

ORDERING PROCEDURE

for ASEPT® Drainage Kit



Newhard Pharmacy
& Long Term Care

Phone: 610-262-6721 Fax: 610-262-7593

1. All patients must submit the completed forms listed below to Newhard Pharmacy & LTC

Detailed Written Order/Letter of Medical Necessity (to be completed by physician)
Patient Information form
Assignment Agreement

Newhard Pharmacy & LTC must have these forms filled out completely before Drainage Kits can be shipped. Newhard Pharmacy & LTC will contact patient within (2) business days of receipt of all completed forms to confirm order and provide anticipated shipment date.

All patients are urged to review and retain copies of:

Patients Rights & Responsibilities
Notice of Privacy Practices

Medicare patients are urged to review and retain copies of the following documents:

Medicare DMEPOS Supplier Standards

2. Please fax (preferred for faster service), or mail all forms listed in #1 above with copies of the front and back of your insurance card(s) to:

Newhard Pharmacy & LTC

1001 Main St.

Northampton, PA 18067

Phone: 610-262-6721

Fax: 610-262-7593

It is essential to submit all completed forms to Newhard Pharmacy & LTC upon discharge from the hospital in order to receive prescribed drainage kits in a timely manner. **FAXED SUBMISSION OF THESE FORMS WILL PROVIDE PATIENT WITH ALL NEEDED SUPPLIES IN THE QUICKEST AND MOST EFFICIENT MANNER.** Initial order processing will occur within 2 business days of receipt of completed paperwork and first order of ASEPT® Drainage Kits can be received within 2-7 business days of receipt of initial paperwork.

TIMELY SUBMISSION OF COMPLETED FORMS IS ESSENTIAL TO AVOID DISRUPTION OF TREATMENT.

ASEPT® Drainage Kit

Newhard Pharmacy & LTC
1001 Main St.
Northampton, PA 18067

**DETAILED WRITTEN ORDER
LETTER OF MEDICAL NECESSITY
for ASEPT® Drainage Kit**



Newhard Pharmacy
& Long Term Care

Phone: 610-262-6721 Fax: 610-262-7593

Please complete all sections.

Section A:

Patient Name: _____ D.O.B. _____ Sex: Male Female
 Phone: _____ Patient Address: _____
 City: _____ State: _____ Zip: _____
 Physician _____ Phone: _____ Fax: _____
 Physician's Address: _____
 City: _____ State: _____ Zip: _____
 Place of Service: Home DOS: _____

Section B:

Primary Diagnosis – Location of Fluid Accumulation (Required)

Diagnosis (ICD-10) Please Check Appropriate Diagnosis

J91.8 Unspecified Pleural Effusion **R18.0** Malignant Ascites Other: _____
J91.0 Malignant Effusion **R18.8** Other Ascites Other: _____

Secondary Diagnosis – Condition Causing Drainage Treatment (Required)

For Example: Diagnosis (ICD-10) C34.90 Lung Cancer, C50.919 Breast Cancer, C56.9 Ovarian Cancer, or I50.xx Heart Failure

Diagnosis _____ Diagnosis _____ Diagnosis _____

Length of Need (Months): _____ **1 – 99 (99 = Lifetime)** **Number of refills** _____

Use Y for Yes, N for No or D for Does Not Apply unless otherwise noted.

- _____ 1. The catheter was placed for refractive pleural effusion and requires drainage.
- _____ 2. The catheter was placed for recurrent ascites and requires drainage.

Please indicate the prescribed patient's drainage requirements.

Single Drain

Once per day (30 ASEPT Drainage Kits in 30 days)
 Every Other Day (15 ASEPT Drainage Kits in 30 days)
 Other (_____ ASEPT Drainage Kits in 30 days)
number

Bilateral Drain

Once per day (60 ASEPT Drainage Kits in 30 days)
 Every other day (30 ASEPT Drainage Kits in 30 days)
 Other (_____ ASEPT Drainage Kits in 30 days)
number

Note: Each case contains 10 ASEPT Drainage Kits. Each drainage kit contains: vacuum bottle with drainage line, Split Foam Dressing, transparent dressing, alcohol wipes (qty. 3) 4 x 4 gauze (qty. 4), gloves, clamp.

Section C: Physician Attestation

I certify that I am the physician on this form. I have reviewed all of the Detailed Written Order. Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information is true, accurate and complete, to the best of my knowledge. I certify that the patient/caregiver is capable and has successfully completed training or will be trained on the proper use of the products prescribed on this Written Order. The patient's record contains supporting documentation that substantiates the utilization and medical necessity of the products listed and Physician notes and other supporting documentation will be provided to Har-Kel, Inc. upon request. I understand any falsification, omission, or concealment of material face on this form may subject me to civil or criminal liability. A copy of this order will be retained as part of the patient's medical record.

Please Sign Here Prescriber's Signature _____

Signature Stamps and Date are not Acceptable

Prescribers Name (Printed) : MD _____ Date ____/____/____ NPI: _____

PATIENT INFORMATION FORM for ASEPT® Drainage Kit



Newhard Pharmacy
& Long Term Care

Phone: 610-262-6721 Fax: 610-262-7593

Patient Care: Complete this section, if applicable, may reduce patient's supply cost

Patient is being discharged to: _____ Vacuum Bottle Size: _____
Home with no nurse in home Hospice 1000 mL
Home with a nurse in home Skilled Nursing Facility 600 mL
Number of bottles discharged with: _____
Name of Provider: _____ Care Start Date: _____ ASEPT 2000 mL bag
Provider Contact: _____ Phone: _____ Drainage Kits

Patient Information: Please, complete the following section or attach the patient's face sheet.

Patient Name: Last _____ First _____ M.I. _____
Patient Phone: _____
Alternate Contact Person: _____ Phone: _____
Address: _____
City: _____ State: _____ Zip: _____

Patient's Insurance Information:

*** Complete Insurance Information is Critical for Timely Shipment of Supplies***

Primary Insurance: _____ Phone: _____
Policy Holder: _____ ID #: _____
Employer or Group Name: _____ Group # _____
Secondary Insurance: _____ Phone: _____
Policy Holder: _____ ID # _____

Hospital Information:

Hospital: _____
Placement Date: _____ Discharge Date: _____
Name of the ASEPT Contact at Physician's Office: _____
Name of Referring Physician: _____

*** Please Fax Completed Forms to: 610-262-7593***

If you would like confirmation that this order was received, please fill out information below:

Phone: _____ or E-Mail: _____

Preserve Original Order or Mail to:

**Newhard Pharmacy
1001 Main St.
Northampton, PA 18067**

Notes: _____

ASSIGNMENT AGREEMENT for ASEPT® Drainage Kit

RECEIPT OF A CASE OF ASEPT® DRAINAGE KITS: I hereby acknowledge that I am to receive ASEPT® Drainage Kits to be supplied by Newhard Pharmacy & LTC. I have received instructions in the proper use, care and disposal of this product.

The following has been given and discussed with me:

- Rights & Responsibilities Product comes with no manufacturer's warranty
- Notice of Privacy Practices Complaint process (how it is reviewed/resolved)
- Medicare Supplier Standards

ASEPT® PRODUCT WARRANTY: I have been advised that the ASEPT® Drainage Kit comes with no manufacturer's warranty but that Newhard Pharmacy & LTC will repair or replace, free of charge, where appropriate, any product that fails to function properly by reason of defect.

ASSIGNMENT OF BENEFITS: I hereby authorize payment of medical benefits directly to Newhard Pharmacy & LTC for the product furnished and further authorize the release of any medical information including without limitation, medical records from all physicians necessary to process an insurance (or Medicare/ Medicare supplemental) claim on my behalf. In addition, should payment in full not be made of this claim, I hereby assign to Newhard Pharmacy LTC all rights of appeal granted me, and grant them the right to act on my behalf in any such appeal as to the claim and product referenced in this Assignment Agreement only.

PATIENT RESPONSIBILITY: The undersigned understands that payment for these product(s) will be made consistent with the Patient's insurance and agrees Patient is responsible to pay all amounts that are not reimbursed by insurance for which I am responsible. I further understand that there may be co-payment and deductible charges that are my responsibility.

I have read this form and its contents have been explained to me and I understand the contents of this Assignment Agreement.

PATIENT NAME: (PRINT) _____

PATIENT SIGNATURE _____

DATE: _____

Authorized signature of responsible party:

NAME OF RESPONSIBLE PARTY: _____

RELATIONSHIP: _____

SIGNATURE RESPONSIBLE PARTY _____

DATE: _____

Please indicate why the patient cannot sign: _____

Submit this form and all required forms to:

Newhard Pharmacy & LTC

1001 Main St.

Northampton, PA 18067

OR

Fax: 610-262-7593

MEDICARE DMEPOS 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.

Palmetto GBA
National Supplier Clearinghouse
P.O. Box 100142 • Columbia, South Carolina • 29202-3142 • (866) 238-9652

A CMS Contracted Intermediary and Carrier

PATIENT RIGHTS & RESPONSIBILITIES

Patient Rights:

1. The patient has the right to considerate and respectful service.
2. The patient has the right to obtain service without regard to race, creed, national origin, sex, age, disability, diagnosis or religious affiliation.
3. Subject to applicable law, the patient has the right to confidentiality of all information pertaining to his/her medical equipment service. Individuals or organizations not involved in the patient's care may not have access to the information without the patient's written consent.
4. The patient has the right to make informed decisions about his/her care.
5. The patient has the right to reasonable continuity of care and service.
6. The patient has the right to voice grievances without fear of termination of service or other reprisal in the service process.

Patient Responsibilities:

1. The patient should promptly notify Newhard Pharmacy & LTC of any equipment failure or damage.
2. The patient is responsible for any equipment that is lost or stolen while in their possession and should promptly notify Newhard Pharmacy & LTC in such instances.
3. The patient should promptly notify Newhard Pharmacy & LTC of any changes to their address or telephone number.
4. The patient should promptly notify Newhard Pharmacy & LTC of any changes concerning their physician.
5. The patient should notify Newhard Pharmacy & LTC of discontinuance of use.
6. Except where contrary to federal or state law, the patient is responsible for any equipment rental and sale charges which the patient's insurance company/companies does not pay.

Please keep this Notice for your records so that there will never be any questions regarding the conditions under which you received this product. Also, please remember that Newhard Pharmacy & LTC will gladly assist you in any way and would appreciate your opinions on the product and our services.

Any equipment complaints should be reported to the Director of Operations at Newhard Pharmacy & LTC We will review the complaints within 5 working days of receipt and resolve the issue. If the issue is unresolved a written response will be sent to the patient within 14 business days.

NOTICE OF PRIVACY PRACTICES

September 23, 2013

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

As part of the federal Health Insurance Portability and Accountability Act of 1996, known as HIPAA, the Facility has created this Notice of Privacy Practices (Notice). This Notice describes the Facility's privacy practices and the rights you, the individual, have as they relate to the privacy of your Protected Health Information (PHI). Your PHI is information about you, or that could be used to identify you, as it relates to your past and present physical and mental health care services. The HIPAA regulations require that the Facility protect the privacy of your PHI that the Facility has received or created.

This Facility will abide by the terms presented within this Notice. For any uses or disclosures that are not listed below (Including Marketing and Selling of PHI), the Facility will obtain a written authorization from you for that use or disclosure, which you will have the right to revoke at any time, as explained in more detail below. **The Facility reserves the right to change the Facility's privacy practices and this Notice.**

HOW THE FACILITY MAY USE AND DISCLOSE YOUR PHI

The following is an accounting of the ways that the Facility is permitted, by law, to use and disclose your PHI.

Uses and disclosures of PHI for Treatment: We will use the PHI that we receive from you to fill your prescription and coordinate or manage your health care.

Uses and disclosures of PHI for Payment: The Facility will disclose your PHI to obtain payment or reimbursement from insurers for your health care services.

Uses and disclosures of PHI for Health Care Operations: The Facility may use the minimum necessary amount of your PHI to conduct quality assessments, improvement activities, and evaluate the Facility workforce.

The following is an accounting of additional ways in which the Facility is permitted or required to use or disclose PHI about you without your written authorization.

Uses and disclosures as required by law: The Facility is required to use or disclose PHI about you as required and as limited by law.

Uses and disclosure for Public Health Activities: The Facility may use or disclose PHI about you to a public health authority that is authorized by law to collect for the purpose of preventing or controlling disease, injury, or disability. This includes the FDA so that it may monitor any adverse effects of drugs, foods, nutritional supplements and other products as required by law.

Uses and disclosure about victims of abuse, neglect or domestic violence: The Facility may use or disclose PHI about you to a government authority if it is reasonably believed you are a victim of abuse, neglect or domestic violence.

Uses and disclosures for health oversight activities: The Facility may use or disclose PHI about you to a health oversight agency for oversight activities which may include audits, investigations, inspections as necessary for licensure, compliance with civil laws, or other activities the health oversight agency is authorized by law to conduct.

Disclosures to Individuals Involved in your Care: The Facility may disclose PHI about you to individuals involved in your care.

Disclosures for judicial and administrative proceedings: The Facility may disclose PHI about you in the course of any judicial or administrative proceedings, provided that proper documentation is presented to the Facility.

Disclosures for law enforcement purposes: The Facility may disclose PHI about you to law enforcement officials for authorized purposes as required by law or in response to a court order or subpoena.

Uses and disclosures about the deceased: The Facility may disclose PHI about a deceased, or prior to, and in reasonable anticipation of an individual's death, to coroners, medical examiners, and funeral directors.

Uses and disclosures for cadaveric organ, eye or tissue donation purposes: The Facility may use and disclose PHI for the purpose of procurement, banking, or transplantation of cadaveric organs, eyes, or tissues for donation purposes.

Uses and disclosures for research purposes: The Facility may use and disclose PHI about you for research purposes with a valid waiver of authorization approved by an institutional review board or a privacy board. Otherwise, the Facility will request a signed authorization by the individual for all other research purposes.

Uses and disclosures to avert a serious threat to health or safety: The Facility may use or disclose PHI about you, if it believed in good faith, and is consistent with any applicable law and standards of ethical conduct, to avert a serious threat to health or safety.

Uses and disclosures for specialized government functions: The Facility may use or disclose PHI about you for specialized government functions including: military and veteran's activities, national security and intelligence, protective services, department of state functions, and correctional institutions and law enforcement custodial situations.

Disclosure for workers' compensation: The Facility may disclose PHI about you as authorized by and to the extent necessary to comply with workers' compensation laws or programs established by law.

Disclosures for disaster relief purposes: The Facility may disclose PHI about you as authorized by law to a public or private entity to assist in disaster relief efforts and for family and personal representative notification.

Disclosures to business associates: The Facility may disclose PHI about you to the Facility's business associates for services that they may provide to or for the Facility to assist the Facility to provide quality health care. To ensure the privacy of your PHI, we require all business associates to apply appropriate safeguards to any PHI they receive or create.

OTHER USES AND DISCLOSURES

The Facility may contact you for the following purposes:

Information about treatment alternatives: The Facility may contact you to notify you of alternative treatments and/or products.

Health related benefits or services: The Facility may use your PHI to notify you of benefits and services the Facility provides.

Fundraising: If the Facility participates in a fundraising activity, the Facility may use demographic PHI to send you a fundraising packet, or the Facility may disclose demographic PHI about you to its business associate or an institutionally related foundation to send you a fundraising packet. No further disclosure will be allowed by the business associates or an institutionally related foundation without your written authorization. You will be provided with an opportunity to opt-out of all future fundraising activities.

FOR ALL OTHER USES AND DISCLOSURES

The Facility will obtain a written authorization from you for all other uses and disclosures of PHI, and the Facility will only use or disclose pursuant to such an authorization. In addition, you may revoke such an authorization in writing at any time. To revoke a previously authorized use or disclosure, please contact John Pavis to obtain a *Request for Restriction of Uses and Disclosures*.

YOUR HEALTH INFORMATION RIGHTS

The following are a list of your rights in respect to your PHI. Please contact John Pavis for more information about the below.

Request restrictions on certain uses and disclosures of your PHI: You have the right to request additional restrictions of the Facility's uses and disclosures of your PHI. The Facility is not required to accommodate a request, except that the Facility is required to agree to a request to restrict disclosures to health insurance plans related to products and services you pay out-of-pocket for.

The right to have your PHI communicated to you by alternate means or locations: You have the right to request that the Facility communicate confidentially with you using an address or phone number other than your residence. However, state and federal laws require the Facility to have an accurate address and home phone number in case of emergencies. The Facility will consider all reasonable requests.

The right to inspect and/or obtain a copy your PHI: You have the right to request access and/or obtain a copy of your PHI that is contained in the Facility for the duration the Facility maintains PHI about you. There may be a reasonable cost-based charge for photocopying documents. You will be notified in advance of incurring such charges, if any.

The right to amend your PHI: You have the right to request an amendment of the PHI the Facility maintains about you, if you feel that the PHI the Facility has maintained about you is incorrect or otherwise incomplete. Under certain circumstances we may deny your request for amendment. If we do deny the request, you will have the right to have the denial reviewed by someone we designate who was not involved in the initial review. You may also ask the Secretary, United States Department of Health and Human Services ("HHS"), or their appropriate designee, to review such a denial.

The right to receive an accounting of disclosures of your PHI: You have the right to receive an accounting of certain disclosures of your PHI made by the Facility.

The right to receive additional copies of the Facility's Notice of Privacy Practices: You have the right to receive additional paper copies of this Notice, upon request, even if you initially agreed to receive the Notice electronically

Notification of Breaches: You will be notified of any breaches that have compromised the privacy of your PHI.

REVISIONS TO THE NOTICE OF PRIVACY PRACTICES

The Facility reserves the right to change and/or revise this Notice and make the new revised version applicable to all PHI received prior to its effective date. The Facility will also post the revised version of the Notice in the Facility.

COMPLAINTS

If you believe your privacy rights have been violated, you may file a complaint with the Facility and/or to the Secretary of HHS, or his designee. If you wish to file a complaint with the Facility, please contact John Pavis if you wish to file a complaint with the Secretary, please write to:

<http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html>

The Facility will not take any adverse action against you as a result of your filing of a complaint.

CONTACT INFORMATION

If you have any questions on the Facility's privacy practices or for clarification on anything contained within the Notice, please contact:

Newhard Pharmacy
John Pavis
1001 Main Street
Northampton, PA 18067
(610) 262-6721