

STORAGE NAME: h1415.hr.doc
DATE: February 14, 2002

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS**

BILL #: HB 1415
RELATING TO: Organ-transplant/Medicaid Services
SPONSOR(S): Representatives McGriff and others
TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH REGULATION
 - (2) FISCAL RESPONSIBILITY COUNCIL
 - (3)
 - (4)
 - (5)
-

I. SUMMARY:

THIS DOCUMENT IS NOT INTENDED TO BE USED FOR THE PURPOSE OF CONSTRUING STATUTES, OR TO BE CONSTRUED AS AFFECTING, DEFINING, LIMITING, CONTROLLING, SPECIFYING, CLARIFYING, OR MODIFYING ANY LEGISLATION OR STATUTE.

Lung transplantation is the treatment of choice for adults and children who will die from end-stage lung disease. The primary diagnoses for individuals with chronic lung disease receiving transplants nationally are cystic fibrosis, idiopathic pulmonary fibrosis, chronic obstructive pulmonary disease, and emphysema. Approximately 60 percent of transplants performed are single lung transplants and 40 percent are double lung transplants.

There are 3 active lung transplant programs in Florida: Shands at the University of Florida; Jackson at University of Miami; St. Lukes at the Mayo Clinic; with a fourth program, Tampa General, expected to begin shortly. Florida has averaged 26 lung transplants annually. Florida is a net exporter of lungs. The number of exported lungs should decrease to 10-15% of the total procured in 2002 because there are more potential recipients on the waiting list at Shands at the University of Florida. At Shands alone, there has been a 50% increase in the number of individuals on the waiting list for lung transplantation.

Medicaid currently covers transplants of kidneys, pancreas, liver, heart, lung and intestines for children. For recipients over the age of 21, Medicaid provides coverage for kidney, liver and heart transplants only. This limitation creates a unique situation in the case of children who have cystic fibrosis and pediatric idiopathic pulmonary fibrosis, since treatments developed in the early 1990s can now be used to slow the lung deterioration. For example, in cystic fibrosis, 30 years ago the median life expectancy was about 8 years. Due to medical advances, the median life expectancy is just under 30 years and increasing. These advances in medical treatment have thus had the effect of delaying the onset of the life-threatening stage of the disease during the childhood and adolescent years until the child passes the age of 21 at which point Medicaid will no longer cover the necessary transplantation.

HB 1415 requires the Agency for Health Care Administration Medicaid program to pay for medically necessary organ transplant services for any recipient who has progressive lung disease that developed before the recipient was 21 years old, subject to the availability of funds and subject to any limitations or directions provided for in the General Appropriations Act or ch. 216, F.S.

AHCA estimates that the bill will provide coverage for transplants for 39 individuals at a total cost of \$3,360,450. The state General Revenue required for the additional coverage will be \$1,390,218.

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The bill creates an undesignated section of law.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|---|--|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

For any principle that received a "no" above, please explain:

Less Government and Individual Freedom: HB 1415 will require additional government funding for lung transplants, which otherwise would have to be paid for by the individual.

B. PRESENT SITUATION:

Organ Transplantation

According to the Organ Transplant Task Force, there is perhaps, no field in medicine that has been as closely scrutinized, studied, and regulated, as perhaps the field of organ transplantation. The first solid organ transplanted into a human was a kidney in 1954. The field of transplantation has matured since then due to improvements in surgical technique, patient selection, tissue typing, organ preservation, immunosuppression and care of the post-transplant patient.

The 2001 Legislature passed SB 684 that is codified as Chapter 2001-277, Laws of Florida, directing the Agency for Health Care Administration (AHCA) to create an Organ Transplant Task Force and instructed to report to the Governor and Legislature by January 15, 2002. The Task Force provided recommendations to the Legislature that included, among other things:

- Because of the average per transplant loss of \$152,000 to each liver transplant program transplanting adult liver Medicaid patients, the Medicaid Reimbursement Model used for adult heart patients should be extended to adult liver patients. Extension of the model should also be applied to adult lung transplant patients.

Organ allocation, the process that determines which organs go to which recipients, is a complex and often contentious issue. Though the schemes differ based on the scientific data particular to each organ and relative to the illness that its failure causes, there are some basic common principals upon which the schemes are developed as well as some common rules used for distribution.

The basic principals on which all allocation schemes are based is a balance between justice and utility, that is, ensuring that all patients in need have an equal access to transplantation, while at the same time utilizing the organs in such a way to get the best results. In matters pertaining to organ transplantation, these principals can be discordant. This tug-of-war between principals is a reality simply because the demand for organs exceeds their availability.

When developing allocation schemes the science relating to the specific organ transplantation is taken into account. For instance, tissue typing (genetic matching of tissues) might be vitally important in outcome following kidney transplantation, but has little, if any, role in the outcome following liver transplantation. Consequently, tissue typing is weighted heavily in the allocation of kidneys, but not at all in the allocation of livers. Body size matching tends to be important for livers, hearts, and lungs and therefore, is taken into account when allocating these organs, but not for kidney or pancreas. In general, pediatric patients are given primacy for pediatric organs. All organs are allocated within compatibility, but not necessarily identical, blood types.

Lung transplantation is the treatment of choice for adults and children who will die from end-stage lung disease. The primary diagnoses for individuals with chronic lung disease receiving transplants nationally are cystic fibrosis, idiopathic pulmonary fibrosis, chronic obstructive pulmonary disease, and emphysema. Approximately 60 percent of transplants performed are single lung transplants and 40 percent are double lung transplants. According to the report from the Organ Transplant Task Force, the lung waiting list is currently increasing at approximately 10% per year and the average number transplantation of lungs performed over the past 3 years is 880.

There are 3 active lung transplant programs in Florida: Shands at the University of Florida; Jackson at University of Miami; St. Lukes at the Mayo Clinic; with a fourth program, Tampa General, expected to begin shortly. Florida has averaged 26 lung transplants annually. The vast majority of lungs transplanted in Florida come from Organ Procurement Organizations (OPOs) within the state. Lungs deemed not suitable for transplantation by one center, either for donor or recipients reasons, may be offered to other centers. Florida is a net exporter of lungs. The number of exported lungs should decrease to 10-15% of the total procured in 2002 because there are more potential recipients on the waiting list at Shands at the University of Florida. At Shands alone, there has been a 50% increase in the number of individuals on the waiting list for lung transplantation.

The Medicaid Program

Medicaid is a medical assistance program that pays for health care for the poor and disabled. The federal government, the state, and the counties jointly fund the program. The federal government, through law and regulations, has established extensive requirements for the Medicaid Program. The Agency for Health Care Administration (AHCA) is the single state agency responsible for the Florida Medicaid Program. The Department of Children and Family Services is responsible for determining Medicaid eligibility and managing Medicaid eligibility policy, with approval of any changes by AHCA.

The statutory provisions for the Medicaid Program appear in ss. 409.901 through 409.9205, F.S. Section 409.903, F.S., specifies categories of individuals who are required by federal law to be covered, if determined eligible, by the Medicaid Program (mandatory coverage groups). Section 409.904, F.S., specifies categories of individuals who the federal government gives state Medicaid programs the choice of covering (optional coverage groups). Sections 409.905 and 409.906, F.S., specify the medical and other services the state may provide under the state Medicaid plan.

Medicaid is an entitlement program. Federal laws and regulations require that states make all Medicaid services available to all categorically eligible recipients regardless of diagnosis. If the Medicaid recipient is a child, however, Medicaid is required to provide additional services (which may not be available to adult Medicaid recipients) to treat an illness identified through health screening.

Medicaid currently covers transplants of kidneys, pancreas, liver, heart, lung and intestines for children. For recipients over the age of 21, Medicaid provides coverage for kidney, liver and heart transplants only. This limitation creates a unique situation in the case of children who have cystic

fibrosis and pediatric idiopathic pulmonary fibrosis, since treatments developed in the early 1990s can now be used to slow the lung deterioration. For example, in cystic fibrosis, 30 years ago the median life expectancy was about 8 years. Today, due to medical advances, the median life expectancy is just under 30 years and increasing. These advances in medical treatment have thus had the effect of delaying the onset of the life-threatening stage of the disease during the childhood and adolescent years until the child passes the age of 21 at which point Medicaid will no longer cover the necessary transplantation.

Payment for transplantation services primarily involves reimbursement for physician services, hospital inpatient services, hospital outpatient services, and prescribed drugs. Under the Florida Medicaid program, coverage for adult inpatient hospital services is limited to 45 days per year. This limitation is problematic for facilities that are performing organ transplants, since individuals in need of organ transplants are frequently in very poor health before the transplant and may exhaust their 45 days of coverage before the transplant episode is complete. According to the Agency for Health Care Administration, the result is a net loss to providers of approximately \$152,000 per adult Medicaid transplant recipient.

Several states, including Texas, Wisconsin, and Florida (for adult heart transplants only), reimburse for transplants on a global payment basis, which covers the evaluation, transplant and the follow-up care required. Under global reimbursement mechanisms, the transplant facility submits the request for the global payment, and then reimburses the other providers involved in the procedure, including physician services, from the global payment received.

C. EFFECT OF PROPOSED CHANGES:

The bill requires the Agency for Health Care Administration Medicaid program to pay for medically necessary organ transplant services for any recipient who has progressive lung disease that developed before the recipient was 21 years old, subject to the availability of funds and subject to any limitations or directions provided for in the General Appropriations Act or ch. 216, F.S.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Requires the Agency for Health Care Administration Medicaid program to pay for medically necessary organ transplant services for any recipient who has progressive lung disease that developed before the recipient was 21 years old, subject to the availability of funds and subject to any limitations or directions provided for in the General Appropriations Act or ch. 216, F.S.

Section 2. Provides for an effective date of July 1, 2002.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The Agency for Health Care Administration estimates that the bill will provide coverage for transplants for 39 individuals at a total cost of \$3,360,450. The state General Revenue required for the additional coverage will be \$1,390,218. See table below for details.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See section "IV Consequences of Article VII, Section 18 of the Florida Constitution" of this analysis.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill provides coverage for services not currently reimbursed by Medicaid. Providers have been rendering these services as uncompensated care, will receive additional revenues, however, if the transplant services are reimbursed on a fee-for-service basis subject to limits on covered hospital days, rather than on a global payment basis, providers may experience uncompensated costs in providing the necessary care.

Upon implementation, eligible individuals with progressive lung diseases will now receive Medicaid transplant reimbursements subject to legislative appropriations and limitations.

According to AHCA: "This bill may affect staffing situations, as a result of an inflow of patients as stated previously for lung transplant services. These patients have a high acuity level for care and staffing may not be prepared for this rapid influx of individuals. Employers of institutions, clinics, laboratories, and other health care providers who deal with individuals with pre-existing/progressive lung diseases may have an influx of patients in their care."

D. FISCAL COMMENTS:

None.

Estimated Cost for Coverage of Adult Lung Transplant Services by Medicaid
 Cost for Lung Transplants for Children:

	Physician	Hospital Inpatient	Hospital Outpatient	Prescribed Drugs	Total
Lung-Double	\$13,758.21	\$85,891.64	\$10,227.90	\$17,857.13	\$127,734.88
Lung-Double, By-Pass	\$95,820.76	\$439,332.91	\$47,453.35	\$65,382.42	\$647,989.44
Lung-Single	\$18,901.05	\$120,857.00	\$7,941.17	\$8,644.95	\$156,344.17
Total	\$128,480.02	\$646,081.55	\$65,622.42	\$91,884.50	\$932,068.49
Recipients	11	11	10	10	
Average Cost/Recipient	\$11,680.00	\$58,734.69	\$6,562.24	\$9,188.45	\$86,165.38
Estimated Cost for Adults:					
Estimated Adult Recipients	39	39	39	39	39
Estimated Cost	\$455,520.00	\$2,290,653.00	\$255,927.00	\$358,350.00	\$3,360,450.00
State Share	\$188,449.00	\$947,643.00	\$105,877.00	\$148,249.00	\$1,390,218.00
Federal Share	\$267,071.00	\$1,343,010.00	\$150,050.00	\$210,101.00	\$1,970,232.00

There is some concern that the estimated potential adult recipients identified in the Medicaid files may be understated because of the use of inconsistent diagnosis codes. The children's caseload in FY 00-01 was 286 for cystic fibrosis.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

Since counties are required to pay 35 percent of the total cost for inpatient hospital days beginning on day 11 and ending on day 45 for a Medicaid-eligible resident of the county, the provisions of this bill may increase costs to counties of residence for transplant recipients.

Article VII, s. 18, Florida Constitution, requires that no county or municipality shall be bound by any general law requiring such local government to spend funds or to take action requiring the expenditure of funds unless the legislature has formally determined in the bill that such law fulfills an important state interest and the bill must pass by at least a 2/3 vote of the membership of each house of the Legislature.

The bill does not contain the required finding of an important state interest.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the revenue raising authority of any city or county.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

The bill does not reduce the amount of state tax shared with a county or city.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

See section "IV Consequences of Article VII, Section 18 of the Florida Constitution" of this analysis.

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B. RULE-MAKING AUTHORITY:

None.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

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