

U.S. Department
of Transportation

**FEDERAL AVIATION
ADMINISTRATION**
Office of Aviation Policy and Plans
Washington, D.C. 20591

84063

OFFICE OF THE
CHIEF COUNSEL
RULES DOCKET
2000 MAY 24 A 11:41

FAA-2000-7119-3

**PRELIMINARY REGULATORY EVALUATION, INITIAL
REGULATORY FLEXIBILITY DETERMINATION, AND
TRADE IMPACT ASSESSMENT**

EMERGENCY MEDICAL EQUIPMENT

NOTICE OF PROPOSED RULEMAKING

(14 CFR Parts 121, and 135)

OFFICE OF AVIATION POLICY, PLANS AND MANAGEMENT ANALYSIS

OPERATIONS REGULATORY ANALYSIS BRANCH, APO-310

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August 1999 (revised September 1999)

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EXECUTIVE SUMMARY

This notice of proposed rulemaking would amend 14 CFR part 121 to require the placement of automatic external defibrillators aboard affected airplanes, to require emergency medical kits to include additional medications and equipment, and to require training of crewmembers, especially flight attendants, in the correct usage of this new equipment. It would not require the use of any equipment as whether to provide medical care is up to the certificate holder. It would also amend part 135 to remove an obsolete specification.

The FAA concludes that the proposed rule is cost-beneficial. Costs for this proposed rule would be \$138.1 million (\$95.6 million, discounted) over a 10-year period. Based on this cost and the estimated 55 lives saved, the rule is estimated to cost \$2.5 million per life saved.

The proposed rule would not have a significant impact on a substantial number of small entities, nor would it constitute a barrier to international trade. The proposed rule does not contain a federal intergovernmental or private sector mandate that exceeds \$100 million in any year, therefore, the requirements of the Unfunded Mandates Reform Act of 1995 do not apply.

INTRODUCTION

This draft regulatory evaluation examines the costs and benefits of modifications to the required emergency medical equipment on those airplanes with a maximum payload of more than 7,500 pounds, operating under 14 CFR part 121 (part 121) for which a flight attendant is required. In addition, the proposal also would require that affected airplanes have automatic external defibrillators (AEDs) available on board and trained personnel to possibly use them. The decision to provide medical care is made by the certificate holder.

The proposed rule is being issued in response to the Aviation Medical Assistance Act of 1998, April 24, 1998 (P.L. 105-170) by which Congress directed the FAA to evaluate the equipment to be included in Emergency Medical Kits (EMKs) and the training of flight attendants on the use of such equipment; to collect data for 1 year on in-flight medical emergencies for determining whether AEDs should be required aboard airlines and at airports; and to determine whether regulatory or legislative action is necessary or issue official notice that action is not necessary.

In addition to the benefit-cost analysis, this regulatory evaluation contains an initial regulatory flexibility determination, which analyzes the economic impact of the proposed regulatory changes on small entities as required by the

Regulatory Flexibility Act of 1980 as amended. This evaluation also contains an assessment of the effect of the proposed regulatory changes on international trade, as required by the Office of Management and Budget. Finally, this document contains an Unfunded Mandate Assessment, as required by the Unfunded Mandates Reform Act of 1995.

BACKGROUND

The incidence of in-flight medical events appears to be growing. In 1986, the FAA adopted a final rule (51 FR 1218) requiring large, passenger-carrying airplanes to carry EMKs. The rule was amended in 1994 (59 FR 52640) to require protective gloves.

The FAA's Civil Aeromedical Institute (CAMI) has conducted four studies on in-flight medical emergencies and the use of EMKs between 1991 and 1999 and reviewed other studies related to in-flight medical emergencies. Two 1991 CAMI reports¹ disclosed that during a 2-year monitoring period a total of 2,322 medical emergencies were documented and resulted in 2,293 actual usages of the medical kit. The most common distress sign was a myocardial problem. A 1997 CAMI report,² based on information obtained from two airlines and two in-flight medical care

¹ "Response Capability During Civil Air Carrier In-flight Medical Emergencies", March 1991; DOT/FAA/AM-91/3 and "Utilization of Emergency Kits by Air Carriers", March 1991; DOT/FAA/AM-91/2. Copies of these and the following reports are in the docket.

² "In-flight Medical care, An Update", February 1997; DOT/FAA/AM-97/2.

companies, (representing a total of nine major U.S. part 121 air carriers)³ over a 3-year period, showed that neurological, syncopal, and cardiac episodes were the most frequent categories of in-flight medical emergencies. CAMI has also analyzed 1,132 in-flight medical incidents⁴, which occurred from October 1, 1996 to September 30, 1997, on six airlines that accounted for approximately 20 percent of U.S. domestic enplanements for the period. The study focused upon the correlation between the in-flight diagnoses of passengers suffering an in-flight medical emergency and the subsequent hospital discharge diagnoses and, in the case of cardiac patients, the agreement rate was 94.1 percent suggesting that the on-board diagnoses were correct.

In light of the changing demographics of passengers (more older people travel by air) and advances in clinical medicine, the aviation industry and the medical community have conducted assessments of in-flight medical care and made the following recommendations in 1997.

An Aerospace Medical Association task force recommended an expanded list of medications and medical supplies for in-flight care and further recommended that U.S. air carriers consider placing AEDs on wide body airplanes, particularly when serving

³ The two in-flight medical care companies provide their services to a total of seven air carriers.

⁴ "The Evaluation of In-flight Medical Care Aboard Selected U.S. Air Carriers from 1996 to 1997" Report to be published.

long haul or over water routes, and providing appropriate training. Also, the Air Transport Association's Medical Panel recommended that member airlines place AEDs on at least 20 percent of their fleet as the initial phase of an implementation program, upgrade emergency kits, and modify flight attendant training.

An AED is a small, battery-powered, device used to deliver an electrical shock to the heart (defibrillation) of a patient in sudden cardiac arrest (SCA). SCA occurs when the heart's electrical impulses suddenly become chaotic, causing the heart to abruptly start pumping blood ineffectively. The only definitive treatment to restore an effective heart rhythm is defibrillation; CPR alone is not effective.

The recommendations for the placement of AEDs aboard airplanes were linked to reports that the key to saving a life in cardiac arrest is speed; the chances of survival decrease 10 percent with every minute without circulation of blood. The Food and Drug Administration's 1996 approval of AEDs usage on airplanes made the recommendations feasible.

COSTS

The FAA has analyzed the expected costs of this regulatory proposal for a 10-year period, 2000 through 2009. As required by the Office of Management and Budget (OMB), the present value of

this cost stream was calculated using a discount factor of 7 percent. All costs in this analysis are expressed in 1998 dollars.

Automatic External Defibrillators

The FAA estimated that there will be 5,600 part 121 airplanes in 2000. These all will be required to carry AEDs. However, several airlines already have placed AEDs aboard their airplanes or have announced their intention to do so. These AEDs should be aboard the airplanes before the rule comes into effect. Together these airlines account for 3,000 airplanes.⁵ Subtracting 3,000 from the 5,600 total yields 2,600 airplanes that will need AEDs. The FAA estimates that the average cost for AEDs of the type acceptable on an airplane is \$3,500. Thus, the cost for purchasing AEDs to carriers that would be mandated to do so by the proposed rule is \$3,500 times 2,600 or \$9.1 million.

The number of airplanes is forecast to grow over the next decade and the proposed rule would apply to all new airplanes entering the part 121 fleet. The FAA estimates the number of airplanes will grow at an estimated average of 4.1 percent per year over the next 10 years⁶. Costs for the AEDs, which will be required

⁵ These carriers have voluntarily incurred an estimated cost of \$10.5 million for AEDs and additional millions for expanded medical kits and appropriate training.

⁶ Source: FAA Aerospace Forecasts - March 1999

on these airplanes during this period, are estimated to be \$8.5 million.

In addition to the initial investment costs, AEDs will incur periodic operating costs. One AED manufacturer, whose product has been voluntarily purchased by many of the airlines, indicates that the AEDs battery pack has a more than 1-year standby life under controlled environment circumstances and that a replacement battery pack costs \$100, at list price. The manufacturer also recommends replacing the device's pads every 18 to 24 months at a cost of \$60. The maintenance cost to the industry to replace these items over the 10-year period would be \$9.1 million.

Combining the these three variables yields a total AED cost of this proposed rule to be \$26.7 million, or \$20.2 million, discounted over the 10-year period as shown in Table 1.

Table 1 - INITIAL AND OPERATING COST OF DEFIBRILLATORS

Year	EXISTING FLEET			NEW AIRCRAFT			MAINTENANCE		TOTAL COST	DISCOUNT RATE-7%	DISCOUNTED COST
	Initial Aircraft	Cost per Aircraft	Initial Cost	Additional Aircraft	Cost per Aircraft	Additional Cost	Total Fleet	Annual Cost (1)			
1	2,610	\$ 3,500	\$ 9,135,000			0	5,610	0	\$ 9,135,000	0.935	\$ 8,541,225
2				212	\$ 3,500	\$ 742,000	5,822	\$ 561,000	\$ 1,303,000	0.873	\$ 1,137,519
3				230	\$ 3,500	\$ 805,000	6,052	\$ 918,800	\$ 1,723,800	0.816	\$ 1,406,621
4				268	\$ 3,500	\$ 938,000	6,320	\$ 954,520	\$ 1,892,520	0.763	\$ 1,443,993
5				252	\$ 3,500	\$ 882,000	6,572	\$ 995,120	\$ 1,877,120	0.713	\$ 1,338,387
6				331	\$ 3,500	\$ 1,158,500	6,903	\$ 1,036,400	\$ 2,194,900	0.666	\$ 1,461,803
7				267	\$ 3,500	\$ 934,500	7,170	\$ 1,084,620	\$ 2,019,120	0.623	\$ 1,257,912
8				278	\$ 3,500	\$ 973,000	7,448	\$ 1,131,180	\$ 2,104,180	0.582	\$ 1,224,633
9				289	\$ 3,500	\$ 1,011,500	7,737	\$ 1,175,000	\$ 2,186,500	0.544	\$ 1,189,456
10				303	\$ 3,500	\$ 1,060,500	8,040	\$ 1,220,580	\$ 2,281,080	0.508	\$ 1,158,789
Total			\$ 9,135,000			\$ 8,505,000		\$ 9,077,220	\$ 26,717,220		\$ 20,160,337

(1) - Based on \$100 to replace battery after 1 year and \$60 to replace pads every 2 years

Emergency Medical Kits

The FAA proposes an enhancement to the current medical kits. Many airlines already exceed the minimum requirements for the new medical kits, particularly those airlines that have voluntarily decided to have AEDs on board. Thus 3,000 of the total 5,600 airplanes affected by the rule already have an updated medical kit. This leaves 2,600 airplanes that will need to purchase the additional items required of an enhanced medical kit. The FAA estimates that the initial cost of these extra items would be \$155 per kit⁷. For the industry, therefore, the first year costs are \$404,600 for enhanced medical kits. The total cost of enhanced medical kits for new airplanes entering the industry fleet over the next 10 years is estimated at \$376,700.

In addition to this cost, there will also be an annual ongoing cost for replacement of items for all airplanes, including those that already have an updated medical kit. The FAA estimates this cost at 35 percent⁸ of the cost of the additional kit items or \$54.25 per kit. The total replacement cost in the second year of

⁷ Based, principally, on the price lists of two major suppliers of in-flight EMKs for the items specified in the NPRM.

⁸ Based on the weighted average cost of automatic kit "updating" programs offered by two leading EMKS suppliers.

the rule would be \$304,300,⁹ and over the proposed rule's 10-year period would be \$3.2 million.

Summing the cost of existing airplanes that would need an enhanced medical kit, new airplanes that would need EMKs, the replacement of items for all airplanes, the total EMK cost of this proposed rule is \$4.0 million or \$2.8 million, discounted, over the 10-year period, as shown in Table 2.

⁹ This is calculated by multiplying the number of airplanes times \$54.25. The FAA estimates that there would be a total of 5,822 airplanes in the proposed rule's second year.

Table 2 - INITIAL AND OPERATING COST OF EXPANDED EMERGENCY MEDICAL KIT

Year	EXISTING FLEET			NEW AIRCRAFT			MAINTENANCE		TOTAL COST	DISCOUNT RATE-7%	DISCOUNTED COST
	Initial Aircraft	Cost per Aircraft	Initial Cost	Additional Aircraft	Cost per Aircraft	Additional Cost	Total Fleet	Annual Cost (1)			
1	2,610	\$155	\$ 404,550				5,610	0	\$ 404,550	0.935	\$ 378,254
2				212	\$155	\$ 32,860	5,822	\$ 304,343	\$ 337,203	0.873	\$ 294,378
3				230	\$155	\$ 35,650	6,052	\$ 315,844	\$ 351,494	0.816	\$ 286,819
4				268	\$155	\$ 41,540	6,320	\$ 328,321	\$ 369,861	0.763	\$ 282,204
5				252	\$155	\$ 39,060	6,572	\$ 342,860	\$ 381,920	0.713	\$ 272,309
6				331	\$155	\$ 51,305	6,903	\$ 356,531	\$ 407,836	0.666	\$ 271,619
7				267	\$155	\$ 41,385	7,170	\$ 374,488	\$ 415,873	0.623	\$ 259,089
8				278	\$155	\$ 43,090	7,448	\$ 388,973	\$ 432,063	0.582	\$ 251,460
9				289	\$155	\$ 44,795	7,737	\$ 404,054	\$ 448,849	0.544	\$ 244,174
10				303	\$155	\$ 46,965	8,040	\$ 419,732	\$ 466,697	0.508	\$ 237,082
			\$ 404,550			\$ 376,650		\$ 3,235,145	\$ 4,016,345		\$ 2,777,388

(1) - Based on 35 % replacement cost

Training

Each certificate holder is responsible for developing, subject to the approval of the FAA, initial and recurrent emergency training programs which ensure that each crewmember that successfully completes the training is adequately trained to perform his or her assigned duties. Whether or not care is provided to a passenger is up to the certificate holder. While all crewmembers would receive familiarization with the new EMK items as well as the location of the AED and its instruction set, only flight attendants would be required to receive training in its operation and related procedures. Even though training is required there is no Federal requirement for any care to be provided by crewmembers or flight attendants. As noted above, whether to provide care is up to the certificate holder.

In view of the various programs used by certificate holders, the FAA has used the number of hours in training programs provided by the American Red Cross and private training providers to estimate the cost of training flight attendants in the proper usage of AEDs and expanded EMKs. Generally, these programs include 4 hours of initial AEDs training plus 4 hours of initial basic life support or CPR instruction, and 4 hours of recurrent training every 24 months. The number of hours times the estimated hourly wage is the basis for the cost of flight attendant training. This training could be conducted "in-house" at minimal cost for

instruction and training equipment; the principal expense would be the flight attendants' salary.

The FAA estimates that 80 carriers would need to certify an instructor and acquire training aids at a cost of \$680 each for a total cost of \$54,400¹⁰. Once properly certified, a trainer could instruct other staff members to conduct the required training without additional "out-of-pocket" expense.

The nine carriers that have already placed AEDs aboard their airplanes have also provided or will provide additional training for their 85,500 flight attendants. For the other carriers, the FAA estimates that 28,800 flight attendants would need to receive the initial training that would be required by the proposed rule at a cost to the industry of \$4.4 million. In addition, all new flight attendants joining the industry over the next 10 years would be required to undergo this training in addition to other mandated training. The FAA estimates that this would cost the industry \$7.3 million. Recurrent training every 24 months for all flight attendants would cost the industry \$91.3 million.

Summing the four cost components, equipment, training some current flight attendants; training all new flight attendants, and recurrent training, the total flight attendant training cost

¹⁰ One supplier provides a "train-the-trainer" course for \$500, an airline industry specific AEDs training video for under \$100, and a refresher training CD-ROM for under \$80.

of this proposed rule is \$103.0 million, \$69.7 million,
discounted, over the next 10 years as shown in Table 3.

Table 3 - AED INITIAL AND RETRAINING FLIGHT ATTENDANT COSTS

Year	INITIAL TRAINING			NEW ATTENDANTS			RECURRENT TRAINING			TOTAL COST	Discount Rate - 7%	DISC. COST	
	Equip. Cost (1)	Current Staff	Cost per Attendant (2)	Initial Cost	New Staff (3)	Cost per Attendant (2)	Additional Cost	Number of Staff	Cost per Attendant (4)				Annual Cost
1	\$54,400	28,806	\$151.04	\$4,350,858	0	\$151.04	\$0	114,275	\$0.00		\$4,405,258	0.935	\$4,118,916
2					4,571	\$151.04	\$690,404	118,846	\$75.52	\$8,630,048	\$9,320,452	0.873	\$8,136,754
3					4,754	\$151.04	\$718,044	123,600	\$75.52	\$8,975,250	\$9,693,294	0.816	\$7,909,728
4					4,944	\$151.04	\$746,742	128,544	\$75.52	\$9,334,272	\$10,081,014	0.763	\$7,691,813
5					5,142	\$151.04	\$776,648	133,686	\$75.52	\$9,707,643	\$10,484,291	0.713	\$7,475,299
6					5,347	\$151.04	\$807,611	139,033	\$75.52	\$10,095,967	\$10,903,578	0.666	\$7,261,783
7					5,561	\$151.04	\$839,933	144,594	\$75.52	\$10,499,772	\$11,339,706	0.623	\$7,064,637
8					5,784	\$151.04	\$873,615	150,378	\$75.52	\$10,919,739	\$11,793,354	0.582	\$6,863,732
9					6,015	\$151.04	\$908,506	156,393	\$75.52	\$11,356,547	\$12,265,052	0.544	\$6,672,188
10					6,256	\$151.04	\$944,906	162,649	\$75.52	\$11,810,799	\$12,755,706	0.508	\$6,479,898
	\$54,400			\$4,350,858			\$7,306,409			\$91,330,036	\$103,041,704		\$69,674,750

(1) - Based on 80 carriers @\$680 each

(2) - Based on 8 hours(4 hours initial AED training + 4 hours of CPR instruction) x \$18.88 per hour

(3) - Based on average growth of 4.1% per year (rate of fleet growth)

(4) - Based on 4 hours x \$18.88 per hour every 24 months

Other Costs

The weight of the AEDs and expanded EMKs would impose a fuel penalty on part 121 carriers. The FAA estimates that the additional weight would be 6 pounds. AED models selected by air carriers weigh 4 to 6 pounds with the weighted average of AEDs purchased to date being 4.5 pounds; the FAA estimates that the extra EMKs items will add 1.5 pounds to the EMKs for a total of 6 pounds. The FAA estimates¹¹ that carriers would incur a weight penalty expense of \$4.4 million, \$3.0 million, discounted, over the next 10 years, if the proposed rule is adopted.

Summary of Increased Costs

The following table summarizes the estimated cost of equipping part 121 airplanes with AEDs, expanded EMKs, training of flight attendants, and fuel expenses over a 10-year period.

Table 4 Total Cost of Proposed Rule

Cost Area	Total Cost	Present Value
AEDs	\$26,717,220	\$20,160,337
EMKs	\$4,016,345	\$2,777,388
Training	\$103,041,704	\$69,674,750
Fuel	\$4,370,000	\$2,956,600
Grand Total	\$138,145,268	\$95,569,074

¹¹ Based on the forecasted airborne hours of operations by various aircraft models, engine configurations, and cost of fuel.

The estimated industry costs over 10 years total \$138.1 million, or \$95.6 million discounted. Public comments are invited; the FAA requests that all comments be accompanied by clear economic documentation.

Benefits

Medical studies show that the chances of surviving ventricular fibrillation, a critical cardiac event, decrease 10 percent with every minute that passes from the onset of the incident.

Providing AEDs, expanding EMKs, and training flight attendants in the proper usage of the equipment may result in a better response to some in-flight cardiac arrest medical events if the certificate holder chooses to provide care. AEDs can quickly determine, within certain parameters, whether a heart shock is necessary and deliver the shock needed to get the heart working again

The experiences of airlines that already carry AEDs have been relatively positive. Qantas, an Australian airline that began installing AEDs in 1991, reports it has eight long-term survivors out of at least 23 people with heart attacks. Dr. David McKenas, American Airlines Medical Director, reports that the AEDs, voluntarily placed aboard its airplanes since July 1997, have been activated on eight patients, five whom revived, although one later died in the hospital.¹²

Up to 15 different Air Transport Association members participated in a 1-year emergency/death incident data collection effort in cooperation with the FAA. This effort was in response to one of the provisions of the Aviation Medical Assistance Act of 1998. The data were collected for the period July 1, 1998 through June 30, 1999. The data collection results reveal that there were 188 death or threat-of-death incidents resulting in a total of 108 deaths. (It should be noted that 11 of these deaths occurred on the ground.) AEDs were used a total of 14 times to deliver at least one shock on board an aircraft. From these events, four passengers were reported as having survived. Assuming the four passengers medical event outcome changed due to the use of AEDs, the AED survival rate per hundred million passenger enplanements is 0.7193¹³. The possible survival rate may have been different if AEDs had been aboard all participating carriers aircraft for the entire data collection period. If the survival rate during the test period had been higher, then the projected number of possible lives saved over the next 10 years would be higher. However, since this cannot be established from the available data, the FAA will use the conservative projection.

¹² "Saving Lives In the Air", New York Times, May 9, 1999.

¹³ Air Transport Association "Preliminary Scheduled Passenger Traffic Statistics", June 1998-March 1999 (4 lives/556,111,000 system enplanements)

Applying the survival rate to the estimated 7.5819 billion¹⁴ enplaned passengers over the next 10 years may result in 55 passenger medical event outcomes being changed by AEDs during that period.

Cost-Benefit Analysis

If the proposed rule becomes effective, the FAA estimates that as many as 55 passenger medical outcomes could possibly be changed over the next 10 years. The cost of implementing this proposed rule is estimated at \$138.1 million over the next 10 years. Based on the estimated cost of \$138.1 million and an estimated 55 lives possibly saved, the rule is estimated to cost \$2.5 million per life saved.

As noted previously in the "Summary of Costs" section, the FAA invites public comments and requests that all comments be accompanied with clear and detailed supporting economic documentation.

Initial Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable

¹⁴ Source: Table 12, FAA Aerospace Forecasts, March 1999

statutes, to fit regulatory and informational requirements to the scale of the business, organization, and government jurisdictions subject to regulation." To achieve that principal, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis (RFA) as described in the Act.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605 (b) of the 1980 act provides that the head of the agency may so certify and a RFA is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The Small Business Administration suggests that "small" represent the impacted entities with 1,500 or fewer employees. For this proposed rule, the small entity group is considered to be part 121 operators (Standard Industrial Classification Code 4512) with

1,500 or fewer employees. The FAA has identified a total of 60 operators that meet this definition.

To determine the impact of the proposed rule on small part 121 operators, the FAA has estimated the annualized cost impact on each of those small entities potentially impacted by the proposed rule. The proposed rule is expected to impose an estimated total cost of \$10.9 million on the 60 small entities over the next 10 years. The annualized cost per small operator is estimated at \$18,300. For purposes of this rulemaking, one percent of the annual cost (\$265,300, in 1998 dollars) to small operators is considered economically significant in that it may entail either an increase in airline ticket fares or a requirement to create operating cost efficiencies to preserve the economic stability of impacted airlines. None of the 60 part 121 small entities would incur a substantial economic impact in the form of higher annual costs in excess of \$265,300, as the result of the proposed rule.

Therefore, the FAA has determined that this proposed rule would not have a significant impact on a substantial number of small entities. Accordingly, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605 (b), the Federal Aviation Administration certifies that this rule would not have a significant economic impact on a substantial number of small entities. The FAA invites public comments and requests that all comments be accompanied with clear and detailed supporting economic data.

INTERNATIONAL TRADE IMPACT ASSESSMENT

The provisions of this proposed rule would have little or no impact on trade for U.S. firms doing business in foreign countries and foreign firms doing business in the United States.

The number of foreign carriers carry AEDs and enhanced EMKs on flights to and from the United States include Air Zimbabwe British Airways, Cathay Pacific, Quantas, Varig, and Virgin Atlantic. U.S. carriers that have voluntarily upgraded their emergency medical equipment account for a majority of the U.S.-flag international service.

UNFUNDED MANDATES REFORM ACT ASSESSMENT

Title II of the Unfunded Mandates Reform Act of 1995 (the Act) codified in 2 U.S.C., 1501-1571, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. Section 204(a) of the Act, 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a proposed "significant intergovernmental mandate." A "significant intergovernmental

mandate" under the Act is any provision in a Federal agency regulation that would impose an enforceable duty upon State, local, and tribal governments, in the aggregate, of \$100 million (adjusted annually for inflation) in any one year. Section 203 of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity to provide input in the development of regulatory proposals.

This proposed rule does not contain a Federal intergovernmental or private sector mandate that exceeds \$100 million a year.