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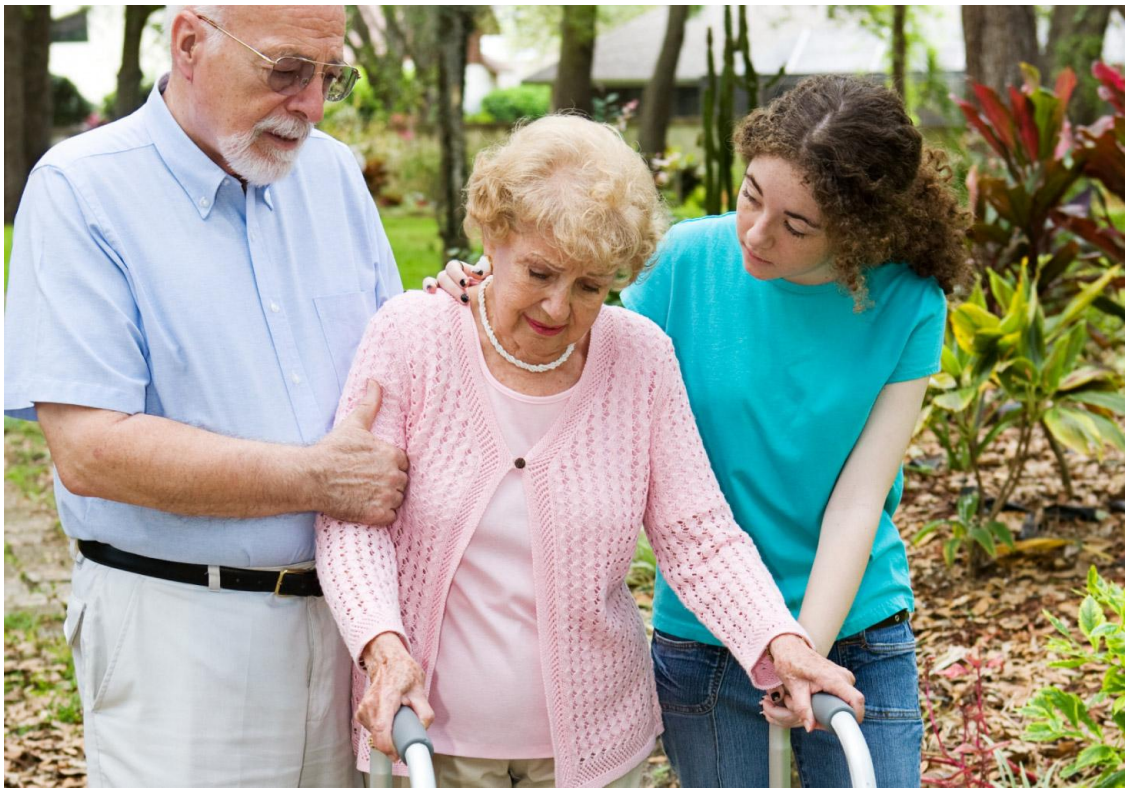

TH CARE AND HUMAN SERVICES POLICY, RESEARCH, AND CONSULTING—**WITH REAL-WORLD PERSPECTIVE.**

Cost Estimates for the Deconsolidation of Medicare Benefit: Surgical Dressings for Wound Care

Prepared for: The Continuum of Care Coalition

Submitted by: The Lewin Group

Date: September 14, 2009
Revised: May 12, 2010

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Executive Summary

The Lewin Group was commissioned by the Continuum of Care Coalition (C3) to estimate the five-year Medicare gross and net costs of *implementing the exclusion of payment for Surgical Dressings from the consolidated per diem cost benefits provided under Part-A for inpatients of Skilled Nursing Facilities (SNF), as well as individuals under a Home Health Plan of Care, and allow for separate payment to be made under Part-B benefits*.[1,2] This analysis was conducted using Congressional Budget Office (CBO) type scoring conventions.

Despite evidence indicating that active surgical dressings are more clinically effective, most Medicare beneficiaries in SNFs and Home Health Plan of Care do not receive advanced, comprehensive wound care. This is because of the high initial acquisition cost of active surgical dressing. The proposed legislation amends title XVIII of the Social Security Act to provide for separate coverage for surgical dressings provided in Home Health Plan of Care or SNF under the Medicare Program. The objective is to implement the exclusion of payment for surgical dressings from the consolidated per diem cost benefits for individuals under a Home Health Plan of Care or inpatients of SNF and allow for separate payment to be made under Part-B benefits for surgical dressings provided. Medicare beneficiaries are entitled to such services and this report will demonstrate how this proposed legislation will improve the quality of care, reduce healing time, and provide a significant national savings.

Based on our analysis, the estimate of five-year net cost savings to Medicare of standardizing coverage of implementing the exclusion of payment for surgical dressings from the Part A inpatient SNF stay and home health plan of care and allow for separate payment to be made under Part B benefits is almost $4 billion (refer to ES 1). This estimate is comprised of Part A cost savings from SNF stay and Home Health Plan of Care and Part B benefits. In addition, we have also estimated an additional cost saving of $0.7 billion over a period of five years for providers adopting active surgical dressings for wound management as a standard of care.

ES 1: Medicare Cost of Separate Payments under Part B for Active Surgical Dressings for Wound Care in SNF and Home Health

	2010	2011	2012	2013	2014	Total
Medicare Part A SNF Cost Savings Due to Proposed Legislation (in $millions)	$242	$331	$406	$462	$523	$1,965
Medicare Part A Home Health Cost Savings Due to Proposed Legislation (in $millions)	$255	$276	$300	$324	$349	$1,504
Medicare Part B Cost Savings Due to Proposed Legislation (in $millions)	$79	$92	$104	$115	$126	$517
Total Medicare Cost Savings (in $millions)	$575	$700	$811	$902	$998	$3,986

[1] Medicare Skilled Nursing Continuity of Care Act of 2009
[2] Medicare Home Health Services Continuity of Care Act of 2009

Purpose of the Study

The Lewin Group was commissioned by the Continuum of Care Coalition (C3) to estimate the five-year Medicare gross and net costs of implementing the exclusion of payment for Surgical Dressings from the consolidated per diem cost benefits provided under Part-A for inpatients of Skilled Nursing Facilities (SNF), as well as individuals under a Home Health Plan of Care, and allow for separate payment to be made under Part-B benefits.[3,4] This analysis will be conducted using Congressional Budget Office (CBO) type scoring conventions.

In this report, the first three sections define wounds, surgical dressings and rationale for the proposed legislation. The third section of the report describes our findings from a literature review on the benefits of surgical dressings for wound care, such as rate of healing, frequency of dressing change and overall cost effectiveness. The final section of the report provides a detailed methodology of the Medicare five-year gross and net costs of the proposed legislation.

Definition of a Wound

A wound is defined as a break in skin or mucous membrane with loss of surface tissue, disintegration and necrosis of epithelial tissue, and often pus. An ulcer or wound can be further classified according to the depth of tissue involvement. An ulcer may be superficial, partial thickness or full thickness. A superficial ulcer only involves the epidermis or outer layer of skin. These ulcers may or may not bleed. A partial thickness ulcer involves the epidermis and a portion of the dermis (usually the first of two dermal layers). A full thickness ulcer involves the epidermis, dermis, and subcutaneous tissue. Full thickness ulcers can also involve deep tissue structures like muscle, bone, or tendon. Ulcers of all etiologies can be classified using the superficial, partial or full thickness descriptors. Pressure ulcers (AKA bed sores, decubitus ulcers) have a specific classification system using *Stages* to describe ulcers due to pressure. This staging system was created by the National Pressure Ulcer Advisory Panel (NPUAP) and is used in current practice throughout all health care settings. The staging definitions are as follows:

Suspected Deep Tissue Injury: Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Stage I: Stage 1 is defined as intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

Stage II: Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

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[3] Medicare Skilled Nursing Continuity of Care Act of 2009

[4] Medicare Home Health Services Continuity of Care Act of 2009

Stage III: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. The depth of a stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

Stage IV: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or a scar may be present on some parts of the wound bed. Often include undermining and tunneling. The depth of a stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.

Unstageable: Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heel serves as "the body's natural (biological) cover" and should not be removed.

Definition of Surgical Dressings for Wound Care

Medicare has defined all wound care dressings as 'surgical dressings'. These surgical dressings can be further divided into 'traditional' (AKA conventional, passive) dressings and 'advanced' (AKA modern, active) dressings. Traditional passive dressings for wound care are primarily gauze and saline based (dry or wet-to-dry). Advanced dressings, hereafter referred to as active surgical dressings, promote and maintain a moist wound environment and/or interact with the wound bed to facilitate healing.[5] These dressings are able to retain sufficient moisture and therefore maintain healing equivalent to a physiologically moist environment. In addition, active dressings do not traumatize the wound bed. While prohibiting the incorporation of gauze fibers into the tissue, active dressings also promote re-epithelialization and enhanced granulation tissue formation.[6] Examples include, but are not limited to, alginates, collagens, films, foams, hydrogels, and hydrocolloids. It makes biological sense to provide a moist environment for the cells that do the work of healing by preventing wounded tissue from drying or incorporating gauze fibers into the healing tissue.[7] Passive dressings adhere to the wound bed and often cause pain and bleeding upon removal, as these dressings are nonselective and remove healthy tissue as well as necrotic tissue.

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5 San Miguel L, Torra i Bou J-E, Soriano JV. Economics of pressure-ulcer care: review of the literature on modern versus traditional dressings. J Wound Care. 2007; 16(1):5-9.

6 Hutchinson, J.J. and Lawrence J.C. Wound infection under occlusive dressings. J Hospital Infection. 1991;17:83-94.

7 Bolton, Laura. Operational Definition of Moist Wound Healing. J Wound Ostomy Continence Nursing. 2007;34(1):23-29.

Since it was first demonstrated that a moist wound environment promoted healing, a number of new technologies have been developed to improve this clinical outcome. These dressings provide not only the optimum environment for re-epithelialization and angiogenesis, but also an environment in which the host's nonspecific phagocytic defense mechanism is able to function.[8] Further, while preventing wounded tissue from drying and prohibiting the incorporation of gauze fibers, the patient's risk to complications such as infection, amputation, scarring, pain, and slower healing times is significantly reduced.[9] These capabilities all contribute to a longer duration between dressing changes for active surgical dressings.

In contrast, moist gauze dressings are unable to provide an ideal environment for wound healing. Fluid is able to evaporate from the outer surface, and the dressings present no physical barrier to the entry of exogenous bacteria.[10] Drying out of the wound surface causes gauze fibers to be incorporated into the wound, resulting in painful dressing changes which simultaneously inhibit new tissue growth. Most importantly, gauze dressings require frequent changing to retain wound moisture as they have a tendency to dry out and stick to the wound surface.

In managing patients with varying forms of wounds, the appropriate choice of dressing is a critical component of treatment. Despite their apparent ineffectiveness, gauze dressings are frequently used due to their lower initial acquisition cost and seeming inexpensiveness. Further, many clinicians are either unaware of what dressings are optimal or do not have access to the appropriate dressings in their setting.[11] One important implication of these findings is that wounds allowed to deteriorate to full-thickness will take twice as long to heal, increasing the clinical, humanistic, and economic burden of wound care and exposing patients to prolonged risk of wound complications, such as pain or infection. The clinical implication of this finding is that it is valuable to direct resources toward healing chronic wounds when first detected and not wait until wounds stop responding to treatment before implementing a valid and consistent treatment approach. This is a clear mandate to intervene early with a higher level of wound care instead of starting with gauze and 'working up' to more advanced protocols of wound care.[12] This reinforces the critical importance that patients receive a treatment modality using active surgical dressings as soon as an ulcer is presented.

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8 Hutchinson, J and Lawrence, J. Wound infection under occlusive dressings. J Hospital Infection. 1991; 17:83-94.

9 Bolton, Laura. Operational Definition of Moist Wound Healing. J Wound Ostomy Continence Nursing. 2007; 34(1):23-29.

10 Ovington, L. Hanging Wet-to-Dry Dressings Out to Dry. J Prevention and Healing. 2002; 15(2):79-84.

11 Jones, K and Fennie, K. Chronic Wounds: Factors Influencing Healing Within 3 Months and Nonhealing after 5-6 Months of Care. J Am Med Dir Assoc. 2007; 8(6):378-87.

12 Bolton, L et al. Wound-Healing Outcomes Using Standardized Assessment and Care in Clinical Practice. J Wound Ostomy Continence Nursing. 2004; 31(2): 65-71.

Current Medicare Coverage Policy Related to Wound Care Dressings in Skilled Nursing Facility and Home Health Services

Wound Care Coverage in SNF

Medicare covers skilled nursing and rehabilitative therapy for beneficiaries being treated in SNF under certain conditions for a limited time. Prior to SNF admission, a 3-day covered hospital stay is required. For qualifying beneficiaries, all necessary services are covered under Medicare Part A for up to 100 days. Following the 20th day of care, beneficiaries are responsible for a $128 daily copayment. Beyond 100 days, the beneficiary may be moved to the Long-Term Care setting, which is covered under Medicare Part B supplemental insurance. Under Part A coverage, wound care supplies are considered "usual and normal" and included in the Consolidated Billing and Prospective Payment System. Under Part B coverage, wound care supplies are separately reimbursable, less the beneficiary's deductible and 20% coinsurance. The lack of separate reimbursement results in the minimal treatment of ulcers with passive wet-to-dry gauze dressings. This is not consistent with the standard of care - moist wound healing.

Wound Care Coverage in Home Health Care (HHC)

Medicare's home health care benefit enables certain beneficiaries with post-acute care needs to receive care in their homes, paying Home Health Agencies (HHA) to administer the care. If certain conditions are met, Medicare will pay for an unlimited number of episodes of care, including skilled nursing care. Skilled nursing care includes services and care that can only be performed safely and effectively by a licensed nurse, of which wound care is a qualifying example. When coverage begins, all medical supplies, such as wound dressings, used by the patient are covered as part of the home health care. Beneficiaries using home health care are not responsible for any copayments or deductibles for these services or supplies. In this setting, Part A coverage extends 60 days for a benefit period and is subject to the Prospective Payment System (PPS) implemented by Centers for Medicare & Medicaid Services (CMS).

In response to home health industry representatives' suggestion that certain nonroutine medical supplies (such as wound care dressings) should be excluded from the PPS and reimbursed separately because of their high cost, the Government Accountability Office (GAO) has conducted a study in which they recommended that CMS collect and analyze the data necessary to determine whether Medicare's home health payments appropriately reflect the differences in nonroutine medical supply costs across types of patients in order to identify problems in the PPS.

In the acute care setting, wound care supplies are separately reimbursable under Medicare Part A coverage.

Background: Rationale for the Proposed Legislation

The CMS generally rely on three criteria to guide the selection of services to be excluded from the PPS rate. To be excluded, services had to be high cost, infrequently needed by SNF beneficiaries, and not likely to be overprovided.[13]

Beneficiaries in SNF and on Home Health Plans of Care generally do not receive advanced, comprehensive wound care. Because of their high initial acquisition cost and confinement by the PPS bundled payment, providers are unlikely to utilize active surgical dressings, and normally administer the traditional saline and gauze method, largely unaware of that it is more expensive over the entire course of treatment. Under current practices, the patient receives a course of treatment using passive dressings for their 100-day Part A stay. As a result of non-healing and wound complications, the patient is moved to a long-term-care facility after 100 days, and a course of treatment with active moisture-retentive dressings is able to be initiated.

Despite anecdotal and empirical evidence indicating that active surgical dressings are much more cost effective than passive dressings, most in the provider community have not introduced active surgical dressings in their facilities. This phenomenon is primarily driven by Medicare payment incentives. Although active surgical dressings are cost effective in the long run, the acquisition cost of active surgical dressings is relatively high. As shown in the following analysis, it can be a substantial portion of the Medicare per diem payment amount.

Description of Proposed Legislation

The proposed legislation attempts to amend title XVIII of the Social Security Act to provide for separate coverage for surgical dressings provided in a Home Health or Skilled Nursing Facility under the Medicare Program. The objective is to implement the exclusion of payment for surgical dressings from the consolidated per diem cost benefits for individuals under a Home Health Plan of Care or inpatients of SNF and allow for separate payment to be made under Part-B benefits for surgical dressings provided. It is important that these services be excluded from the PPS rate to help ensure beneficiary access to appropriate care and it also provides a significant cost savings opportunity to the Medicare program.

Key Study Findings

As shown in ***Exhibit 1***, the estimate of five-year net cost savings to Medicare of standardizing coverage of implementing the exclusion of payment for surgical dressings from the Part A inpatient SNF stay and home health plan of care and allow for separate payment to be made under Part B benefits is almost $4 billion. This estimate comprises of Part A cost savings from SNF stay, home health episode and Part B benefits. In addition, we have also estimated a cost saving of $0.7 billion over a period of five years for providers adopting active surgical dressings for wound management as a standard of care.

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[13] General Accounting Office, "Skilled Nursing Facilities: Services Excluded from Medicare Daily Rates Needs to be Evaluated," August 21, p. 2.

Exhibit 1: Medicare Cost of Separate Payments under Part B for Active Surgical Dressing for Wound Care in SNF and Home Health

	2010	2011	2012	2013	2014	Total
Medicare Part A SNF Cost Savings Due to Proposed Legislation (in $millions)	$242	$331	$406	$462	$523	$1,965
Medicare Part A Home Health Cost Savings Due to Proposed Legislation (in $millions)	$255	$276	$300	$324	$349	$1,504
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Total Medicare Cost Savings (in $millions)	$575	$700	$811	$902	$998	$3,986

Literature Review Findings: Comparison Between Passive Dressings and Active Surgical Dressings

In this section, we have compared passive dressings with active surgical dressings along several dimensions such as frequency of dressing changes, healing time, rate of healing, rate of infection and cost effectiveness of active surgical dressings.

Frequency of Dressing Changes

A significant benefit of using active surgical dressings is the reduction in the frequency of dressing changes that must be performed by nursing personnel. In most of the recent studies, this was the primary factor driving cost savings, and in the long-run can affect the staffing needs and utilization for the provider. While traditional saline-gauze dressings are typically changed one to three times a day (once per shift), the requirement for modern dressings, while variable, was consistently less often. ***Exhibit 2*** provides a synopsis of our literature review on comparison of passive and active surgical dressings as it relates to frequency of dressing changes. A recent review of literature (Economics of pressure ulcer care) on cost-effectiveness, comparing modern and traditional (gauze) dressings for the treatment of pressure ulcers, identified 14 studies reporting a comparison of dressing change frequency. In these studies, the mean frequency of change was 15 per week for traditional dressings (range: 7-28, median: 14) compared to 2.5 for modern dressings (range: 1.4-7, median: 2).

A study at the Bay Pines VA Healthcare System (Florida) found that using a modern foam dressing reduced the mean number of dressing changes per week from 12.9 to 4.9 per patient. As a result, approximately 3 hours of Registered Nurse (RN) time per patient per week is available for other duties. Every 12 patients switched from gauze releases the equivalent of one full time RN per week. "The main determinant of cost-effectiveness in the study was the lower frequency of dressing change observed in the foam treatment regimen."

In the home health care setting, the largest proportion of the total cost of wound care is attributable to charges for home nursing visits for dressing changes. These charges are significantly higher for patients undergoing passive dressing treatment because a significantly higher number of home nursing visits were required (Capasso).

Exhibit 2: Evidence Table for Comparison of Passive and Active Surgical Dressings for Frequency of Dressing

Author	Title	Year	Country	Type of Study	Active Dressing	Passive Dressing	Frequency of dressing changes	
							Active	Passive
Wyatt G, Payne, Posnett et al.	A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus traditional saline gauze dressing in the treatment of stage II pressure ulcers	2009	USA	RCT	Modern polyurethane foam dressing	Saline-soaked gauze	4.9 per week per patient	12.9 per week per patient
Sebern MD	Pressure Ulcer Management in Home Health Care: Efficacy and Cost Effectiveness of Moisture Vapor Permeable Dressing	1986	USA	RCT	Moisture vapor permeable (MVP) dressing	Gauze and tape	Daily to three times per week, depending on adherence of the dressing	Every 24 hours
Colwell JC, Foreman MD, Trotter JP	A comparison of the efficacy and cost effectiveness of two methods of managing pressure ulcers	1993	USA	RCT	Hydrocolloid	Gauze	0.42 times per day	4.1 times per day
Capasso VA, Munro BH	The cost and efficacy of two wound treatments	2003	USA	Retrospective cohort	Amorphous hydrogel	Wet-to-dry normal saline gauze	In the home health care setting, the largest portion of the total cost of wound care is attributable to the charges for home nursing visits for dressing changes. These charges are significantly higher for	
Guest JF, Ruiz FJ, Mihai A, Lehman A	Cost effectiveness of using carboxymethylcellulose dressing with gauze in the management of exuding venous leg ulcers in Germany and the USA	2005	USA & Germany	Retrospective Evidence-based model	Carboxymethylcellulose dressing (CMCD)	Gauze	Germany: 0.6/day USA: 0.4/day	Germany: 1.4/day USA: 1.7/day
Kerstein et al.	Cost and cost effectiveness of venous and pressure ulcer protocols of care	2001	USA	Modeling study	Hydrocolloid	Wet saline gauze	2.19/week (1.0-3.4)	14.41/week (range 7-21)
Ohura T, Sanada H,	Economics of pressure-ulcer care: review of the literature on modern versus tradtional dressings	2007	USA	Review	Foam (adhesive)	Gauze and tape	2.5/week	15.03/week
Hollisaz et al.	A randomized clinical study comparing hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers	2004	Not indicated	RCT	Group 1: Hydrocolloid Group 2: Phenytoin	Group 3: Saline-soaked gauze	Hydrocolloid: Twice weekly Phenytoin: Daily	Gauze: Twice daily
Kaya et al.	The effectiveness of a hydrogel dressing compared with a standard management of pressure ulcers	2005	Not indicated	RCT	Hydrogel dressing	Povidone-iodine soaked gauze	Every 4 days	Daily

A randomized controlled trial at the University of Chicago Hospitals compared frequency of dressing change between gauze and hydrocolloid dressings, while also incorporating nursing time required per dressing change. The moist gauze dressings were changed an average of 4.1 times per day, requiring 7.95 minutes per change versus 0.42 times per day and 7.30 minutes per change for the hydrocolloids. Using stated supply costs and a standard weight wage rate for nursing time, the result as the average per diem costs of labor and supplies were lower for the hydrocolloid dressings ($3.55) than for the moist gauze dressings ($12.26). Further, the hydrocolloid treatment regimen generated an average savings of 29 minutes per pressure ulcer per day. This time savings may have ramifications for labor costs in some acute care institutions by reducing acuity ratings of patients with pressure ulcers, thereby decreasing the level of staffing. The time saved in dressing changes may also be of psychological benefit for the staff as pressure ulcers are perceived as a great time burden on the providers of nursing care.

In a decision model study, based on published clinical outcomes, by Catalyst Health Economics Consultants, the management of exuding venous leg ulcers was evaluated, and the use of a carboxymethylcelluouse (CMCD) hydrocolloid dressing compared to gauze was found to be the dominant treatment. In the subsequent sensitivity analysis, the number of dressing changes per day was evaluated. For CMCD- and gauze-treated patients, the base case values were 0.4 and 1.7 (a fourfold difference), and the threshold values were 1.2 and 0.6, respectively.

In the Sebern study, the saline gauze dressings were changed every 24 hours, while the moisture vapor permeable (MVP) dressing was changed daily to three times per week, depending on adherence of the dressing. In the Yale School of Nursing study, a higher number of dressing changes was found to influence non-healing of the wound.

Rate of Healing

Exhibit 3 includes our findings on literature review on healing time and rate of healing.

In the Bay Pines VA Healthcare System study, ten patients (50%) in the foam group were healed within the 28-day study period compared to six (38%) in the gauze group.

A 2002 study in France compared saline gauze and hydrocolloid DuoDERM dressing protocols of care in the treatment of pressure ulcers and venous leg ulcers, based on clinical outcomes and treatment patterns obtained in published literature. After 12 weeks of treatment, the analysis showed a 51 percent healing rate in the saline gauze group compared to 61 percent using DuoDERM.

A prospective randomized study conducted in the home care setting (Sebern) found that 64% of grade (stage) II ulcers healed at 8 weeks in response to treatment with a transparent moisture vapor permeable dressing (MVP), compared to 0% with gauze and tape dressings. Further, the grade II ulcers using the MVP dressings had a significantly lower final grade, which indicates healing, than those using the gauze dressing. In addition to improved healing status, a greater median percent in wound area was found for grade II ulcers using the MVP dressing. Grade II ulcers in the control group had a 52% median decrease in area, whereas those in the experimental group had a 100% median decrease.

A prospective randomized, controlled study conducted at The University of Chicago Hospitals evaluated the treatment of 97 ulcers, divided between moist gauze and DuoDERM hydrocolloid dressings. Total ulcer healing was achieved for 1 (2%) and 11 (22%) of the ulcers in the gauze and hydrocolloid groups, respectively.

A 2001 meta-analysis (Kerstein et al) at Mount Sinai Medical Center compared the proportion of ulcers healed for gauze and hydrocolloid DuoDERM dressing treatments. At 12 weeks, the weighted average healing rate was 51% for pressure ulcers and 39% of venous ulcers healed using gauze based treatment. Hydrocolloids dressings resulted in a 61% and 51% healing rate for the two ulcer types, respectively.

A randomized, controlled trial, conducted by VR Driver et al., compared the treatment of non-healing diabetic foot ulcers using a platelet-rich plasma (PRP) gel against a saline gel control. In this study, the rate of ulcer healing, evaluated at 12 weeks, was 81.3% for the PRP gel and 42.1% for the saline gel.

A randomized clinical trial conducted in Iran by S. Kordestani et al. compared the wound healing rates and incidence of infections in wounds treated with either a bioactive dressing or a gauze control for a 21 day period. In the control group, 15% (4/26) of the wounds healed, while 24 became infected with polymicrobial growth, requiring antibiotics. None of the patients were discharged before day 21. In the treatment group, 85% (29/34) healed, and the five remaining healed during the three-month follow up period. None of the wounds became infected.

At the Yale School of Nursing, a retrospective review of medical records of subjects with chronic pressure, diabetic, or venous ulcers using a structured data collection form and protocol was conducted at four sites located in diverse geographic areas. The study was conducted to

identify factors that influence the healing of chronic wounds within 3 months of starting treatment, compared to factors influencing wounds after 5 or 6 months of treatment. It was concluded that greater utilization of active moisture-retentive dressings in the first 3-months of treatment was associated with improvement in healing rates. The use of gauze dressings in this study did not influence healing at either 3 or 6 months.

Exhibit 3: Findings on Healing Time and Rate of Healing for Passive and Active Surgical Dressings

Author	Title	Year	Country	Type of Study	Setting	Active Dressing	Passive Dressing	Healing Time	Rate of Healing (%)	
									Active	Passive
Wyatt G, Payne, Posnett et al.	A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus traditional saline gauze dressing in the treatment of	2009	USA	RCT	Subjects drawn from five centers providing wound care: hospital inpatient wards, a hospital-based	Modern polyurethane foam dressing	Saline-soaked gauze	Mean time free of ulcer: Foam group: 9.3 days/patient Gauze group: 6.9 days/patient	10 patients (50%) were healed within 28 day study period.	6 patients (38%) were healed within 28 day study period.
Xakellis GC, Chrischilles EA	Hydrocolloid versus saline-gauze dressings in treating pressure ulcers: a cost effectiveness	1992	USA	RCT	Long-term care facility	Occlusive hydrocolloid	Saline gauze	Active: 9 days Gauze: 11 days		
Sebern MD	Pressure Ulcer Management in Home Health Care: Efficacy and Cost Effectiveness of Moisture Vapor Permeable Dressing	1986	USA	RCT	Home care	Moisture vapor permeable (MVP) dressing	Gauze and tape	Grade II ulcers, using the MVP dressings had a significantly lower final grade, which indicates healing.	At 8 weeks, 64% (14/24) of grade II ulcers. 100% median decrease in area.	At 8 weeks, 0% of grade II (0/12) ulcers. 52% median decrease in area.
Colwell JC, Foreman MD, Trotter JP	A comparison of the efficacy and cost effectiveness of two methods of managing pressure ulcers	1993	USA	RCT	Tertiary care center	Hydrocolloid	Gauze	Average length of time subjects remained in study was 17 days, with a range of 6 to	22% (11/48) ulcers healed	2% (1/49) ulcers healed.
Capasso VA, Munro BH	The cost and efficacy of two wound treatments	2003	USA	Retrospective cohort	Home health agency/Home nursing care	Amorphous hydrogel	Wet-to-dry normal saline gauze	Comparable rate of wound closure in both treatment groups.		
Dougherty EJ	An evidence-based model comparing the cost-effectiveness of platelet-rich plasma gel to alternative therapies for patietns with nonhealing diabetic foot ulcers	2008	USA	Retrospective Evidence-based model	Not indicated	Platelet rich plasma (PRP) gel	Wet-to-moist saline gauze		Healing at 12 week: 81.3%	Healing at 12 weeks: 42.1%
Guest JF, Ruiz FJ, Mihai A, Lehman A	Cost effectiveness of using carboxymethylcellulose dressing with gauze in the management of exuding venous leg ulcers in Germany and the USA	2005	USA & Germany	Retrospective Evidence-based model	Not indicated	Carboxymethylcellulose dressing (CMCD)	Gauze		Healing at 18 weeks: 30%	Healing at 18 weeks: 13%
Redekop WK, McDonnell J, Verboom P, Lovas K, Kalo Z	The cost effectiveness of Apligraf treatment of diabetic foot ulcers	2003	Netherlands	Markov-based simulation model	Not indicated	Apligraf	Good wound care (GWC): offloading, debridement, and moist dressings	Apligraf use increased the amount of ulcer-free time by 1.53 months (7.78 to 6.25) and reduced the risk of amputation (6.3% to 17.1%)		
Kerstein et al.	Cost and cost effectiveness of venous and pressure ulcer protocols of care	2001	USA	Modeling study	Hypothetical managed-care plan	Hydrocolloid	Wet saline gauze		At 12 weeks Pressure ulcer: 61% Venous ulcer: 51%	At 12 weeks Pressure ulcer: 51% Venous ulcer: 39%
Ohura T, Sanada H, Mino Y	Economics of pressure-ulcer care: review of the literature on modern versus tradtional dressings	2007	USA	Review	Not indicated	Foam (adhesive)	Gauze and tape			
Gorse GJ, Messner RL	Improved pressure sore healing with hydrocolloid dressings	1987	Not indicated	Prospective comparative study	Not indicated	Hydrocolloid	Saline-soaked gauze		71%	50%
Aguilo Sanchex et al.	Traditional dressings or cures in a moist environment	2001	Spain	RCT	Not indicated	Hydrocolloid	Soaked gauze		57%	29%
Hollisaz et al.	A randomized clinical study comparing hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers	2004	Not indicated	RCT	Not indicated	Group 1: Hydrocolloid Group 2: Phenytoin	Group 3: Saline-soaked gauze		Hydrocolloid: 74.2% Phenytoin: 40%	Gauze: 26.7%
Kaya et al.	The effectiveness of a hydrogel dressing compared with a standard management of pressure ulcers	2005	Not indicated	RCT	Not indicated	Hydrogel dressing	Povidone-iodine soaked gauze		84% re-epithelialized	54% re-epithelialized

Rate of Infection

Some modern dressings not only protect the wound against dehydration, but they also prevent contamination and provide an environment which facilitates healing by retaining cells needed to phagocytose (break down and digest) bacteria and facilitate repair. This may help explain why wounds dressed with moisture-retentive dressings heal more expediently and are less likely to become infected that wounds dressed with traditional gauze-type dressings (AJ Boulton, Diabetic foot ulcers).

In a Manchester diabetic clinic, a retrospective study of clinical outcomes showed that 2.5% of ulcers treated with hydrocolloid dressings became infected compared to 6% of ulcers managed with traditional gauze type dressings (Bolton LL, Boulton AJM).

A study at the UK-based Wound Healing Research Institute (Hutchinson) collated data from 50 controlled and 103 uncontrolled trials on a variety of wounds, comparing treatment with occlusive dressings (hydrocolloids, hydrogels, foams, and polyurethane films) to conventional (non-occlusive) dressings. When broken down to determine the rates of infection in treating wounds specifically, the rate of infection for controlled studies was 4.7% (n=507) for conventional dressings and 2.07% (n=723) occlusive. When expanded to include all studies, the infection rate drops to 0.82% (n=2201) for occlusive dressing treatment.

As part of a review of occlusive dressings conducted by J. Hutchinson (Deeside, UK) and M. McGuckin (Ardmore, PA), clinical infection rates associated with various dressings were presented. In the treatment of ulcers, the infection rate was 6.5% (18/279) for conventional gauze dressings compared to 1.1% (15/1319) for occlusive dressings. Although not all studies

were controlled with non-occlusive dressings, infection rates under occlusion were always significantly lower than with conventional dressings.

An economic model, developed by Edward Dougherty using published clinical data and pricing information, was used to evaluate the cost-effectiveness of a platelet-rich plasma (PRP) gel against a saline gel control in treating non-healing diabetic foot ulcers. Relevant probability inputs for the rate of ulcer recurrence at one year were 4% for the PRP gel and 26% for the saline gel. Published literature was also used to incorporate the infection and amputation rates of these unhealed ulcers.

Cost Effectiveness

In a 2002 article in the Journal for Prevention and Healing, Liza Ovington outlines the factors contributing to the cost of wound care as the sum of the price of the dressing, labor cost of having a health care professional change the dressing, indirect costs of ancillary supplies and services used in changing the dressing (e.g., gloves and biohazard waste disposal), and the cost of duration of care (e.g., facility charges and travel costs for home care). It is further emphasized that several studies have been done to establish that advanced wound dressings can be cost-effective simply by taking into account the cost of labor. This is due to the general observation that a more expensive dressing requiring less frequent dressing changes and shorter healing times is less expensive to use.

In the Bay Pines VA Healthcare System study, the perspective of the analysis was cost to the healthcare provider of the dressings. The mean weekly cost of dressings and other materials was significantly lower in the foam group. Materials cost was $32 per patient per week in the foam group compared with $58 in the gauze group. Factoring in the difference in labor requirements, total cost was $91 per patient in the foam group compared with $209 in the gauze group. The driver of lower cost per week was the lower frequency of dressings change in the foam group; however this must be linked to patient outcomes in evaluating cost effectiveness. The mean time free of ulcer (days healed) was 9.3 days per patient in the foam group compared with 6.9 days in the group treated with gauze. The analysis shows that overall costs are lower in the foam group and that on both measures of cost effectiveness, the foam option is dominant.

The 2002 cost-effectiveness model (Meaume et al), set in France, estimated the cost per patient healed over a 12 week treatment period using saline gauze to be €2510 for pressure ulcers and €1722 for venous leg ulcers. Using the hydrocolloid DuoDERM, the cost per patient healed was €662 and €1018 for pressure and venous leg ulcers, respectively.

In the Sebern Home Health Care study, a considerable difference was found between the total cost of nursing visits and supplies for stage II ulcers. The mean eight-week cost of treatment per ulcer using gauze dressings was $1359, but for the MVP dressing it was $845. Cost savings resulted when nursing visits could be reduced because MVP pouch dressing changes were required every two days instead of daily.

In a non-experimental, retrospective chart review of home care records (Capasso), the average total cost of wound care was $1,140 higher for patients in the normal saline group (M=$3,774) than for patients in the hydrogel group (M=$2,634). The largest proportion of the total cost of wound care was attributable to charges for home nursing visits for dressing changes, which

were required by patients 33% more in the normal saline group. There was no significant difference in the cost of wound care supplies between the normal saline group (M=$133) and the hydrogel group (M=$180). In the restrictive home health economic environment of Medicare's prospective payment system, using dressings that have to be changed less frequently is beneficial to patients and their family members.

The Catalyst Economics decision model compared health care costs in Germany and the United States, from the perspective of payers, using Medicare reimbursement data. The cost of starting treatment with CMCD or gauze in Germany was expected to be €2020 and €2654 respectively at 18 weeks. Additionally, the cost of starting treatment with CMCD or gauze in the USA was expected to be $3797 and $5288 respectively. The cost of managing CMCD-treated patients was less than that of gauze-treated patients in both countries due to decreased nursing and physician costs associated with a lower frequency of CMCD dressing changes compared to gauze. Of these totals, in Germany, the 18 week expected supply cost of CMCD dressings is €222.79, 11% of the total costs. The expected supply cost of gauze dressings is €66.17, 2.5% of the total costs. In terms of nursing, including home and office visits, the expected costs for CMCD treatment is €603.89 (30%) and €1379.56 (52%) for gauze treatment. A similar pattern exists in the United States model. Expected costs for CMCD dressings is $223.48, contributing 6% to the total, and $23.75 for gauze treatment, less than 1% of the total. The expected cost of nursing visits is $584.18 (15%) for CMCD treatment and $2,252.22 (43%) for gauze treatment.

In the University of Chicago Hospitals study, cost-effectiveness was defined as the sum of the costs of the supplies used and the labor required to apply and maintain each of the dressings throughout the course of treatment. Supply cost also incorporated the use of ancillary products. Supply usage costed out per dressing change at $6.15 for the hydrocolloids versus $0.47 for the moist gauze. However, when considering the frequency of dressing changes, the average per diem costs of labor and supplies were lower for the hydrocolloid dressings at $3.55 than for moist gauze dressings at $12.26. The average length of stay for the subjects in this study was 17 days, with a range of 6 to 56 days. When the costs and differences in requirements between dressings were calculated over the duration of the patients' treatment period, the average total cost per hydrocolloid case was $53.68 versus an average total cost per moist gauze case of $176.90.

In the 2001 Kerstein et al meta-analysis, observed differences were generally to variances in outcomes and costs differences related to frequency of dressing changes. In the treatment of pressure ulcers, the average material costs for saline gauze treatment was $92.43 at $0.54 per dressing change, and average nursing costs were $996.05. For hydrocolloid treatment, average materials costs were $270.50 at $9.14 per dressing change, and average nursing costs were $170.37. Over the course of a 12 week treatment period, the cost-effectiveness model assessed the cost per ulcer healed at $2,179 for saline gauze and $910 for the hydrocolloid dressing. All costs are at year 2000 prices.

In "Financial costs of inpatient pressure ulcers to an acute care facility," Alterescu addresses the ability of a provider to realize the potential cost savings resulting from a decrease in labor requirement for a facility using surgical dressings. "It should be understood that the manner in which nursing time is purchased will determine how savings can be achieved. The more

flexible the nurse staffing, the more capability there is for achieving a savings through preventive strategies and decreased acuity."

These cost analyses and model estimations only consider direct health care costs borne by payers and providers, and not the indirect costs of patients, including quality of life measurement, or individuals in the health care setting, and society. As such, despite the demonstrated cost effectiveness, the overall benefits of treatment with active dressings may still be underestimated.

Methodology

The purpose of this study is to develop cost models that will estimate the implementation of the exclusion of payment for Surgical Dressings from consolidated per diem cost benefits provided under Part A for SNF stay as well as individuals under a Home Health plan of care and allow for separate payments to be made under Part B. The model demonstrates how the use of surgical dressings translates into Medicare cost savings through faster, effective healing and avoidance of adverse events, such as infection, gangrene or amputation. In addition, the model also estimates provider cost savings due to the use of surgical dressings.

There are four major modules that help us estimate costs –Part A Medicare costs in SNF and home health, Part B costs and cost to the provider. For each of these cost modules, the following components were included in the models:

1) Determine the size of target population

2) Estimate the extent to which surgical dressings will be used as standard of care

3) Calculate the cost of the proposed legislation

4) Determine the impact of adopting active surgical dressings as standard of care

5) Determine the cost savings due to active surgical dressings

The remaining parts of this document describe the steps currently used to develop the above model components.

Methodology for Estimation of Part A Medicare Expenditures in SNF due to Proposed Legislation

Medicare Part A expenditures in SNFs due to the proposed legislation are calculated as the difference in costs between the baseline estimate under current policy and the expenditures under the proposed legislation. Hence, the first part of the methodology describes the baseline estimate under current policy.

Baseline Estimate of Part A Medicare Expenditures in SNF for Wound Care

Exhibit 4 shows the detailed build-up of the Medicare expenditures in SNFs for wound care.

1. Projected number of Part A and B Medicare beneficiaries over the five-year period from 2010 to 2014 (Source: Office of Actuary, CMS).

2. Based on the recent MedPAC Report to Congress, we estimated that about 5 percent of Medicare beneficiaries are likely to use SNFs over a period of five years.

3. The number of beneficiaries likely to use SNFs is calculated as the product of the projected number of Part A and B Medicare beneficiaries (line 1) and the percent of Medicare beneficiaries that are likely to use SNFs over a period of five years (line 2).

4. The percent of beneficiaries in SNFs with wound care is based on our analysis of 2007 SNF MDS data. Using the 5th day assessment, we calculated the prevalence of Stage III and Stage IV wounds.

5. The number of Medicare beneficiaries that present with wound care issues in SNFs and are likely to be treated by passive surgical dressings, is the product of the percent of beneficiaries in SNFs with wound care (line 4), the number of beneficiaries in SNFs with wound care (line 3) and an assumed rate of 90 percent of beneficiaries with wound care treated by passive dressings.

6. The average length of stay (portion of length of stay that is SNF) for Medicare beneficiaries with wound care is based on two estimates – one from the analysis of SNF MDS data for patients with wound care and the other from March 2009 MedPAC Report to Congress.

7. Medicare payment per diem for SNFs is based on the March 2009 MedPAC Report to Congress.

8. Part A Medicare expenditures for patients with wound care is calculated as the product of the number of Medicare beneficiaries that present with wound care issues in SNFs and are likely to be treated by passive surgical dressings (line 5), average length of stay (portion of length of stay that is SNF) for Medicare beneficiaries with wound care (line 6) and the SNF Medicare payment per diem (line 7). This does not include expenditures associated with complications and adverse events due to non-healing of wounds.

9. The proportion of patients receiving passive dressings that are likely to have clinical infection is based on a review article by Hutchinson and Lawrence.[14] Based on a review of 50 articles, the review article states that the overall rate of clinical infection in wounds treated by conventional or occlusive dressings is approximately 5.37 percent.

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[14] J.J. Hutchinson and J.C. Lawrence, "Wound Infection Under Occlusive Dressings," Journal of Hospital Infection, 1991, volume 17, pp 83 -94.

10. The number of patients with clinical skin infections is calculated as the product of the SNF beneficiaries receiving passive dressings for wound care (line 5) and the percent of patients that are likely to have skin infections (line 9).

11. The additional cost due to infection is based on the Hutchinson article.

12. The proportion of patients receiving passive dressings that are likely to have gangrene is based on Redekop article. This article provides the transitional probability from unhealed ulcer to gangrene.

13. The number of patients with gangrene is calculated as the product of the SNF beneficiaries receiving passive dressings for wound care (line 5) and the percent of patients that are likely to have gangrene (line 12).

14. The additional cost due to infection is based on the Redekop article.

15. The proportion of patients receiving passive dressings that are likely to have amputation is based on Redekop article. This article provides the transitional probability from unhealed ulcer to amputation.

16. The number of patients with amputation is calculated as the product of the SNF beneficiaries receiving passive dressings for wound care (line 5) and the percent of patients that are likely to have amputation (line 15).

17. The additional cost due to amputation is based on the DRG payment for amputations for FY 2010. This is a very conservative estimate and does not include the costs for rehabilitation and treatment after the amputation. In addition, the estimate does not include the Part B physician fees for the procedure of amputation. This additional cost is reflected in our section on Part B Medicare expenditures.

18. The total additional cost due to infection, gangrene and amputation under current policy is the sum of the product of the number of patients with infection (gangrene and amputation) with the additional costs associated with each of the above mentioned conditions.

19. The total Part A expenditures related to wound care in SNFs under current policy is the sum of the Part A expenditures for wound care and the total additional cost due to infection, gangrene and amputation under current policy.

Exhibit 4: Estimation of Medicare Part A Expenditures Related to Wound Care in SNF under Current Policy

Line	Description	2010	2011	2012	2013	2014	Total
1	Number of beneficiaries	36,172,884	36,825,632	37,836,039	39,079,024	40,244,368	
2	Percent of beneficiaries in skilled nursing facilities	5%	5%	5%	5%	5%	
3	Number of beneficiaries using SNFs	1,808,644	1,841,282	1,891,802	1,953,951	2,012,218	9,507,897
4	Percent of beneficiaries In SNFs with wound care	10.30%	10.30%	10.30%	10.30%	10.30%	
	Baseline Estimates						
5	Number of beneficiaries in SNFs that present with wound care issues and are treated by passive dressing	167,661	170,687	175,370	181,131	186,533	881,382
6	Average number of days in SNFs per beneficiary with wound care	50	50	50	50	50	
7	Medicare per diem payment for Part A SNF stay	$350	$361.90	$374.20	$386.93	$400.08	
8	Part A Payment for SNF patients with wound care	$2,934,073,036	$3,088,577,757	$3,281,213,808	$3,504,234,071	$3,731,427,883	$16,539,526,554
9	Percent of (5) with skin infections	5.37%	5.37%	5.37%	5.37%	5.37%	
10	Number of Patients with skin infections	9,003	9,166	9,417	9,727	10,017	47,330
11	Additional Cost due to Skin Infection	$1,900	$1,964.60	$2,031.40	$2,100.46	$2,171.88	
12	Percent of (5) with gangrene	1.6%	1.6%	1.6%	1.6%	1.6%	
13	Number of Patients with gangrene	2,701	2,750	2,825	2,918	3,005	14,199
14	Additional Cost due to gangrene	$2,400	$2,482	$2,566	$2,653	$2,743	
15	Percent of (5) with amputation	1.3%	1.3%	1.3%	1.3%	1.3%	
16	Number of Patients with amputation	2,251	2,291	2,354	2,432	2,504	11,833
17	Additional Cost due to Amputation	$5,450	$5,635	$5,827	$6,025	$6,230	
18	Total Additional Cost due to Amputation, Gangrene and Infection under Current Policy	$35,856,091	$37,744,229	$40,098,355	$42,823,793	$45,600,234	$202,122,702
19	Total Part A Expenditures Related to Wound Care in SNFs under Current Policy	$2,969,929,127	$3,126,321,986	$3,321,312,162	$3,547,057,864	$3,777,028,117	$16,741,649,256

Estimate of Part A Medicare Expenditures in SNF for Wound Care Under Proposed Legislation (refer to Exhibit 5)

20. The number of beneficiaries in SNFs that present with wound care issues and are treated by active/passive dressings is the same as line 5.

21. The percent that are still likely to be treated by passive dressings is assumed to be 50 percent for the first year and decline to almost 15 percent by the fifth year.

22. The number of SNF beneficiaries that are still likely to be treated by passive dressings is calculated as the product of the number of beneficiaries in SNFs that present with wound care issues (line 20) and the proportion of these beneficiaries that are still likely to be treated by passive dressings (line 21). Compared to 881 million over the time period of 2010 to 2014 that are treated by passive dressings under current policy, about 252 million are treated by passive dressings over the same time period under proposed legislation. Hence, we assumed a 71 percent decline in the use of passive dressings for the first five years under the proposed legislation among SNF beneficiaries.

23. Based on the utilization of passive dressings under proposed legislation, Part A expenditures for beneficiaries using passive dressings in SNFs is calculated as the product of the number of SNF beneficiaries that are still likely to be treated by passive dressings (line 22), the average length of stay (line 6) and the Part A Medicare per diem payment for SNF (line 7). Over a period of the first five years, the total Part A Medicare expenditures amount to more than $4.6 billion.

24. The percent of wound care SNF patients that are likely to be treated by active surgical dressings is assumed to be 50 percent for the first year and then increased to 85 percent by the fifth year.

25. The number of SNF beneficiaries that are likely to be treated by active surgical dressings is calculated as the product of the number of beneficiaries in SNFs that present with wound care issues (line 20) and the proportion of these beneficiaries that are likely to be treated by active surgical dressings (line 24).

26. The average number of days for SNF wound care patients that are treated with active surgical dressings is assumed to be 42 days. This assumption is based on two recent articles.[15, 16]

27. Medicare per diem payment for SNFs is based on the March 2009 MedPAC Report to Congress. This is the same as line 7. This is a very conservative estimate. With the expeditious healing rate associated with active surgical dressings, patients are likely to be in less pain and have higher functional status thereby resulting in a lower case mix index and per diem payment amount.

28. Based on the utilization of active surgical dressings under proposed legislation, Part A expenditures for beneficiaries using passive dressings in SNFs is calculated as the product of the number of SNF beneficiaries that are likely to be treated by active surgical dressings (line 25), the average length of stay (line 26) and the Part A Medicare per diem payment for SNF (line 7 or line 27). Over a period of the first five years, the total Part A Medicare expenditures amount to approximately $10 billion.

29. Total Part A payment for SNF wound care patients under the proposed legislation is the sum of the payments for passive and active surgical dressings.

    Lines 30 to 32 provide the rate of complications for unhealed wounds, namely infection, gangrene and amputation for patients receiving active surgical dressings. The rate of infection, gangrene and amputation are substantially lower among patients receiving active surgical dressings compared to passive dressings. For instance, the rate of infection for patients receiving active surgical dressings is 3.2 percent compared to 5.4 percent.[17]

33. Total Part A payment for SNF wound care patients under the proposed legislation is the sum of the payments for passive and active surgical dressings as well as the sum of the payment for complications due to unhealed wounds for both passive and active surgical dressing patients' under the proposed legislation.

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[15] Wyatt G. Payne, et.al., "A Prospective, Randomized Clinical Trial to Assess the Cost-effectiveness of a Modern Foam Dressing versus a Traditional Saline Gauze Dressing in the Treatment of Stage II Pressure Ulcers," Ostomy Wound Management, February 2009, pp. 50 – 55.

[16] Levin and O'Neal, "The Diabetic Foot,"

[17] J.J. Hutchinson and J.C. Lawrence, "Wound Infection Under Occlusive Dressings," Journal of Hospital Infection, 1991, volume 17, pp 83 -94.

Part A Medicare Cost Savings due to the proposed legislation is the difference between Part A expenditures under proposed legislation (line 33) and under current policy (line 19). Over a span of the first five years of the proposed legislation, the savings amount to approximately $1.9 billion. This represents 1.5 percent of Medicare SNF expenditures over the same time period.

Exhibit 5: Estimation of Medicare Part A Expenditures Related to Wound Care in SNF under Proposed Legislation

Line	Description	2010	2011	2012	2013	2014	Total
	Estimation of Medicare Part A Expenditures Under Proposed Legislation						
20	Number of beneficiaries in SNFs that present with wound care issues	167,661	170,687	175,370	181,131	186,533	881,382
21	Percent of Wound Care SNF Patient that are likely to still treated by Passive Dressing	50%	35%	25%	20%	15%	
22	Number of wound care SNF patients that are still likely to be treated by passive dressing	83,831	59,740	43,843	36,226	27,980	251,620
23	Part A Payment for SNF wound care patients that are treated with passive dressing	$1,467,036,518	$1,081,002,215	$820,303,452	$700,846,814	$559,714,182	$4,628,903,181
24	Percent of Wound Care SNF Patient that are likely to be treated by active surgical dressing	50%	65%	75%	80%	85%	
25	Number of wound care SNF patients that are likely to be treated by active surgical dressing	83,831	110,946	131,528	144,905	158,553	629,762
26	Average number of days in SNFs per beneficiary upon treatment with active surgical dressing	42	42	42	42	42	
27	Medicare per diem payment for Part A SNF stay with active surgical dressing	$350	$361.90	$374.20	$386.93	$400.08	
28	Part A Payment for SNF patients with wound care for active surgical dressing	$1,232,310,675	$1,686,363,455	$2,067,164,699	$2,354,845,296	$2,664,239,508	$10,004,923,633
29	Part A Payment for SNF patients with wound care under the proposed legislation	$2,699,347,193	$2,767,365,670	$2,887,468,151	$3,055,692,110	$3,223,953,691	$14,633,826,815
30	Percent of (25) with skin infections	3.20%	3.20%	3.20%	3.20%	3.20%	
31	Percent of (25) with gangrene	0.96%	0.96%	0.96%	0.96%	0.96%	
32	Percent of (25) with amputation	0.80%	0.80%	0.80%	0.80%	0.80%	
33	Total Part A Expenditures Related to Wound Care in SNFs under Proposed Legislation	$2,727,958,617	$2,795,195,889	$2,915,413,792	$3,084,671,935	$3,253,891,051	$14,777,131,285
34	Medicare Part A SNF Cost Savings Due to Proposed Legislation	$241,970,509	$331,126,097	$405,898,371	$462,385,928	$523,137,066	$1,964,517,971

Methodology for Estimation of Part A Medicare Expenditures in Home Health due to Proposed Legislation

Medicare Part A expenditures in home health due to the proposed legislation are calculated as the difference in costs between the baseline estimate under current policy and the expenditures under the proposed legislation. Hence, the first part of the methodology describes the baseline estimate under current policy.

Baseline Estimate of Part A Medicare Expenditures in Home Health for Wound Care

Exhibit 6 shows the detailed build-up of the Medicare expenditures in home health for wound care.

1. Projected number of Part A and B Medicare beneficiaries over the five-year period from 2010 to 2014 (Source: Office of Actuary, CMS).

2. Based on the recent MedPAC Report to Congress, we estimated that about 8.9 percent of Medicare beneficiaries are likely to use home health for the first two years. The recent MedPAC Report to Congress also states that the proportion of Medicare beneficiaries

likely to use home health is projected to increase over time. Hence, we have assumed a modest increase in the proportion of Medicare beneficiaries likely to use home health in the next three years.

3. The number of beneficiaries likely to use home health is calculated as the product of the projected number of Part A and B Medicare beneficiaries (line 1) and the percent of Medicare beneficiaries that are likely to use home health over a period of five years (line 2).

4. The percent of beneficiaries in home health with wound care is estimated at 6.3 percent and is based on a peer reviewed article.[18]

5. The number of Medicare beneficiaries that present with wound care issues in home health and are likely to be treated by passive surgical dressings is the product of the percent of beneficiaries in home health with wound care (line 4) and the number of beneficiaries in home health with wound care (line 3).

6. The average number of home health episodes for Medicare beneficiaries with wound care of 1.9 is based on March 2009 MedPAC Report to Congress. The MedPAC report also discusses that the number of home health episodes per Medicare beneficiary has risen in the past few years.

7. Average Medicare payment per episode for home health is based on the March 2009 MedPAC Report to Congress. The payment per episode is inflated by the hospital Market Basket Index.

8. Part A Medicare expenditures for home health patients with wound care is calculated as the product of the number of Medicare beneficiaries that present with wound care issues in home health and are likely to be treated by passive surgical dressings (line 5), average number of episodes for Medicare beneficiaries with wound care (line 6) and the home health Medicare payment per episode (line 7). This does not include expenditures associated with complications and adverse events due to non-healing of wounds.

   Lines 9 to 19 are based on the rate of infection, gangrene and amputation for wound care patients. The rate of complications for wound care in home health is similar to the module in the baseline estimate in SNF.

[18] Schwein T. et Al., "Pressure Ulcer Prevalence and the role of negative pressure wound therapy in home health quality outcomes," Ostomy Wound Management, "2005, Sept, 51(9), 47-50

Exhibit 6: Estimation of Medicare Part A Expenditures Related to Wound Care in Home Health under Current Policy

Line	Description	2010	2011	2012	2013	2014	Total
1	Number of beneficiaries	36,172,884	36,825,632	37,836,039	39,079,024	40,244,368	
2	Percent of beneficiaries using home health	8.9%	8.9%	9.1%	9.2%	9.3%	
3	Number of beneficiaries using home health	3,219,387	3,277,481	3,443,080	3,595,270	3,742,726	17,277,944
4	Percent of beneficiaries In home health with Stage III & IV	6.30%	6.30%	6.30%	6.30%	6.30%	
			Baseline Estimates				
5	Number of beneficiaries in home health with Stage III & IV wounds	202,821	206,481	216,914	226,502	235,792	1,088,510
6	Average number of episodes per home health user	1.9	1.9	1.9	1.9	1.9	
7	Average Medicare payment for home health episode	$2,705	$2,797	$2,892	$2,990	$3,092	
8	Part A Payment for home health patients with wound care	$1,042,400,376	$1,097,291,914	$1,191,926,719	$1,286,928,942	$1,385,261,084	$6,003,809,035
9	Percent of (5) with skin infections	5.4%	5.4%	5.4%	5.4%	5.4%	
10	Number of Patients with skin infections	10,952	11,150	11,713	12,231	12,733	58,780
11	Additional Cost due to Skin Infection	$1,900	$1,964.60	$2,031.40	$2,100.46	$2,171.88	
12	Percent of (5) with gangrene	1.6%	1.6%	1.6%	1.6%	1.6%	
13	Number of Patients with gangrene	3,286	3,345	3,514	3,669	3,820	17,634
14	Additional Cost due to gangrene	$2,400	$2,482	$2,566	$2,653	$2,743	
15	Percent of (5) with amputation	1.4%	1.4%	1.4%	1.4%	1.4%	
16	Number of Patients with amputation	2,738	2,787	2,928	3,058	3,183	14,695
17	Additional Cost due to Amputation	$5,450	$5,635	$5,827	$6,025	$6,230	
18	Total Additional Cost due to Amputation, Gangrene and Infection under Current Policy	$43,617,747	$45,914,605	$49,874,463	$53,849,694	$57,964,262	$251,220,771
19	Total Part A Expenditures Related to Wound Care in home health under Current Policy	$1,086,018,124	$1,143,206,519	$1,241,801,182	$1,340,778,636	$1,443,225,345	$6,255,029,806

Estimate of Part A Medicare Expenditures in Home Health for Wound Care Under Proposed Legislation

20. The number of beneficiaries using home health that present with wound care issues and are treated by active/passive dressings is the same as line 5.

21. The percent that are still likely to be treated by passive dressings is assumed to be 5 percent for the first year and then in the following years there is virtually no passive dressing provided. In the home health environment, the hospital discharge planner is more likely to recommend active surgical dressings before the home health episode.

22. The number of home health beneficiaries that are still likely to be treated by passive dressings is calculated as the product of the number of beneficiaries in home health that present with wound care issues (line 20) and the proportion of these beneficiaries that are still likely to be treated by passive dressings (line 21).

23. Based on the utilization of passive dressings under proposed legislation, Part A expenditures for beneficiaries using passive dressings in home health is calculated as the product of the number of home health beneficiaries that are still likely to be treated by passive dressings (line 22), the average number of episodes (line 6) and the Part A Medicare per episode payment for home health (line 7).

24. The percent of wound care home health patients that are likely to be treated by active surgical dressings is assumed to be 95 percent for the first year and then in the latter years is increased to 98 percent.

25. The number of home health beneficiaries that are likely to be treated by active surgical dressings is calculated as the product of the number of beneficiaries in home health that present with wound care issues (line 20) and the proportion of these beneficiaries that are likely to be treated by active dressings (line 24).

26. The average number of episodes for SNF wound care patients that are treated with active surgical dressings is assumed to be 1.2 episodes.

27. Medicare payment per episode for home health is based on the March 2009 MedPAC Report to Congress. This is the same as line 7.

28. Based on the utilization of active surgical dressings under the proposed legislation, Part A expenditures for beneficiaries using active surgical dressings in home health is calculated as the product of the number of home health beneficiaries that are likely to be treated by active surgical dressings (line 25), the average number of episodes (line 26) and the Part A Medicare per episodes payment for home health (line 7 or line 27). Over a period of the first five years, the total Part A Medicare expenditures amount to approximately $4.4 billion.

29. Total Part A payment for SNF wound care patients under the proposed legislation is the sum of the payments for passive and active surgical dressings and amounts to $4.7 billion over a period of 5 years.

    Lines 30 to 32 provide the rate of complications for unhealed wounds, namely infection, gangrene and amputation for patients receiving active surgical dressings. The rate of infection, gangrene and amputation are substantially lower among patients receiving active surgical dressings compared to passive dressings. For instance, the rate of infection for patients receiving active surgical dressings is 3.2 percent compared to 5.4 percent.[19]

33. Total Part A payment for home health wound care patients under the proposed legislation is the sum of the payments for passive and active surgical dressings as well as the sum of the payment for complications due to unhealed wounds for both passive and active surgical dressing patients' under the proposed legislation.

34. Part A Medicare cost savings due to the proposed legislation is the difference between Part A expenditures under proposed legislation (line 33) and under current policy (line 19). Over a span of the first five years of the proposed legislation, the savings amount to approximately $1.5 billion. This represents approximately 10 percent of Medicare home health expenditures for 2009.

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[19] J.J. Hutchinson and J.C. Lawrence, "Wound Infection Under Occlusive Dressings," Journal of Hospital Infection, 1991, volume 17, pp 83 -94.

Exhibit 7: Estimation of Medicare Part A Expenditures Related to Wound Care in Home Health under Proposed Legislation

Line	Description	2010	2011	2012	2013	2014	Total
	Estimation of Medicare Part A Expenditures Under Proposed Legislation						
20	Number of beneficiaries in home health that present with wound care issues	202,821	206,481	216,914	226,502	235,792	1,088,510
21	Percent of Wound Care home health Patient that are likely to still treated by Passive Dressing	5%	2%	2%	2%	2%	
22	Number of wound care home health patients that are still likely to be treated by passive dressing	10,141	4,130	4,338	4,530	4,716	27,855
23	Part A Payment for home health wound care patients that are treated with passive dressing	$52,120,019	$21,945,838	$23,838,534	$25,738,579	$27,705,222	$151,348,192
24	Percent of Wound Care home health Patient that are likely to be treated by active surgical dressing	95%	98%	98%	98%	98%	
25	Number of wound care home health patients that are likely to be treated by active surgical dressing	192,680	202,352	212,576	221,972	231,076	1,060,656
26	Average number of home health episodes per beneficiary upon treatment with active surgical dressing	1.44	1.44	1.44	1.44	1.44	
27	Average Medicare payment for home health episode with active surgical dressing	$2,705	$2,796.97	$2,892.07	$2,990.40	$3,092.07	
28	Part A Payment for home health patients with wound care for active surgical dressing	$752,613,072	$817,263,017	$887,747,021	$958,504,676	$1,031,742,455	$4,447,870,241
29	Part A Payment for home health patients with wound care under the proposed legislation	$804,733,091	$839,208,856	$911,585,555	$984,243,255	$1,059,447,677	$4,599,218,433
30	Percent of (14) with skin infections	3.20%	3.20%	3.20%	3.20%	3.20%	
31	Percent of (14) with gangrene	0.96%	0.96%	0.96%	0.96%	0.96%	
32	Percent of (14) with amputation	0.80%	0.80%	0.80%	0.80%	0.80%	
33	Total Part A Expenditures Related to Wound Care in home healths under Proposed Legislation	$831,469,154	$866,791,630	$941,547,177	$1,016,592,960	$1,094,269,170	$4,750,670,091
34	Medicare Part A Home Health Cost Savings Due to Proposed Legislation	$254,548,970	$276,414,889	$300,254,005	$324,185,676	$348,956,175	$1,504,359,715

Methodology for Estimation of Part B Medicare Expenditures due to Proposed Legislation

In this section we estimate the Part B expenditures due the proposed legislation. Based on the current policy, patients are likely to avail themselves of active surgical dressings after their SNF stay. By this time, the wounds would have worsened and might take longer to resolve. On the other hand, under the proposed legislation, active surgical dressings can be applied during the SNF stay. Such a practice will allow the wounds to heal faster.

Exhibit 8 provides a detailed cost estimate of Part B Medicare expenditures due to the proposed legislation.

1. Proposed number of Part B Medicare beneficiaries from 2010 to 2014.

2. The number of beneficiaries likely to receive active surgical dressings after SNF stay and home health episode is estimated as about 60 percent of beneficiaries that are likely to be treated by active surgical dressings. A recent article states that by 30 days the healing rate is 38 percent compared to 50 percent for active surgical dressings. Based on this proportion, about 455,467 former SNF wound care patients are likely to receive active surgical dressings after the SNF stay.

3. The cost per visit is estimated as $28 based on the analysis of 2006 Physician service summary file.

4. The number of visits is calculated as four visits per week for a period of six months. We estimated four visits based on SNF regulation.[20]

5. Medicare Part B expenditures for active surgical dressings under current policy is the product of the number of beneficiaries likely to receive active surgical dressings after SNF stay and home health episode (line 2), the cost per visit (line 3) and the number of visits (line 4). Over a span of five years, it is assumed to be $1.4 billion.

6. On line 6 and 9, we provide our estimate of patient with active surgical dressings during the SNF stay (and during home health episode) and after the SNF stay (and after home health episode) respectively. These estimates are derived from the estimate of Part A Medicare expenditure due to the proposed legislation.

7. Same as line 3.

8. The number of visits of 52 is calculated as four visits per week for a period of three months.

9. The number of beneficiaries likely to receive active surgical dressings after a SNF stay and home health episode is estimated as about 60 percent of beneficiaries that are likely to be treated by active surgical dressings under the proposed legislation.

10. The final Medicare Part B Medicare expenditure includes the cost of active and passive dressings as well as the Part B Medicare expenditures for amputations avoided. Over a period of five years, the Part B Medicare Cost Savings will amount to more than half a billion dollars.

[20] CMS Manual 100-7, State Operations Manual, Appendix PP - Guidance To Surveyors, Long Term Care Facilities

Exhibit 8: Estimation of Medicare Part B Expenditures Related to Wound Care under Proposed Legislation

Line	Description	2010	2011	2012	2013	2014	Total
1	Number of beneficiaries	36,172,884	36,825,632	37,836,039	39,079,024	40,244,368	190,157,947
	Baseline Estimates						
2	Number of beneficiaries likely to receive active surgical dressing after SNF stay and HH episode	222,290	226,301	235,370	244,580	253,395	1,181,936
3	Cost per Visit	$28.50	$29.47	$30.47	$31.51	$32.58	
4	Number of visits	103	103	103	103	103	
5	Medicare Part B Costs due to Active Dressing After SNFStay Under Current Policy	$651,626,100	$685,939,939	$737,687,286	$792,614,171	$849,100,100	$3,716,967,597
	Estimation of Medicare Part B Expenditures Under Proposed Legislation						
6	Number of beneficiaries likely to receive active surgical dressing during SNF stay and HH episode	276,511	313,298	344,103	366,877	389,629	1,690,418
7	Cost per Visit	$28.50	$29.47	$30.47	$31.51	$32.58	
8	Number of visits	52	52	52	52	52	
9	Number of beneficiaries likely to receive active surgical dressing after SNF stay and HH episode	56,383	38,322	28,908	24,454	19,617	167,685
10	Medicare Part B Costs due to Active Dressing During SNFStay Due to Proposed Legislation	$575,072,069	$596,251,997	$635,831,524	$680,325,011	$725,792,800	$3,213,273,402
11	Cost of Amputations Avoided	$2,120,332	$2,400,746	$2,635,785	$2,809,738	$2,983,493	$12,950,094
10	Medicare Part B Cost Savings Due to Proposed Legislation	$78,674,364	$92,088,688	$104,491,546	$115,098,898	$126,290,793	$516,644,289

Methodology for Estimation of Change in Provider Costs due to Proposed Legislation

Healthcare providers are frustrated by the fact that they spend 50 percent more nursing time with patients with ulcers.[21]

Exhibit 9 shows the provider costs that could be eliminated due to the proposed legislation that promotes active surgical dressings. The model is similar to the previous model of Part A expenditures for SNFs and home health. Below we have described the provider cost inputs that were included in this model.

Lines 7 and 17: The following cost inputs were used to estimate the per diem cost of care for the respective treatment modalities. These assumptions were based on the reviewed published literature and expert consensus. The numbers were rounded in the direction to favor a conservative cost savings estimate. The initial per diem cost is inflation adjusted annually across the model's five year span.

[21] Janice C. Colwell, Marquis D. Foreman and Jeffrey P. Trotter, "A Comparison of the Efficacy and Cost Effectiveness of Two Methods of Managing Pressure Ulcers, "Decubitus, July 1993, volume 6, number 4, pp. 28 – 36.

Exhibit 9: Derivation of Provider Costs for Passive and Active Dressing

	Passive	Active
Frequency	3	1
Nursing time required (minutes)	30	30
RN hourly rate	$25.00	$25.00
Dressing supplies	$0.50	$10.00
Pain medication	$2.00	$0.50
Per diem cost	$41.00	$23.00

Exhibit 10: Estimation of Provider Cost Savings Due to Implementation of Proposed Legislation

Line	Description	2010	2011	2012	2013	2014	Total
1	Number of beneficiaries	36,172,884	36,825,632	37,836,039	39,079,024	40,244,368	
2	Percent of beneficiaries in skilled nursing facilities	5%	6%	6%	6%	6%	
3	Number of beneficiaries using SNFs	1,808,644	2,209,538	2,270,162	2,344,741	2,414,662	11,047,748
4	Percent of beneficiaries In SNFs with wound care	10.30%	10.30%	10.30%	10.30%	10.30%	
	Baseline Estimates						
5	Number of beneficiaries in SNFs that present with wound care issues and are treated by passive dressing	186,290	227,582	233,827	241,508	248,710	1,137,918
6	Average number of days in SNFs per beneficiary	40	40	40	40	40	
7	Per diem Cost of Care: Passive Dressings	$41.00	$42.39	$43.84	$45.33	$46.87	
8	Total Provider Costs	$305,516,176	$385,925,145	$409,995,478	$437,862,391	$466,250,798	$2,005,549,987
9	Total Providers' Expenditures Related to Wound Care in SNFs under Current Policy	$305,516,176	$385,925,145	$409,995,478	$437,862,391	$466,250,798	$2,005,549,987
	Estimation of Providers' Expenditures Under Proposed Legislation						
10	Number of beneficiaries in SNFs that present with wound care issues	186,290	227,582	233,827	241,508	248,710	1,137,918
11	Percent of Wound Care SNF Patient that are likely to still treated by Passive Dressing	75%	60%	25%	20%	15%	
12	Number of wound care SNF patients that are still likely to be treated by passive dressing	139,718	136,549	58,457	48,302	37,307	420,332
13	Providers' Expenditures for SNF wound care patients that are treated with passive dressing	$229,137,132	$231,555,087	$102,498,869	$87,572,478	$69,937,620	$720,701,186
14	Percent of Wound Care SNF Patient that are likely to be treated by active surgical dressing	25%	40%	75%	80%	85%	
15	Number of wound care SNF patients that are likely to be treated by active surgical dressing	46,573	91,033	175,370	193,207	211,404	717,586
16	Average number of days in SNFs per beneficiary upon treatment with active surgical dressing	30.4	30.4	30.4	30.4	30.4	
17	Per diem Cost of Care: Active Dressings	$23.00	$23.78	$24.59	$25.43	$26.29	
18	Total Providers' Expenditures SNF patients with wound care for active surgical dressing	$32,563,553	$65,814,356	$131,098,554	$149,343,114	$168,964,741	$547,784,318
19	Total Providers' Expenditures Related to Wound Care in SNFs under Proposed Legislation	$261,700,686	$297,369,443	$233,597,423	$236,915,592	$238,902,360	$1,268,485,504
20	Total Providers' Cost Savings	$43,815,491	$88,555,701	$176,398,054	$200,946,799	$227,348,438	**$737,064,483**

The provider cost savings are not reflected as savings to the Medicare program.

Conclusion

While the technology available for wound care has improved considerably since the advent of traditional saline gauze dressings, this has not resulted in the adoption of these available treatment methods. The high acquisition costs of the active surgical dressings associated with advanced wound care have deterred providers operating in Medicare's Prospective Payment System (PPS). While active surgical dressing are more expensive, clinical trials have shown significant benefits of active surgical dressings due to lower frequency of dressing changes and

an increase in the rate of healing, which contribute to a more cost effective strategy over the duration of treatment. The proposed legislation to de-consolidate surgical dressings from PPS for SNF and Home Health Plan of Care will result in the five-year cost savings described above to Medicare Part A, Part B, and to Providers of these services. At the same time, this change in payment structure will also increase the number of beneficiaries with access to the most effective and modern treatment modality in wound care.