

## MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman Jim Barnett at 1:30 p.m. on February 2, 2009, in Room 136-N of the Capitol.

All members were present.

Senator Kelsey - absent

Committee staff present:

Nobuko Folmsbee, Office of the Revisor of Statutes  
Doug Taylor, Office of the Revisor of Statutes  
Kelly Navinsky-Wenzl, Kansas Legislative Research Department  
Terri Weber, Kansas Legislative Research Department  
Jan Lunn, Committee Assistant

Others attending:

See attached list

Conferees appearing before the committee:

Justin Cessna, Private Citizen  
Doug Farmer, State Employee Health Benefits Plan, Kansas Health Policy Authority  
Richard Morrissey, Interim Director, Division of Health, Kansas Department of Health and Environment  
Jennifer Lowry, MD, Children's Mercy Hospital, Kansas City  
Harold Swedlund, Chairman, Kansas Advocacy Committee, American heart Association  
Phil Nusser, Private Citizen  
Richard Sigle, Jr., Kansas Heart Disease and Stroke Prevention Program  
J. J. Lutz, Private Citizen  
Moji Fanimoukun, Staff Attorney, League of Kansas Municipalities  
Steve Sutton, Kansas Board of EMS

Chairman Barnett welcomed Justin Cessna, Wichita, Kansas. Mr. Cessna testified before the Public Health and Welfare Committee in January 2008 regarding his obesity, its impact on his health, and the fact that his insurance would not cover bariatric surgery which was recommended as life-saving treatment by his primary care provider. As a result of his testimony, a law was enacted that required the Kansas Health Policy Authority, in collaboration with the Insurance Commissioner, to conduct a study on the impact of extending coverage for bariatric surgery to the State Employee Health Benefit Program, the affordability of coverage in the small business employer group and the high-risk pool, and the possibility of reinsurance or state subsidies for reinsurance.

Mr. Cessna informed committee members that following that meeting, he was given the life-saving gift of bariatric surgery from the financial assistance of Dr. James Hamilton and Dr. Bernita Berntsen, Tallgrass General, Vascular and Bariatric Surgery, St. Francis Hospital, and Dr. David Bishop, St. Francis Hospital Anesthesiology. Mr. Cessna reported that 231 days following his procedure (Attachment 1), he has lost 125 pounds, decreased dosages of multiple medications, and decreased his insulin 75% with perfect glucose control.

Senators questioned how the lap band was adjusted, what diet changes/adjustments were made, how exercise is incorporated into his daily regime, components of pre- and post-followup, and the costs of the procedure. Mr. Cessna clarified the procedure for adjusting the band, post-procedure food intake is approximately one cup of food for each meal, the pre-procedure psychiatric/education evaluation and the post-procedure followup requirements.

Doug Farmer, Director State Employee Health Benefits Plan (SEHP), Kansas Health Policy Authority, provided detailed testimony covering the issue of bariatric surgery (Attachment 2). Mr. Farmer indicated that health plan changes in 2008 provide for non-surgical obesity treatment, expanded coverage for dietitian consultation, and additional coverage for prescription weight-loss medications. He indicated that in the last several years, an explosion in bariatric surgery technology and research has occurred. He reported that if bariatric surgery coverage were added to the State Employee Health Benefits Plan, the potential financial impact could be as much as \$15 million. However, new research supports the long-

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term value of this procedure with improved health/longevity and reduced medical costs.

Senators questioned whether data exists from states who have implemented bariatric surgery coverage. Specifically, surgical costs based on a patient's Body Mass Index (BMI) by surgical procedure type (Roux n y and lap band). Mr. Farmer indicated the one recommendation from other states appears to be covering skin removal when gastric bypass has been performed; this recommendation is not data-driven.

Chairman Barnett recognized Nobuko Folmsbee, Revisor of Statutes Office, to brief committee members on **SB 82** which would allow the Kansas Department of Health and Environment to continue its lead poisoning prevention program and **SB 102** which shields any person who aids another using an automated external defibrillator (AED) from liability for civil damages as long as actions are above ordinary standards.

### **SB 82 - Repealing K.S.A. 2008 Supp. 65-1,214.**

Senator Barnett opened the hearing on **SB 82** - Repealing K.S.A. 2008 Supp. 65-1,214, and recognized Richard Morrissey, Interim Director of the Kansas Department of Health and Environment, who provided a history (Attachment 3) of the childhood lead poisoning prevention act of 1999, activities, workforce development, funding, challenges, and recommendation to support **SB 82**.

Dr. Jennifer Lowry, pediatrician, toxicologist and clinical pharmacologist at Children's Mercy Hospital was present to support the proposed legislation. Dr. Lowry indicated that while progress has been made relative to childhood lead poisoning, the risk to children has not been removed, and 2010 objectives will not be met (Attachment 4). Dr. Lowry discussed the KDHE Childhood Lead Poisoning and Prevention Program emphasizing that the eradication of lead poisoning in children is based on prevention, education, and management of lead poisoning in the home. Dr. Lowry emphasized that such progress can only result from passage of **SB 82**. Discussion was heard relative to numbers of children tested, numbers of positive tests, and costs for serum lead tests to the State.

Upon a motion by Senator Haley to pass out **SB 82** favorably and a second by Senator Schmidt; the motion carried.

### **SB 102 - Emergency medical services; use of automated external defibrillator.**

Senator Barnett called upon Richard Morrissey, Interim Director of the Kansas Department of Health and Environment, who testified in support of **SB 102**. He indicated that passage of this legislation is expected to result in additional automated external defibrillators (AEDs) being placed in public places where lay rescuers would be more inclined to use them knowing they are immune to civil liability (Attachment 5).

Harold Swedlund, American Heart Association, discussed AED technology, the use of the device by lay rescuer, and the importance of immediate treatment to improve survival from sudden cardiac arrest (Attachment 6).

Phil Nusser from St. John, Kansas, related his experience refereeing a high school basketball game in Ellinwood, Kansas, when he experienced cardiac arrest. An AED was available and was used to deliver the cardiac defibrillation which allowed his heart to reestablish an effective rhythm (Attachment 7).

Richard Sigle, Jr., paramedic, brought an AED and demonstrated the simplicity of the device. Tai Houtz, a KU pharmacy intern with Senator Vicki Schmidt, was asked to participate in the 3-minute demonstration serving as a lay rescuer. Mr. Sigle's comments are attached to these minutes (Attachment 8).

J. J. Lutz appeared to relate his story about how an AED saved his life on January 31, 2007. A unit was used at Seaman High School on that day, and Mr. Lutz encouraged passage of **SB 102** (Attachment 9).

Moji Fanimoukun, staff attorney for the League of Kansas Municipalities, discussed her support of **SB 102**. She indicated the removal of the barrier limiting AEDs be used only by trained, qualified individuals allows cities the opportunity to better protect their staff, constituents, and public (Attachment 10).

Steve Sutton, Deputy Director, Kansas Board of Emergency Medical Services, provided testimony supporting

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the passage of **SB 102** and indicated that the use of an AED provides many stricken with cardiac arrest another chance to live (Attachment 11).

Senator Barnett closed the hearing on **SB 102**.

The meeting was adjourned at 2:34pm

The next meeting will be on Tuesday, February 3, 2009.

Senate Public Health and Welfare

Guest List

Date: 2-2-09

|                    |  |
|--------------------|--|
| Mari Fogel-KSNT    |  |
| Rocky Arnold-KSNT  |  |
| Cynthia Smith      | SCU Health System                                |
| Joshua Cessner     | <del>SCU Health System</del>                     |
| Justin Cessner     |  |
| Misty Jimerson     | KDHE   |
| Richard Sigle Jr   | Kansas Heart Disease & Stroke prevention program |
| Michelle Phillips  | Capital Strategies                               |
| Sean M. Smith      | KBENS  |
| Susan Kang         | KDHE   |
| Dick Morrissey     | KDHE   |
| Paula F Clayton    | KDHE   |
| THOMAS LANGER      | KDHE   |
| Susan Zalenski     | J & J  |
| Audrey D. Dussan   | Visitor  |
| Carolyn Mendenhall | His St. No. Cassin                               |
| Janice Nusser      | Visitor  |
| Charlotta Perry    | Visitor  |
| Bill Sneed         | ANIP   |
| Julia Mowers       | KS BHA   |
| Kristi Dankrab     | KS BHA   |
| Leigh Beck         | Hein Law Firm                                    |
| Bob Williams       | KS Osteopathic Med Assoc.                        |
| Joe DAVISON        | KMS  |
| Kim Williams       | American Heart Assoc.                            |



## Jan Lunn - Testimony

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**From:** Justin Cessna <j\_cessna37@hotmail.com>  
**To:** <jan.lunn@senate.ks.gov>  
**Date:** 2/2/2009 8:28 AM  
**Subject:** Testimony

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Justin Cessna  
 1539 W 30<sup>th</sup> CT N  
 Wichita, KS. 67204  
 (316) 305-0145

Testimony before the Senate Public Health and Welfare Committee

2/2/2009

Again I am humbled and privileged to be asked to appear here before the Senate Public Health and Welfare Committee to give an up\date on my progress.

Last January Senator Barnett invited me to testify about my struggle with morbid obesity and the frustration with my insurance companys lack of coverage despite the fact that they were spending more money treating the effects of obesity than they would paying for the lap band weight loss surgery to correct the problem.

After this meeting I was extremely blessed to be given a life saving gift when Senator Barnett offered to help me financially get the surgery I needed. Working with Dr. Hamilton who also testified here last year and the Tallgrass General and Vascular Surgeon Group here in Topeka with whom he works, they offered to wave their surgical and medical fees. They provided one of their surgical teams headed by Dr. Bernita Berntsen to do the surgery. On June 6<sup>th</sup> 2008 (exactly one year after having suffering heart failure I was admitted to St. Frances Hospital here in Topeka to undergo the lap band procedure. The surgery went flawlessly thanks to the extremely talented skills of Dr. Berntsen and her team along with the great care of the St. France Hospital staff.

It has now been 241 days 1 hour and \_\_\_ Minutes since my life saving surgery; but whos counting. I have lost as of this morning an astonishing 125 pounds. That has been an average of a little over pounds a day.

Last year I was on 10 different medications; today only five. My insulin intake for type 2 diabetic has dropped 75% with perfect control. Last year I had no control. My doctor believes I will be off all diabetic medication within the next 50 to 75 pounds of weight loss.

I was off all heart and blood pressure medications after 4 months post surgery. My blood pressure taken at my doctors office last week was 118/68 (normal). Blood work taken then came back and on the copy Dr. Bloom sent to me at home was a hand written note reading and I quote All Perfect! I didnt think it

Public Health and Welfare

Date:

02/02/09

file://C:\Documents and Settings\jalunn.LG\Local Settings\Tem

Attachment:

would ever happen. (End quote.) And with a yellow highlighter maker a star was made on the copy (probably by his wonderful nurse Condi). Something I havent received since probably the 4<sup>th</sup> grade.

If not for the generosity of Senator Barnett and the Tall Grass Surgical Group I would for sure be on the roles of the disabled today and without exaggeration or being overly dramatic possibility even deceased.

After the weight lose surgery the changes have been rapid and life has drastically improved. I shared this with Senator Barnett several months ago that I have gained one important thing from this experience and that was HOPE! Something a person cannot buy and something I had lost completely before that call in late 2007 from Senator Barnett after sending him a letter as head of this committee asking for his help.

I now owe him a debt and that is (without trying to sound clich) to pay it forward to all my fellow Kansans who suffer from the very treatable often prejudged and very deadly disease of obesity.

I wanted to make this update brief but I am open to any questions you may have.

Sincerely,

Justin Cessna

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Windows Live Hotmailmore than just e-mail. [See how it works.](#)

1-2



## Public Health & Welfare Committee: SB 511 – Study on Coverage for Bariatric Surgery

February 2, 2009  
Doug Farmer  
Director, State Employee Health Benefits Plan  
Kansas Health Policy Authority

1



## Overview

History  
State Employee study 2006  
New research  
Estimated impact of coverage  
Summary  
Staff recommendations for bariatric  
surgery

2





## History

Prior to Plan Year 2008, all treatment for obesity was excluded from coverage under the State Employee Health Plan (SEHP)

Medicaid reimbursed for weight-loss medications but excluded coverage for bariatric surgery

The Health Care Commission (HCC) considered coverage for bariatric surgery in 2006

KHPA engaged in Statewide Health Reform initiative in 2007 and 2008 emphasizing prevention and wellness

Consistent with KHPA initiatives in the area of prevention and wellness, HCC decided to cover preventive and non-invasive obesity treatments for 2008 under SEHP

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## Health Care Commission Review of Bariatric Surgery in 2006

### Findings:

- Preventive, non-invasive treatment was not covered
- Relatively high incidence of complications and even death
- Morbidity and mortality vary considerably with experience of surgeon and hospital
- No Centers of Excellence in Kansas
- Long-term cost-effectiveness not yet demonstrated

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## Health Care Commission Review of Bariatric Surgery in 2006

### KHPA Staff Recommendations for State Employee Health Plan (SEHP):

- Educate consumers on available options for promoting wellness and addressing weight problems

- Review SEHP plans for 2008 to examine possible expansion in preventive benefits

- Review HealthQuest program to consider initiatives in the following areas:

  - Physician-supervised weight management

  - Behavior modification

  - Healthy eating

  - Exercise

- SEHP and Medicaid Staff review of bariatric surgery exclusion

  - Retain exclusion of bariatric surgery

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## Employee Health Plan Changes in 2008

- Provide coverage for non-surgical treatment of obesity

- Expanded coverage for consultation with a dietitian

  - Coverage not limited to diabetics

- Added coverage for prescription weight loss medications

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## HealthQuest for 2008

### Healthy Lifestyle Programs Includes:

- Healthy eating and weight management information

- Health coaches to provide ongoing support

- Teleclass: Healthy Weight

- Online class and tools

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## New Developments

Kansas now has two Centers of Excellence for bariatric surgery as designated by the American Society for Bariatric Surgery  
Centers for Medicare & Medicaid Services (CMS) has 3 certified centers in Kansas to provide bariatric services to Medicare beneficiaries

- Limited geographic area

- Continued increase in prevalence of bariatric surgery

- Explosion in research

- Emerging evidence of the positive health impact for the extremely obese

- Continued advancement in procedures and knowledge of quality indicators

- Widespread, but proscribed, coverage by Medicaid

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## New Research

Surgery reduces excess body weight by half after two years, and reduces total body weight by 16% after ten years

Surgery reduces long-run obesity-related mortality by 50%-90%

Surgical costs may be recoverable in as little as 4-5 years, depending upon the patient

Studies compare efficacy of different procedures

Significant risks accompany the surgery, but are lower in accredited and high-volume centers

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## Estimated Financial Impact

Estimated cost of coverage for the State Employee Health Plan:

As much as \$15 Million in first year

Costs depend on required pre-conditions

Long run net savings to the state

Additional costs of coverage in Medicaid

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## Medicaid

Continues to provide reimbursement for prescription weight-loss medications with prior authorization

Provides for reimbursement for medical nutrition therapy for children under the KanBeHealthy program

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## Summary

### Recognized Problem

Obesity is epidemic in the U.S. and in Kansas

Increasing individual, employer, and societal costs for chronic diseases due to overweight and obesity

New evidence supporting long run value of bariatric surgery

Improved health and longevity

Reduced medical costs

Improved safety through experience and targeting of services

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## Staff Recommendations

Emphasize value of preventive care

Changes have been made to State Employee Plan

Recommendations being developed for Medicaid

Develop recommendation for HCC to cover bariatric surgery in the SEHP

Use Medicare coverage as a starting point

Work with weight loss and surgical experts to target surgery to those who can benefit most

Consider Medicaid coverage if funding is available

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<http://www.khpa.ks.gov/>

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*Coordinating health & health care  
for a thriving Kansas*



**KANSAS HEALTH POLICY AUTHORITY  
REPORT TO  
JOINT COMMITTEE ON HEALTH POLICY OVERSIGHT  
ON A STUDY OF  
COVERAGE OF BARIATRIC SURGERY  
IN  
THE STATE EMPLOYEES HEALTH PLAN**

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State Employee Health Plan:  
Phone: 785-368-6361  
Fax: 785-368-7180

State Self Insurance Fund:  
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Fax: 785-296-6995

## **Purpose of the Study**

The purpose of this study is to analyze the effects of bariatric surgery for the morbidly obese, and to make recommendations for potential state coverage of these procedures as required by SB 511. In collaboration with the Kansas Insurance Department, the Kansas Health Policy Authority examined the impact of extending coverage for bariatric surgery in the State Employee Health Benefits plan, and the affordability of coverage in the public and private sectors. The study includes emerging research evidence of the positive health impacts and risks for the morbidly obese, qualifications for the patients and the surgeons that determine when bariatric surgery is appropriate or necessary, and a cost analysis.

## **Introduction**

### Obesity in the United States and Kansas

Obesity can be defined as having a very high amount of body fat in relation to lean body mass. Individuals with a Body Mass Index, or BMI, of 30 or higher are normally considered obese. Data from the Behavioral Risk Factor Surveillance Survey show that the incidence of obesity in the United States has been increasing rapidly since 1985<sup>1</sup>. In 2007, the overall rate of obesity in the United States was 25.6%, which included 26.4% of men and 24.8% of women. The percentage of Kansas adults who were obese in 2007 was 26.9.

The health risks of obesity are numerous and severe. Obesity has been linked to a number of chronic diseases<sup>2</sup>, including:

- Hypertension (high blood pressure)
- Osteoarthritis (a degeneration of cartilage and its underlying bone within a joint)
- Dyslipidemia (for example, high total cholesterol or high levels of triglycerides)
- Type 2 diabetes
- Coronary heart disease
- Stroke
- Gallbladder disease
- Sleep apnea and respiratory problems
- Some cancers (endometrial, breast, and colon).

### Bariatric Surgery and Treatment Options for Obesity

Obesity treatment options can be categorized as either surgical or non-surgical. In the non-surgical category are behavioral treatment, diet modifications and drug treatment. Recently, upon the realization that for morbid obesity (i.e. weighing twice the ideal weight) the non-surgical approaches were largely ineffective, attention has turned to surgical options<sup>3</sup>.

Bariatric surgery was first performed at the University of Minnesota in the 1950s. The procedure has since evolved, and in 1991 the National Institutes of Health issued a statement recommending that surgical options or bariatric surgery be considered for patients with morbid obesity<sup>3</sup>. Between 1993 and 2003, the number of surgeries performed increased from 20,000 to more than 120,000 as the procedure was increasingly seen as effective in initiating and maintaining weight loss and reducing comorbidities<sup>3</sup>.



Bariatric procedures generally fall into two categories<sup>4</sup>:

- 1.) Restrictive (gastric banding "lapband", vertical banded gastroplasty) limits an individual's ability to ingest large quantities of food and slows the speed at which food empties from the stomach.
- 2.) Combination (gastric bypass with Roux-y, Duodenal Switch, or Biliopancreatic Division) procedure combines both restrictive and malabsorptive techniques. This procedure restricts food intake and bypasses the first and second segments of the small intestine. This procedure makes the stomach smaller to restrict food intake and alters digestion (bypasses sections of the small intestine).

The patient will need on-going medical care after the surgery, such as<sup>5,6</sup> nutritional counseling to maintain a healthy diet, physician evaluation, <sup>6</sup>blood work, and continued use of vitamin supplements and minerals due to malabsorption on a life long basis. If the patient loses a significant amount of weight due to the surgery, there is a potential need or request for skin reduction surgery to remove excess skin from areas such as the abdomen, arms, chin, and legs.

## **The Costs and Benefits of Bariatric Surgery**

### Cost of Surgery and Return on Investment

According to information provided by KHPA's actuaries, the charges for bariatric surgery in 2005 were over \$30,000 per procedure including hospital fees. There is evidence to suggest a relatively short timeframe for return on investment, however. A retrospective case-control study that matched 3,651 bariatric surgery patients with surgery-eligible control subjects and found that, on average, total surgery costs were recovered after 53 months. This number includes a 77 month recovery period for operations performed between 1999 and 2002, and a 49-month recovery period for surgeries performed between 2003 and 2005, reflecting the improvements made during this time to both the cost-effectiveness and quality of the surgery which resulted in fewer complications<sup>7</sup>. Yet the results of this study should be received with prudence. An accompanying editorial<sup>8</sup> published with the aforementioned study in the American Journal of Managed Care cited two major shortcomings of this study: First, the return on investment estimates in the study are driven by rising costs in the matched control group rather than decreased costs from the surgery group. Second, the estimates assume a constant differential in costs between the two groups after 19 months which can only be confirmed or repudiated after the actual cost data becomes available.

### Surgical Outcomes, Risks, and Quality

*Short-term outcomes:* <sup>9</sup>Research pertaining to 136 studies indicates that a significant number of individuals who had bariatric surgery experienced significant improvement, up to and including complete remediation, of four comorbidities of an overweight or obese diagnosis: diabetes, hyperlipidemia, hypertension and obstructive sleep apnea. Other studies have shown that bariatric surgery leads to large improvements in insulin insensitivity for diabetics early after surgery, even before any significant weight loss has occurred.<sup>10</sup>

*Intermediate outcomes:* <sup>5</sup>Two years after surgery, individuals usually have lost 50% to 60% of their excess body weight with the combination procedure and 40% to 50% with the restrictive

procedure. Some individuals experience a weight gain after 2 years which is estimated at 15% of the maximum weight loss. Weight gain is attributed to lack of remaining on the postoperative diet.

*Long-term outcomes:* <sup>5,11</sup> The Swedish Obese Subjects study, which assessed the long-run outcomes of bariatric procedures, found an average weight loss of 16% of initial body weight at 10 years. At the end of the ten years, subjects were less likely to have type 2 diabetes, hypertension, high triglycerides, or high levels of uric acid. However, this study consisted of highly motivated self-selected volunteers, so there is reason to doubt that the results apply to a broad-based population such as state employees. In any event, the results suggest that the initial weight loss associated with this class of procedures may dissipate slowly over time from an initial level of about half of their excess body weight.

Other long-term studies have shown variable results. A retrospective cohort study<sup>12</sup> of 9949 patients after Roux-en-Y gastric bypass surgery found a long-term decrease in mortality of 92% for diabetes-related deaths, 60% for cancer-related deaths and 56% for coronary artery disease and over the 18-year study period. However, the rates of death not caused by disease (such as death by accident or suicide) were 58% higher in the surgery group than in the control group.

*Outcomes dependent on operative procedure:* Two randomized clinical trials enrolling a total of 231 patients compared patient outcomes of a gastric bypass method known as Roux-en-Y with results from vertical banded gastroplasty<sup>13</sup>. Results showed that at 12 and 36 months after surgery patients enrolled in the Roux-en-Y gastric bypass lost substantially more weight than those assigned to vertical banded gastroplasty (42.43 kg versus 34.45kg at 12 months and 39.73 kg versus 30.65 kg at 36 months). Other studies have shown similar outcomes, resulting in the conclusion that Roux-en-Y produces greater weight loss than vertical banded gastroplasty.

#### *Outcomes dependent upon patient characteristics*

##### Postoperative risks:

1. <sup>5</sup>Acute nausea, plugging and vomiting affects approximately one to two thirds of the individuals.
2. <sup>5</sup>Acute gastric dumping (nausea, flushing, bloating, faintness, fatigue, and severe diarrhea) affects 50% to 70% of individuals.
3. <sup>5,6</sup>Nutritional deficiencies to include anemia, osteoporosis, and metabolic bone disease affects approximately 25%-30% of individuals who undergo this procedure.
4. <sup>6</sup>More than one third develop gallstones.
5. <sup>5</sup>Mortality rate is approximately 1%.

##### Additional surgery:

1. <sup>6,14</sup>Surgical reversal as medically necessary due to complications from the original surgery, such as obstruction or stricture.
2. <sup>14</sup>A previous bariatric surgical procedure may be revised or converted to another procedure due to lack of weight loss when medically necessary.

*Variable quality:* There are potentially significant risks associated with bariatric surgery and these risks can vary substantially across providers. Because of these risks, Medicare has

determined that it will only pay for bariatric surgery when performed at a facility they deem to be a Center of Excellence. When undergoing such a procedure as bariatric surgery, the patient should be in the hands of a skilled surgeon to ensure quality of care.<sup>15</sup> To qualify as an American Society for Bariatric Surgery Center of Excellence, the Center must be able to document to the Surgical Surgery Review Corporation the following:

- 1) Provide evidence as to resources (e.g. equipment, supplies, training of surgeons, and consultant services) available to perform surgery;
- 2) Excellent short and long term outcomes;
- 3) The center is required to have 125 bariatric cases per year or the surgeon must have 50 cases per year/125 lifetime cases.

Kansas now has three facilities that meet the coverage criteria for CMS. These centers are:

- Minimally Invasive Surgery Hospital in Lenexa
- Shawnee Mission Medical Center in Shawnee Mission
- St. Francis Health Center in Topeka.

## **Health Insurance Coverage of Bariatric Surgery**

### Medicare Coverage

Medicare announced in November of 2005 that it would begin covering bariatric surgery for beneficiaries under age 65 for open and laparoscopic Roux-en-Y gastric bypass and adjustable gastric banding. Coverage was only available under certain clinical circumstances and for facilities meeting Medicare's evidence-based standards for bariatric surgery<sup>16</sup>. This coverage was extended to all beneficiaries (including those over 65) in 2006<sup>17</sup>.

### Medicaid Coverage

Medicaid coverage of bariatric surgery varies by state, but the vast majority of state Medicaid programs (45 of 51) cover bariatric surgery in some capacity<sup>18</sup>. The six states that currently do not cover bariatric surgery are:

- Kansas
- Kentucky
- Mississippi
- Montana
- New Jersey
- Texas.

Additionally, several states exclude coverage under certain conditions. The following table compares obesity treatment coverage in all 50 states and the District of Columbia.

State Medicaid Coverage and Treatment Standards for Adults with Obesity<sup>18</sup>

| State          | State provides specific guidance for treatment of obesity | State covers and pays for nutritional assessment and consultation | State covers and pays for drug therapy for the treatment of obesity | State covers and pays for bariatric surgery |
|----------------|---|---|---|---|
| Alabama        | N   | SE  | SE  | + <sup>1</sup>                              |
| Alaska         | N   | +P  | SE  | +*  |
| Arizona        | N   | +   | N   | +   |
| Arkansas       | N   | N   | N   | +*  |
| California     | N   | SE  | N   | +*  |
| Colorado       | N   | SE  | +*  | + <sup>2</sup>                              |
| Connecticut    | N   | SE  | N   | +   |
| Delaware       | N   | +*  | +*  | +*  |
| D.C.           | N   | N   | N   | +*  |
| Florida        | N   | SE  | N   | +C  |
| Georgia        | G   | +   | SE  | +*  |
| Hawaii         | N   | SE  | N   | +*  |
| Idaho          | N   | +C  | N   | +C  |
| Illinois       | N   | SE  | N   | + <sup>3</sup>                              |
| Indiana        | N   | +   | +   | +   |
| Iowa           | N   | +   | +*  | +*  |
| Kansas         | N   | SE  | +   | SE  |
| Kentucky       | N   | +   | N   | SE  |
| Louisiana      | N   | +   | +   | +   |
| Maine          | N   | +   | N   | +*  |
| Maryland       | N   | N   | N   | +*  |
| Massachusetts  | N   | N   | N   | + <sup>4</sup>                              |
| Michigan       | N   | +P  | N   | +C  |
| Minnesota      | N   | +   | +*  | +*  |
| Mississippi    | N   | +   | +*  | SE  |
| Missouri       | N   | +C  | N   | + <sup>5</sup>                              |
| Montana        | N   | SE  | N   | SE <sup>6</sup>                             |
| Nebraska       | N   | SE  | N   | + <sup>7</sup>                              |
| Nevada         | N   | +   | N   | + <sup>8</sup>                              |
| New Hampshire  | N   | SE  | N   | + <sup>9</sup>                              |
| New Jersey     | N   | SE  | N   | SE  |
| New Mexico     | N   | SE  | N   | +*  |
| New York       | N   | N   | N   | + <sup>10</sup>                             |
| North Carolina | N   | +   | N   | +* <sup>11</sup>                            |
| North Dakota   | N   | +L  | N   | +*  |
| Ohio           | N   | SE  | SE  | +*  |
| Oklahoma       | N   | +   | SE  | + <sup>12</sup>                             |
| Oregon         | N   | +P  | N   | +*  |
| Pennsylvania   | N   | +   | N   | +*  |

| State Medicaid Coverage and Treatment Standards for Adults with Obesity <sup>18</sup> |                 |    |    |                 |
|---|-----------------|----|----|-----------------|
| Rhode Island  | N               | +  | N  | +*              |
| South Carolina  | N               | +C | +* | +               |
| South Dakota  | N               | SE | N  | + <sup>13</sup> |
| Tennessee   | N               | SE | N  | + <sup>14</sup> |
| Texas   | N               | SE | N  | SE              |
| Utah  | N               | SE | N  | +*              |
| Vermont   | G <sup>15</sup> | +  | N  | +*              |
| Virginia  | N               | +P | +* | +*              |
| Washington  | N               | +P | SE | +               |
| West Virginia   | N               | SE | N  | +*              |
| Wisconsin   | N               | +L | +* | +               |
| Wyoming   | N               | SE | SE | + <sup>3</sup>  |

| Symbol | Meaning   |
|--------|---|
| N      | State manual provides no guidance or does not mention specific service or treatment |
| G      | State manual provides detailed guidance for treating adult obesity                  |
| SE     | Specified service is specifically excluded  |
| +      | State covers and reimburses for specified service                                   |
| *      | Prior authorization required  |
| P      | Services provided as part of prenatal care only                                     |
| C      | Services only considered if comorbid condition exist                                |
| L      | Services are specifically limited in some way                                       |

- Alabama will not cover Gastric Bypass for patients with a history of a previous Gastric Bypass procedure.
- Colorado does not reimburse for CPT code 43845.
- Illinois and Wyoming approve gastric bypass on a case-by-case basis.
- Massachusetts will not cover CPT codes 43842, 48343, or 43845.
- Missouri will not cover SPT codes 43770, 43771, 43772, 43773, or 43774.
- Montana has no CPT codes for obesity surgery in its fee schedule nor does it mention obesity in its provider manual.
- Nebraska excludes lleal bypass and intestinal surgery and will not cover other surgeries when the sole diagnosis is obesity.
- Nevada excludes intestinal bypass and gastric balloon.
- New Hampshire does not cover CPT codes 43645 or 43845.
- New York does not cover CPT code 43845.
- North Carolina does not cover investigational procedures including jejunoileal bypass, biliopancreatic bypass, gastric wrapping, gastric banding, jejunocolostomy, and mini-gastric bypass.
- Oklahoma does not include CPT codes 43842 or 43843 in its fee schedule.
- South Dakota does not cover CPT codes 43644, 43645, 43770, 43771, 43772, 43773, 43774, 43845, or 43848.
- Coverage offered through TennCare, Tennessee's managed care program. It is unclear if this service is covered through traditional fee for service Medicaid.
- Vermont does not include obesity treatment language in its provider manual. However, the state offers an extensive adult obesity toolkit at their website: <http://healthvermont.gov/>.

Bariatric surgery is also covered by a few private health plans, although coverage varies by plan type and location.

### **Cost to State Employee Health Benefit Plan**

During the 2008 Kansas Legislative Session, KHPA prepared an estimate of the cost to include bariatric surgery in the State Employee Health Plan (SEHP). We estimated the surgical costs for 2008 to be \$12,750,000. This amount would have covered 425 such surgeries without any limitations on such surgeries (unlike Medicare and other private insurance). For 2010, our estimate is increased to \$14,598,000 to account for a 4.5% annual pricing trend and an increased number of utilizers.

These estimates are based on crude population-based estimates of the prevalence of obesity in the state employee population, since no direct measures are available. In addition, the estimates represent an upper bound since they presume the application of only the minimal, Medicare-based criteria to coverage of the surgery. Other insurers and several state Medicaid programs target surgeries at a smaller population of those who would benefit most. Gross expenditures for bariatric surgery under the state employee plan would depend upon the eligibility criteria selected by the Health Care Commission, and could thus be less than the estimates above.

In addition, new research supports the identification of offset savings to the health plan due to the ongoing health improvements of those who have had the surgery. Research summarized above indicates full payback of surgical costs in as little as four years. These savings would be more likely if the surgery were targeted at a smaller group, where the health risks of obesity and the likelihood of successful post-operative compliance with ongoing treatment are highest. A key offset to the documented savings from surgery-related health improvements is the fact that employees who receive SEHP-covered bariatric surgery will leave the plan at some point in the future (at retirement, if not sooner), taking their improved health and offset savings with them. It is also possible that the prospect of receiving bariatric surgery could attract employees into state service, and that some of those employees might leave state service sooner than might otherwise occur.

Taking all of these factors into account introduces many uncertainties into estimates of the overall financial impact of bariatric coverage in the state employee health plan. Financial models of these net impacts suggest that bariatric surgery would increase state employee health expenditures in the first two to three years as the high up-front costs of surgery are incurred for all currently-eligible employees who wish to take advantage. Surgical costs would decline in future years as utilization fell to include only those newly eligible due to increasing weight, new employment, etc. Offset savings due to improved health would grow steadily for several years as the cumulative number of employees with the surgery – and who would otherwise be incurring higher obesity-related health care costs – would increase. Annual net costs would likely turn to savings in as few as three or four years. Cumulative costs would turn to long run total savings within about 10-12 years. Cumulative savings in the second decade of coverage could reach into the tens of millions of dollars based on the promising research results that have become available in the two years. The assumptions underlying these estimates need to be reviewed by medical care experts before taking any action, but suggest that a modest short-term

investment in bariatric surgery would result in substantial long-run improvement in the health of covered employees and the financing of state employee health benefits.

### **Eligibility Criteria in Public and Private Health Plans**

#### <sup>19</sup>Medicare

In order for a bariatric surgery to be covered by Medicare, Medicare requires the patient to have a Body Mass Index equal to or greater than 35 (e.g. 200 lbs. for a 5'5" person). The individual must also have at least one of the following associated diseases: Hypertension, Type II diabetes, degenerative joint disease involving the lower back, hips, knees, ankles, or feet, gastroesophageal reflux, sleep apnea, obesity hypoventilation syndrome, female sexual hormone dysfunction including the syndrome of polycystic ovaries, amenorrhea, hirsutism, or (Stein-Leventhal syndrome), urinary incontinence or pseudotumor cerebri.

Prior to being considered as a candidate for surgery, the patient must undergo prerequisite treatment, including: Dietary education and evaluation, pharmacological management and a psychological evaluation. The patient must also agree to post-operative care that includes medical/surgical management, dietary counseling and planning, and psychological counseling where it is medically necessary.

#### <sup>14</sup>Cigna

In order for bariatric surgery to be covered, Cigna requires the patient to have the following conditions:

The patient's BMI must be 40 or greater for at least one year *or* a BMI of between 35 and 39.9 for at least one year with one or more co-morbidities (type 2 diabetes, hypertension, hyperlipidemia, coronary artery disease, or sleep apnea) that have failed to respond to nonsurgical treatment methods. Additionally, the patient must be at least 18 years of age and/or have obtained full skeletal growth, have documented participation and compliance in a weight-loss program for at least 6 months (again, participation must have occurred within the last one to two years) and a medical, psychological and nutritional evaluation.

#### <sup>20</sup>Minnesota Medicaid

The Minnesota Medicaid program has different coverage criteria for adult and adolescent surgery candidates. For adults, the patient must either have a BMI of 40 or higher *or* a BMI of 35-40 with one or more comorbidities (severe cardiac disease, type 2 diabetes, obstructive sleep apneas and other respiratory disease, pseudo-tumor cerebri, gastroesophageal reflux disease, hypertension, hyperlipidemia, or severe joint or disc disease that interferes with daily functioning). The BMI level must have persisted for at least two years before the operation.

For adolescents, the patient must either have (1) a BMI of 40 or higher with one or more comorbidities, including type 2 diabetes, obstructive sleep apnea, pseudotumor cerebri, or severe or complicated hypertension, *or* (2) a BMI of 50 or higher with one or more comorbidities including hypertension, dyslipidemias, nonalcoholic steatohepatitis, venous stasis disease, significant impairment in activities of daily living (ADL), intertriginous soft-tissue infections, stress urinary incontinence, gastroesophageal reflux disease, arthropathies in weight-bearing

joints, or obesity-related psychosocial distress. The recipient must have attained physiologic maturity as measured by reaching Tanner stage IV development and 95% of adult height.

For both adults and adolescents, the patient must have made at least one serious medically supervised attempt of at least six months' duration to lose weight in the past. The patient is also required to provide a written statement of their current eating habits and complete a full medical and psychiatric examination prior to surgery. Minnesota Medicaid is unique in requiring a signed statement by the patient detailing the patient's commitment to lose weight, expectations of the surgical outcomes, willingness to make permanent lifestyle changes and participate in a long-term postoperative care plan. A similar statement of support is required from the custodial parent or guardian for all adolescent patients.

### Recommendations

Given the demonstrated safety and efficacy of the procedures, which improve the quality of life, reduce long-run costs, and reduce mortality, KHPA plans to develop recommendations for the HCC that will provide limited coverage of bariatric surgery in the SEHP. Recommendations will be based on the input of medical professional to identify specific coverage criteria that will result in the targeting of this surgery to those who can benefit most, thereby improving health outcomes and reducing costs to the State.

The criteria may begin with the criteria adopted for coverage within Medicare, which require performance of the surgery at a Center for Excellence, and failure at other weight-reduction methods, along with a signed commitment by the patient to follow through with all after-care recommendations. KHPA will plan to seek counsel from those with expertise in weight loss and bariatric surgery to develop initial coverage criteria to be recommended to the Health Care Commission (HCC), the governing body with direct responsibility for determining SEHP benefits. Future consideration of coverage within Medicaid will depend upon the availability of state funds for the initial investment phase of coverage.

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**STUDY OF  
IMPACT OF EXTENDING  
COVERAGE FOR  
BARIATRIC SURGERY IN  
THE SMALL BUSINESS  
EMPLOYER GROUP AND  
THE HIGH RISK POOL**

**Kansas Insurance Department**

**October 31, 2008**

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## PREFACE

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### House Bill No. 2672

HB 2672 was an act concerning the Kansas health policy authority that amended K.S.A. 38-2006, 39-968 and 65-435a, repealing the existing sections; and also repealed K.S.A. 46-2507.

One of the issues considered by the Legislature was the medical and societal epidemic of obesity and the potential for higher mortality rates for individuals with obesity and the economic impact on medical expenses. In New Section 1 of HB 2672 the Legislature requested that the Kansas health policy authority conduct a study on the topic of bariatric surgery and a study on the impact of extending insurance coverage for bariatric surgery. **In conducting the study on the impact of extending insurance coverage for bariatric surgery, the authority was directed to collaborate with the commissioner of insurance ("Commissioner") with regard to the affordability of coverage in the small business employer group and the high risk pool.**

### Study Process

The Commissioner's study process incorporated the following six activities:

1. A survey of the 25 insurers licensed to sell small group coverage in Kansas.
2. Review and analysis of the responses provided by 13 insurers, including costs, potential economic impact on premiums, and related comments.
3. A request for benefits and cost information from the third party administrator and utilization review organization for the Kansas Health Insurance Association (the Kansas high risk pool) regarding coverage for bariatric surgery provided to its members.
4. A request for input from the consulting actuary for KHIA regarding the impact of costs for bariatric surgery on premiums.
5. Review and analysis of the benefits and cost information provided by KHIA's third party administrator, utilization review organization, and consulting actuary.
6. Internet research to obtain national data regarding costs and risk of complications for bariatric surgery.

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## PART I - AFFORDABILITY OF COVERAGE IN THE SMALL GROUP MARKET

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### Introduction

The Commissioner conducted a survey of all 25 insurance companies currently licensed to sell small group coverage in Kansas by posing the following question: "What would be the impact on premiums if coverage for bariatric surgery was provided in the small group market?"

The Commissioner received complete responses from 13 insurers, all of whom expressed reservations about providing a definitive response to the question in the absence of specific information regarding the specific amount and type of benefits to be provided and the criteria or factors to be used to determine the medical necessity for bariatric surgery services. In addition, they were reluctant to attempt to calculate the possible economic impact on premiums with no reliable data to suggest the number and type of procedures that might be requested by their insureds. The insurers who provided incomplete responses expressed an inability to provide a meaningful or accurate answer to the question posed in the absence of such information. Those insurers who provided complete responses stated that the economic impact on premiums would likely increase dramatically if the demand for costly bariatric surgery procedures and services became significant once coverage was provided.

### Demand

All insurers confirmed that coverage for bariatric surgery is currently not provided in the small group market but is available to large groups and self-funded employers. They indicated they receive very few requests for or inquiries about bariatric surgery from their insureds, which may be due, at least in part, to the general knowledge among insureds that weight loss benefits are generally excluded from coverage. However, the insurers also acknowledged they receive frequent inquiries from their contracting providers regarding the possibility of coverage for bariatric surgery. Under these circumstances it would be difficult to project the level of demand for bariatric surgery services if coverage were made available to small groups.

### Cost of Treatment

The insurers indicated a cost of \$10,000 to \$25,000 for bariatric surgery, depending on the type of procedure performed and associated costs, with a lower cost for procedures such as gastric banding (LAP-BAND) and higher costs for more invasive procedures such as gastric bypass. In data submitted to the Kansas Health Insurance Information System (KHIIS) by all insurers, for calendar years 2002 through 2007, 143 patients received insurance benefits for bariatric surgery during this six year period for total provider charges of approximately \$6.5 million, including surgical fees, anesthesiologist charges and associated hospital fees, and actual benefits paid in the amount of \$2.3 million. The average provider charge per patient was \$45,428 with an average benefit payment of \$16,371. The costs reported in response to the

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Commissioner's survey and the KHIIS cost data do not include any costs related to any subsequent treatment or care required due to complications following bariatric surgery.

A study released by the U.S. Department of Health & Human Services in 2006 reported that four of every 10 obesity surgery patients experience complications within 6 months following surgery, including dumping syndrome, which includes vomiting, reflux, and diarrhea, anastomosis complications (resulting from the joining of the intestine and stomach), such as leaks or strictures, abdominal hernias, infections, and pneumonia. The study reported medical care spending for patients experiencing complications averaged \$36,542, including their initial hospital stay, while spending for patients without complications averaged \$25,337. For patients requiring hospital readmittance due to complications, costs averaged \$65,031.<sup>20</sup>

### **Impact on Premiums**

The 13 insurers who responded estimated an increase in premiums in the range of 1/2% to 8%, for an average of 3.07% for the group. However, as stated above, the insurers indicated that these percentages could prove to be inadequate based on the demand for bariatric surgery services and the incidence of complications and their related costs. These estimates appear to be consistent with the 1% to 3% impacts experienced by the four states that currently mandate coverage for morbid obesity treatment.<sup>20</sup>

## **PART II - KANSAS HEALTH INSURANCE ASSOCIATION (KHIA) (KANSAS HIGH RISK POOL)**

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### **The Kansas Health Insurance Association**

The Kansas Health Insurance Association is a nonprofit legal entity created by the Kansas Legislature pursuant to the Kansas uninsurable health insurance plan act of 1992, K.S.A. 40-2117, *et seq.* Under its plan of operation KHIA provides health care benefits for Kansas residents who are unable to purchase health insurance or obtain coverage for an existing medical condition, who have exhausted their health insurance benefits, who have been quoted insurance rates more than the KHIA rate, or otherwise qualify under the federal Health Insurance Portability and Accountability Act (HIPAA).

As of August 31, 2008 KHIA had 1,907 members in 11 plans, with deductibles ranging from \$500 to \$10,000 per year. KHIA provides comprehensive benefits comparable to those offered in the commercial individual market, including prevention services, inpatient hospital care, maternity, emergency room, mental health/substance abuse, home health care, and prescription drug benefits, with an individual lifetime maximum benefit of \$2,000,000. For plan year 2007 KHIA paid benefits totaling \$18.7 million.

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### Coverage for Bariatric Surgery

Under the standard benefit provisions of the KHIA policy, the "treatment of obesity" is excluded from coverage unless the treatment is determined to be "Medically Necessary" by KHIA's utilization review organization ("URO"). The term "Medically Necessary" is defined in the policy as

a service or supply that:

- (a) is appropriate and consistent with the diagnosis in accordance with generally accepted standards of medical practice as determined by a Utilization Review Organization;
- (b) is not considered Experimental or Investigative;
- (c) could not have been omitted without adversely affecting the Insured person's condition or quality of medical care; and
- (d) is the most appropriate supply or level of service that can be provided on a cost effective basis.

### Utilization Review Organization Determination Process

When a health care provider seeks pre-certification for a bariatric surgery procedure for the KHIA member/patient, such as gastric bypass or gastric banding, the provider is required to submit the following information to the URO for a determination of medical necessity:

- Medical records from the previous six months, relating to the patient evaluation and treatment to date, including diagnostic lab work (must include glucose and thyroid studies). The testing done should have been performed within the previous six months.
- A detailed history that includes co-morbidities.
- A psychosocial/psychiatric evaluation that documents patient understanding of the procedures and needed follow-up care
- The surgical approach and any additional procedures requested, including post-operative needs such as nutritional and psychological support, and weight, exercise and diet monitoring
- Documented current height, weight and BMI
- Six months of documented exercise regimen (including dates and results)
- Six months of physical - dietician monitored diet program (including dates and results)

- 
- Physician verification that patient is a minimum of 100 pounds above the weight indicated by Federal guidelines

In addition to reviewing the information provided above, the URO also considers the following factors in making a determination of medical necessity<sup>20</sup>:

- Patient has a BMI of 40 or greater
- Patient has a BMI of 35 or greater and a clinically serious condition exists (e.g., obesity hypoventilation, sleep apnea, diabetes, hypertension, cardiomyopathy, musculoskeletal dysfunction)
- Patient's failure to lose weight significantly or regaining of weight despite compliance with a multidisciplinary nonsurgical program, including low- or very low-calorie diet, supervised exercise, behavior modification, and support, with possible medication
- No specifically correctable cause for obesity (e.g., an endocrine disorder)
- Full growth
- Patient is receiving treatment in a surgical program experienced in obesity surgery, characterized by surgeons experienced with gastric bypass and a multidisciplinary approach, including all of the following:
  - Preoperative medical consultation and approval
  - Preoperative psychiatric consultation and approval
  - Nutritional, exercise, and psychological counseling

### **Financial Impact**

From January 1, 2005 through September 30, 2008 (almost four plan years), KHIA paid benefits for bariatric surgery, including both gastric bypass and gastric banding (LAP-BAND) for nine members at a total cost of \$95,508.34, for surgical fees, hospital fees, and anesthesia, for an average of \$10,612 per procedure. The range of costs for these nine patients was \$2,897 to \$41,130, with the difference in range attributable to whether the patient underwent the a less expensive procedure, such as lap-banding, or the more invasive gastric bypass procedure and whether the patient had other health conditions which required additional treatment or care at the time of the bariatric procedure. These figures reflect the amount paid after the application of patient deductibles, co-insurance, and the negotiated discount with the provider. The actual amount charged by the providers for these procedures was \$233,095, for an average charge of \$25,899. The range for those charged amounts was \$8,454 to \$114,073. These figures do not reflect any subsequent costs incurred for these patients in the weeks and months following their bariatric surgery due to complications.

KHIA's consulting actuary indicated that given the limited number of bariatric surgery procedures covered by KHIA over the past four plan years, there has been no significant impact on member premiums. However, if the criteria and documentation required to determine medical necessity for these procedures were relaxed or reduced KHIA might be expected to

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experience increased costs, and resulting increases in premiums, due to greater numbers of procedures being approved and performed.

### PART III - REINSURANCE ISSUES

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Information regarding reinsurance coverage for high medical costs experienced by small groups has been previously provided to the Legislature in conjunction with other studies and requests for information.<sup>20</sup> However, the types of reinsurance previously described - prospective (before costs occur) or retrospective (after costs occur) - and the financing of the cost of such reinsurance, either by small group insurers paying for the cost of reinsurance through premiums or assessments or the state paying all or some portion of the cost as a subsidy to the small group insurance market through the use of state general funds, or other taxes could be used to cover the costs for bariatric surgery.

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Kathleen Sebelius, Governor  
Roderick L. Bremby, Secretary

DEPARTMENT OF HEALTH  
AND ENVIRONMENT

[www.kdheks.gov](http://www.kdheks.gov)

Division of Health

**Repeal of the sunset provision in the  
Kansas residential childhood lead poisoning prevention act.  
Senate Bill No.82**

**Presented to the  
Committee on Public Health and Welfare**

**By  
Richard Morrissey, Interim Director  
Division of Health  
Kansas Department of Health and Environment**

**February 2, 2009**

Chairman Barnett and Members of the Committee, my name is Richard Morrissey, I am the Interim Director of the Division of Health at the Kansas Department of Health and Environment. I am here today to testify in support of SB82, which would allow the agency to continue our lead poisoning prevention program.

History:

The negative health effects of lead poisoning are well documented. The passage of the Kansas childhood lead poisoning prevention act in 1999 authorized the KDHE to begin lead poisoning prevention activities at a program level within the division of health. Children in our state continue to be at risk for lead poisoning due to the prevalence of lead based-paint on Kansas homes.

Health Concerns:

Homes built prior to 1978 share a common denominator, the probability of having been painted with lead-based paint, the older the home the greater the probability and the hazard. Census information provides us with proof concerning the risk of lead poisoning in Kansas. Over 70% of the homes in Kansas were built prior to 1978. In some Kansas communities over 90% of the homes were built prior to 1978. The threat of lead poisoning extends to every county, every community and every family in Kansas.

During the past nine years program activities have included public outreach and education, testing of children and adults, compiling data, training a professional lead abatement work force and enforcing regulations so that Kansas is a safer place to live and raise a family.

OFFICE OF THE DIRECTOR OF HEALTH  
CURTIS STATE OFFICE BUILDING, 1000 SW JACKSON ST., STE. 300, TOPEKA, KS 66612-1368

Voice 785-296-1086 Fax 785-7 Public Health and Welfare

Date:

Attachment:

02/02/09

During the lead program's existence we have directly assisted hundreds of Kansas families and lead poisoned children. Over 250,000 blood lead tests on children and more than 60,000 blood lead tests on adults have been performed and monitored in our state. Program efforts are having a positive effect on lowering the mean blood lead level in our state, yet sadly our state's average remains higher than the national average and many Kansas children have never been screened for lead poisoning.

#### Work Force Development:

Our program has assisted over 800 workers who are now skilled in lead abatement techniques and are certified by our program. We have helped over 300 firms statewide become licensed to perform regulated lead activities, and we continually monitor the work practices of more than 9,000 construction, remodeling, and painting firms statewide that work on Kansas homes built prior to 1978.

#### Funding:

All program activities are funded through grants, cooperative agreements, contracts, and fees for service. No state dollars have been expended on this program. Program efforts have delivered nearly \$6 million in grant funding to Kansas that has been used to repair and remediate lead in homes in Wyandotte County. Economic models indicate total economic impact to our state for these activities is over \$11 million. The program continues to apply for this type of funding and is seeking to expand HUD funded work to communities statewide.

#### Challenges Ahead:

New EPA regulations were published in 2008 that will require all contractors in the remodeling, renovation and painting trades to be certified in lead safe work practices by April 2010, so that they can safely maintain older homes. Our program is working to assist Kansas contractors meet the requirements of the new regulations in a manner significantly less costly than the EPA program alternative.

#### Recommendations:

The KDHE lead poisoning prevention program has contributed positively to improving public health and has created economic opportunity for business and workers in Kansas. With your affirmation we will continue this work. We ask that you report Senate Bill 82 favorably for passage. I thank you for the opportunity to appear before the committee today, and will now stand for questions.

Committee on Public Health and Welfare  
Senate Bill 82  
Testimony of Jennifer A. Lowry, MD

Hello. My name is Dr. Jennifer Lowry. I am here to provide testimony as a supporter of the Kansas Department of Health and Environment's Childhood Lead Poisoning and Prevention Program. Currently, I am a pediatrician, toxicologist and clinical pharmacologist at Children's Mercy Hospitals and Clinics in Kansas City, MO. In addition to caring for the children of Kansas at that institution, I also serve Kansas in two additional roles. First, I am the Medical Director to the University of Kansas Hospital Poison Control Center. As you may be aware, the Poison Control Center helps the public and health care professionals in the management of exposures to poisons, whether drugs or environmental exposures. Second, I am the Director to the Pediatric Environmental Health Specialty Unit for EPA Region 7 which is located at Children's Mercy Hospital but serves the states of Iowa, Nebraska, Missouri and Kansas in the diagnosis and treatment of environmental exposures that occur in children. In all three of these capacities, I have developed a strong relationship with the KDHE's Childhood Lead Poisoning and Prevention Team.

There are three objectives of the Healthy People 2010 Program that I have worked with KDHE on to improve the health of Kansas' children. These are stated below:

**(Obj. 8-11):** The proportion of children aged 1 to 5 years who had elevated blood-lead levels decreased from 4.4 percent in 1991–1994 to 1.6 percent in 1999–2004. Among non-Hispanic black children in that age range, the decrease was from 11.2 percent in 1991–1994 to 3.1 percent in 1999–2004. The target is zero percent.

**(Obj. 8-13):** The number of visits to a healthcare facility that results from exposure to pesticides decreased from 22,933 in 1997 to 19,168 in 2004. The target is 11,398.

**(Obj. 8-25):** Within the context of the umbrella objective to reduce exposure to pesticides, heavy metals, and certain environmental chemicals, the progress of several subobjectives was a featured topic of the data presentation. The blood-level concentration of cadmium in the total population aged 1 year and older was 1.30 micrograms per liter ( $\mu\text{g/L}$ ) in 2000–2002 (1.3  $\mu\text{g/L}$  in 1999–2000). The target is 0.9  $\mu\text{g/L}$ . The blood-level concentration of lead in the total population aged 1 year and older decreased from 4.9  $\mu\text{g/L}$  in 1999 to 4.40  $\mu\text{g/L}$  in 2001–2002. The target is 3.4  $\mu\text{g/L}$ . The blood-level concentration of mercury in children aged 1 to 5 years decreased from 2.3  $\mu\text{g/L}$  in 1999–2000 to 1.90  $\mu\text{g/L}$  in 2000–2001. The target is 1.6  $\mu\text{g/L}$ . In females aged 16 to 49 years (i.e., of childbearing age), the blood-level concentration of mercury decreased from 7.1  $\mu\text{g/L}$  in 1999–2000 to 4.60  $\mu\text{g/L}$  in 2000–2001, surpassing the target of 5.0  $\mu\text{g/L}$ . The serum concentration of lindane (beta-HCH) in persons aged 12 years and older decreased from 68.9 nanograms per gram lipid (ng/g lipid) in 1999–2000 to 43.3 ng/g lipid in 2001–2002, which bettered the target of 48.2 ng/g lipid.

As you can read in Obj. 8-11, while we have made progress in regard to childhood lead poisoning over the past 20 years, we have failed to remove the risk to children and do not plan to meet the 2010 objectives listed. Lead is a neurotoxin that is more commonly found in paint and soil. Lead was placed in paint in the early 1900's as a preservative and, thus, allowed the paint to last for years. The manufacture of leaded paint ceased in the late 1970's, but the effects continue to be seen due to the large number of older homes

that still contain this hazard. Young children are at higher risk for the development of lead poisoning due to their curious nature and high hand to mouth activity. Peeling paint from window sills, doors, walls, and porch railings are readily available to the curious child. In addition, the paint is sweet and attractive to children.

The maximum brain growth for a person occurs from birth to 3 years of age when the brain reaches its adult size. However, the brain is not fully formed and connected until the early 20's. As I previously mentioned, lead is a neurotoxin that has no role in the human body. It disrupts cellular mechanisms that can have long standing effects that may become permanent. Unfortunately, the early effects are subtle and may not be known until the lead levels is high and the child's body burden is large. Over time and as the levels increase, the child can develop anemia (levels of 25), kidney problems, IQ deficits (levels of 15), convulsions (levels of 100), encephalopathy (levels of 70) and death. In addition, newer studies suggest that disease such as ADHD, behavioral problems and learning deficits can be seen with levels as low as 5 mcg/dl. And, while the the average lead concentrations across the nation are decreasing, I continue to see children present with elevated blood lead levels above the reportable level of 10 mcg/dl. In fact, the PEHSU was notified of over 100 children in Kansas over the past 5 years with lead levels above 15. Approximately one-third required chelation therapy. All of these children were referred by or involved with the KDHE Lead Program.

As I mentioned, I collaborate with the programs in the 4 state region. I can tell you that Iowa, Nebraska, nor Missouri can meet the gold standard that the State of Kansas provides to the children and their families. The staff of your Childhood Lead Poisoning Program is the most knowledgeable in regard to lead poisoning that have met at the state level. Their nurse case managers are an incredible asset to me, my staff and the families that need their help. While I can aid them in the management of their lead poisoning, I rely on the staff at KDHE to help with the assessment of the home and ensuring that proper management, remediation, and treatment are provided to these families. Without them, I would not be able to ensure the safety of the families of Kansas that are exposed to this poison. Children who require treatment for their elevated blood lead levels cannot be treated in a home that is contaminated, as the treatment can increase the absorption of lead if it continues to be ingested on the medicine. KDHE's Program ensures that home is "clean" and safe for the child to be treated. This saves us time and money as without the "clean" home, the child would require the 19 day treatment occur in a hospital. If a child does require hospitalization for chelation therapy, KDHE can ensure the home is safe the child to be discharged to.

Local health departments are not equipped or as knowledgeable as the program that is currently in place. Often times, I have had to teach the local health departments on what the treatment levels are and what the consequences may be if a home is not properly assessed. In addition, my experience with other State Programs that rely solely on the local health departments is that many children have "fallen through the cracks" and have not had proper follow up to ensure they are not further exposed to lead. Physicians have called me because they don't know what to do with a child with an elevated lead level

and not had guidance from their local health department. In addition, I have had cases in which children have been inappropriately chelated and put at risk for an adverse event.

As you may be aware, Medicaid mandates that all children at ages 1 and 2 receive a blood draw for a lead level. This currently is not done within the state of Kansas to the degree that it should. In addition, the Centers for Disease Control and Prevention (CDC) has mandated for universal testing in high risk areas and universal screening in lower risk areas. In the high risk areas of the State of Kansas, universal testing is not done, including on those children on Medicaid. The Staff of KDHE's Lead Poisoning and Prevention Program help me in this regard by providing education to physicians in Kansas on the need for testing. While the numbers of children that are poisoned by lead is decreased, children remain at risk and are found to have elevated levels. Your staff helps to educate the health care communities.

In addition, the KDHE staff has made a great effort in the prevention of lead poisoning. Their staff works with local and regional do-it-yourself stores in the education of the proper way of remodeling homes. It is because of this effort that I had a family come in for testing. They had started to remodel their home and was offered the booklet by a store employee. Once they read it, they asked their pediatrician for a lead test. It came back mildly elevated on their child and the family moved out of the home temporarily for the home to be cleaned. The lead levels are down and the child is healthy. However, without the education provided to them, this child would have been at higher risk.

While I can provide you with many more examples of the families who have received help from the Program provided by KDHE and the State of Kansas or the families in which lead poisoning was prevented because of the efforts, the end statement will be the same. Lead poisoning will not be eradicated by the year 2010. There continues to be much to do in regard to the education and the management provided to those at highest risk for lead poisoning...our children. The efforts to plan the objectives for Healthy People 2020 are underway. Those that have participated in the progress review of 2010 have agreed that environmental health, community and public health, and individual health are interdependent. It is their, and my, belief that we should reinforce primary prevention with greater efforts to control or eliminate sources of lead in children's environment before they are poisoned. In conjunction with those efforts, we agree that we should seek to overcome some physicians' apparent lack of concern about secondary prevention and resistance to recommended screening, which often develops as the prevalence of lead poisoning in children declines. I cannot do this on my own. I need your help to do this. I need your help to care for the children of Kansas. And, I feel that their best hopes in the prevention, education, and management of lead poisoning and the home environment lies in the continuation of the KDHE Childhood Lead Poisoning and Prevention Program.

Thank you.



*Kathleen Sebelius, Governor  
Roderick L. Bremby, Secretary*

DEPARTMENT OF HEALTH  
AND ENVIRONMENT

[www.kdheks.gov](http://www.kdheks.gov)

**Testimony on Senate Bill 102  
AED Legislation**

**Presented to  
Committee on Public Health and Welfare**

**By  
Richard Morrissey, Interim Director of Health  
Kansas Department of Health and Environment**

**Presentation Date  
February 2, 2009  
Room 136-N**

Chairman Barnett and members of the Committee on Public Health and Welfare, I am Richard Morrissey, Interim Director of Health at the Kansas Department of Health and Environment. I am pleased to present testimony today in support of SB102, which amends current legislation to provide immunity to any person who renders emergency care or treatment using an automated external defibrillator or AED. The current statute (65-6149a) provides immunity only for those deemed "qualified persons". Therefore, the purpose of this bill is to extend the protection to lay responders.

In the first minutes after collapse, many victims of cardiac arrest demonstrate an abnormal heart rhythm called ventricular fibrillation (VF), which causes the heart to quiver so that it does not pump blood effectively. Treatment of VF requires delivery of a shock with a defibrillator allowing the victim's normal heart rhythm to resume.

According to the American Heart Association, approximately 250,000 deaths are caused by coronary artery disease in the out-of-hospital setting annually in the United States and that at least 20,000 lives could be saved annually by use of AEDs. We know that the key to survival is timely initiation of a "chain of survival", which includes activating of 9-1-1; initiating CPR; early defibrillation

using an AED and early access to medical care. Because of recent technological advances, an AED has recently become an important medical tool and has been designed so that non-medical personnel can use one very easily.

The machine is highly accurate and user-friendly with voice and audio prompts that guide the user through the steps of operation. The rescuer turns the AED on and attaches it to the victim using adhesive electrode pads which then record and analyze the victim's cardiac rhythm. If a shock is indicated, the AED charges to the appropriate energy level and "tells" the rescuer to deliver a shock. If the device does not detect VF no shock will be delivered. If the device is fully automated and a shock is indicated, the AED can deliver a shock without further action by the rescuer. AEDs require little maintenance and are relatively inexpensive costing below \$2000.00.

This legislation would potentially reduce deaths from sudden cardiac arrest by increasing the likelihood that immediate CPR and defibrillation will be provided within 3 to 5 minutes of the victim's collapse. The protection from liability provided by this bill is expected to result in more AEDs being placed in public places, including workplaces where lay rescuers would be more inclined to use them, knowing they have immunity from liability. Because of the automated nature of operation, use by lay responders is considered quite safe.

Thank you for your consideration of this important public health issue. A vote for SB102 is your chance at saving a life in your district. I will be pleased to stand for questions.

February 2, 2009

TO: Senate Committee on Public Health & Welfare

FROM: Harold Swedlund  
Chairman of the Kansas Advocacy Committee  
For the American Heart Association

RE: Testimony on SB 102—concerning emergency medical services; relating to use of auto-  
mated external defibrillator

Mr. Chairman and members of the Committee:

Thank you for allowing me to testify on this important proposal. My name is Harold Swedlund and I am a volunteer for the American Heart Association.

Cardiovascular disease is the leading cause of death for adults in the United States, including Kansas. The American Heart Association (AHA) estimates that sudden cardiac arrest is responsible for about 250,000 out-of-hospital deaths annually.

Since the 1990's the AHA has called for innovative approaches to reduce time to cardiopulmonary resuscitation (CPR) and automated external defibrillators (AEDs) and improve survival from sudden cardiac arrest. The AED has become an important tool to treat a person in cardiac arrest. The AED device guides the user through the process by audible or visual prompts without requiring any discretion or judgment. As of 2001, all fifty states have enacted defibrillator laws or adopted regulations.

What SB 102 would allow is a "Good Samaritan" exemption from liability for any individual who renders emergency treatment with an AED. Why we support SB 102 and feel it necessary is to increase the survival rate of victims of witnessed sudden cardiac arrest or ventricular fibrillation, which causes the heart to quiver so that it does not pump blood effectively.

AEDs are highly accurate, user-friendly computerized devices with voice and audio prompts that guide the user through the critical steps of operation. AEDs were designed for use by lay rescuers to reduce time to defibrillation for victims of VF sudden cardiac arrest. The rescuer attaches the AED to the victim with adhesive electrodes or pads. If the device is fully automated and a shock is indicated, the AED can deliver a shock without further action by the rescuer.

For every minute of delay between collapse and defibrillation, the victim's chance of survival from VF sudden cardiac arrest falls by 7 to 10%. Survival-to-hospital discharge rates of 49% - 75% have been reported in places when a victim of a witness VF sudden cardiac arrest receives immediate bystander CPR and AED shock delivery within 3 to 5 minutes of collapse.

We would respectfully ask for your favorable consideration of SB 102. Thank you.

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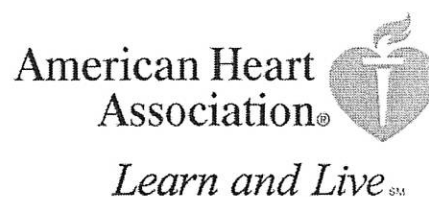
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# Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION



**Community Lay Rescuer Automated External Defibrillation Programs. Key State Legislative Components and Implementation Strategies. A Summary of a Decade of Experience for Healthcare Providers, Policymakers, Legislators, Employers, and Community Leaders From the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy**

Tom Aufderheide, Mary Fran Hazinski, Graham Nichol, Suzanne Smith Steffens, Andrew Buroker, Robin McCune, Edward Stapleton, Vinay Nadkarni, Jerry Potts, Raymond R. Ramirez, Brian Eigel, Andrew Epstein, Michael Sayre, Henry Halperin and Richard O. Cummins

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## Community Lay Rescuer Automated External Defibrillation Programs

### Key State Legislative Components and Implementation Strategies

### A Summary of a Decade of Experience for Healthcare Providers, Policymakers, Legislators, Employers, and Community Leaders From the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy

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Brian Eigel, PhD; Andrew Epstein, MD, FAHA; Michael Sayre, MD;  
Henry Halperin, MD, FAHA; Richard O. Cummins, MD, MPH, MSc

**Abstract**— Cardiovascular disease is a leading cause of death for adults  $\geq 40$  years of age. The American Heart Association (AHA) estimates that sudden cardiac arrest is responsible for about 250 000 out-of-hospital deaths annually in the United States. Since the early 1990s, the AHA has called for innovative approaches to reduce time to cardiopulmonary resuscitation (CPR) and defibrillation and improve survival from sudden cardiac arrest. In the mid-1990s, the AHA launched a public health initiative to promote early CPR and early use of automated external defibrillators (AEDs) by trained lay responders in community (lay rescuer) AED programs. Between 1995 and 2000, all 50 states passed laws and regulations concerning lay rescuer AED programs. In addition, the Cardiac Arrest Survival Act (CASA, Public Law 106-505) was passed and signed into federal law in 2000. The variations in state and federal legislation and regulations have complicated efforts to promote lay rescuer AED programs and in some cases have created impediments to such programs. Since 2000, most states have reexamined lay rescuer AED statutes, and many have passed legislation to remove impediments and encourage the development of lay rescuer AED programs. The purpose of this statement is to help policymakers develop new legislation or revise existing legislation to remove barriers to effective community lay rescuer AED programs. Important areas that should be considered in state legislation and regulations are highlighted, and sample legislation sections are included. Potential sources of controversy and the rationale for proposed legislative components are noted. This statement will not address legislation to support home AED programs. Such recommendations may be made after the conclusion of a large study of home AED use. (*Circulation*. 2006;113:0000-0000.)

**Key Words:** AHA Scientific Statements ■ fibrillation ■ defibrillation ■ resuscitation ■ sudden cardiac arrest

Cardiovascular disease is a leading cause of death for adults  $\geq 40$  years of age.<sup>1,2</sup> The American Heart Association (AHA) estimates that sudden cardiac arrest is responsible for  $\approx 250\,000$  out-of-hospital deaths annually in the United States.<sup>3</sup> Since the early 1990s, the AHA has called for innovative approaches to reduce time to cardiopulmonary

resuscitation (CPR) and defibrillation and improve outcome from sudden cardiac arrest.<sup>4</sup> In the mid-1990s, the AHA launched a public health initiative to promote early CPR and early use of automated external defibrillators (AEDs) by trained lay responders in community public access defibrillation (PAD) programs.<sup>5-7</sup> In 1998, in response to requests

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from its training network, the AHA circulated an internal report to assist in developing legislation that would remove barriers to these programs.<sup>8</sup>

Between 1995 and 2000, all 50 states passed laws and regulations governing lay rescuer AED programs. In 2000, the Cardiac Arrest Survival Act (CASA) was passed and signed into federal law (Public Law 106-505). CASA called for the development of guidelines for establishing AED programs in federal buildings. CASA provides limited immunity from civil liability for the emergency AED user and the AED acquirer if the state has not otherwise granted immunity for such persons under other statutes. Since 2000, most states have reexamined lay rescuer AED statutes, and many have passed legislation giving grants to local governments to obtain AEDs and to require AEDs or AED programs in certain venues (eg, state buildings, health clubs).

The AHA applauds state and federal policymakers and advocates across the country for enacting lifesaving legislation to promote lay rescuer AED programs. After a decade of experience, the AHA has collected information about policies, legislation, and regulations and their impact on the establishment and success of community lay rescuer AED programs.

The purpose of this policy statement is to help policymakers develop new legislation or revise existing legislation to remove barriers to effective community lay rescuer AED programs. Important areas that should be considered in state legislation and regulations are highlighted, and examples of model legislation are included. Potential sources of controversy and the rationale for proposed legislative components are noted. This statement will not address legislation to support home AED programs. Such recommendations may be made after the conclusion of a large study of home AED use.

### Background

As noted above, the AHA estimates that ~250 000 deaths are caused by coronary artery disease in the out-of-hospital setting annually in the United States.<sup>3</sup> This number is commonly accepted as a surrogate for the number of sudden cardiac arrests that occur in the out-of-hospital setting annually. The median published rate of survival to hospital discharge for witnessed sudden cardiac arrest in the United States is 6.4%.<sup>9-11</sup>

In the first minutes after collapse, many victims of witnessed sudden cardiac arrest demonstrate an abnormal heart rhythm called ventricular fibrillation (VF), which causes the heart to quiver so that it does not pump blood effectively.<sup>12</sup> Treatment of VF requires delivery of a shock with a defibrillator. Delivery of a shock can stop VF (defibrillation), allowing the victim's normal heart rhythm to resume. The victim needs CPR to maintain blood flow to the heart and brain until a defibrillator is available and often requires CPR in the first minutes *after* defibrillation until the heart is able to pump blood effectively.<sup>13,14</sup> CPR is important both before<sup>15</sup> and after<sup>16</sup> defibrillation for improving survival from VF sudden cardiac arrest. Even a brief interruption of chest compression can be detrimental.<sup>17</sup>

AEDs are highly accurate, user-friendly computerized devices with voice and audio prompts that guide the user

through the critical steps of operation. AEDs were designed for use by lay rescuers and first responders to reduce time to defibrillation for victims of VF sudden cardiac arrest.<sup>18</sup> The rescuer turns the AED on and attaches it to the victim with adhesive electrodes or pads. The AED records and analyzes the victim's cardiac rhythm. If a shock is indicated, the AED charges to the appropriate energy level and prompts the rescuer to deliver a shock. If the device is fully automated and a shock is indicated, the AED can deliver a shock without further action by the rescuer. AEDs require little maintenance and are relatively inexpensive (<\$2000).

As of August 8, 2005, the US Food and Drug Administration (FDA) classified AEDs as Class 3 medical devices, with most requiring a prescription. This means that AEDs require "special controls" to ensure their safety and effectiveness. One goal of the prescription requirement is to ensure that AEDs are used in organized programs with appropriate planning and oversight, appropriate training of anticipated rescuers, and appropriate monitoring of the quality of care associated with use of these devices. Although the AHA strongly supports these program elements, it could find no published evidence that the prescription requirement itself increased the likelihood of rescuer training or effective AED use. In 2004, the FDA cleared the labeling of one commercially available AED without a prescription. It is anticipated that similar labeling will be cleared for more AEDs in the near future. Such labeling may make AEDs available for home use. At this time there is insufficient evidence for the AHA Emergency Cardiovascular Care (ECC) Committee to make recommendations about home AED programs.

Successful lay rescuer AED programs should increase the survival rate of victims of witnessed VF sudden cardiac arrest. Two factors have a significant impact on adult survival from VF sudden cardiac arrest: the time from collapse to defibrillation and the time from collapse to CPR. If no CPR is provided, for every minute of delay between collapse and defibrillation, the victim's chance of survival from VF sudden cardiac arrest falls by 7% to 10%.<sup>19,20</sup> If bystander CPR begins immediately after collapse, the fall in survival is more gradual, decreasing ~3% to 4% for every minute between collapse and defibrillation.<sup>19,20</sup> Survival-to-hospital discharge rates of 49% to 74% have been reported in airports,<sup>21</sup> commercial airlines,<sup>22,23</sup> casinos,<sup>24</sup> and community police AED programs<sup>16,25-28</sup> when a victim of witnessed VF sudden cardiac arrest receives immediate bystander CPR and shock delivery within 3 to 5 minutes of collapse. Bystander CPR can double<sup>19,20</sup> or triple<sup>29</sup> survival rates at many intervals to defibrillation. AED programs that fail to shorten time to defibrillation and time to bystander CPR have not documented any improvement in survival rates.<sup>30</sup>

In 2000, to determine the effectiveness of community lay rescuer AED programs on survival from out-of-hospital sudden cardiac arrest in a large prospective study, the AHA joined the National Heart, Lung, and Blood Institute (NHLBI) and others to fund a randomized controlled trial of community lay rescuer AED programs. In this study, the Public Access Defibrillation (PAD) trial,<sup>31</sup> nearly 20 000 rescuers were trained in 993 facilities in 24 urban and suburban regions in North America. The trial reported the

outcome of attempted resuscitation in 239 episodes of out-of-hospital sudden cardiac arrest. In this study, all lay rescuers in all study units were trained to recognize emergencies, phone 9-1-1, and provide CPR. Lay rescuers in half of the study sites were also trained and equipped to use AEDs. Fifteen victims of VF sudden cardiac arrest treated in lay rescuer CPR programs without AEDs survived to hospital discharge. During the same period, 30 victims of VF sudden cardiac arrest who were treated in programs that also included early defibrillation with AEDs survived to hospital discharge.<sup>31</sup> The differences between the programs were statistically significant and supported the authors' conclusion that promotion of organized lay rescuer AED programs could save thousands of lives in the United States every year.

Grassroots support for community lay rescuer AED programs has been strong, but placement of AEDs and their use by lay rescuers have raised concerns about legal liability for rescuers, owners of the premises on which AEDs are placed, buyers of AEDs, physician prescribers (if appropriate) of AEDs, public defibrillation program directors, and persons responsible for rescuer training. These nonrescuer program participants are referred to as "facilitators" in this statement.

Questions also have been raised about the amount of training and support required to establish the programs. In the PAD trial, even when extensive initial training was provided to anticipated rescuers, bystander CPR was performed for only  $\approx 65\%$  of the victims of sudden cardiac arrest, and AEDs delivered shocks to only 34% of victims at sites where rescuers were trained and equipped to use AEDs.<sup>31</sup> These results show that even in a well-designed lay rescuer AED program, training in CPR as well as AED use is needed.

Successful community lay rescuer programs require attention to planning as well as training. For example, AEDs must be placed in conspicuous locations, and rescuers must rehearse early recognition of an emergency, early call to the emergency medical services (EMS) system, early CPR, and early defibrillation. The program must be linked with the EMS system and must have a plan for retraining and ongoing quality improvement.

### Legislative Efforts to Support Community Lay Rescuer AED Programs

As noted above, all states have legislation or regulations to facilitate lay rescuer AED programs, but these laws and regulations and their components vary widely from state to state. A complete list of existing state legislation and regulations is available at the AHA Web site ([www.americanheart.org/statepolicy](http://www.americanheart.org/statepolicy)).

The passage of CASA in 2000 played an important role in triggering the acceptance of AEDs as lifesaving devices and setting the standards for immunity protection for AED use. As noted above, CASA provides limited immunity for rescuers and, under some conditions, for those who acquire AEDs. CASA "supersedes the law of the state" if the state "has no statute or regulations to provide persons in such class with immunity from civil liability for . . . [the use] . . . of automated external defibrillator devices in emergency situations." At the time CASA was enacted, it filled the gap in liability protection for AED acquirers in  $\approx 12$  states.

### Essential Elements of Community AED Programs

The AHA has identified 4 essential elements of AED programs.<sup>32,33</sup> These elements have been ratified by experts of the AHA ECC Committee as important for increasing survival from witnessed prehospital VF sudden cardiac arrest. These program elements are briefly described below, and they are further explained in the subsequent discussion of key legislation elements.

1. **Planned and practiced response.** The AHA recommends planning and oversight of community lay rescuer AED programs by a person with experience and expertise in resuscitation programs. Such a person is typically a health-care professional with experience in occupational health, emergency, or cardiovascular care. The program director decides on the number and location of AEDs placed. AEDs should be placed where there is a high likelihood of sudden cardiac arrest. In the PAD trial, such locations had the equivalent of  $\geq 250$  adults  $> 50$  years of age present for 16 hours per day or a history of an average of  $\geq 1$  witnessed sudden cardiac arrest every 2 years.<sup>31</sup> The local EMS agency may provide useful information on placement of AEDs (see below). When possible, AEDs should be placed where they can be reached within a short (1 to 1½ min) brisk walk from all areas in the program site. The program director helps to decide whether AEDs should be placed in a highly visible location to facilitate their use by bystanders who are not part of the organized response plan. The program director also oversees the training and retraining of anticipated rescuers, confirms that devices are properly maintained, develops a mechanism to report AED use, establishes a link to the local EMS service, evaluates AED use, and supports a process of quality improvement.
2. **Training of anticipated rescuers in CPR and use of the AED.** This element does not require training of every potential rescuer but does require the training of anticipated rescuers. Thus, rescuers who are likely to be present should be trained, but the site should not be expected to train every person who could possibly be present. The goal is to ensure that a trained rescuer is present at all times (eg, during business hours). In training, high priority should be placed on recognizing the emergency; phoning 9-1-1; providing CPR and early defibrillation; and using an AED in a safe, appropriate, and effective manner. CPR training should stress that rescuers must deliver effective chest compressions with minimal interruption.<sup>33</sup> Training should include practice in response to a simulated arrest at regular intervals so that responders are familiar with their roles in the resuscitation effort.
3. **Link to the local EMS system.** At a minimum, the program director should inform the local EMS dispatcher that an AED program has been established and give the type and location of AED(s) on site. The AED program must develop a reporting procedure with the EMS system to share patient information. The EMS system also may be able to give information about public locations where sudden cardiac arrest has occurred or provide personnel or other resources to help establish the program and the process of ongoing quality improvement (see below). Each community must decide on the best course of action for its members.
4. **A process of continuous quality improvement, including a plan for on-site AED maintenance and readiness-**

for-use checks. Quality improvement protocols should be used to evaluate the program response to any cardiac arrest. The *Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care* recommended that programs establish a goal of  $\leq 90$  seconds from arrival of the AED at the victim's side to delivery of the first shock.<sup>32</sup> Program directors and participants must identify and eliminate factors that cause delay in CPR or delivery of the first shock with the AED. In airports<sup>21</sup> and casinos,<sup>24</sup> high rates of survival to hospital discharge after witnessed VF arrest have been documented when immediate CPR was provided and defibrillation occurred within 3 to 5 minutes of the victim's collapse. In the casino study, the rate of survival from witnessed VF sudden cardiac arrest was 74% when the first shock was delivered within 3 minutes but fell to 49% when the first shock was delivered between 3 and 5 minutes after collapse.<sup>24</sup> In the airport study,<sup>21</sup> the rate of survival from witnessed VF sudden cardiac arrest was 74%; all victims received bystander CPR, and a shock was delivered within 5 minutes of collapse. In that study, AEDs were located within a brisk 1-minute walk from any location.

Additional information on AED program implementation is available at <http://www.americanheart.org/presenter.html?identifier=3027304>.

### Recommended State AED Legislation

In general, advocates for AED legislation will need to adapt legislation for each state, but all AED legislation should be broad enough to be "permissive" or "facilitating." The AHA has a policy Web site ([www.americanheart.org/statepolicy](http://www.americanheart.org/statepolicy)) to assist policymakers in developing legislation tailored to their state's needs.

The legislation typically begins with a preamble to document the need for the legislation and its potential benefits. Specific sections within the legislation should recommend important program components without "micromanaging" implementation. The AHA recommends addressing these 4 key components in AED legislation:

1. Good Samaritan limited immunity (without qualification) for rescuers and program facilitators
2. CPR and AED training for anticipated rescuers
3. Link with the EMS system
4. Support of the following program elements to increase the likelihood of successful resuscitation of victims of sudden cardiac arrest:
  - a. Planned and practiced response
  - b. Plan for training of anticipated rescuers in CPR and use of an AED
  - c. Plan for link with EMS system
  - d. Plan for ongoing process of quality improvement, including evaluation of each episode of sudden cardiac arrest, on-site maintenance, and readiness-for-use checks

### State AED Legislation Preamble

Simple yet powerful statistics support this type of AED legislation. First, the legislation should note the approximate number of state deaths from sudden cardiac arrest. The number of state deaths can be found in state reports, or

**TABLE 1. Preamble for State Legislation Supporting Community Lay Rescuer Automated External Defibrillation Programs**

- Whereas out-of-hospital sudden cardiac arrest results in the death of approximately 55 persons/100 000 population per year and approximately 20% of these arrests are caused by sudden ventricular fibrillation that occurs in the presence of witnesses (so-called "witnessed ventricular fibrillation sudden cardiac arrest"), and
- Whereas, in the population of (state), approximately (state population\* divided by 1818) citizens will die of cardiac arrest every year, and
- Whereas lay rescuer programs that provide early recognition, early cardiopulmonary resuscitation, and early defibrillation within the first minutes of a cardiac arrest can increase survival of victims of witnessed ventricular fibrillation sudden cardiac arrest by 7 times or more and so should save an estimated (the state population\* divided by 27 750) or more additional victims of sudden cardiac arrest every year in this state, and
- Whereas automated external defibrillators are extremely accurate computerized devices that can be operated by laypersons with minimal training, and
- Now, therefore, be it enacted by the \_\_\_\_ of the State of \_\_\_\_, etc.

Note: This increase in survival rate is derived from the estimated frequency of sudden cardiac arrest in the population (55/100 000 population per year) and predicted improvement in survival of witnessed VF sudden cardiac arrest with activation of a community lay rescuer AED program. An estimated 20% of all episodes of sudden cardiac arrest are witnessed VF arrests (most in public places). The estimated increase in survival is conservatively calculated as an increase from  $\approx 6\%$  survival of victims of witnessed VF sudden cardiac arrest with delayed CPR and defibrillation to survival of  $\geq 40\%$  of victims of witnessed VF sudden cardiac arrest with prompt recognition, early CPR, and early defibrillation. Therefore, of the 11 people who die of witnessed VF sudden cardiac arrest per year per 100 000 population,  $\geq 40\%$  (4.4 per 100 000 per year) would be expected to survive with establishment of community lay rescuer AED programs.

advocates can use the population of the state to estimate this number (see Table 1). The estimated incidence of sudden cardiac arrest reported in the United States is 0.55 per 1000 (55 per 100 000).<sup>1,2,31,34,35</sup>

### Key Components in Legislation to Facilitate Successful Community Lay Rescuer AED Programs

#### *Good Samaritan Limited Immunity for Rescuers and Program Facilitators*

#### *Key: Good Samaritan Limited Immunity for Rescuers*

A major impediment to lay rescuer use of AEDs is the failure to provide Good Samaritan limited immunity to lay rescuers who use AEDs in emergencies. Good Samaritan legislation is intended to protect rescuers from civil liability as long as the rescuer provides reasonable and prudent care in good faith. The AHA recommends that state legislation extend Good Samaritan limited immunity to any AED user, without conditions such as a requirement for training. Good Samaritan limited immunity should extend to anyone who acts in good faith, without specific compensation, as a reasonable and prudent person with the same level of training would respond. Although training of anticipated rescuers is recommended, Good Samaritan limited immunity should cover serendipitous or unexpected users who act in good faith.

Many states have removed an important impediment to the establishment of community lay rescuer AED programs by

**TABLE 2. Sample Wording of Legislation to Address Good Samaritan Limited Immunity for AED Users**

| Wording That May Create an Impediment<br>(Not Recommended)*   | Wording That May Facilitate Legislation (Recommended)†  |
|---|---|
| <p>"Any person who has attended and successfully completed a course in cardiopulmonary resuscitation that has been approved by the State Board of Health, who in good faith and without compensation, renders or administers emergency cardiopulmonary resuscitation, cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator . . . shall not be liable."</p> | <p>"Any person who in good faith and without compensation renders or administers emergency cardiopulmonary resuscitation, cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator . . . shall not be liable."</p> |

\*From House Bill 2097, General Assembly of Virginia, 1999 (amended in 2003). The 1999 legislation was amended because it required training as a condition for Good Samaritan limited immunity. This created an expectation for serendipitous rescuers that is more stringent than for any other Good Samaritan acts.

†From House Bill 1860, General Assembly of Virginia, 2003.

extending Good Samaritan limited immunity to lay rescuers who use the AED as part of gratuitous service in an emergency. CASA also provides limited immunity for lay rescuers in federal buildings. Some states, however, have added conditions to the limited immunity provision for lay rescuers, even when rescuers operate as Good Samaritans. Such conditions can create impediments to establishment of community AED programs (see Table 2).

As noted above, Good Samaritan laws typically require that emergency care be rendered gratuitously, or they differentiate Good Samaritan care from that delivered by health-care professionals in the context of employment. Responders such as police officers and firefighters who are required to provide CPR and use AEDs in the course of their duties still can be considered Good Samaritans if they are not specifically paid for the attempted resuscitation itself. For example, the Good Samaritan statute may state, "For purposes of this section, the term 'compensation' shall not be construed to include the salaries of police, fire, or other public officials or personnel who render such emergency service." These potential rescuers are typically paid the same salary whether or not they are called on to render aid on a given day: They receive no specific compensation for the emergency response or rescue, so their response is considered gratuitous.

Corporations may attempt to maintain Good Samaritan status for their employees who are AED rescuers by requesting that employees volunteer for resuscitation training and rescue "duty" and be trained and equipped to provide CPR and use an AED. Whether this approach is helpful for a specific entity must be assessed on the basis of local laws and after consultation with competent counsel and risk-management professionals.

Some corporations have added insurance riders to existing policies to cover AED use by their personnel. The Las Vegas gaming casinos, for example, took this approach to their AED program, in which security officers were trained in AED use.<sup>24</sup> The purchase of insurance riders for lay rescuers is not the norm, however.

In recent years, some insurance carriers have advised policyholders that placement of AEDs on a property is covered under a general liability plan. In fact, some insurance companies offer resources to encourage the development of community lay rescuer AED programs. For example, some insurers offer grants for the purchase of AEDs.<sup>36</sup>

In some states, opposition to broadening of the Good Samaritan legislation raises the concern that actions beyond

ordinary and simple negligence (ie, *gross negligence, willful or wanton behavior, flagrant indifference to safety, intent to harm*, and other standards set out by specific states) will be protected by such amendments to the Good Samaritan legislation. However, Good Samaritan *limited* immunity means that immunity is limited to simple negligence.

The definition of misuse of the AED that constitutes an action beyond simple negligence will need to be determined by the courts. Risk of negligent use of an AED is reduced by recommended program components, such as approved training of designated or likely (anticipated) rescuers in CPR and use of the AED, course supervision, and skills review—a classic risk-management approach. A standard, broad-based Internet search and a search by legal search services for reported cases<sup>37</sup> and news stories about allegations of or awards for negligent use of AEDs did not reveal any such claims at the time this statement went to press. Although these search techniques have inherent limitations, we are unaware at this time of any claims alleging negligent use of AEDs. This information is not intended to provide legal advice or endorsements of any specific services. A lawyer should be consulted about the application of this information to particular situations.

*Recommended: Good Samaritan Limited Immunity for AED Program Facilitators*

Another impediment to development and implementation of AED programs has been the lack of limited immunity from legal action for several groups involved in AED programs. These groups include premises owners, AED acquirers, program directors, and trainers; these are referred to collectively as program facilitators.

*Limited Immunity for Premises Owners and AED Acquirers.* Major insurance carriers now routinely provide liability insurance without additional charge for sites or buildings where AEDs are placed. Some insurers offer discounts in liability insurance premiums when AED programs are established, and some insurance carriers have developed educational materials to support the establishment of community lay rescuer AED programs. Although premises owners may fear liability resulting from the use of an AED, such liability is likely to be very limited. We are aware of no lawsuits filed against lay rescuers or premises owners related to the attempted use of an AED in a Good Samaritan effort to save the life of a victim of prehospital cardiac arrest. The only lawsuits identified<sup>37</sup> cited failure to have AEDs on the premises. As

**TABLE 3. Sample Wording of Legislation to Address Good Samaritan Limited Immunity for AED Owners/Acquirers**

Example of Recommended Wording for Facilitating Legislation

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Section 1. Article 1B of Chapter 90 of the General Statutes is amended by adding a new section to read:

§ 90–21.15. Emergency treatment using automated external defibrillator; immunity.

(a) It is the intent of the General Assembly that, when used in accordance with this section, an automated external defibrillator may be used during an emergency for the purpose of attempting to save the life of another person who is in or who appears to be in cardiac arrest. . . (d) . . . the person responsible for the site where the automated external defibrillator is located when the person has provided for a program of training. . . shall be immune from civil liability arising from the use of an automated external defibrillator.

Modified from Senate Bill 1269, North Carolina General Assembly, 2000.

noted above, CASA provides limited immunity for the AED acquirer if not already provided or specified under state legislation. The AED acquirer can be a tenant or property manager of a building owned by another entity. In such cases, although the manager may have limited immunity, the building owner may not. CASA limited immunity may not apply if harm to the victim arises from one of the following:

- Failure to establish a link with the local EMS system
- Failure to properly maintain the AED
- Failure to train expected responders in the use of the AED

Ideally, state legislation will extend Good Samaritan limited immunity to premises owners (see Table 3) and the AED owner/acquirer, even in the event of the failures listed above.

*Limited Immunity for Physician Prescribers and Facilitators.* In recent years, the price of malpractice coverage for AED program prescription and oversight has fallen. If this trend continues, it is anticipated that there will be no additional cost of medical malpractice insurance for physicians who prescribe AEDs. In addition, if the FDA clears more AEDs for use without a prescription, the prescription requirement may gradually be eliminated. As noted above, the AED program is most likely to improve survival from witnessed VF sudden cardiac arrest if the program includes a planned and practiced response, appropriate training and equipment, a link with the local EMS system, and a process of ongoing quality improvement. Whether or not a prescription is required, it is helpful if a healthcare provider or resuscitation expert oversees the planning and implementation of the program, including training, monitoring of quality

**TABLE 4. Sample Wording of Legislation to Address Limited Immunity for Physician Facilitators and Program Directors**

Example of Recommended Wording to Address Limited Immunity for Physician Facilitators and Program Directors

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"Immunity from civil liability will be provided to:

(3) Any physician or other medical professional who authorizes, directs, or supervises the installation or provision of automated external defibrillator equipment in or on any premises or conveyance other than a medical facility."

Modified from Senate Bill 51, Georgia House of Representatives, 2001; GA Code 51–1-29.3.

**TABLE 5. Sample Wording of Legislation to Address Limited Immunity for Trainers of Anticipated AED Rescuers**

Example of Recommended Wording to Address Limited Immunity for Trainers

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"No person or entity which teaches or provides a training program for cardiopulmonary resuscitation that includes training in the use of automated external defibrillators shall be held liable for any civil damages as a result of such training or use if such person or entity has provided such training in a manner consistent with the usual and customary standards for the providing of such training."

Modified from Senate Bill 132, Kansas State Legislature, 2003; K.S.A. 65–6149a.

improvement, device maintenance, and link to the EMS system. If limited immunity is provided to physician facilitators (eg, prescribers where applicable) or program directors, the wording may follow that in Table 4.

*Limited Immunity for Trainers.* Trainers of anticipated AED program rescuers have not been granted limited immunity in most states, and they are not mentioned in CASA. When state legislation provides Good Samaritan limited immunity for trainers, the immunity typically specifies that the trainer must deliver training in accordance with the guidelines and policies of an approved or national training organization and the trainer must be authorized to deliver that course or curriculum (see Table 5).

**Key: CPR and AED Training for Anticipated Lay Rescuers**

Although limited immunity for lay rescuers should not be contingent on training, the AHA strongly recommends that AED programs ensure the training of anticipated rescuers in CPR and use of AEDs. This training should include early recognition of signs of cardiac arrest; indications for phoning 9-1-1; and training in rescue breathing, chest compressions, and safe and efficient use of an AED. These rescuer actions are time critical and require not only initial training but frequent retraining to maintain effective responses. Many community lay rescuer AED programs have documented the link between prompt rescuer actions (recognition of the emergency, early CPR, and shock delivery within 3 to 5 minutes) and survival from VF sudden cardiac arrest.<sup>16,21,24,26,28,30,38</sup>

Although AEDs are user friendly and the steps in their operation are often intuitively obvious, the effectiveness of an AED for cardiac arrest requires more than simple operation. The rescuer must know when to use an AED (ie, recognize cardiac arrest), how to operate it, how to troubleshoot it (eg, a hairy or sweaty chest may prevent good contact between the skin and electrode pads), and how to combine AED use with CPR.

CPR remains a critical component of a successful AED program for several reasons. First, the rescuer must recognize sudden cardiac arrest (ie, the victim is unresponsive and not breathing). Because immediate bystander CPR improves survival from VF sudden cardiac arrest,<sup>15,19,20,29,39</sup> the rescuer also should be able to perform CPR until the AED is available and after a shock ends VF. In a prospective analysis of VF waveform during resuscitation of victims of VF cardiac

arrest, predicted survival from VF was increased when the interval between interruption of chest compressions and delivery of the shock was kept to  $\leq 15$  seconds.<sup>17</sup> The efficient integration of CPR with AED use requires training and frequent practice. In addition, improvements in AED rhythm recognition and function are needed to minimize the time required for the AED to analyze the victim's rhythm, recommend shock delivery, charge, and deliver a shock. Such improvements will reduce interruptions in chest compressions. Additional improvements may also include the ability of AEDs to perform analysis with CPR in progress.

Recent studies have also shown that both prehospital<sup>40</sup> and in-hospital<sup>41</sup> healthcare providers deliver compressions of insufficient depth and interrupt compressions too often during CPR. Such reports support the need for stringent CPR training and frequent practice to ensure that rescuers can deliver compressions of correct depth and can minimize interruptions of chest compressions during CPR.

It is important to note that few victims with VF cardiac arrest demonstrate an organized rhythm at 60 seconds after elimination of VF by shock.<sup>13,42</sup> Many demonstrate pulseless electrical activity in the first minutes after successful defibrillation.<sup>14,42</sup> The victim of VF cardiac arrest requires CPR until the heart is able to pump blood effectively.

For all of these reasons, anticipated rescuers should be trained in a course that integrates CPR and use of the AED. It is important to include the recommendation for training and frequent retraining of anticipated rescuers in community lay rescuer AED legislation.

#### **Key: Link With EMS System**

The director of a community lay rescuer AED program should inform the EMS system that an AED is on site. State EMS lead agencies request this notification, and it should be listed as an expectation: The owner "shall" notify rather than "is requested to" or "is encouraged to" in state AED legislation.

Notification of the EMS system is helpful for several reasons. The EMS agency can serve as the interface between the AED program and the public service answering agency. If the dispatcher knows the type and location of an AED at the site of the emergency, the dispatcher can direct the rescuer to get the AED and can coach the rescuer in both CPR and AED use. If the EMS agency wants to be more involved, the agency may help train expected AED users and may play an important role in the continuous quality improvement process of the program. Finally, EMS notification is important because EMS providers will need to obtain data from any AED used to treat cardiac arrest.

Some states have legislated the establishment of an AED "registry," requiring that AED programs be registered with the local EMS agency. The purpose of such registries is to ensure that EMS dispatchers know where AEDs are placed so that they can direct a 9-1-1 caller to get and use an AED that is on site. Some states, such as Utah (Senate Bill 95/2003) and New Hampshire (Senate Bill 386/2002), have established statewide registries for the collection and distribution of information on the location of commercially owned devices. If state EMS agencies support the term "registration," it can

be used. A formal registration system may be too costly and burdensome for small volunteer EMS programs, though, so for this reason, the term "notification" is recommended.

#### **Recommended: Support of "Best Practice" Program Elements**

The program director should evaluate any episode of sudden cardiac arrest at the program site and evaluate the performance of rescuers and the use of the AED. This is done to reduce time to CPR and time to delivery of a shock, helping the program achieve the goal of improving the rate of survival from sudden cardiac arrest. The continuous quality improvement process should include EMS personnel if possible.

The AED should be stored and maintained according to the manufacturer's recommendations and the recommendations provided in nationally accepted courses in CPR and use of AEDs.<sup>43,44</sup> Newer AEDs conduct internal battery and circuitry checks continuously and visually indicate when service or a battery change is needed. This "design for dormancy" means that minimal maintenance is necessary, such as a "readiness-for-use" visual check for "service needed" or other status indicator, confirmation of the physical integrity of the device, and a check of the contents of the carrier case. A checklist from the AED manufacturer can be copied and posted near the AED and initialed and dated to confirm that the device is checked at appropriate intervals.

The AHA recommends that the AED be stored in a carrying case near a telephone so that the device can be retrieved when 9-1-1 is phoned.<sup>43,44</sup> Placing the AED near a telephone shortens the time to EMS call and AED retrieval and simplifies teaching and EMS instructions. Consistent use of these common-sense recommendations will facilitate training and dispatcher instructions.

#### **Related AHA Public Policy Initiatives**

On any given day, up to 20% of the combined US adult and child population can be found in school. Although sudden cardiac arrest is much less common in children than in adults, it can occur in children and adolescents. Parents of children who have died suddenly have started a strong grassroots effort to create AED programs in schools. In response to questions about such programs and the increasing potential for medical emergencies in schools, the AHA issued a scientific statement that recommends that schools develop a medical emergency response plan<sup>45</sup> to deal with a variety of life-threatening conditions, including sudden cardiac arrest. The complete statement is available on the AHA Web site (<http://circ.ahajournals.org/cgi/content/full/109/2/278>).

The AHA recommends that school medical emergency response plans have the following components: an effective and efficient system of campus-wide communication, a coordinated and practiced response plan, risk reduction, training and equipment for first aid and CPR, and a lay rescuer AED program in schools with an established need.<sup>45</sup> After considering several factors, some schools may decide that a need exists for a lay rescuer AED program. For example, schools with a large number of adult employees, volunteers, and visitors or schools with large, sprawling campuses that are not quickly accessible to EMS systems may wish to establish a lay rescuer AED program.



**TABLE 6. Key Program Components to Recommend in State AED Legislation****1. Limited immunity for rescuers (key) and facilitators (recommended):**

- *Good Samaritan limited immunity for rescuers that is not dependent on training.* The statute should confer *limited immunity to lay rescuers who use AEDs.* This limited immunity should not be conditional on nor require training for the good faith effort to be covered.
- *Good Samaritan limited immunity for program facilitators, including premises owners, AED acquirers, trainers, and physician prescribers (where applicable).*

**2. Recommendation for training of anticipated/expected rescuers. Training should integrate both CPR and AED skills. Note that this does not affect serendipitous AED users/bystanders who happen upon the scene.**

The statute *should require training of expected rescuers in an approved course that integrates both CPR and AED skills.* To maintain utmost flexibility with the training requirement, the statute should not prescribe a specific number of hours needed for a rescuer to be considered "trained."

**3. Link with EMS systems:** The statute should require that the local EMS system be notified about AEDs placed within its response area. Some EMS systems may wish to require registration, but not all EMS systems have the resources to establish a registry.

**4. Support of elements that contribute to effective lay rescuer AED programs:**

The statute should require a planned and practiced response. Typically this requires

- A planned and practiced response (can specify delegation of authority to a healthcare provider program director).
- Training of anticipated rescuers in CPR and AED use with a practice goal of immediate CPR and delivery of the first shock to victims of VF sudden cardiac arrest within 3 minutes of the victim's collapse.
- A link with the EMS system (see above).
- A process of ongoing quality improvement. The program director should evaluate each episode of sudden cardiac arrest and decide what steps are needed to improve response and minimize time to CPR and time to delivery of the first shock with an AED. The program director should implement a plan for on-site maintenance and readiness-for-use checks of the AED.

In 2002, the state of New York enacted a law requiring school districts, county vocational education and extension boards, and charter schools to provide and maintain at least 1 AED on site and in each instructional school facility. In addition, Assembly Bills 8779 and 10577 required that at least 1 staff member trained in CPR and the use of an AED be present at all school-sponsored activities.

In 2002, the AHA published an update to a 1998 statement recommending the development of AED programs in health clubs with >2500 members.<sup>46</sup> The statement encouraged the development of AED programs in facilities of sufficient size that an episode of sudden cardiac arrest might be predicted to occur there within a several-year period. The statement is available on the AHA Web site (<http://circ.ahajournals.org/cgi/content/full/105/9/1147>).

Some states have filed legislation requiring or encouraging the establishment of lay rescuer AED programs in health clubs. Illinois enacted a law (HB 4232) that requires physical fitness facilities to have at least 1 AED, a trained AED user, and a written plan for managing medical emergencies. New York State enacted a law (2004: S 6803/A.5084) requiring all health clubs, fitness centers, health spas, health studios, gyms, weight control studios, and martial arts/self-defense schools with a membership  $\geq 500$  to have at least 1 AED and at least 1 person (employee or volunteer) on the premises during the hours of operation who is trained in CPR and use of an AED. Other states, such as Michigan (2003: SB 50), New Jersey (2003: S. 1106/A. 453), and Rhode Island (2004: SB 2948) have acted on similar legislation in the past few years.

The PAD trial documented the lifesaving effect of well-organized lay rescuer AED programs in public places,<sup>31</sup> but at least two thirds of all out-of-hospital episodes of sudden cardiac arrest occur in homes.<sup>47,48</sup> A study is underway to determine the effectiveness of home AED programs. The results of this study may support further legislative efforts. At this time there is insufficient data for the AHA ECC Committee to make recommendations about home AED programs.

### Summary

This statement describes the key program components to include in state legislation and regulations addressing community lay rescuer AED programs. The goal of the legislation should be to reduce deaths from sudden cardiac arrest by encouraging the development of programs that will increase the likelihood of immediate bystander CPR and defibrillation being provided within 3 to 5 minutes of the victim's collapse. Table 6 lists the key components recommended for community lay rescuer AED programs.

### Additional Resources

The AHA has prepared additional support materials and guidelines for AED initiatives. The following materials may be helpful:

- Model AED legislation, AED Policy Toolkit: [www.americanheart.org/statepolicy](http://www.americanheart.org/statepolicy)
- State-by-state policy analysis (review of state actions): [www.ncsl.org/programs/health/aed.htm](http://www.ncsl.org/programs/health/aed.htm)
- AED programs Q & A: <http://www.americanheart.org/presenter.jhtml?identifier=3011859#training>
- AED program implementation resources: <http://www.americanheart.org/presenter.jhtml?identifier=3027304>
- Medical Emergency Response Plan for Schools statement: <http://circ.ahajournals.org/cgi/content/full/109/2/278>

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| Smith Steffens, Suzanne | AHA                                     | None  | None   | None  | None  | None               | None   | None                                    |
| Stapleton, Edward       | SUNY Stony Brook                        | Laerdal Med grant to study CPR*                       | None   | None  | None  | None               | Currents, AHA publications   | None                                    |

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest conflict of interest.

†Significant conflict of interest.

## Reviewers' Disclosures

| Reviewer Name                   | Employment         | Research Grant                     | Speakers<br>Bureau/<br>Honoraria | Stock<br>Ownership | Consultant/<br>Advisory<br>Board | Other  |
|---------------------------------|--------------------|------------------------------------|----------------------------------|--------------------|----------------------------------|--|
| Wanchun Tang, MD,<br>FCCP, FCCM | None               | Philips Medical, Zoll Medical, AHA | None                             | None               | None                             | None   |
| Richard E. Kerber               | University of Iowa | Philips Medical Systems*           | None                             | None               | None                             | Laerdal Foundation for<br>Acute Medical Care,*<br>NHLBI† |

\*Modest conflict of interest.

†Significant conflict of interest.

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AMERICAN HEART ASSOCIATION

# PHIL NUSSER

209 N. BROADWAY  
ST. JOHN, KS

Testimony presented to the Senate Committee on Public Health & Welfare  
SB 102—AED's  
February 2 , 2009

Mr. Chairman and members of the Committee:

I am Phil Nusser. I live in St. John, Kansas. One of my life's enjoyments is to referee basketball games. I stand before you today because an AED was used to save my life on Tuesday, January 6, 2009. Thank you for allowing me to share my story:

Great Bend Tribune...Fast action and the presence of an automated external defibrillator saved the life of a referee during a basketball game at Ellinwood High School on Tuesday.

"If it had to happen, he was in the right place at the right time," said Janice Nusser, wife of referee Phil Nusser of St. John. Nusser, who is also the Stafford County Roads and Bridge supervisor, has refereed about eight years, Janice Nusser said. On Tuesday, he went down during the third quarter of the girls' game.

EHS Girls' Basketball Coach Bill Maddy heard and saw referee Dick Smith blow his whistle and point at Nusser. Half-way across the court from Nusser, Maddy said he realized from the way Nusser was lying it was not a normal injury. He turned around and ran to get the AED, which is located in the Commons Area between the two gyms.

A police officer and school nurse Shannon Heape called 911. By then, Jane Billinger, a 2007 EHS graduate and emergency medical technician who was at the game, had done a quick assessment and determined Nusser was not breathing and did not have a pulse. Jim Elsen, an Ellinwood firefighter, and Lana Brown started cardiopulmonary resuscitation. Billinger used the AED once to restart Nusser's heart before the ambulance crew arrived. "She kept her cool and did what she needed to do before the crew got there," said Debbie Glenn, Ellinwood Emergency Medical Service director and proud teacher. "It's pretty awesome."

Billinger graduated from Glenn's EMT high school class in May, passing her state tests and working for Ellinwood EMS when she is home from college.

The AEDs were placed in the schools two years ago, Glenn said, after the city received a Department of Justice grant to purchase two units. The school purchased an additional unit. The city and school district have an agreement for placement of the two units at the school. Glenn provides CPR and AED training for school personnel every two years. "It really makes us feel good about the program," said Ellinwood City Administrator Robert Peter of the high school EMT training and AEDs.

After seeing Nusser was in good hands, Maddy, EHS Principal Brian Rowley and EHS Athletic Director Monte Doll, had everyone in the stands who was not helping move into the Commons Area. The players were sent to their locker rooms. Everyone cooperated, Maddy said. Several people commented on the cooperation and help offered by those present. Seven to 10 young men formed a protective shield between the audience and Nusser to give them privacy.

By the time the ambulance left, Nusser was conscious, Maddy said. After talking it over, the decision was made to resume the game, since Nusser was conscious, he said. "If he had still been unconscious, we were done for the night," he said.

Nusser was transported to Ellinwood District Hospital and Life watched to Promise Regional Medical Center in Hutchinson, Glenn said. Janice Nusser said doctors found some blockage and a blood clot. The clot was removed and a stent inserted. After a rough night, he was resting comfortably, she said, and was expected to be transferred out of the intensive care unit Wednesday afternoon.

"Thank God for all of it," Janice Nusser said, referring to the fact EMTs were on hand and the AED. "I think every school should have a defibrillator. We're very, very thankful they had one. It made the difference between life and death." She said her husband's prognosis was pretty good and his goal is to return to refereeing.

The AED was helpful in saving my life and passing SB 102 will be helpful in saving additional lives. Thank you.

**Phil Nusser**

**Public Health and Welfare**

**Date:**

02/02/09

**Attachment:**

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**Testimony on Senate Bill 102  
AED Legislation**

**Presented to  
Committee on Public Health and Welfare  
By  
Richard Sigle Jr, Paramedic**

**February 2, 2009  
Room 136-N**

Chairman Barnett and members of the committee, I am Richard Sigle Jr. I am a Paramedic and a volunteer for the Kansas Heart Disease and Stroke Prevention Program, which is managed by KDHE. I am pleased to present testimony today in support of SB102.

My testimony today comes from several stand points- first as a professional rescuer and second as an educator. The primary thought I want to leave with you is that this bill will be another step forward in saving more lives in this great state of Kansas. It also will be an example to the rest of the nation of what we can accomplish when we do the right thing.

When sudden cardiac arrest occurs, any delay in that person receiving CPR and early defibrillation is literally measured in seconds. In 30 seconds 3.5 to 5.0% of their chance of survival is lost. For every minute an individual loses between 7-10 percent of their chance of survival.

Under the previous language the only people who could administer the life saving defibrillation were those who were qualified. While protection under the Good Samaritan provision is afforded to the qualified rescuer the lay person who may have access to an AED is not afforded such protection. As the presence and awareness of AED's have increased, we have not yet expanded the protection to good samaritans. As a professional rescuer I have been present when someone has been saved by an AED and while rejoicing in the fact that a life was saved, I more frequently find myself saddened at the cases where I wonder if only someone had been there with the AED would the outcome have changed.

As an educator I know how simple the AED is to use. When training someone who has never used the AED, I start off simply by telling them if you can turn the machine on and follow the voice prompts it will tell you what to do. I cannot recall in all the classes and students that I have taught, of an instance where someone has not been able to figure out how to use it with little or no assistance. While older models of AED's were more cumbersome and had a higher degree of difficulty in use, the newer AED's are virtually fool proof. One brand that I will not name is even available over the counter. The newer AED's take further advantage of technology by advising the user to ensure that they have called 911 and can even coach them in the other needed part CPR. When the AED is demonstrated most people are in awe of how easy it really is. The usual response is "is that it?"

In conclusion, I want to reinforce that the need for the passage of this bill is measured in lives. The dollar cost is no more than our time here today and consideration of this legislation today. It is in my professional opinion that the passage of this law will only further promote the use and placement of AED's in more places. The motto of my business is "saving a life is everyone's business." Today it is your business. By your consideration today you may just save the life of someone you love.

I thank you for the opportunity to appear before the committee today. I have a demonstration of the unit available that will take no more 3 minutes of your time to see the simplicity of the AED. I will now stand for any questions.

**Public Health and Welfare**

**Date:**

**Attachment:**

02/02/09

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February 2, 2009

TO: Senate Committee on Public Health & Welfare Committee

FROM: Jason Lutz or JJ

RE: Testimony on SB 102—AED

My name is JJ and I appreciate your time in listening to my story about an AED. My mom considers me a normal teenager with all the typical interests of a teenage boy. I like to listen to music, hang out with his friends, go driving, and girls. In junior high school years, I participated in some sports such as football, soccer, track, and wrestling. I took a break from that sports schedule as a sophomore and explored performing arts and foreign language. I studied French and enjoy addressing people with my new found language. I have been a good student and have always been an honor-roll student. I want to go to college and eventually be a lawyer and travel the world.

On January 31<sup>st</sup>. of 2007, I got up for school just like any other school morning; got ready, ate breakfast and I usually tell my mom that I love her and was leaving to meet the bus. Mom would usually say, "I love you too, have a good day at school, and I will be at school when you get home so I will see you late tonight." But the day didn't happen that way.

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By Barbara Hollingsworth, The Capital-Journal  
Published Thursday, March 08, 2007

JJ Lutz was on his way to see a teacher — not that he remembers any of that now. What he remembers is an angel telling him to wake up and opening his eyes to find himself in the hospital. For the Seaman High School sophomore, Jan. 31 is a day gone from his memory.



JJ Lutz, Seaman High School sophomore, thanks Maurice Koch, security officer, as Garrie Oppitz, school nurse, looks on during a meeting Wednesday honoring the two faculty members who saved the teen's life when he had heart problems Jan. 31.

Mike Burley / The Capital-Journal

For his parents, it is the day they began learning far more about the human heart than they ever planned, a day when the lives of two people they didn't know became forever tied to theirs and a day when a machine they had never thought a thing about gave their 15-year-old son a shot at life.

"You guys are heroes to me," JJ's father, Jason Lutz, told school nurse Garrie Oppitz. "You were there. You saved my son's life." They hugged Wednesday afternoon after school staff members and JJ's family watched Oppitz and security officer Maurice Koch receive recognition for coming to JJ's aid from Cardiac Science, the producer of automated external defibrillators. "I'm just doing what I trained to do," Oppitz said.

**Heart Disease and Stroke. You're the Cure.**

5375 SW 7th St. ~ Topeka, KS 66606 785-228-3437 785-272-2425 [linda.decoursev@heart.org](mailto:linda.decoursev@heart.org)

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02/02/09

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After all, Oppitz has been a registered nurse for 23 years. She has given cardiopulmonary resuscitation in the past but always in settings with doctors and nurses rushing around. This was different.

At about 10:30 a.m. Jan. 31, students rushed to her office to say a student had passed out in the hall. Both Koch and Oppitz had seen JJ around school, but they didn't know much about the teenager, who had played sports but was becoming more interested in drama.

Soon after reaching JJ's side, Oppitz knew it was a life-or-death situation. JJ wasn't breathing and had no pulse. As she and JJ's family would learn later, a serious arrhythmia had caused the previously healthy teenager's heart to malfunction. They began CPR — 30 compressions to two breaths.

Then Oppitz called for the AED, a device that delivers a shock that can restore normal heart rhythm. It had sat unused in the school for about five years. Now that they needed it most, it was about 15 feet away from where JJ had fallen on his way to see a teacher. JJ's mom, Tammy Crouse, didn't know schools had defibrillators.

"I knew the hospitals had them and the old folks' homes had them, but not schools," said the mother of five. "I never thought one would be used on a 15-year-old — not my 15-year-old."

JJ spent 16 days in the hospital. He said he is feeling good and would love to be back at school, but his parents are keeping a tight rein on his activities for now.

His parents want to share with others what they learned Jan. 31. JJ's father, Jason Lutz, and his stepfather, Joshua Crouse, talked at length Wednesday about how they believe AEDs should be required in schools throughout the nation, with two or more spread out in larger buildings. Thousands of lives could be saved each year using the devices that cost \$1,500 to \$2,000 each, they said.

"Seconds count when you have to choose to use one of these things," Crouse said.

Seaman Unified School District 345 will have AEDs in all of its schools this fall and is training staff members to use them, as well as administer CPR and first aid. Other area districts also have made the AEDs a priority. Shawnee Heights USD 450 and Auburn-Washburn USD 437 have at least one in each school and central office. Topeka USD 501 has the devices in its middle and high schools, its central office and a couple at Hummer Sports Park.

After all these weeks, Oppitz feels a connection to Lutz's family — one that is difficult to describe. Maybe it has to do with seeing JJ up and around again or the way his mom hugs her knowing that the words "thank you" just don't seem to cover it.

Then JJ's dad calls Oppitz and Koch "heroes," and it doesn't sound right to the nurse. She doesn't feel like a hero. Over and over, she told the teen's family she was just doing her job. But they know what they see. "All I can say is thank you because you gave me and his mom back a gift we could never repay," Jason Lutz said.

By passing SB 102, it will help save lives. I encourage you to give a gift to the Kansans. Merci beaucoup pour vous ecoutant. (Thank you a lot for listening.) Au revoir (goodbye).





League of Kansas Municipalities

300 SW 8th Avenue  
Topeka, Kansas 66603-3912  
Phone: (785) 354-9565  
Fax: (785) 354-4186

To: Senate Public Health and Welfare Committee

From: Moji Fanimokun, Staff Attorney

Date: February 1, 2009

Re: Proponent for SB 102

First, I would like to thank the committee for allowing the League of Kansas Municipalities to appear today in support of SB 102. The League would like to offer its support for Senate Bill 102. For a little over a year, the League has encouraged its member cities to install automated external defibrillators. The League published an article in the Kansas Government Journal highlighting the benefits of automated external defibrillators and also conducted a round-table discussion advocating for their usage at its annual conference this past year.

Currently, for a city to fall under the immunity provisions of the law a qualified individual who has attended a special training session must be the person to use the automated external defibrillators. Much of the feedback the League has received regarding automated external defibrillators has centered on the lack of training programs available in many of the smaller and rural areas around the state. Therefore, many cities have chosen not to install the automated external defibrillators because of the current provisions requiring a trained qualified individual to use the system and the liability they may be subjected to by not having the opportunity to have a trained qualified individual in place. There are user-friendly instructions accompanied with each automated external defibrillator that would allow almost anyone successful usage of the machine.

Because SB 102 would remove the barrier limiting automated external defibrillators to be used only by a trained qualified individual and allows the opportunity for our member cities to better protect their staff and constituents, the League would like to offer its support for this SB 102. I will be happy to answer any questions the committee may have.

[www.lkm.org](http://www.lkm.org)

Public Health and Welfare

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# KANSAS

DENNIS ALLIN, M.D., CHAIR  
ROBERT WALLER, EXECUTIVE DIRECTOR

KATHLEEN SEBELIUS, GOVERNOR

## BOARD OF EMERGENCY MEDICAL SERVICES

### Testimony

**Date:** February 2, 2009  
**To:** Senate Committee on Public Health and Welfare  
**From:** Steve Sutton, Deputy Director   
**RE:** 2009 Senate Bill 102

Chairman Barnett and members of the Senate Committee on Public Health and Welfare, thank you for the opportunity to provide testimony on the Senate Bill 102, my name is Steve Sutton and I am the Deputy Director for the Kansas Board of Emergency Medical Services (KBEMS).

In an effort to sustain life, and create a "chain of survival", the link between early activation of the EMS system, early bystander CPR, early delivery of a shock from an AED, and early advanced life support has been recognized as having a significant impact on patient survival. This bill provides a lawful "certainty" that those citizens with no training, who are willing to provide a lifesaving intervention to a heart patient, are held harmless from any legal ramifications when such care is provided with no malicious or ill intent. As Kansans, we routinely come to the aid of our neighbor believing a lawsuit is impossible because our assistance is provided out of concern for the loss of life. However, as a recent case in California demonstrates, that does not always hold true. The case involves an injured patient in a car, removed by bystanders who believed she was in danger of being killed in an explosion after the accident. Once evaluated at the hospital, the patient was determined to be paralyzed. She subsequently sued her rescuers believing that if "trained" personnel had removed her, she would not have been paralyzed. KBEMS would hope to never have a lawsuit of this nature cast a shadow over the saving of a life. But, 2009 SB 102 ensures that with proper execution, those who would attempt to save a life with no malicious or gross intent, can do so free of legal intrusion.

The Kansas Board of Emergency Medical Services, in concert with the American Heart Association (AHA) and Kansas Department of Health and Environment (KDHE) fully supports the passage of 2009 SB 102 in its current form. AED's save lives, and their presence and use should not be restricted by the possibility of lawsuits outside of willfully and knowingly employing the use of the AED for any other purpose than its function.

Your passage of 2009 SB 102 enhances the "continuity of care" and provides many stricken with a cardiac arrest, another heart beat, another chance to live.

LONDON STATE OFFICE BUILDING, 900 SW JACKSON STREET, ROOM 1031, TOPEKA, KANSAS 66612-1228

Voice 785-296-7296 Fax 785-296-6212 www.k

Public Health and Welfare

Date:

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02/02/09

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**Amendments**

None

**Conclusion**

Thank you for allowing me to testify in support of Senate Bill 102 and I will stand for any questions you may have.