization of this product and know that I can contact KCI USA, Inc. at 1-800-275-4524 for additional information.
9. In the event that my insurer pays me directly, I agree to forward all payments to KCI USA, Inc., P.O. Box 301328, Dallas, TX, 75303-1328.
10. I understand: (i) KCI has the option to provide new or used equipment; (ii) that I shall not modify or alter the equipment; (iii) that I will notify KCI immediately of any equipment problems; (iv) that the equipment is only to be used upon the order and direction of my doctor; (v) that the equipment is only to be used with KCI authorized disposables (i.e., dressings).
11. I understand that the equipment rental charges will continue until the date I call KCI USA, Inc. at 1-800-275-4524 to pick up the rental product.

Additional Terms Governing Use, Return, and Payment:

- i. In the event of patient's default in payment, or the default of patient's insurer, health benefit plan or other third party payor, KCI shall be entitled to recover the equipment and shall not be liable to the patient or to the patient's representatives or heirs for any injury or damage resulting from the discontinuation of treatment with the equipment.
- ii. KCI shall be entitled to all expenses, court costs, and reasonable attorney fees for the collection of any patient responsibility amounts that are past due and to enforcement of this AOB. All past amounts shall bear interest at the lesser of 1.5% per month or at the highest rate permitted by law.
- iii. This AOB and any dispute arising out of the goods and services provided shall be governed and construed according to the laws of the State of Texas without regard to its conflict of laws provision, and venue shall lie exclusively with a court of proper jurisdiction in Texas. Any dispute arising out of this Agreement shall be resolved by binding arbitration in accordance with the rules of the Judicial Arbitration and Mediation Services (JAMS).

# Patient Rights and Responsibilities

## Patient's Bill of Rights and Responsibilities

The Patients' Bill of Rights and Responsibilities has three goals:

1. To strengthen consumer confidence that the healthcare system is fair and responsive to consumer needs;
2. To reaffirm the importance of a strong relationship between patients and their healthcare providers; and
3. To reaffirm the critical role consumers play in safeguarding their own health.

### Your Rights

As a patient you have certain rights including but not limited to the following:

- Information. Patients have the right to receive accurate, easily understood information to assist them in making informed choices.
- Choice. Patients have the right to a choice of health care providers.
- Access to Emergency Services. Patients have the right to access emergency health services when and where the need arises.
- Being a Full Partner in Health Care Decisions. Patients have the right to fully participate in all decisions related to their health care.
- Care Without Discrimination. Patients have the right to considerate, respectful care from all members of the healthcare industry at all times and under all circumstances.
- Privacy. Patients have the right to communicate with healthcare providers in confidence and to have the confidentiality of their individually identifiable health care information protected.
- Speedy Complaint Resolution. Patients have the right to a fair and efficient process for resolving differences.

## Your Responsibilities

As a patient you have certain responsibilities including, but not limited to the following:

- Provide information - give accurate and complete health information concerning your past illnesses, hospital stays, medications, allergies and other pertinent items. You are also responsible for providing documentation required by your insurance company.
- Ask questions - when you do not understand medical conditions, equipment instructions, and/or medical terminology.
- Follow instructions - adhere to your developed/updated treatment plans.
- Accept consequences - for not following the treatment plan instructions of your doctor and nurse.
- Understand your benefits - for what your insurance company will or will not authorize for durable medical equipment (DME) benefits.
- Product responsibilities - your doctor has prescribed this medical device for the treatment and care of your wound. This is a rental device and cannot be resold. Prompt return of this device is required once therapy is completed.
- Show respect and consideration - to those who are assisting you in your treatment plan.
- Meet financial commitments - you are responsible for any applicable co-insurance, co-payments, or private pay amounts not covered by your insurance provider.
- Take on new responsibilities - In a healthcare system that affords patients rights and protections, patients must also take greater responsibility for maintaining good health.

# Notice of Privacy Practices

Notice of Privacy Practices (effective 13 September 2013)

THIS NOTICE DESCRIBES HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

If you have any questions about this notice, please contact

Acelity Health Care Compliance Department at 1-210-255-6605.

## **Purpose of This Notice**

This notice will tell you about the ways in which KCI may use and disclose the protected health information (“PHI”) that identifies you. We also describe your rights and certain obligations we have regarding the use and disclosure of PHI.

## **Our Pledge Regarding Protected Health Information:**

We understand that health information about you and your health is personal. We are committed to protecting health information about you. We create a record of the products and services that we provide to you. We need this record to provide you with quality products and services used in your care and to comply with certain legal requirements. This notice applies to the entire PHI we use and disclose related to the products and services used in your care. Your personal doctor, healthcare provider and other entities providing products or services to you may have different policies or notices regarding their use and disclosure of your PHI.

## **Our Legal Requirements**

We are required by law to:

- make sure that health information that identifies you is kept private;
- give you this notice of our legal duties and privacy practices with respect to PHI about you;
- notify you if we are unable to agree to a requested restriction on how your information is used or disclosed;
- accommodate reasonable requests that you may make to communicate PHI by alternative means or at alternative locations;

- obtain your written authorization to use or disclose your PHI for purposes other than those listed below and permitted under law; and
- follow the terms of the notice that currently is in effect.

### **Who Will Follow Our Privacy Practices**

This notice describes KCI's practices and that of:

- All KCI employees, staff and other company personnel for U.S. operations or any KCI affiliate or subsidiary in which work performed on behalf of U.S. operations is subject to the Health Insurance Portability and Accountability Act of 1996.
- KCI USA, Inc. and KCI Medical Puerto Rico, Inc.

### **Your Rights Regarding Protected Health Information About You**

You have the following rights regarding PHI we maintain about you:

**Right to Inspect and Copy.** You have the right to inspect and copy PHI that may be used to make decisions about your care. Usually, this includes medical and billing records. To inspect and copy PHI that may be used to make decisions about you, you must submit a request in writing to the Acclivity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. You have the right to request a readily-producible form in which your PHI may be delivered. If you request a copy of the information, we will charge a fee for the costs of copying, mailing or other supplies associated with your request. We may deny your request to inspect and copy in certain circumstances. If you are denied access to PHI, you may request that the denial be reviewed. Another person chosen by us will review your request and the denial. We will comply with the outcome of that review.

**Right to Amend.** If you feel that PHI we have about you is incorrect or incomplete, you may ask us to amend the information. You have the right to request an amendment for as long as the information is kept by or for us. To request an amendment, a request must be made in writing to the Acclivity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. In addition, you must provide a reason that supports your request. We may deny your request for an amendment if it is not in writing or does not include a reason to support the request. In addition, we may deny your request if you ask us to amend information that:

- Was not created by us, unless the person or entity that created the information is no longer available to make the amendment;
- Is not part of the PHI kept by or for us;
- Is not part of the information which you would be permitted to inspect and copy; or
- Is accurate and complete.

**Right to an Accounting of Disclosures.** You have the right to request an “accounting of disclosures.” This accounting is a list of the disclosures we made of PHI about you. KCI will provide an accounting of all but the following disclosures:

- Those made for treatment, payment and health care operations;
- Those made to you about your own PHI;
- Those made to persons involved in your care or other notification purposes;
- Those made pursuant to an authorization signed by you disclosing specific uses and disclosures;
- Where the disclosures are part of a Limited Data Set;
- Where the disclosures are incidental to an otherwise permissible disclosure;
- For national security or intelligence purposes; and
- To correctional institutions or law enforcement custodial situations.

To request this list or accounting of disclosures, you must submit a request in writing to the Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. Your request must state a time period that may not be longer than six years from the date of service and may not include dates before April 14, 2003. Your request should indicate in what form you want the list (i.e., paper or electronic). The first list you request within a 12-month period will be free. For additional lists, we will charge you for the costs of providing the list. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before any costs are incurred.

**Right to Request Restrictions.** You have the right to request a restriction or limitation on the PHI we use or disclose about you for treatment, payment or health care operations. You also have the right to request a limit on the PHI we disclose about you to someone who is involved in your care or the payment for your care, like a family member or friend. We are not required to agree to your request. If we do agree, we will comply with your request unless the information is needed to provide you emergency treatment. To request restrictions, you must make a request in writing to the Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. In your request, you must tell us (i) what information you want to limit; (ii) whether you want to limit our use, disclosure or both; and (iii) to whom you want the limits to apply, for example, disclosures to your spouse.

**Right to Restrict Certain Disclosures to Health Plans.** You have the right to restrict certain disclosures of PHI to a health plan when you pay out of pocket in full for health care items or services.

**Right to Notice of Breach of Unsecured PHI.** You have the right to receive notice in the event that unsecured PHI identifying you has been, or is reasonably believed to have been used, accessed, acquired or disclosed in an unauthorized manner.

**Right to Request Confidential Communications.** You have the right to request that we communicate with you about medical matters in a certain way or at a certain location. For example, you can ask that we only contact you at work or by mail. To request confidential communications, you must make your request in writing to the Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, Texas, 78249. We will not ask you the reason for your request. We will accommodate all reasonable requests. Your request must specify how or where you wish to be contacted.

**Right to Revoke Authorization.** You have the right, in those instances where written authorization is required, to revoke such authorization to use or disclose PHI except to the extent action has already been taken. Such revocation must be in writing.

**Right to a Paper Copy of This Notice.** You have the right to a paper copy of this notice. You may ask us to give you a copy of this notice at any time. Even if you have agreed to receive this notice electronically, you are still entitled to a paper copy of this notice.

You may obtain an additional copy of this notice at our website, [www.acelity.com](http://www.acelity.com), under the menu heading "For Patients." To obtain a paper copy of this notice, you must contact the Acelity Health Care Compliance Department at 1-210-255-6605.

## **How We May Use And Disclose Protected Health Information About You**

The following categories describe different ways that we are permitted to use and disclose PHI as a health care provider. Certain of these categories may not apply to our business and we may not actually use or disclose your PHI for such purposes. Not every use or disclosure in a category will be listed. However, all of the ways we are permitted or required to use and disclose PHI, without your authorization, will fall within one of the categories.

**For Treatment.** We may use or disclose PHI about you to assist healthcare professionals and providers provide you with medical treatment or services. For example, we may provide PHI related to your use of our products or services to your home health agency or clinic for purposes of documenting your wound progress or we may provide PHI to a discharge planner in the hospital you were treated at to help them arrange for continued care in your home or another facility to which you are being discharged.

**For Payment.** We may use and disclose PHI about you so that the products and services we provide you may be billed to and payment may be collected from you, an insurance company or a third party. For example, we may need to receive from or disclose to your health plan, Medicare or the medical facility you resided in information about the products and services we provided to you so they or another responsible payor can pay us and so they can seek payment or reimbursement for the products and services provided to you or another payor. This may specifically include information required for the Initial Statement of Ordering Physician, Assignment of Benefits, wound progress notes, and discharge information. We may also tell your health care provider or plan about a product or service you are going to receive to obtain prior approval or to determine whether your provider or plan will cover that product or service.

**For Health Care Operations.** We may use and disclose PHI about you for our health care operations and we may use and disclose PHI about you to other health care providers involved in your care for certain health care operations they have to undertake. These uses and disclosures are necessary to run our company and make sure that users of our products receive the most cost effective and therapeutic products possible. Examples of health care operations activities by KCI include but are not limited to delivery, pick-up and service functions, collection efforts, internal auditing, business planning (including analysis of product length of stay, utility, or development / improvement of reimbursement methods or policy), assessing the quality of care and outcomes in your case and similar cases, and quality assurance / improvement activities. We may also combine PHI about many patients to decide what additional products and services we should offer, what products and services are not needed, and to justify how effective our products are in the care of individuals such as you. We may also disclose information to medical facilities and independent researchers for review and learning purposes. We may remove information that identifies you from this set of PHI so others may use it to study health care and health care delivery without learning who the specific patients are.

**Notices / Reminders.** We may use and disclose PHI to contact you or arrange for your health care provider to contact you regarding product delivery, maintenance, in-service or pick-up.

**Product Alternatives.** We may use and disclose PHI to tell you or your health care provider about possible product alternatives that may be of interest to you, except that we may not do so without your authorization to the extent that we receive direct or indirect remuneration for such use or disclosure of PHI.

**Individuals Involved in Your Care or Payment for Your Care.** We may disclose to a family member, other relative, close personal friend of yours or any other person identified by you PHI directly relevant to such person's involvement with your care or payment for your health care when you are present for, or otherwise available prior to, a disclosure and you are able to make health care decisions, if: (i) we obtain your agreement; (ii) we provide you with the opportunity to object to the disclosure and you fail to do so; or (iii) we infer from the circumstances, based upon professional judgment, that you do not object to the disclosure. We may obtain your oral agreement or disagreement to a disclosure. However, if you are not present, or the opportunity to agree or object to the disclosure cannot practicably be

provided because of your incapacity or an emergency circumstance, we may, in the exercise of professional judgment, determine whether the disclosure is in your best interests, and, if so, disclose only PHI that is directly relevant to the person's involvement with your health care.

**Research.** Under certain circumstances, we may use and disclose PHI about you for research purposes. For example, a research project may involve comparing the health and recovery of all patients who received one product or service to those who received another, for the same condition. Also, a research project may involve the gathering of treatment data for certain patients and conditions in order to support the clinical efficacy or new product indications for products that we provide. Most research projects, however, are subject to a special approval process. This process evaluates a proposed research project and its use of PHI, trying to balance the research needs with patients' need for privacy of their PHI. We may, however, disclose PHI about you to people preparing to conduct a research project, for example, to help them look for patients with specific medical needs, so long as the PHI they review does not leave our premises. We will in most circumstances ask for your specific authorization if the researcher will have access to your name, address or other direct identifying information that reveals who you are.

**As Required By Law.** We will disclose PHI about you when required to do so by federal, state or local law. For example, we may disclose information for judicial and administrative proceedings pursuant to legal authority; to report information related to victims of abuse, neglect or domestic violence; or to assist law enforcement officials in their law enforcement duties.

**Government Functions.** We may use and disclose PHI about you as required for specialized government functions such as protection of public officials, reporting to various branches of the armed services or national security activities authorized by law.

**To Avert a Serious Threat to Health or Safety.** We may use and disclose PHI about you when necessary to prevent a serious threat to your health and safety or the health and safety of the public or another person. Any disclosure, however, would only be to someone able to help prevent the threat.

**Business Transfers.** There may arise in the course of business the acquisition or sale of our business assets (Business Transfers). Such Business Transfers may involve the sale or purchase of PHI. Also, in the event that KCI USA, Inc. or one of the other entities listed on page one of this notice are acquired or substantially all of its assets are acquired, PHI likely will be one of the transferred assets.

**Workers' Compensation.** We may release PHI about you for workers' compensation or similar programs. These programs provide benefits for work-related injuries or illness.

**Public Health Activities.** We may use or disclose your PHI for public health activities such as assisting public health authorities or other legal authorities to prevent or control disease, injury or disability. This may also include reporting required by the Food and Drug Administration or other agencies whose jurisdiction we and our products are subject to.

**Health Oversight Activities.** We may disclose PHI to a health oversight agency for activities authorized by law. These oversight activities include, for example, audits, investigations, inspections, and licensure. These activities are necessary for the government to monitor the health care system, government programs, and compliance with civil rights laws.

**Lawsuits and Disputes.** If you are involved in a lawsuit or a dispute, we may disclose PHI about you in response to a court or administrative order. We may also disclose PHI about you in response to a subpoena, discovery request, or other lawful process by someone else involved in the dispute, but only if we receive reassurance from the requestor that efforts have been made to tell you about the request and obtain your written authorization or to obtain an order protecting the information requested.

**Coroners, Medical Examiners and Funeral Directors.** We may release PHI to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or determine the cause of death.

**Organ / Tissue Donation.** We may use or disclose your PHI for cadaveric organ, eye or tissue donation purposes.

## Other Uses Of Protected Health Information

Other uses and disclosures of PHI not covered by this notice or otherwise permitted by the laws that apply to us will be made only with your written authorization. Your authorization will not be required if KCI uses or discloses health information, for purposes other than as covered by this notice or permitted by law if KCI removes any information that individually identifies you before disclosing the remaining information. Certain uses and disclosures of PHI, including those uses and disclosures of PHI for marketing purposes, and disclosures that constitute a sale of PHI require your authorization. If you provide us authorization to use or disclose PHI about you, you may revoke that permission, in writing, at any time. If you revoke your permission, we will no longer use or disclose PHI about you for the reasons covered by your written authorization. You understand that we are unable to take back any disclosures we have already made with your permission, and that we are required to retain our records of the products and services that we provided to you.

## Changes To This Notice

We reserve the right to change our information practices and to make the new provisions effective for all PHI we maintain. We also reserve the right to change this notice at anytime. We reserve the right to make the revised or changed notice effective for PHI we already have about you as well as any information we receive in the future. We will post a copy of the current notice on our website at [www.acelity.com](http://www.acelity.com). The notice will contain on the first page, in the top right-hand corner, the effective date.

## Complaints

If you believe your privacy rights have been violated, you may file a complaint with us or with the Secretary of the Department of Health and Human Services. To file a complaint with us, you must submit it in writing to the following individual: Privacy Officer, Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, Texas, 78249. **You will not be penalized for filing a complaint.**

## Contact

For more information regarding this Notice of Privacy Practices and your rights hereunder, contact: Privacy Officer, Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, Texas, 78249, or by phone at 1-210-255-6605.

# Medicare Supplier Standards

## Medicare DMEPOS Supplier Standards



**Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).**

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.

9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.

19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date - October 1, 2009
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date- May 4, 2009
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.

## State Specific Information

**There are specific state requirements for patient information for Home Medical Providers and Home Medical Equipment in Florida and Tennessee. All information outlined below has been supplied via other documents or within this manual. These specific requirements or information are listed by state below:**

### Tennessee Standards for Home Care Organizations providing HME

[www.state.tn.us/sos/rules/1200/1200-08/1200-08-29.pdf](http://www.state.tn.us/sos/rules/1200/1200-08/1200-08-29.pdf)

#### Basic Functions

- KCI will supply written guidelines relating to patient and/or caregiver training and education that include at a minimum:
  - Financial responsibilities
  - Equipment use and maintenance
  - Patient rights and responsibilities
  - Troubleshooting procedures
  - How to contact the agency during regular business and after-hours

### Florida Home Medical Equipment Provider Standards and Guidelines

[http://www.fdhc.state.fl.us/Inside\\_AHCA/index.shtml](http://www.fdhc.state.fl.us/Inside_AHCA/index.shtml)

Toll free phone number for Florida's Central Abuse Registry

- As your provider, KCI must inform you or your immediate family of the right to report abusive, neglectful, or exploitative practices.
- To report abuse, neglect, or exploitation, please call toll free 1-800-962-2873 or you may call AHCA at 1-888-419-3456.

Emergency Services:

- KCI can be contacted and services can be made available 24 hours per day, 7 days per week via KCI's Advantage Center at 1-800-275-4524.
- KCI's servicing locations maintain an on-call professional to supply services in emergency situations.

## Florida Special Needs Registry

The Florida Division of Emergency Management, in coordination with each local emergency management agency in the state, developed a registry to allow residents with special needs to register with their local emergency management agency to receive assistance during a disaster. The statewide registry provides first responders with valuable information to prepare for disasters or other emergencies.

Providing as much information as possible will allow emergency management officials to plan accordingly for future disasters. You will be emailed periodically to verify the information provided is correct and to make any necessary changes. Individual surveys will be archived after one year if not verified.

Why should you register?

- To receive important information from local emergency management officials about evacuation and sheltering options available to you.
- **IT MAY SAVE YOUR LIFE!**

Will my privacy be protected?

The information within the registry will only be used in the planning for and provision of emergency and/or disaster services. Additionally, Florida Statute 252.905 declares any information furnished by a person or business to the Florida Division of Emergency Management for the purpose of being provided assistance with emergency planning is exempt from F.S. 119.07 (1) and s.24 (a), Art. I of the State Constitution. Information provided through the registry is therefore exempt from public records requests made of the Division.

Completing the Florida Special Needs Registry does not automatically qualify the individual for a special needs shelter. Additional information will be provided by your local emergency management agency regarding evacuation and sheltering options available to you. For more information on your local options, please visit <http://www.floridadisaster.org/disability/specialneeds> for contact information. Please select your county to view important information and register.

For registry questions, please contact the Florida Special Needs Registry Help Desk:

Email: [FLSNRsupport@deltaone.com](mailto:FLSNRsupport@deltaone.com)

Phone: 800-374-9689

TTY: 800-395-1878

## Maryland – State Specific Addendum Sheet

**As described in this guide, KCI offers a fair and efficient process for resolving differences without fear of retribution or disruption in services. Patients may submit complaints directly to the State of Maryland at the below address and phone number:**

Barbara Fagan, Program Manager Office of Health Care Quality  
Spring Grove Center  
55 Wade Avenue  
Catonsville, Maryland  
21228  
1-800-492-6005

## Customer Contact Information

**For questions regarding this product, supplies, maintenance, or additional information about KCI products and services, please contact KCI or a KCI authorized representative, or:**

**In the US** call 1-800-275-4524 or visit [www.acelity.com](http://www.acelity.com)

### Quality of Care

For Concerns or Questions

If you have a concern regarding safety or the quality of services you are receiving from KCI, you may file a complaint by calling 1-800-275-4524. If you believe that your concern was not adequately addressed you can contact KCI's accrediting organization, the Accreditation Commission for Health Care, Inc., at (919) 785-1214.









Cover contains 10% PCW (Post Consumer Waste)

Printed with Soy inks

To learn more about KCI V.A.C.<sup>®</sup> Therapy Systems, please visit our website at [www.acelity.com](http://www.acelity.com) or call us at 1-800-275-4524.



An Acelity Company

NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for KCI products and therapies.

Please consult a physician and product instructions for use prior to application.

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