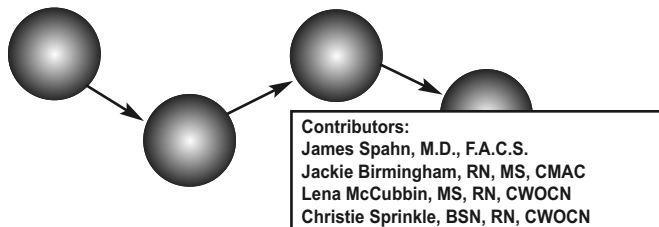


Connection the Dots

Understanding the seriousness and complexity of pressure ulcers relating to the Continuum of Care



1

Copyright © 2009, EHOB, Inc.

For proper Continuum of Care, these four areas connect the dots.

- **Governmental Regulations**
- **Legal Responsibilities**
- **Good Medical Standards of Care**
- **Reasonable Cost**

2

Copyright © 2009, EHOB, Inc.

By connecting the dots, proper Continuum of Care is accomplished.

Pressure Ulcer Management from Admittance through Discharge and Beyond...



- **Acute Care**
- **Emergency Room**
- **Operating Room**
- **Post Anesthesia Care Unit**
- **Intensive Care**
- **Nursing Unit**
- **Step Down**
- **Sub-Acute Care**
- **Skilled Nursing Care**
- **Assisted Living Care**
- **Home Health Care**
- **Home (Self Care)**

3

Copyright © 2009, EHOB, Inc.

Regulations

Regulations

Social Security Act of 1965

through

Deficit Reduction Act of 2006

Regulations

Discharge Planning is legally mandated by the Social Security Act § 1861

Social Security (A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

Social Security (B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and other patients upon the request of the patient, patient's representative, or patient's physician.

Social Security (C) Any discharge planning must be done on a timely basis.

Social Security (D) Discharge Planning evaluations must include an evaluation of a patient's likely need for appropriate post-hospital services.

Regulations

Social Security Act Sec. 484.18

Condition of Participation:

Acceptance of patients, plan of care, and medical supervision mandates that hospitals, long-term care facilities, home care agencies, etc ALL must comply with the Social Security Act Regulations.

Regulations

JCAHO has “Deemed Status”

JCAHO represents Medicare and thus acts as ‘agents’. With deemed status, JCAHO has authority in meeting governmental regulations.

With deemed status, JCAHO’s surveys can take the place of CMS inspections. And it allows organizations to undergo both accreditation and CMS reviews at one time.

Regulations (Approximately 2004)

JCAHO has “Deemed Status”

What adverse event categories are currently monitored by the MPSMS? Currently the MPSMS is counting the national rates for Medicare beneficiaries in the following adverse event categories: blood stream infections, central venous catheter adverse events, adverse drug events, inpatient acquired pressure ulcers, and ventilator associated pneumonia. The MPSMS is also counting the rates of adverse events associated with hip and knee replacements as well as the postoperative rates of deep vein thrombosis, pulmonary embolism, pneumonia, urinary tract infection, and myocardial infarction.

David Hunt, MD, FACS
Centers for Medicare & Medicaid Services
Office of Clinical Standards & Quality

Regulations

2006 CMS reported the top 6 Medicare cases that were deemed preventable adverse events as secondary diagnosis.

1. Pressure Ulcers - 322,946
2. Staphylococcus Aureus Bloodstream Infections/ Septicemia - 29,500
3. Catheter-Associated Urinary Tract Infections - 11,780
4. Objects Left in Patients During Surgery - 764
5. Air Embolisms - 45
6. Blood Incompatibility - 33

10
Copyright © 2009, EHOB, Inc.

Regulations

NOW

- Voluntary Reporting of Patient Safety Adverse Events
National Quality Forum
- MSDRG - Medical Severity Diagnosis Related Group
- Post-Acute MDS - Care Tool
- Medical Error Reporting at the State Level

11
Copyright © 2009, EHOB, Inc.

Regulations

The Playbook

Tag 314 - Guidance to Surveyor for Long Term Care Facilities

12
Copyright © 2009, EHOB, Inc.

Regulations

What's Next?

1. Oversight Component of CMS
 - Fines
 - Recapture of DRG
 - Responsibility for Future Pressure Ulcer Care
2. Pay for Performance
3. Who Knows?

Legal

Legal

The details in federal statutes and regulations have set an easily identifiable industry standard for the care of pressure ulcers. This standard, and survey results applying it, have made negligence cases involving pressure ulcers easier to prove. It is not surprising, therefore, that facilities cited for violations involving pressure ulcers have lost significant cases.

Bennett RG, O'Sullivan J, DeVito EM, Remsburg R. The increasing medical malpractice risk related to pressure ulcers in the united states. American Geriatrics Society. 2000;48:73-81

Legal

Pressure ulcers remain an area where worst practices are more common than best practices.

Ferrell Ba, Josephson K, Norvid P, Alcorn H. Pressure ulcers among patients admitted to home care. American Geriatrics Society. 2000;1046

16
Copyright © 2009, EHOB, Inc.

Legal

**Fatal Medical Errors Said to be More Widespread
“...Other leading causes of death from preventable errors include bed sores that lead to infection...”
Wall Street Journal, 2004**

**Why do so many still die needlessly in hospitals
“...Nearly 60% of safety incidents involved the failure to diagnose and treat conditions that developed in the hospital, bedsores and post operative infections...” USA TODAY, 2004**

17
Copyright © 2009, EHOB, Inc.

Legal

**Medicare Plans to Stop Paying - 2008
“...Hospitals will no longer receive payment for patients who acquire a pressure ulcer following admission to the hospital...”
Wall Street Journal, 2007
AMED News, 2007**

18
Copyright © 2009, EHOB, Inc.

Legal Fiduciary Responsibilities

Negligence and Malpractice

Negligence:

A general term that denotes lacking in due care; carelessness; A deviation from standard of care that a reasonable person would use in a particular set of circumstances.

Anyone, including non-medical persons, can be liable for negligence.

Malpractice:

To be liable for malpractice, the person committing the wrong must be a professional. The court defines malpractice as the failure of a professional person to act in accordance with the prevailing professionals standards, or failure to foresee consequences that a professional person, having the necessary skills and education, should foresee.

19

Copyright © 2009, EHOB, Inc.

Legal Fiduciary Responsibilities

The same type of acts may form the basis for negligence or malpractice.

If performed by a non-professional person the result is negligence; if performed by a professional person, the acts could be the basis for a malpractice lawsuit.

In order to prove negligence or malpractice the following elements must be established:

- Duty owed the patient;
- Breach of duty owed the patient;
- Forseeability;
- Causation;
- Injury; and Damages.

20

Copyright © 2009, EHOB, Inc.

Legal Fiduciary Responsibilities

Nurses, like other licensed professionals, are regulated by various state laws.

One important state law that directly affects the practice of nursing is the nursing practice act. Nurses have an ethical and legal responsibility to maintain the currency of their practice in today's changing health care system and to be familiar with the nurse practicing act.

21

Copyright © 2009, EHOB, Inc.

Legal

Accountability

Accepted Standards of Care
American Nurse Association Code for Nurses
Nurse Practicing Act
Hippocratic Oath
State Licensing
Fiduciary Responsibilities

Legal

Patient's choice to not accept suggested medical treatment.

Proper Documentation Required

1. Recommend medical care based on best medical practice criteria.
2. Explain benefits and expectations related to recommended care.
3. Patient chooses not to accept suggested medical treatment.
4. Explain expected adverse results associated with the refusal of medical treatment.
5. Ask patient to reconsider choice.
6. Have patient or legal advocate put the refusal in writing.

Medical Standards
Protocols

Medical Standards

Problem Solving

1. Recognizing the Problem
2. Understanding the Problem
3. Addressing the Problem

25

Copyright © 2009, EHOB, Inc.

Medical Standards

1. Recognizing the Problem

“Despite the publication of clinical practice guidelines addressing pressure ulcer prevention and treatment by the Agency for Health Care Policy and Research (AHCPR) within the past decade, the length of stay and cost associated with pressure ulcers continues to rise.”

Whittington K, Patrick, M, Roberts JL. A national study of pressure ulcer prevalence and incidence in acute care hospitals. *JWOCN*2000;27(4):209.

Allman RM, Goode PS, Burst N, Bartolucci AA, Thomas DR. Pressure ulcers, hospital complications, and disease severity: impact on hospital costs and length of stay. *Adv Wound Care* 1999; 12:22-30.

26

Copyright © 2009, EHOB, Inc.

Medical Standards

1. Recognizing the Problem

↑ \$ ≠ ↑ Clinical Outcomes

Maklebust J. An update on horizontal support surfaces. *Ostomy/Wound Management* 1999; 45,1A (Suppl): 708-77S.

Cuddigan J, Frantz R. Pressure ulcer research: Pressure ulcer treatment. *Advances in Wound Care* 1998; 11(6):294-300.

Baharestani M. Pressure ulcers in an age of managed care: A nursing perspective. *Ostomy/Wound Management* 1999; 45(5): 18-40.

Blue Cross and Blue Shield Association. *Tec Special Report. Pressure-reducing support surfaces in the prevention and treatment of pressure ulcers: Group 1-2-3 technologies.* BlueCross BlueShield Association, Kaiser Permanente; 1998.

27

Copyright © 2009, EHOB, Inc.

Medical Standards

1. Recognizing the Problem

With stress growing from quicker hospital discharges and increasing patient acuity, pressure ulcer assessment and management are important areas for education and quality improvement in home care

Ferrell Ba, Josephson K, Norvid P, Alcorn H. Pressure ulcers among patients admitted to home care. American Geriatrics Society. 2000;1046

28
Copyright © 2009, EHOB, Inc.

Medical Standards

1. Recognizing the Problem

It is estimated that 30% of all admissions to home care are at serious risk for new pressure ulcers. Patients at risk of developing pressure ulcers or those who had existing ulcer were found to be undertreated.

Ferrell Ba, Josephson K, Norvid P, Alcorn H. Pressure ulcers among patients admitted to home care. American Geriatrics Society. 2000;1046

29
Copyright © 2009, EHOB, Inc.

Medical Standards

1. Recognizing the Problem

The problem of pressure ulcers among older adults receiving home health care rivals the problem of pressure ulcers among other adults in hospitals and long-term care facilities.

Bergquist S. Pressure ulcer prevention in older adults receiving home health care: implications for use with the OASIS. Advances in Skin and Wound Care. 2002; 139.

30
Copyright © 2009, EHOB, Inc.

Medical Standards

2. Understanding the Problem

Pressure Ulcer: Mechanical stress induced ischemic necrosis of three-dimensional soft tissue predominantly of nutritionally and mobility impaired individuals due to placement on a support surface.

Pressure ulcer definition according to Dr. Spahn.

31
Copyright © 2009, EHOB, Inc.

Medical Standards

2. Understanding the Problem

Little is known about predicting pressure ulcer development in home health care patients. The few studies conducted in this setting found that urine or stool incontinence, altered levels of activity and mobility, recent discharge from an institutional setting, or more functional impairment were associated with the presence of a pressure ulcer.

Bergquist S. Pressure ulcer prevention in older adults receiving home health care: implications for use with the OASIS. *Advances in Skin and Wound Care*. 2002; 139.

32
Copyright © 2009, EHOB, Inc.

Medical Standards

2. Understanding the Problem

Understanding the relationship between soft tissue injury and support surfaces (i.e. bed, ER cart, OR table, chair, etc)

Since The body is 3-dimensional.

Then Deliverance of gradient pressure and shear mechanical stresses by the support surface (solids, gels and powered fluids).

Will Cause soft tissue distortion, change in velocity and flow pattern of the circulation, causing endothelial damage resulting in ischemia and possible infarction of the soft tissue at risk (pressure ulcer).

33
Copyright © 2009, EHOB, Inc.

Medical Standards

2. Understanding the Problem

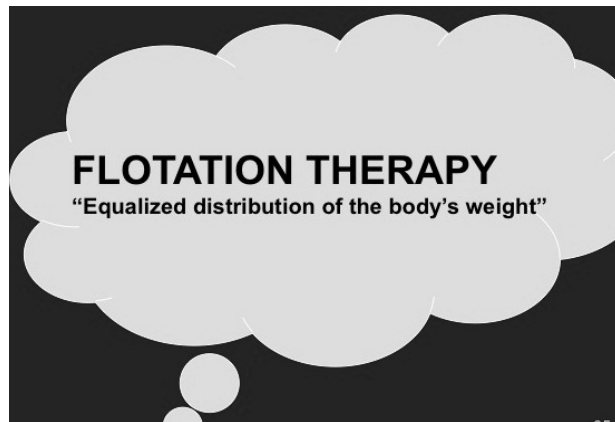
When Selecting a Support Surface

- Thus** Selection of these types of media must be evaluated by Scientific facts and soft tissue strain visualization (CT or MRI scanning) since pressure mapping is 2-dimensional and unreliable in defining causation of soft tissue distortion.
- Therefore** If the body is 3-dimensional then volumetric support (flotation) is needed to maintain proper tissue orientation.
- Then** A static media (gas, liquid, sol) is needed to float the body in a flexible container that is properly filled or inflated.
- And** Static air is preferred to liquid or sol because it has less density and no viscosity.

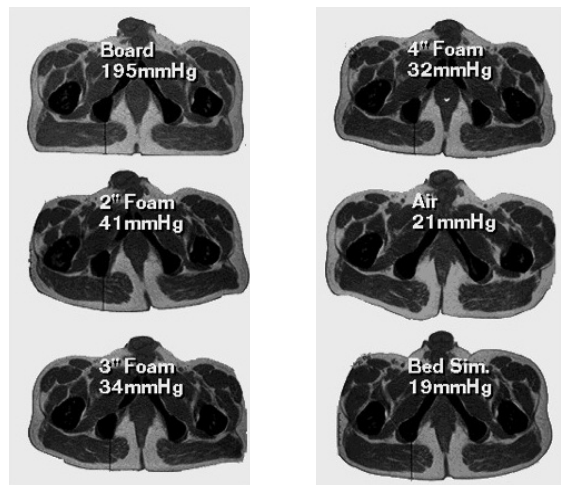
34
Copyright © 2009, EHOB, Inc.

Medical Standards

2. Understanding the Problem



35
Copyright © 2009, EHOB, Inc.



36
Copyright © 2009, EHOB, Inc.

Basic scientific principles relating to mechanics and physics explain the effects of various support surfaces.

- **Basic physics**
 - 200 BC
 - Archimedes
 - 17th Century
 - Boyle
 - Pascal
 - Newton
 - Hooke's
 - Young's Modulus
 - Shear Modulus
 - Bulk Modulus
- **Physical properties of media**
 - **Static (non-powered)**
 - Gas
 - minimal molecular bonding
 - Liquid
 - moderate molecular bonding
 - Solid
 - strong molecular bonding
 - **Dynamic (powered)**
 - Fluid
 - Gas

37
Copyright © 2009, EHOB, Inc.

Medical Standards

2. Understanding the Problem



Nature's Flotation

38
Copyright © 2009, EHOB, Inc.

Medical Standards

Please Remember

- No support surface can protect the ankle/heel region from pressure ulcers at all times

Not because they are bad products

This occurs because of:

- Recumbent Physiologic Changes
- Hemodynamics
- Anatomy of the region

39
Copyright © 2009, EHOB, Inc.

Medical Standards

3. Addressing the Problem

Usage of pressure-reducing devices alone can cause an increase in the incidence of pressure ulcers while protocols decrease incidence by 50%.

Moody BL, Finale JE, Thompson M, Vaillancourt D, Symonds G, Bonasoro C. Impact of staff education on pressure sore development in elderly hospitalized patients. *Archives of Internal Medicine*, 1988; 124:2241-2243.

Lyder CH, Preston J, Grady JN, Scinto J, Allman R, Bergstrom N, Rodeheaver G. Quality of care for hospitalized medicine patients at risk for pressure ulcers. *Archives of Internal Medicine*. 2001; 161:1549-1554.

40
Copyright © 2009, EHOB, Inc.

Medical Standards

3. Addressing the Problem

Protocols are the “Glue” that holds everything together throughout the Continuum of Care and beyond.

41
Copyright © 2009, EHOB, Inc.

Medical Standards

3. Addressing the Problem

IMPORTANT

Deliver Good Medical Standards of Care by

- Recognizing pressure ulcer risks (i.e. awareness).
- Performing skin assessment & risk analysis on a scheduled basis (i.e Braden Scale, Norton Scale).
- Developing and applying appropriate protocols relating to pressure ulcer prevention and treatment.
- Beginning discharge planning at admission and continuing through the next level of care.

42
Copyright © 2009, EHOB, Inc.

Medical Standards

3. Addressing the Problem

Clinical Protocols for Pressure Ulcers Should Address:

1. Cognition
2. Mobilization & Ambulation (motor and/or sensory)
3. Nutrition and Hydration
4. Moisture (excessive or dryness) and incontinence (urinary/fecal/combo)
5. General Medical Co-Morbidities (Medication Use)
6. Existing Pressure Ulcers (Suggested DTI, Stage I, II, III, IV and Unstageable)
7. Previous Pressure Ulcers (Closed Stage III, IV, Unstageable and DTI)
8. Contact with medical devices (i.e., braces, orthotics, cannulas, tubing) and/or any object in contact with the body
9. Patient chooses not to accept part or all of the suggested medical treatment

43
Copyright © 2009, EHOB, Inc.

Medical Standards

Develop an Individualized Care Plan

44
Copyright © 2009, EHOB, Inc.

Medical Standards

WHO

By all caregivers and support staff

HOW

With a timely assessment and risk analysis

WHEN

On admission and through scheduled assessments throughout a patient's stay and discharge

WHY

Health-impaired people develop pressure ulcers

WHERE

In all places and on all surfaces utilized throughout the Continuum of Care

45
Copyright © 2009, EHOB, Inc.

Medical Standards

Why Follow Protocols

Prevention and treatment strategies for pressure ulcers were found to be limited before admission to home care.

Ferrell Ba, Josephson K, Norvid P, Alcorn H. Pressure ulcers among patients admitted to home care. American Geriatrics Society. 2000;1046

Medical Standards

Why Follow Protocols

Unhealthy people who are immobile and nutritionally impaired are at risk for developing pressure ulcers

And

Unhealthy, immobile and nutritionally impaired people will remain at risk until ALL of these conditions are corrected.

Medical Standards

Why Follow Protocols

Support surface protection should occur immediately and be maintained throughout the acute, sub-acute, and chronic continuum of care.

Medical Standards

Why Follow Protocols

Only 54% of patients with pressure ulcers were placed on a pressure-reducing device and only 18% of those at risk for developing new ulcers were receiving pressure reduction.

Ferrell Ba, Josephson K, Norvid P, Alcorn H. Pressure ulcers among patients admitted to home care. American Geriatrics Society. 2000;1046

49
Copyright © 2009, EHOB, Inc.

Medical Standards

Why Follow Protocols

ALL SUPPORT SURFACES SHOULD:

Redistribute weight equally in a 3-dimensional manner.

Minimize pressure, shear and friction injury.

Assist in moisture and temperature control.

Minimize surface contamination and bioaerosol spread.

Be easy to clean.

Aid in patient transferring and mobilization.

Be compatible with multiple surfaces

Be cost effective.

50
Copyright © 2009, EHOB, Inc.

Medical Standards

Why Follow Protocols

ALL SUPPORT SURFACES SHOULD:

- **Fulfill regulatory requirements.**
 - **Flame retardant**
 - **Bio-compatibility**
 - **Antimicrobial**
 - **FDA regulations**
 - **Good manufacturing processes (i.e. ISO)**
- **Address safety and comfort of the patient.**
 - **Low-profile design (i.e. height, entrapment)**
 - **Pliable but durable**
 - **Latex Free**

51
Copyright © 2009, EHOB, Inc.

Medical Standards

Why Follow Protocols

ALL LOWER EXTREMITY PRODUCTS SHOULD:

Elevate heel (Dewedge).

Protect side of foot and ankle.

Neutralize weight of lower extremity (Delever).

Maintain and promote circulation.

Address foot drop and lateral rotation of the ankle.

Allow access to the foot for inspection/treatment as well as range of motion techniques.

Facilitate the musculoskeletal pump.

Be lightweight

Be cost effective.

52
Copyright © 2009, EHOB, Inc.

Medical Standards

Why Follow Protocols

ALL LOWER EXTREMITY PRODUCTS SHOULD:

- Fulfill regulatory requirements.
 - Flame retardant
 - Bio-compatibility
 - Antimicrobial
 - FDA regulations
 - Good manufacturing processes (i.e. ISO)
- Address safety and comfort of the patient.
 - Pliable but durable
 - Latex Free

53
Copyright © 2009, EHOB, Inc.

Medical professionals should...

Deliver Good Medical Standards of Care

while

Following Governmental Regulations

and

Fulfilling Legal Responsibilities

at a

Reasonable Cost

while considering

A Seamless Continuum of Care

54
Copyright © 2009, EHOB, Inc.

Medical Standards

IMPORTANT



Protocols Should Follow The Patient to the Next Level of Care!

55

Copyright © 2009, EHOB, Inc.

Upon Patient Discharge

Pressure Ulcer Prevention and Treatment on Discharge

Assess risk factors and/or soft tissue damage

Develop preventative or treatment strategies for the next level of care consistent with existing facility protocols

Assisting patients at risk or who have existing pressure ulcers by:

- A. Informing
- B. Educating
- C. Providing patient choices for the next level of care...AND

56

Copyright © 2009, EHOB, Inc.

Upon Patient Discharge

D. Helping select products and obtain for the next level of care

- ➔ Send products used in facility to the next level of care with the patient.
- ➔ Contact post-acute facility, SNFS or homecare agency who utilize proper protocols and products of choice.
- ➔ Refer the patient to a DME who supplies the proper products of choice.
- ➔ Refer the patient to retail to obtain proper products of choice.
- ➔ Refer the patient with no means to obtain proper products of choice to social services

57

Copyright © 2009, EHOB, Inc.

Upon Patient Discharge

Healthcare Professionals Must :

**Practice Good Medical Standards of Care
Follow Governmental Regulations
Fulfill Legal Responsibilities**

But often there is...

**A “Disconnect” between patient product needs
and reimbursement**

58
Copyright © 2009, EHOB, Inc.

Reasonable Cost

“The Disconnect”

59
Copyright © 2009, EHOB, Inc.

Reasonable Cost

The ‘Disconnect’

Patients, who are at risk for pressure ulcers become, “disconnected from the continuum of care” when they cannot always meet the stringent coverage and payment rule of Medicare, and private insurance. For this reason, products that can be purchased at a reasonable cost must be made available to assist patients and caregivers.

60
Copyright © 2009, EHOB, Inc.

Reasonable Cost

Changing Times

From a:

Reimbursement Driven System

To a:

Consumer Driven System

61

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Reasonable Cost Improves Compliance

3 main goals of Discharge Planning

Foster appropriate utilization of healthcare services (i.e. appropriate patient, appropriate level, appropriate time)

Manage the clinical and financial risk of the patient, the provider and the caregiver.

Patient must be given choices for their products and services.

62

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Buying Direct

**WHY BUY DIRECT? When a patient is at risk for pressure ulcers, the caregiver is responsible...
Even if insurance is questionable!**

63

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Buying Direct

Factors Affecting Patient's Choice of Support Surfaces

A. Availability of product

- Time of delivery
- Set-up time required
- Willingness of DME to supply facility and/or patient's choice of products

B. Understanding reimbursement

- Reimbursement amount & co-payment requirements
- Fulfilling proper criteria for insurance claim
- Understanding financial ramifications when insurance claims are denied
- Understanding insurance coverage re-evaluations for continued usage of products.

64

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Buying Direct

Factors Affecting Patient's Choice of Support Surfaces

C. Ease of use

- Use on existing home support surfaces (i.e. beds, chairs, sofas, etc.).
- Transportability
- Ease of cleaning.
- Availability of timely services on the product.
- Availability of support for use of the product.

D. Understanding hidden costs when using products.

- Electricity
- Space requirements
- Cost of delivery and set up of product
- Need for multiple product usage on various surfaces.

65

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Buying Direct

Factors Affecting Patient's Choice of Support Surfaces

E. Duration of use

- Product warranty vs. clinical effectiveness.

F. Reliability and safety of the product

- Flame retardant
- Effectiveness of the product to help prevent contamination - Antimicrobial
- Ability to clean without changing the clinical effectiveness of the product.
- Biocompatibility - prevents adverse effects when the body is placed against the product.

66

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Buying Direct

Buying direct from the manufacturer is ideal for patients who:

Cannot meet the medical necessity requirements of insurance

Are denied insurance coverage

Cannot find the recommended product

Manage their own medical spending

Are frustrated with tedious insurance forms and Medicare red tape

Require minimal set-up and timely delivery

67

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Buying Direct

If a patient's condition is...

Low Risk	Moderate Risk	High Risk
Insurance Coverage Questionable	Insurance Coverage Possible	Insurance Coverage Probable
BUY DIRECT	BUY DIRECT	BUY DIRECT or DME

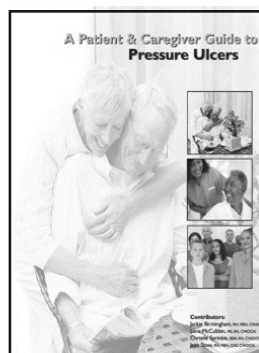
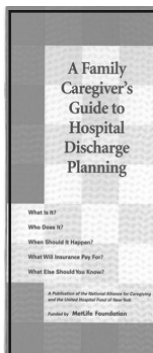
68

Copyright © 2009, EHOB, Inc.

Reasonable Cost

Buying Direct

Patient and Caregiver Education



69

Copyright © 2009, EHOB, Inc.

Conclusion

The products should be:

**Clinically Proven
Cost Effective
Patient & Caregiver Friendly**

Conclusion

Connect the Dots with...

**Good Medical Standards of Care
Governmental Regulations
Legal Responsibilities
Reasonable Cost**

Who benefits...

**The Facility
The Physicians
The Nurses
The Patients**