

Lymphedema Treatment Act HR 930 / Senate companion pending

SUPPORTERS INCLUDE:

- American Medical Association
- American Cancer Society
- Oncology Nursing Society
- American Acad. of Physical Medicine and Rehabilitation
- American Occupational Therapy Association
- American Physical Therapy Association
- Wound, Ostomy and Continence Nurses Society
- LIVESTRONG
- Colon Cancer Alliance
- Susan G. Komen
- Ovarian Cancer National Alliance
- Lymphatic Education and Research Network
- National Lymphedema Network

ORIGINAL SPONSORS:

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ABOUT LYMPHEDEMA:

Lymphedema (chronic lymphatic system failure) has a multitude of causes. It is marked by an accumulation of lymph fluid (swelling) in parts of the body where lymph nodes or lymphatic vessels are damaged or inadequate. Millions of Americans are affected by this chronic but treatable condition, most commonly from cancer.

Untreated or inadequately treated lymphedema is progressive, leading to complications, comorbidities, loss of function, disability, and in some cases even death. Compression therapy is the essential cornerstone of lymphedema treatment, without which patients cannot effectively manage their condition. Coverage for compression will enable patients to maintain their overall health, activities of daily living, and quality of life.

CONGRESSIONAL INTENT - WHY THIS LEGISLATION IS NEEDED:

Starting in 2001, the Medicare program issued an advisory on the importance of compression garments. A year later, a National Coverage Determination announcement was published highlighting such garments as part of a conservative treatment regimen intended to reduce and control lymphedemarelated swelling. Despite the announcement, HHS has yet to officially provide coverage for compression supplies, indicating legislative authority is needed.

Lymphedema is the end result of *any* significant impairment to all or part of the **lymphatic organ system**. To exclude the primary treatment for *all* causes of lymphedema (i.e. compression therapy) is equivalent to excluding treatment for *all* forms of heart or lung disease.

A growing number of Medicare beneficiaries are affected by lymphedema as cancer survivorship increases.

WHAT THIS LEGISLATION WILL DO:

- Provide for Medicare coverage of doctor-prescribed compression supplies under the Durable Medical Equipment (DME) category.
- Reduce the total healthcare costs associated with this disease by decreasing the incidence of complications, co-morbidities and disabilities resulting from this medical condition.
- Cost report from Avalere Health available at: http://lymphedematreatmentact.org/about-the-bill/lta-info-packet-for-congress/



LYMPHEDEMA: NOT ONE DISEASE

Chronic lymphatic-system failure (lymphedema) occurs in 3-5 million Americans across a wide spectrum of diseases.



Over 40 rare diseases are associated with primary lymphedema including:

- · Aagenaes Syndrome
- Adams-Oliver Syndrome
- C.H.A.R.G.E. Syndrome
- · C.L.O.V.E.S. Syndrome
- * Carbohydrate Deficient Glycoprotein (types 1a, 1b, 1h)
- · ardio-facial-cutaneous Syndrome
- * Choanalatresia-lymphedema Syndrome
- * Congenital Lymphedema (non-Milroy's)
- Ectodermal Dysplasia Anhidrotic
- · Immunodeficiency Osteopetrosis
- · Lymphedema Syndrome
- Fabray's Disease
- · Gorham's Disease
- Hennekam Syndrome
- · Hypotrichosis Lymphedema Telangiectasia
- Klippel Trenaunay Syndrome
- Klippel-Trenaunay-Weber Syndrome
- · Lipedema
- · Lymphedema Distichiasis Syndrome
- · Lymphedema Myelodysplasia (Emberger Syndrome)
- · Lymphedema Praecox
- · Lymphedema Tarda
- · Lymphedema-Distichiasis
- Macrocephaly-Capillary Malformation
- Maffucci Syndrome

- Meige Syndrome
- · Microcephaly-Chorioretinopathy-Lymphedema-Mental Retardation Syndrome
- · Milroy's Disease
- Mucke Syndrome
- Neurofibromatosis
- · Nonne-Milroy Disease
- Noonan's Syndrome
- Oculo-Dento-Digital Syndrome
- * Parkes-Weber Syndrome
- Phelan McDermid Syndrome
- · Prader Willi Syndrome
- Progressive Encephalopathy-Hypsar -rhythmia-Optic Atrophy Syndrome
- Protein Losing Enteropathy (associated with numerous forms of congenital heart disease)
- Proteus Syndrome
- · Spina bifida
- Thrombocytopenia with Absent Radius Syndrome
- Trisomy 13,18,21
- · Turner's Syndrome
- Velocardiofacial Syndrome
- · W.I.L.D. Syndrome

90% of all cases are Secondary (acquired) 1.2.4.5

Secondary cases can be broken into two categories:

of all cases are **non-cancer** related.

Any significant damage to the lymphatic organ system can result in lymphedema. Causes include:

- Burns
- Radiation
- · Ilio-femoral bypass
- · Rheumatoid arthritis
- Infection
- Surgery
- Paralysis
- Trauma

of all cases are **cancer** related.

The overall cancer-related incidence rate is 15.5%. Specific rates include:

- · Breast 40%
- · Melanoma 16%
- · Sarcoma 30%
- · Genital-urinary 10%
- Gynecological 20%
- · Head and neck 4%
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- 2. Vascular Medicine. 1998: (3): 145-156
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- 4. Cancer. 2010: 116: 5138-49
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- 6. Annals of the New York Academy of Sciences. 2008: 1131: 147-154
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For more information visit our website LymphedemaTreatmentAct.org

THINGS YOU MAY NOT KNOW ABOUT LYMPHEDEMA

Lymphedema is chronic swelling caused by a build-up of fluid that occurs when the lymphatic system is either faulty or damaged.

Damaged vessels blocking the normal flow of lymphatic fluid

Most physicians in the United States are taught about the lymphatic system for 1 hour or less during their 4 years of medical school training.

There is no known cure for lymphedema, but it can be effectively treated. Compression therapy is the most critical component of treatment. Without it, patients are at increased risk for complications and disability.

Medicare, and many private insurance policies do NOT cover compression garments, wraps, or bandages — the supplies needed for compression therapy.

The Lymphedema
Treatment Act is a bill,
currently in Congress, that
aims to improve insurance coverage
for compression supplies, allowing
lymphedema patients to maintain a
healthy and productive life.

An estimated 3-5 million Americans suffer from lymphedema — including many that are undiagnosed or undertreated. That is more than ALS, Cystic Fibrosis, Multiple Sclerosis, Muscular Dystrophy, and Parkinson's Disease combined.



2 out of 5 breast cancer patients will develop lymphedema within 5 years of surgery.*

Swollen tissue due to buildup of lymphatic fluid

Causes of Lymphatic Dysfunction

- A. Lymph node removal for cancer treatment
- B. Injury to lymphatic vessels due to trauma or infection
- C. Venous insufficiency, causing overload of lymphatic vessels
- D. Congenital malformation of lymphatics



Visit our website to learn more about lymphedema and how to support this bill.

LymphedemaTreatmentAct.org

Estimated Number of Constituents in Each State Who Would Directly Benefit from Passage of the Lymphedema Treatment Act



The Avalere Health¹ cost analysis for the Lymphedema Treatment Act demonstrated that nationally, 0.57% of all Medicare patients are diagnosed with lymphedema. Based on this and state Medicare data², here are the estimates of affected Medicare beneficiaries in each state.

State	Estimate of Medicare Patients with Lymphedema	State	Estimate of Medicare Patients with Lymphedema
Alabama	5427	Nebraska	1770
Alaska	426	Nevada	2338
Arizona	6016	New Hampshire	1424
Arkansas	3400	New Jersey	8484
California	30,788	New Mexico	2030
Colorado	4107	New York	19043
Connecticut	3610	North Carolina	9655
Delaware	967	North Dakota	807
DC	500	Ohio	12135
Florida	21716	Oklahoma	3852
Georgia	8117	Oregon	4025
Hawaii	1339	Pennsylvania	14469
ldaho	1494	Rhode Island	1159
Illinois	11743	South Carolina	5053
Indiana	6454	South Dakota	868
lowa	3269	Tennessee	6831
Kansas	2758	Texas	19620
Kentucky	4882	Utah	1842
Louisiana	4419	Vermont	722
Maine	1701	Virginia	7407
Maryland	5093	Washington	6337
Massachusetts	6798	West Virginia	2412
Michigan	10639	Wisconsin	5838
Minnesota	5045	Wyoming	517
Mississippi	3180	Guam	78
Missouri	6404	Puerto Rico	5059

^{1.} http://lymphedematreatmentact.org/wp-content/uploads/2016/05/Avalere-Score.pdf

^{2.} http://kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=0

The Function of Compression and Why Current Medicare Coverage of Lymphedema Treatment is Inadequate



As stated by the National Cancer Institute, "The goal of lymphedema treatment centers on controlling limb swelling and minimizing complications."

Under current Medicare policy, lymphedema patients have coverage for Manual Lymphatic Drainage (MLD), performed by a qualified Medicare provider such as a physical or occupational therapist, and, when certain conditions are satisfied, a pneumatic compression pump. The function of both of these treatment modalities is to reduce the volume of stagnant lymph fluid in the affected body part or parts.

The function of compression is to maintain the affected body part in its reduced state and prevent it from swelling further. Without the use of compression garments and/or the other compression supplies outlined in the Lymphedema Treatment Act, MLD and lymphedema pumps provide no lasting benefit and do not enable the patient to maintain their condition.

Medicare does recognize and acknowledge the necessary role compression plays in the treatment of lymphedema.

Lymphedema pumps, if prescribed, may be covered by Medicare (per National Coverage Determination 280.6²) after "a four-week trial of conservative therapy" has shown little or no benefit. This "conservative therapy" must include the "use of an appropriate compression bandage system or compression garment". The Decision Summary of the Decision Memo for Lymphedema Pumps (CAG 00016N³) states providers should, "Encourage patients to use compression garments between pump sessions to prevent reaccumulation of fluid".

Pumps are generally used for an hour a day. A person cannot perform most any activity of daily living while using the pump. As demonstrated by the images below, the compression sleeve that comes with a pump (seen left) is far different from the compression garments and other compression supplies that must be worn continuously to prevent fluid reaccumulation (shown to the right and center).

The Lymphedema Treatment Act will close the unintended gap in coverage that prevents Medicare beneficiaries from accessing these medically necessary, doctor prescribed compression supplies, which are the cornerstone of the standard of care for lymphedema.







¹ http://www.cancer.gov/about-cancer/treatment/side-effects/lymphedema/lymphedema-hp-pdq#section/all

² https://www.cms.gov/medicare-coverage-database/details/ncd-

details.aspx?NCDId=225&ncdver=1&DocID=280.6&SearchType=Advanced&bc=IAAAABAAAAA&

https://www.cms.gov/medicare-coverage-database/details/nca-details.aspx?NCAId=50&ver=6&NcaName=Lymphedema+Pumps&DocID=CAG-00016N&bc=gAAAABAAAAAA&

Compression in the Treatment of Lymphedema



The following is a condensed version of supportive materials.

The complete document is found on our website at:

http://lymphedematreatmentact.org/about-the-bill/lta-info-packet-for-congress/

Materials prepared by Julie Hanson MD, FAAP, CLT-LANA,

Lymphedema Advocacy Group Board Member and Medical Advisor.

SECTION 1:

Existing Federal Action or Precedent Regarding Compression

- CMS Decision Memo on Pneumatic Pumps¹
 Standard management of lymphedema typically includes positioning (elevation), manual lymphatic drainage, exercise, and compression garments or wraps. Patients should use compression garments between pump sessions to prevent reaccumulation of fluid.
- 2. MEDCAC Meeting on Lymphedema Treatment Protocols (2009)² When isolating individual modalities of treatment, the highest level of confidence was found in compression.^{3 4}
- 3. Tricare Coverage of Compression for Members of the Military⁵ "Medical grade compression (pressure) stockings are a covered benefit as durable medical equipment. TRICARE covers two pressure stockings per limb per calendar year when medically necessary."
- 4. Women's Health and Cancer Rights Act (WHCRA) of 1986 The required coverage includes: Treatment of physical complications of the mastectomy, including lymphedema.

SECTION 2:

Evidence for the Effectiveness of Compression

- 5. National Lymphedema Network Position Statement on The Diagnosis and Treatment of Lymphedema (2011) ⁷
 - "Following achievement of maximal volume reduction with Complete Decongestive Therapy, patients should be fitted with a compression garment."
- 6. Cochrane Database of Systematic Reviews ~ Physical therapies for reducing and controlling lymphoedema of the limbs (2008)⁸

The use of compression bandaging and garments was more effective than garments alone. Additionally, they noted that when comparing no treatment to the use of compression garments alone, the garments were deemed beneficial.

- 7. The Breast ~ Supportive Care After Curative Treatment for Breast Cancer (survivorship care): Resource Allocations in Low and Middle income countries. A Breast Health Global Initiative 2013 Consensus Statement (2013)⁹ The evidence supports the use of compression bandages and garments as the most "basic" level of care to be provided in countries with even the most sparse of resources.
- 8. International Lymphedema Framework ~ Compression Hosiery (Garments) in Lymphedema (2006)¹⁰

 Studies with follow-up periods of six months to five years showed that compression garments are effective in reducing and/or maintaining lymphedema of the arm and leg both in primary and secondary lymphedema.
- 9. International Lymphedema Framework ~ Compression Management, A Position Document on Compression Bandaging (2012)¹¹

Regarding compression bandaging: Lymphedema requires constant compression, if discontinued edema will recur rapidly.

- National Breast and Ovarian Centre (Australia) ~ Review of Research Evidence on Secondary Lymphoedema: Incidence, Prevention, Risk Factors, and Treatment (2008)¹²
 - Compression is "an essential component of combination physical therapies" and that conservative treatment (including compression) "leads to significant reductions in limb volume."
- Lymphatic Research and Biology ~ The Standard of Care for Lymphedema: Current Concepts and Physiological Considerations (2009)¹³

"It is well known that lymphedema, left untreated, will progressively become worse. The earlier lymphedema is detected and properly treated, the better will be the outcome. Early detection and treatment can lead to near normalization of a swollen limb or an edematous trunk, and a greater chance of minimizing or avoiding significant complications.

12. Support Cancer Care ~ The Treatment of Lymphedema Related to Breast Cancer: a Systematic Review and Evidence Summary (2004)¹⁴

"Patients should be advised that lymphedema is a lifelong condition and that compression garments must be worn on a daily basis. Patients can expect stabilization and/or modest improvement of edema with the use of the garment in the prescribed fashion."

13. Clinical Journal of Oncology Nursing ~Demystifying Lymphedema: Development of the Lymphedema Putting Evidence Into Practice Card (2008)¹⁵

Non-adherence with low-stretch compression bandaging and compression sleeves represent risk factors for progressive lymphedema, and continued use of compression bandaging allows for further volume reduction even during maintenance therapy.

14. Canadian Medical Association Journal ~ Clinical Practice Guidelines for the Care and Treatment of Breast Cancer: Lymphedema (2001)¹⁶

Evidence supported the use of compression garments and their use as the "primary therapy" for lymphedema.

15. Annals of Oncology ~ Conservative Treatment of Postmastectomy Lymphedema: A Controlled, Randomized Trial (1991)17

Both groups improved however there were no significant differences and the authors concluded "a good result could be obtained simply and economically" in the group treated with compression alone.

SECTION 3:

Evidence for Reduced Healthcare Expense

16. Journal of The American Physical Therapy Association ~ Breast Cancer Related Lymphedema: Comparing Direct Costs of a Prospective Surveillance Model and a Traditional Care Model (2012)¹⁸

Determined that the annual direct cost to manage early stage lymphedema with compression garments and minimal therapy was \$636.19 versus \$3,124.92 in the more advanced stages.

17. Journal of Clinical Oncology ~ Incidence, Treatment Costs, and Complications of Lymphedema After Breast Cancer Among Women of Working Age: A 2-Year Follow-Up Study (2007)¹⁹

"Poorly managed lymphedema may lead to complications needing medical attention, which increases the costs of care."

18. Rehabilitation Oncology Journal ~ Effects of **Complete Decongestive Therapy on the Incidence** Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema²⁰

The study revealed that treatment, primarily consisting of compression including bandaging and custom garments, reduced the average annual hospitalizations among the study participants from 8.5/year down to 0.67/year, a decrease of 12 fold.

19. The American Journal of Infection Control ~ Outcomes and management costs in patients hospitalized for skin and skin-structure infections (2011)21

Found that the length of stay per episode was 9.5-17.2 days and cost ranged from \$40,046 - \$80,093 per hospital stay. Costs are expected to have risen modestly since that time.*

> *Note that even at the lower end of the cost range per hospitalization, a 12 fold reduction in hospitalizations per year could be expected to decrease the cost from \$343,391/year to \$26,830/year.



For more information visit our website LymphedemaTreatmentAct.org

References:

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3.https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id51a.pdf

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6.http://www.cms.gov/medicare-coverage-database/(S(3iepps3hnwcrz5es0ppyu045))/ details/nca-decision-memo.aspx?N

7. https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id51a.pdf

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9.http://www.thebreastonline.com/article/S0960-9776(13)00214-2/pdf

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11. http://www.lympho.org/portfolio/compression-therapy-a-position-document-on-compression-bandaging/

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14. https://www.ncbi.nlm.nih.gov/pubmed/15095073

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JAMES L. MADARA, MD

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May 6, 2016

The Honorable Maria Cantwell United States Senate 511 Hart Senate Office Building Washington, DC 20510

Dear Senator Cantwell:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our support for S. 2373, the "Lymphedema Treatment Act." This bill would help fill a treatment gap for patients with lymphedema by providing for Medicare coverage of certain lymphedema compression treatment items as durable medical equipment (DME) items.

Lymphedema afflicts millions of Americans, with the majority of cases caused by cancer treatments that damage the body's lymph transport and immune functions. When left untreated or under-treated, lymphedema is progressive and can put patients at greater risk for serious infections or other costly complications. While certain treatments for breast cancer-related lymphedema are required by law to be covered by private insurance plans, Medicare beneficiaries with lymphedema currently lack coverage for compression therapy, an essential component of care they must use to manage their chronic disease. As a result, many patients are not receiving appropriate and evidence-based treatment, which results in a decline in their health status and quality of life. Your bill would fix this treatment gap by specifically covering certain lymphedema compression treatment items under Medicare as DME items as long as they are prescribed by a physician or non-physician health professional to the extent authorized under state law.

The AMA applauds your leadership in sponsoring the Lymphedema Treatment Act and is pleased to support this important bill.

Sincerely,

James L. Madara, MD

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American Cancer Society Cancer Action Network 901 E Street NW, Suite 500 Washington, DC 20004 202.661.5700 www.acscan.org

August 05, 2015

The Honorable David G. Reichert United States House of Representatives 1127 Longworth House Office Building Washington, DC 20515-0601

Dear Representative Reichert:

On behalf of millions of cancer patients, survivors and their families, the American Cancer Society Cancer Action Network (ACS CAN) commends you for your leadership in introducing H.R. 1608, the Lymphedema Treatment Act of 2015.

The Lymphedema Treatment Act of 2015 would require Medicare to cover all necessary medical supplies appropriate for the treatment of lymphedema for beneficiaries. The Medicare program currently does not cover the critically necessary compression supplies used in the daily treatment of lymphedema. Patient access to physician prescribed compression supplies can prevent recurring infections and eventual disability in lymphedema patients. Currently, compression supplies used for the treatment of lymphedema patients are not classified under any existing Medicare benefits category.

Lymphedema affects millions of Americans nationwide, and there is currently no known cure. Patient access to medical supplies that help treat lymphedema is imperative, and important for patient quality of life. Patients who have undergone surgery or radiation therapy for cancer, namely breast cancer, may be at a high risk of developing lymphedema. Also, surgical procedures treating breast cancer often require the removal of lymph nodes which puts breast cancer survivors at an even higher risk. This is why the Lymphedema Treatment Act is so important, and we look forward to working with you on the legislation during the 114th Congress.

Thank you again for your leadership on this important issue. Please contact Keysha Brooks-Coley on my staff at 202-661-5720, or <u>Keysha.brooks-coley@cancer.org</u> if we can be of assistance in any way.

Sincerely,

Christopher W. Hansen

President



1111 North Fairfax Street Alexandria, VA 22314-1488 703 684 2782 703 684 7343 fax www.apta.org May 24, 2016

The Honorable Maria Cantwell United States Senate 511 Hart Senate Office Building Washington, D.C. 20510

The Honorable Charles Grassley United States Senate 135 Hart Senate Office Building Washington, D.C. 20510

Dear Senator Cantwell and Senator Grassley:

On behalf of the more than 93,000 members of the American Physical Therapy Association (APTA), I write to thank you for introducing the *Lymphedema Treatment Act* (S. 2373), which will be invaluable in assisting Medicare beneficiaries who are impacted by lymphedema.

APTA commends the legislation and its provision of improved Medicare coverage for compression supplies, including compression garments, bandaging systems, and other devises necessary for the treatment of lymphedema. This legislation provides extensive and detailed descriptions of the categories of lymphedema treatment supplies that would be required to be covered, while authorizing the Secretary to expand coverage for additional supplies so long as those items are determined to be effective in preventing or treating lymphedema. Currently, Medicare beneficiaries lack coverage for the compression therapy necessary for the treatment of lymphedema. Passage of this legislation would ensure access to these indispensable items for individuals suffering from lymphatic impairments and conditions.

Physical therapists provide a crucial role in the treatment of lymphedema. While there is no cure for this condition, early detection, treatment, and management are crucial to alleviating symptoms. Physical therapists aid in manual lymph drainage as well as the fitting and adjustment of compression garments. Additionally, physical therapists provide patients with specialized exercises to be performed while wearing compression garments and are an important source of information regarding how to avoid injury and infection, improve skin care, and utilize diet to decrease fluid retention.

Thank you for your commitment to improving the lives of individuals suffering from lymphedema. Please contact Stephanie Katz, Senior Congressional Affairs Specialist, at stephaniekatz@apta.org or 703-706-3177, if you have any questions or would like additional information.

Sincerely,

Sharon L. Dunn, PT, PhD, OCS

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President

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June 22, 2015

Honorable David Reichert 1127 Longworth House Office Building Washington, DC 20515

RE: Support of H.R. 1608, the Lymphedema Treatment Act

Dear Congressman Reichert:

On behalf of the Oncology Nursing Society (ONS), I write to thank you for introducing H.R. 1608, the Lymphedema Treatment Act. H.R. 1608 will improve insurance coverage for the doctor-prescribed compression supplies that are the cornerstone of lymphedema treatment.

As you know, lymphedema is a chronic condition affecting millions of Americans that is most often caused by cancer treatments that damage the body's lymph system or immune functions. Due to the painful swelling that results from lymphedema, compression therapy is an essential component of treatment. Despite being an ongoing necessity, compression supplies are not covered by Medicare. H.R. 1608 would close this coverage gap by requiring Medicare to cover lymphedema compression items.

In addition to providing cancer treatment, oncology nurses maintain principal responsibility for managing treatment side-effects. Maximizing quality of life and minimizing treatment side-effects such as lymphedema are central goals of oncology nurses. H.R. 1608 will afford our nurses the opportunity to be more effective caregivers and ultimately will result in more successful outcomes for cancer patients nationwide.

ONS is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.

Please know that ONS and its members very much appreciate your leadership on the issue of access to lymphedema treatment. We stand ready to work with you and your staff to reduce and prevent suffering from cancer. We would be happy to discuss ways in which ONS may be of assistance in this endeavor, and would encourage you to contact Alec Stone, MA, MPA, ONS Director of Health Policy, at astone@ons.org. We look forward to engaging in an ongoing dialogue to address issues of importance to our cancer patients and ways in which we can promote public health.

Sincerely,

Margaret Barton-Burke, PhD, RN, FAAN President, Oncology Nursing Society

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