

REPORT OF THE  
SPECIAL ADVISORY COMMISSION ON MANDATED  
HEALTH INSURANCE BENEFITS

**MANDATED COVERAGE FOR  
RECONSTRUCTIVE BREAST SURGERY  
House Bill 1010**

TO THE GOVERNOR AND  
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA  
RICHMOND  
[2002]

[DATE]

To: The Honorable Mark Warner  
Governor of Virginia  
and  
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 2.2-2504 and 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of House Bill 1010 regarding a proposed mandate of coverage for Mandated Coverage for Reconstructive Breast Surgery.

Respectfully submitted,

Stephen H. Martin  
Chairman  
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## **Introduction**

The Senate Committee on Commerce and Labor referred House Bill 1010 to the Advisory Commission for review during the 2002 Session of the General Assembly of Virginia. House Bill 1010 was patroned by Delegate Mitchell Van Yahres. House Bill 1010 amends and reenacts § 38.2-3418.4 of the Code of Virginia. If enacted, this legislation would revise the current mandate of coverage for breast reconstruction after mastectomy to include coverage of a new medical technique called the deep inferior epigastric perforator (DIEP) flap procedure.

The Advisory Commission held a public hearing on November 12, 2002 in Richmond, Virginia to receive comments on House Bill 1010. In addition to the bill's chief patron, one interested party spoke in favor of the proposed bill, and had previously provided written comments in favor of the legislation.

A representative of the Virginia Association of Health Plans (VAHP) spoke in opposition to the bill and provided written comments. A representative from Medical College of Virginia also opposed House Bill 1010.

The Advisory Commission is expected to conclude its review at the next Advisory Commission meeting and vote on the bill.

## **Summary of Proposed Legislation**

House Bill 1010 revises the current mandate of coverage for breast reconstruction after mastectomy to include coverage of a new medical technique called the Deep Inferior Epigastric Perforator (DIEP) flap procedure.

The current mandate requires that insurers proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization (HMO) providing a health care plan for health care services provide coverage for reconstructive breast surgery under such policy, contract or plan delivered, issued for delivery or renewed. The bill defines "reconstructive surgery" as surgery performed as a result of a mastectomy to re-establish symmetry between the two breasts.

## **Breast Reconstruction Surgery**

The American Cancer Society (ACS) estimated that 4,600 women in Virginia would be diagnosed with breast cancer in 2001. Breast reconstruction may be the recommended treatment after mastectomy has been performed.

The TRAM (transverse rectus abdominus myocutaneous) flap procedure is the most utilized type of autologous reconstruction. The procedure takes approximately six to eight hours to complete and requires a woman to remain overnight in the intensive care unit, and to spend several additional days in the hospital.

According to the American Society of Plastic and Reconstructive Surgeons (ASPRS), 19 percent of all total breast reconstruction procedures utilize the TRAM flap. The TRAM flap is an attached flap that involves sacrificing at least one entire rectus abdominus muscle. The TRAM flap procedure takes skin from the abdomen and leaves it attached to one or two of the stomach muscles, which are then cut inferiorly off the pubic bone. The muscles are then tunneled and brought up to the breast area. With the TRAM flap, the tissue flap remains attached to the muscle and its blood supply. A modification of the TRAM flap, the free TRAM flap, uses a much smaller piece of abdominal muscle; blood is supplied through microsurgical dissection and transplanted blood vessels.

The ASPRS notes that the average length of hospitalization for reconstructive surgery is 5.3 days. Follow-up treatment can range from 8 to 48 months.

### **Deep Inferior Epigastric Perforator (DIEP flap)**

The DIEP flap procedure is divided into two steps. The initial step is to identify suitable blood vessels in the chest to supply the DIEP flap after the transfer by utilizing high-powered loupe magnification. The blood vessels range from 1.6 to 3.0 mm in diameter, and are extremely delicate.

The other half of the surgery involves dissecting and isolating the DIEP flap. Dissection is begun laterally and continued medially until the first perforators are identified. As few as one and as many as five suitable perforators are chosen for the transfer. The grizzle or fascia around the base of the perforating blood vessels is cut. Loupe magnification and the operating microscope are used to help trace the perforating blood vessels through the rectus muscle down to the common deep inferior epigastric vessels. The flap is isolated on only its vascular pedicle. The pedicle is then divided and the flap is placed on the chest. The vascular pedicle is connected to the recipient blood vessels in the chest, and blood flow is restored to the DIEP.

The next step is to close the abdomen. No synthetic mesh is used because the muscle is left intact. The belly button is freed of skin attachments but is left attached to the abdominal wall. Flexing the operating room table at the patient's waist level facilitates pulling down the remaining abdominal skin and fat like a large window shade to the lower border of the abdominal wound. The

wound is then repaired and a new hole made in the abdominal skin for the belly button. The location of the belly button is correct because it was never moved. Only the skin around the belly button was repositioned.

The final step is contouring the flap, securing it to the chest wall, and making it into a breast. Care is taken during this portion of the procedure to not have the weight of the flap pull on the vascular pedicle. At the conclusion of the surgery, Vaseline gauze dressing is placed on both the reconstructed breast and the abdomen. No tape is used, which avoids any tape burns caused by removal of the dressing.

### **Medical Efficacy**

Dr. Robert J. Allen, Chief of Plastic and Reconstructive Surgery at the Louisiana State University Health Sciences, indicated in July 2000 to Robert Goldwyn, M.D., Editor of Plastic and Reconstructive Surgery that the DIEP flap procedure should be considered a first-line treatment for breast reconstruction. He further stated that patients should be informed of their right to preserve their muscle tissue by utilizing the DIEP flap, and that the myocutaneous flap (TRAM) should only be used when it is necessary to transfer muscle tissue to restore function.

According to a 1997 study in the British Journal of Plastic Surgery, five percent of a group of free TRAM flap patients had hernias one year after undergoing surgery, while none occurred among a comparable group of DIEP flap patients. Forty-seven percent of the TRAM patients reported chronic lower abdominal pain, compared to twenty-five percent of the DIEP patients. TRAM patients' trunk flexibility was also markedly reduced after surgery, while DIEP patients could perform the same range of exercises they did prior to surgery.

Allen recently completed a review of 87 perforator flap patients, and found the average hospital stay for the DIEP patients was shorter than the average stay for TRAM patients.

Dr. Andrea Pozez, a plastic and reconstructive surgeon at the Medical College of Virginia acknowledged that she knows of no physicians in Virginia currently performing the DIEP. Dr. Pozez also noted her support for current law, stating that the existing mandate allows for any reconstructive procedures to be performed.

Dr. Pozez recognized that surgeons might perform the same general procedure using different techniques. However, she noted that it would be inappropriate to specify the exact procedure in the Code of Virginia, in consideration of the advancement of technology or updating of procedures.

The American Medical Association's Current Procedural Terminology Codes (CPT) lists specific procedural codes pertaining to specific common procedures performed by physicians. The purpose of the terminology is to provide a uniform language that would accurately describe medical, surgical, and diagnostic services, and would thereby provide an effective means for reliable nationwide communication among physicians, patients, and third parties. CPT is the most widely accepted nomenclature for the reporting of physician procedures and services under government and private health insurance programs.

The Surgery Guidelines of the CPT indicate that its general audience understands that services provided by the physician to any patient may vary. According to Dr. Pozez, although several different reconstruction techniques are included under the "Repair and/or Reconstruction" heading in the CPT, she asserted that a DIEP flap procedure could be coded as "19366 - Breast reconstruction with other technique," and it would be a covered procedure.

### **Current Industry Practices**

Sixty of the top writers of accident and sickness insurance in Virginia were surveyed regarding House Bill 1010. Fifty companies responded by the deadline. Fourteen companies indicated that they have little or no applicable health insurance business in force in Virginia and, therefore, could not provide the information requested. Of the thirty-six respondents that completed the survey, all provide coverage for reconstructive breast surgery, as required by the Women's Health and Cancer Rights Act of 1998.

A majority of respondents to the Bureau of Insurance survey were unable to provide cost information relating to House Bill 1010 stating that these specific costs were already included in the overall medical premium. TRIGON and its subsidiaries Healthkeepers, Peninsula HealthCare and Priority Health Care, reported that coverage for the DIEP procedure is unprecedented, in that, to date, no claim has ever been submitted for the procedure.

### **Social Impact**

The availability of DIEP flap surgery is limited due to the required extensive training in microsurgery. An estimated eight percent of U.S. surgeons regularly perform the DIEP procedure, according to Allen. The ASPRS reports that microsurgical flap procedure is performed at a rate of five percent of all breast reconstructions.

According to the Virginia Health Institute (VHI), for Calendar Year 2000, there were 174 Breast Reconstructions in Virginia. In Calendar Year 2001, there were 216 Breast Reconstructions in Virginia.

The Women's Health and Cancer Rights Act (WHCRA), signed into federal law on October 21, 1998, contains protections for patients who elect breast reconstruction in connection with a mastectomy. For plan participants and beneficiaries receiving benefits in connection with a mastectomy, plans offering coverage for a mastectomy must also cover reconstructive surgery and other benefits related to a mastectomy.

Under WHCRA, mastectomy benefits must include coverage for reconstruction of the breast on which the mastectomy was performed; surgery and reconstruction of the other breast to produce a symmetrical appearance; prostheses and physical complications at all stages of mastectomy, including lymphedemas.

Any benefit that is not mandated by state law must be covered under the WHCRA. The issue of preemption does not arise where state law requires at least the same level of coverage for reconstructive breast surgery as the WHCRA.

WHCRA applies to group health plans, health insurance companies or HMOs, if the plan or coverage provides medical and surgical benefits with respect to a mastectomy. The WHCRA requires coverage for reconstructive surgery in a manner determined in consultation with the attending physician and the patient.

### **Financial Impact**

The VHI reported that in Calendar Year 2000, the average cost of a breast reconstruction was \$15,072. In 2001, the average breast reconstruction cost was \$16,887.

In a recent study in a major medical journal, the issues of cost-effectiveness, viability, and success rate of the DIEP are addressed. The study shows that for the DIEP, as compared to the free TRAM flap, resource costs are identical. The cost of the TRAM procedure, including doctor's fees, anesthesiology, and hospital stay was approximately \$18,000, including the mastectomy. Dr. Allen compared the cost of the perforator flap procedure to TRAM flap, indicating that the study, shows that costs are approximately half that of the TRAM, or \$9,000.

### **Similar Legislation in Other States**

A preliminary review of the National Insurance Law Service (NILS) indicates that the DIEP was not introduced as new legislation in any other U.S. state, and is not currently mandated.

## **Review Criteria**

### **SOCIAL IMPACT**

- a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

According to Dr. Robert Allen, an estimated eight percent of U.S. surgeons regularly perform the DIEP procedure. The American Society of Plastic and Reconstructive Surgeons (ASPRS) reports that the microsurgical flap procedure is performed at a rate of five percent of all breast reconstructions.

The Virginia Association of Health Plans (VAHP) indicated in written comments that the DIEP procedure was not being performed anywhere in Virginia.

- b. *The extent to which insurance coverage for the treatment or service is already available.*

Sixty of the top writers of accident and sickness insurance in Virginia were surveyed regarding House Bill 1010. Fifty companies responded by the deadline. Fourteen companies indicated that they have little or no applicable health insurance business in force in Virginia and, therefore, could not provide the information requested. Of the thirty-six respondents that completed the survey, all indicated that they provide coverage for reconstructive breast surgery, as required by the Women's Health and Cancer Rights Act of 1998.

Dr. Andrea Pozez, who opposed House Bill 1010, stated her belief that existing laws allow for recognized reconstructive techniques to be performed and covered by insurance, including the DIEP procedure.

The VAHP indicated in written comments that no health plan responding to a pertinent VAHP survey indicated an exclusion of coverage for the DIEP procedure.

- c. *If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.*

Proponents stated that the DIEP flap procedure is the standard of care in many medical centers in the country, and that the TRAM is obsolete because the procedure is unable to preserve the function of the rectus abdominis muscle and avoid long-term complications. Additionally, immediate post-operative inconveniences are increased, and there is no certainty that all activities of daily life would be preserved.

Opponents stated that insurance coverage is generally available at the state and federal level. The VAHP believed that coverage is generally available, and it also stated in written comments that health plans do not determine the surgical method of reconstruction.

- d. *If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.*

Insurers contend that coverage is generally available if medically diagnosed to be the treatment as determined by the physician and the patient.

Proponents expressed dissatisfaction that coverage for the DIEP was not generally covered by insurance. One proponent reported paying out-of-pocket for the procedure and having to file bankruptcy because of her inability to meet that financial obligation.

- e. *The level of public demand for the treatment or service.*

According to the Virginia Health Institute (VHI), for Calendar Year 2000, 174 breast reconstructions were performed in Virginia. In Calendar Year 2001, 216 breast reconstruction surgeries were performed in Virginia.

- f. *The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.*

One proponent testified that she was denied coverage for the DIEP procedure when she sought pre-authorization through her managed care plan.

Dr. Andrea Pozez, a plastic and reconstructive surgeon at the Medical College of Virginia, reported that she knew of no physicians in Virginia currently performing the DIEP procedure.

TRIGON and its subsidiaries, Healthkeepers, Peninsula HealthCare and Priority Health Care, report that the DIEP procedure is unprecedented, in that, to date, no claim has ever been submitted.

- g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.*

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts is unknown.

- h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

The Advisory Commission is not aware of any information or relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of this mandated benefit during this review.

#### FINANCIAL IMPACT

- a. The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

A proponent testified that the cost of the procedure was more expensive, but it would prove to be cost-effective in the long-term because fewer follow-ups would be required. The patient's abdominal cavity would not be invaded, and muscles would not be removed. There would be less probability of developing hernia problems, back problems, or becoming wheel chair bound. The patient's quality of life would be improved because of the DIEP technique.

According to a 1997 study in the British Journal of Plastic Surgery, five percent of a group of free TRAM flap patients had hernias one year after undergoing surgery, while none occurred among a comparable group of DIEP flap patients. Forty-seven percent of the TRAM patients reported chronic lower abdominal pain, compared to twenty-five percent of the DIEP patients. TRAM patients' trunk flexibility was also markedly reduced after surgery, while DIEP patients could perform the same range of exercises they did prior to surgery.

- b. The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

Proponents contended that House Bill 1010 would increase appropriate use because it allows for an improved quality of life after surgery for the patient. This procedure might be considered more often, but it is only used for the treatment of breast reconstruction, and breast reconstruction is already covered.

Opponents stated the procedure is already covered. Enacting House Bill 1010 would not increase appropriate or inappropriate use of treatment. An opponent noted that health plans do not determine the surgical method of reconstruction.

- c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

Proponents believe the DIEP technique should be considered the standard of care. Dr. Allen stated that patients should be informed of their right to preserve their muscle tissue by utilizing the DIEP flap, and that the myocutaneous flap (TRAM) should only be used when it is necessary to transfer muscle tissue to restore function.

Opponents believe that current legislation allows the attending physician and the patient to determine which surgical technique is appropriate. The DIEP technique is already considered a valid technique, although special training is required.

- d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

Physicians trained in the DIEP technique are already performing the specialized microsurgery. In a letter date 3/15/01 to Christine Palazzolo, Dr. Alex Keller explained that few providers perform the DIEP because an additional year of microsurgery training is necessary and the learning curve is steep. The procedure is tedious, requiring very careful teasing out of abdominal fat from the abdominal muscles. Moreover, working with blood vessels is painstaking work. The technique requires attentiveness, and operating room time is longer. Dr. Alex Keller recently indicated that he was unaware of any physicians in Virginia currently performing the DIEP flap procedure.

Opponents stated that mandating House Bill 1010 would set a precedent for every specialist to want to have his specialty mandated.

- e. *The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

A majority of respondents to the Bureau of Insurance survey were unable to provide cost information relating to House Bill 1010, stating that these specific costs were already included in the overall medical premium.

It is unlikely that this proposed coverage would increase or decrease the administrative expenses of insurance companies and administrative expense of policyholders because it would apply to all policyholders equally and is not likely to result in significant increase in claims submissions because of the limited providers.

*f. The impact of coverage on the total cost of health care.*

The impact on the total cost of healthcare is not expected to be significant.

MEDICAL EFFICACY

*a. The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.*

Proponents stated that the medical efficacy of the DIEP procedure significantly relates to improving a patient's quality of life compared to the TRAM flap, which is the current standard of care. According to a 1997 study in the British Journal of Plastic Surgery, five percent of a group of free TRAM flap patients had hernias one year after undergoing surgery, while none occurred among a comparable group of DIEP flap patients. Forty-seven percent of the TRAM patients reported chronic lower abdominal pain, compared to twenty-five percent of the DIEP patients. TRAM patients' trunk flexibility was also markedly reduced after surgery, while DIEP patients could perform the same range of exercises they did prior to surgery.

Opponents expressed several concerns with regard to mandating coverage for the DIEP procedure. Although the DIEP technique requires specialized training, it is included in the current mandate for reconstructive breast surgery.

According to Dr. Pozez, although several different reconstruction techniques are included under the "Repair and/or Reconstruction" heading located in the "Surgery" section of the CPT, she asserted that a DIEP flap procedure could be coded for insurance coverage as "19366 - Breast reconstruction with other technique," and it would be a covered procedure.

b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

1) *The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.*

Not applicable.

2) *The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

#### EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

Proponents argue that the coverage is consistent with the role of health insurance and addresses a broad medical and social need, although the DIEP is an advanced breast reconstruction surgery recommended for women after mastectomy has been performed. It would allow the patient to achieve a quality of life that cannot be achieved any other way.

Opponents argue that this bill overlooks the impact of medical and technological advancements. The VAHP noted that technology would continue to improve all providers' ability to treat patients more efficiently while simultaneously assuring quality, appropriateness, and effectiveness of care. Opponents also noted that legislative mandates, such as House Bill 1010, interfere in the physician-patient relationship by arbitrarily preempting a physician's clinical decision-making ability.

b. *The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.*

Proponents believe that mandating the DIEP procedure will increase availability of the treatment for those mastectomy patients choosing DIEP over another surgical technique.

Opponents of House Bill 1010 questioned whether there was a need for the language proposed in the bill. In both oral and written comments, opponents

stated that existing legislation allows for the DIEP to be performed as a covered procedure.

At the time the legislation was drafted, no physician in Virginia was performing the procedure. Also, health plans reported they provided coverage for the procedure as required by federal law.

*b. The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.*

In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insureds.

**RECOMMENDATION**

**CONCLUSION**