

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 67****[Docket No. 26493]****RIN 2120-AG30****Special Issuance of Third-Class Airman Medical Certificates to Insulin-Treated Diabetic Airman Applicants****AGENCY:** Federal Aviation Administration, DOT.**ACTION:** Policy statement.

SUMMARY: This document announces the new policy of the Federal Aviation Administration (FAA) regarding individuals with insulin-treated diabetes mellitus (ITDM) who apply for airman medical certification. It also addresses comments received concerning this policy as requested in a December 1994 Federal Register notice. The new policy will permit special issuance of third-class airman medical certificates to certain ITDM individuals who meet selection criteria and who successfully comply with an FAA-approved monitoring protocol.

EFFECTIVE DATE: December 23, 1996.**FOR FURTHER INFORMATION CONTACT:**

Tina Lombard, Program Analyst; Aeromedical Standards Branch (AAM-210); Office of Aviation Medicine; Federal Aviation Administration, 800 Independence Avenue, SW.; Washington, DC 20591; telephone (202) 267-9655; telefax (202) 267-5399.

SUPPLEMENTARY INFORMATION:**Background**

In late 1994, the FAA published a notice in the Federal Register (59 FR 67246, December 29, 1994) of its intent to consider a policy change concerning ITDM individuals who apply for airman medical certificates. The FAA opened docket no. 26493 and invited comment to it on a medical evaluation and monitoring protocol for possible use as the basis of a policy change that would permit certain insulin-using diabetic individuals to receive special issuance of airman medical certificates. The 90-day comment period on this proposed policy closed on March 29, 1995. This document responds to the comments received from the 1994 notice and to the comments from a 1991 petition of the American Diabetes Association (ADA). This document also states the policy of the Federal Air Surgeon concerning the special issuance of medical certificates to diabetic airman applicants.

Part 67 of Title 14 of the Code of Federal Regulations (CFR) (14 CFR part

67) details the standards for the three classes of airman medical certificate. A first-class medical certificate is required to exercise the privileges of an airline transport pilot certificate, while a second- and third-class medical certificate is required to exercise the privileges of a commercial pilot and private pilot certificate, respectively. An airman applicant who is found to meet the appropriate medical standards, based on medical examination and evaluation of the individual's history and condition, is entitled to a medical certificate without restrictions other than the limit of its duration prescribed in the regulations. Paragraph (a) of §§ 67.113, 67.213, and 67.313 of part 67 sets forth the standards for determining an individual's eligibility for first-, second-, or third-class medical certification based on a medical history or clinical diagnosis of diabetes mellitus. An individual with diabetes using oral hypoglycemic drugs or insulin for control is not eligible for medical certification under these standards.

Under § 67.401, Special Issue of Medical Certificates, the Federal Air Surgeon has the discretion to issue a medical certificate to an individual who does not meet the applicable provisions of subparts B, C, or D of part 67. The Federal Air Surgeon considers relevant factors on a case-by-case basis to determine whether the individual's medical conditions, medication, or other treatment is consistent with aviation safety and will permit special issuance of a medical certificate. The Federal Air Surgeon may authorize a special medical flight test, practical test, or medical evaluation to ensure that the duties authorized by the class of medical certificate applied for can be performed without endangering air commerce during the period in which the certificate would be in force. In determining whether the special issuance of a third-class medical certificate should be made to an applicant, the Federal Air Surgeon considers the freedom of an airman, exercising the privileges of a private pilot certificate, to accept reasonable risks to his or her person and property that are not acceptable in the exercise of commercial or airline transport pilot privileges, and, at the same time, considers the need to protect the public safety of persons and property in other aircraft and on the ground. Special issuance of a medical certificate may impose conditions and limitations on an individual to ensure safety. These conditions may include limiting the duration of a certificate, operational

and/or functional limitations, and the results of subsequent medical evaluations.

In the late 1980's, the FAA began to grant special issuance of medical certificates to individuals who controlled their diabetes with diet and oral hypoglycemic drugs. It has been, however, the long-standing policy of the Federal Air Surgeon not to consider an individual for special issuance of a medical certificate where the individual has a clinical diagnosis of insulin-treated diabetes mellitus.

This policy was based on concerns about the long-term medical risks associated with diabetes, including cardiovascular, neurological, ophthalmological, and renal pathologies. Of even greater concern, especially in the aviation environment, was the immediate risk posed by hypoglycemia or low blood glucose. Every diabetic is at some risk for hypoglycemia which can produce impaired cognitive function, seizures, unconsciousness, and death. Moreover, functional incapacitation associated with hypoglycemia may occur insidiously and may not be recognized by the diabetic or by other observers. Diabetics using insulin are at greater risk for hypoglycemia than those treated by diet or oral hypoglycemic agents.

The FAA has continued to review its policy of not granting special issuance of medical certificates to ITDM individuals. In 1992, the FAA instituted a program to permit, in select cases, ITDM air traffic control specialists (ATCS) to continue their safety-related duties. These ATCS's are individually evaluated and, if appropriate, returned to duty with intensive monitoring under a special medical protocol.

The protocol implemented for ATCS's with ITDM was developed by a panel of distinguished endocrinologists at the request of the Federal Air Surgeon and includes careful evaluation of the individual's medical history, risk stratification, and the efficacy of his or her efforts to control the disease. Those determined acceptable by the FAA to perform air traffic control duties are monitored by frequent blood glucose measurements while on duty. In addition, the blood glucose level is maintained somewhat higher than usual to prevent or reduce the likelihood of incapacitating hypoglycemia. The protocol also requires close supervision and prohibits solo duty.

In February 1991, the ADA petitioned the FAA to amend its policy to permit ITDM individuals to be issued airman medical certificates on a case-by-case basis. The petition was published in the Federal Register (56 FR 10383, March

12, 1991). The ADA further requested the creation of an FAA-appointed medical task force to develop a medical protocol capable of permitting case-by-case review.

In view of its ongoing success with ATCS's, the FAA reviewed its experience and collected data and presented them to the same panel of distinguished endocrinologists for its consideration and recommendations. A new, modified protocol was proposed by the panel for possible use as the basis for a change in the current special issuance policy regarding ITDM airman applicants.

Policy Statements

After careful consideration of the (1) comments to Docket No. 26493, Policy Concerning the Special Issuance of Medical Certificates to Diabetic Airman Applicants; Request for comments; (2) comments to the 1991 petition by the American Diabetes Association (56 FR 10383, March 12, 1991); (3) monitoring experience of the FAA medical waiver program for ATCS's with ITDM; (4) medical advances in the treatment of diabetes; and (5) evaluation of the proposed medical protocol, the Federal Air Surgeon has determined that selected ITDM individuals can be considered for special issuance of an airman medical certificate under the conditions of the evaluation and monitoring protocol with the following restrictions:

(1) ITDM individuals may be issued only a third-class airman medical certificate.

(2) ITDM individuals may exercise only the privileges of a student, recreational, or private pilot certificate.

(3) ITDM individuals are prohibited from operating an aircraft as a required crewmember on any flight outside the airspace of the United States of America.

(4) ITDM individuals are required to be in compliance with the monitoring requirements of the following protocol while exercising the privileges of a third-class airman medical certificate:

I. Initial Evaluation of Individuals With Insulin-Treated Diabetes Mellitus

A. Individuals with ITDM who have no otherwise disqualifying conditions, especially significant diabetes-related complications such as arteriosclerotic coronary or cerebral disease, retinal disease, or chronic renal failure, will be evaluated for special issuance of a third-class medical certificate if they:

1. Have had no recurrent (two or more) hypoglycemic reactions resulting in a loss of consciousness or seizure within the past 5 years. A period of 1

year of demonstrated stability is required following the first episode of hypoglycemia; and

2. Have had no recurrent hypoglycemic reactions requiring intervention by another party within the past 5 years. A period of 1 year of demonstrated stability is required following the first episode of hypoglycemia; and

3. Have had no recurrent hypoglycemic reactions resulting in impaired cognitive function which occurred without warning symptoms within the past 5 years. A period of 1 year of demonstrated stability is required following the first episode of hypoglycemia.

B. In order to provide an adequate basis for an individual medical determination, the person with ITDM seeking special issuance of a medical certificate must submit the following to: Federal Aviation Administration, Civil Aeromedical Institute, AAM-310, 6500 South MacArthur, Oklahoma City, OK 73125.

1. Copies of all medical records concerning the individual's diabetes diagnosis and disease history and copies of all hospital records, if admitted for any diabetes-related cause, including accidents and injuries.

2. Copies of complete reports of any incidents or accidents, particularly involving moving vehicles, whether or not the event resulted in injury or property damage, if due in part or totally to diabetes;

3. Results of a complete medical evaluation by an endocrinologist or other diabetes specialist physician acceptable to the Federal Air Surgeon (hereafter referred to as "specialist"). This report should detail the individual's complete medical history and current medical condition. The report must include a general physical examination and, at a minimum, the following information:

(a) Two measurements of glycated hemoglobin (total A1 or A1C concentration and the laboratory reference normal range), the first at least 90 days prior to the current measurement;

(b) A detailed report of the individual's insulin dosages (including types) and diet utilized for glucose control;

(c) Appropriate examinations and tests to detect any peripheral neuropathy or circulatory insufficiency of the extremities;

(d) Confirmation by an ophthalmologist of the absence of clinically significant eye disease. The eye examination should assess, at a minimum, visual acuity, ocular tension,

and presence of lenticular opacities, if any, and include a careful examination of the retina for evidence of any diabetic retinopathy or macular edema. The presence of microaneurysms, exudates, or other findings of background retinopathy, by themselves, are not sufficient grounds for disqualification unless it prevents the subject from meeting visual standards. However, individuals with active proliferative retinopathy or vitreous hemorrhages will not be considered for special issuance of a medical certificate until the condition has stabilized and this has been confirmed by an ophthalmologist; and

4. Verification by a specialist that the individual has been educated in diabetes and its control and has been thoroughly informed of and understands the monitoring and management procedures for the condition and the actions that should be followed if complications of diabetes, including hypoglycemia, should arise. Such verification should also contain the specialist's evaluation as to whether the individual has the ability and willingness to properly monitor and manage his or her diabetes and whether diabetes will adversely affect his or her ability to safely control an aircraft. The presence or absence of recurrent severe hypoglycemia and hypoglycemia unawareness should be noted. (See I.A. 1., 2. and 3 above.)

C. The ITDM individual applying for special issuance of a medical certificate should have been receiving appropriate insulin treatment for at least 6 months prior to submitting a request for special issuance of a medical certificate.

D. Special medical flight test. If the Federal Air Surgeon determines that there is need for an ITDM applicant to demonstrate his or her ability to comply with the medical protocol, the Federal Air Surgeon, under the provisions of § 67.401, may require a special medical examination and/or medical flight test prior to a determination of the applicant's eligibility for special issuance of a medical certificate.

II. Guidelines for Individuals With ITDM Who Have Been Granted Special Issuance of Airman Medical Certificates

A. Individuals with ITDM who are granted special issuance of third-class airman medical certificates must:

1. Submit to a medical evaluation by a specialist every 3 months. This evaluation must include a general physical examination and a report of glycated hemoglobin (total A1 or A1C) concentration. This evaluation shall also contain an assessment of the

individual's continued ability and willingness to monitor and manage properly his or her diabetes and of whether the individual's diabetes or its complications could reasonably be expected to adversely affect his or her ability to safely control an aircraft.

2. Carry and use a digital whole blood glucose measuring device with memory that is acceptable to the FAA. Provide records of all daily blood glucose measurements for review by the specialist at each 3-month evaluation required above and, if required, to the FAA at any time.

3. Provide to the FAA, on an annual basis, written confirmation by a specialist that the individual's diabetes remains under control and without significant complications and that he or she has demonstrated reasonable accuracy and recordation of his or her blood glucose measurements with the above described device.

4. Provide to the FAA, on an annual basis, confirmation by an ophthalmologist of the absence of clinically significant disease that would prevent the individual from meeting current visual standards.

5. Provide to the FAA, immediately, a written report of any episode of hypoglycemia associated with cognitive impairment, whether or not it resulted in an accident or adverse event.

6. Provide a written report to the FAA, immediately, of involvement in any accidents, including those involving aircraft and motor vehicles, or other significant adverse events, whether or not they are believed related to an episode of hypoglycemia.

7. Provide to the FAA, immediately upon determination by a specialist or other physician, any evidence of loss of diabetes control, significant complications, or inability to manage the diabetes. In such a case, the individual shall cease exercising the privileges of his or her airman certificate until again cleared medically by the FAA.

III. Glucose Management Prior to Flight, During Flight, and Prior to Landing

A. Individuals with ITDM shall maintain appropriate medical supplies for glucose management at all times while preparing for flight and while acting as pilot-in-command (or other flightcrew member). At a minimum, such supplies shall include:

1. An FAA-acceptable whole blood digital glucose monitor with memory;
2. Supplies needed to obtain adequate blood samples and to measure whole blood glucose; and

3. An amount of rapidly absorbable glucose, in 10 gram (gm) portions, appropriate to the potential duration of the flight.

B. All disposable supplies listed above must be within their expiration dates.

C. The individual with ITDM, acting as pilot-in-command or other flightcrew member, shall establish and document a blood glucose concentration equal to or greater than 100 milligrams/deciliter (mg/dl) but not greater than 300 mg/dl within ½ hour prior to takeoff. During flight, the individual with ITDM shall monitor his or her blood glucose concentration at hourly intervals and within ½ hour prior to landing. If a blood glucose concentration range of 100–300 mg/dl is not maintained, the following action shall be taken:

1. Prior to flight. The individual with ITDM shall test and record his or her blood glucose concentration within ½ hour prior to takeoff. If blood glucose measures less than 100 mg/dl, the individual shall ingest an appropriate 10 gm glucose snack (minimum 10 gm) and recheck and document blood glucose concentration after ½ hour. This process shall be repeated until blood glucose concentration is in the 100–300 mg/dl range. If blood glucose concentration measures greater than 300 mg/dl, the individual shall follow his or her regimen of blood glucose control, as provided to the FAA by his or her attending physician, until the measurement of blood glucose concentration permits adherence to this protocol.

2. During flight.

(a) One hour into the flight, at each successive hour of flight, and within ½ hour prior to landing, the individual shall measure and document his or her blood glucose concentration. Listed below are blood glucose concentration ranges and the actions to be taken when they occur during flight:

(1) Less than 100 mg/dl: The individual shall ingest a 20 gm glucose snack and recheck and document his or her blood glucose concentration after 1 hour.

(2) 100–300 mg/dl: The individual may continue his or her flight as planned.

(3) Greater than 300 mg/dl: The individual shall land as soon as practicable at the nearest suitable airport.

(b) The individual, as pilot, is responsible for the safety of the flight and must remain cognizant of those factors that are important in its successful completion. Accordingly, in recognition of such elements as adverse weather, turbulence, air traffic control

changes, or other variables, the individual may decide that a scheduled, hourly measurement of blood glucose concentration during the flight is of lower priority than the need for full, undivided attention to piloting. In such cases, the individual shall ingest a 10 gm glucose snack. One hour after ingesting of this glucose snack, the individual shall measure and document his or her blood glucose concentration. If the individual is unable to perform the measurement of his or her blood glucose concentration for the second consecutive time, the individual shall ingest a 20 gm glucose snack and shall land as soon as practicable at the nearest suitable airport. The individual, under these circumstances, is not required to measure and document his or her blood glucose concentration within ½ hour prior to landing.

3. Prior to landing. Except as noted above, the individual must measure and document his or her blood glucose concentration within ½ hour prior to landing.

Rationale for Policy Statement

The Federal Air Surgeon has found that the medical certification of selected ITDM individuals who agree to comply with the above protocol is appropriate. As noted above, this decision was reached after reexamining the policy concerning ITDM individuals, reviewing the comments received from the 1991 ADA petition and the 1994 diabetes notice, and by evaluating the proposed protocol of the expert panel of endocrinologists. In formulating this new policy, the Federal Air Surgeon also reviewed the success of FAA's program for ATCS's with ITDM and considered the medical and technological advances in the treatment of diabetes.

This protocol requires thorough screening of an ITDM individual's medical history for evidence of hypoglycemic episodes or impaired mentation. Findings from medical studies indicate that such screening should effectively exclude those at significant risk for incapacitation caused by hypoglycemia. In the report of the "Conference on Diabetic Disorders and Commercial Drivers," prepared for the Federal Highway Administration in March 1988, the authors recommended certification for certain ITDM drivers whose history revealed the absence of recurrent hypoglycemia resulting in loss of consciousness or seizure, the absence of development of seizure or coma without antecedent prodromal symptoms, and the absence of recurrent ketoacidosis. In a more recent technical review entitled "Hypoglycemia,"

published in *Diabetes Care*, Volume 17, Number 7, July 1994, Philip E. Cryer, M.D., Joseph N. Fisher, M.D., and Harry Shamoon, M.D., discuss clinical issues and current knowledge related to hypoglycemia. Cited in this review is a study which found that a history of prior severe hypoglycemia is the most powerful predictor of subsequent severe hypoglycemia. Another study discussed in this review presents data which show that ITDM individuals with histories of hypoglycemic unawareness are at about sevenfold increased risk for severe hypoglycemia as opposed to those ITDM individuals who are able to recognize developing hypoglycemia and take action to prevent its progression to severe hypoglycemia. Further data regarding the significance of histories of severe hypoglycemia are contained in a study conducted by the Diabetes Control and Complications Trial (DCCT) Research Group of Bethesda, MD, and reported in *The American Journal of Medicine*, Volume 90, April 1991, entitled "Epidemiology of Severe Hypoglycemia in the Diabetes Control and Complications Trial." This study describes the epidemiology of severe hypoglycemia and identifies patient characteristics or behaviors associated with severe hypoglycemia in patients with insulin-dependent diabetes mellitus. Data obtained from this study indicate that a history of severe hypoglycemia and longer duration of diabetes predicts a higher risk for hypoglycemia. Finally, on May 24, 1990, in testimony before the Subcommittee on Post Office and Civil Service, House of Representatives, Robert Ratner, M.D., Director, Diabetes Center, George Washington University Medical Center, emphasized that "(h)istory provides us with the greatest independent indicator of those individuals at highest risk for this complication (hypoglycemia) of diabetes care, and it does allow exclusion of this group."

The Federal Air Surgeon has found that advancements in the knowledge, treatment, and self-management of diabetes have made certification of ITDM individuals possible under certain circumstances. More efficient techniques for self-monitoring blood glucose, a better understanding of the dietary needs of diabetic individuals, and the improved education level of diabetic individuals result in better control of diabetes, enabling an individual to significantly mitigate the risk of hypoglycemia. The protocol that an ITDM individual must follow, as outlined under this policy, will allow for adequate blood glucose control prior

to and during flight through a comprehensive regimen of blood glucose monitoring and management, thus providing an appropriate level of safety during operation of an aircraft.

In developing this policy, consideration was given to the performance of FAA ATCS's with ITDM in continuing their safety-related duties. This program has been closely monitored since it was instituted in 1991 and has been incident-free since its inception. This record was maintained despite the 40-hour rotating work week required of an ATCS, a significantly longer daily work period of concern for safety than that of a student, recreational, or private pilot who flies for relatively short periods on a daily, weekly, monthly, or occasional basis.

Special issuance of an airman medical certificate to an ITDM individual is restricted by this policy to an applicant for a third-class medical certificate. In determining whether the special issuance of a third-class medical certificate should be made to an applicant, the Federal Air Surgeon, under § 67.401, considers the freedom of an airman, exercising the privileges of a student, recreational, and private pilot certificate, to accept reasonable risks to his or her person and property that are not acceptable in the exercise of commercial or airline transport pilot privileges, and, at the same time, considers the need to protect the safety of persons and property in other aircraft and on the ground.

Discussion of Comments

As noted above, in December 1994, the FAA published a notice requesting comment on a possible policy change concerning ITDM individuals who apply for airman medical certification. The FAA invited comment on a medical evaluation and monitoring protocol for possible use as the basis of a policy change. In addition, it invited comment on whether ITDM individuals should be restricted by class of medical certificate (e.g., only third-class medical certificate), restricted by class of airman certificate (e.g., private pilot, etc.), or restricted by operational limit (e.g., dual pilot operation only or no multiengine aircraft operation). This notice drew a large response from the aviation community, the medical community, members of Congress, and the general public. Over 800 comments were received and placed in the docket.

The FAA received comments on this notice from 93 pilots; 26 medical organizations, including university-affiliated associations and diabetes treatment centers; 150 physicians, including 13 aviation medical

examiners; 2 aviation trade associations; and 541 private individuals and members of Congress.

The ADA, an organization with more than 280,000 members and 800 chapters and affiliates, strongly urged the FAA to end its blanket prohibition of medical certification of ITDM individuals. The ADA urged the implementation of a policy without restriction to class of medical certificate, class of airman certificate, or by operational limitation. The Association endorsed a waiver system with stringent guidelines, such as the guidelines set out for comment by the FAA.

ADA stressed the need for case-by-case review of ITDM individuals. The Association stated that, just as not all nondiabetic persons should be certified, not all individuals with ITDM should be certified. The ADA stated that individuals who are not impacted by diabetic conditions affecting judgment and performance in the cockpit should be considered for medical certification. In their letter of March 2, 1995, they advocated exclusion of ITDM individuals at highest risk for incapacitation (e.g., history of hypoglycemic reaction resulting in unconsciousness, and episode of severe hypoglycemia without warning symptoms, or recurrent severe hypoglycemia). The ADA contended that blood glucose monitoring and the availability of carbohydrates can eliminate the majority of incidents of severe hypoglycemia and substantially reduce the number of episodes of mild hypoglycemia. The Association, a strong advocate of fair and equitable legal and societal standards for persons with diabetes, also contended that FAA's current policy on ITDM airman applicants is inconsistent with FAA's own policy of providing individual evaluation of ATCS's with ITDM.

In February 1991, the ADA petitioned the FAA to amend the special issuance provisions of part 67, or, alternatively, amend the FAA special issuance policy to permit the special issuance of medical certificates to individuals with ITDM on a case-by-case basis. The ADA also requested the creation of an FAA-appointed medical task force to develop a medical protocol to permit case-by-case review. Comments received on the petition totaled 160, most of which supported the special issuance of medical certificates for individuals with ITDM. These comments are similar to those received in response to FAA's notice requesting comments on a proposed policy change (59 FR 672463, December 29, 1994) and are addressed below. That portion of ADA's 1991 petition which requests a rulemaking

amendment of the special issuance section of part 67 was addressed in "Revision of Airman Medical Standards and Certification Procedures and Duration of Medical Certificates; Final Rule," (Docket No. 27940), that was published in the Federal Register on March 19, 1996 (61 FR 11238).

Comments were received from 24 state affiliates of the ADA. They unanimously supported a change in FAA policy to individually evaluate ITDM airman applicants. The affiliates emphasized the need for this policy to include stringent medical standards to ensure aviation safety. They stressed that ITDM applicants must meet all the conditions of the proposed medical evaluation and monitoring protocol, with the provision that, if any single condition is not met, no medical certificate should be granted.

The Aircraft Owners and Pilots Association (AOPA) supported a change in FAA policy concerning ITDM individuals, citing the improved education level of ITDM individual, enhanced self-management techniques, and state-of-the-art blood glucose monitoring meters. AOPA pointed to the success of the FAA policy of case-by-case certification of diabetics using oral hypoglycemic agents. AOPA stated that they believe this policy does not compromise safety; and, therefore, it is reasonable to extend this policy to ITDM individuals. AOPA urged that special issuance of medical certificates to ITDM applicants be available for any class of certificate. According to the Association, individuals should be considered based on their medical condition and not on the type of flying activities in which they engage.

The Experimental Aircraft Association (EAA) supported the special issuance of medical certificates to ITDM applicants. EAA supported the protocol which requires tight control of the initial issuance of medical certification after individual evaluation and a continuing program to ensure compliance.

Comments from five FAA aviation medical examiners (AME), all who support a change in policy, urged restriction of medical certification to private pilots. Three of these AME's stated that if the program with those restrictions proved successful, the program should be extended after a period of time to include first- and second-class medical certification. One AME, who is also a pilot, stated that an ITDM individual who is shown to have consistently and methodically maintained blood glucose control would have the self-discipline to follow an approved protocol and the self-

discipline required of a safety conscious pilot.

In general, private individuals supported a change in FAA's policy concerning the special issuance of medical certificates to ITDM airman applicants. Most commenters contended that medical certification of diabetic individuals should be conducted on an individual, case-by-case basis and that only applicants meeting strict eligibility guidelines be considered for medical certification. Many commenters stated that advances in medical knowledge and improved technology make control of blood glucose easier and more effective and, therefore, should allow certain ITDM individuals to be medically certified without compromising aviation safety.

Those individuals who commented on the medical evaluation and monitoring protocol cited it as being appropriately stringent; and they stated that adherence to this protocol should address any safety concerns of the aviation community and the public. The requirement of the protocol to individually assess an ITDM applicant's physical condition, assess his or her medical background and records, and review the ability of the applicant to manage his or her disease was emphasized repeatedly in responses from individual commenters as being appropriate. In addition, most of the comments received from certified diabetes educators, registered dietitians, registered nurses, etc. were in favor of a policy change and echoed the above individual commenters.

There was a divergence of opinion as to the class of airman medical certificate that should be offered under a special issuance, with the majority of individual commenters stating that special issuance should be offered for all classes of airman medical certification. A smaller but significant number of respondents advocated granting special issuance of third-class medical certificates only.

In addition, many individual commenters stated that a requirement for dual pilot operation would be in the interest of safety and would address the issue of hypoglycemic reaction and incapacitation during flight. Opinion was split on whether the requirement for dual pilot operation should apply to all classes of airman medical certificates or only to third-class medical certificates held by private pilots.

In opposition to the policy was the American Association of Clinical Endocrinologists (AACE). AACE opposed any policy change which would permit ITDM individuals to be eligible for medical certification. It

stated that the associated risks of this disease cannot be eliminated and that granting medical certification would pose unnecessary risks to both the patient and the general populace. AACE contended that the physiological effects of flight and the constraints of operating an aircraft decrease the likelihood of proper monitoring and management of blood glucose levels while in flight and increases the risk of impairment of incapacitation of ITDM individuals.

The Endocrine Society also opposed any change of FAA policy regarding ITDM individuals. The Society stated that, if a special issuance of a medical certificate is to be granted, an ITDM individual who has had even one severe hypoglycemic reaction within the last 3 years should not be eligible for issuance of a medical certificate. It further contended that food ingestion should never be permitted in lieu of hourly in-flight glucose testing, that an ITDM individual should have another qualified pilot in the cockpit at all times, and that an ITDM individual should not be allowed to pilot commercial aircraft. The Society pointed to the results of a recent study on the treatment of individuals with ITDM which shows that proper treatment of patients with ITDM requires tighter control of blood glucose levels and leads to an unavoidably higher risk of hypoglycemic reaction. According to the Society, tight control of the blood glucose level of an ITDM individual produces significantly better long term outcome through the reduction of the occurrence of nephropathy, retinopathy, and neuropathy. Therefore, the Society stated, appropriate treatment of ITDM individuals would unavoidably lead to a higher risk of hypoglycemic reaction, which should preclude these patients from obtaining special issuance of a medical certificate.

There was opposition by 17 physicians, one of whom is a pilot, to the proposed change in policy. They stated that the FAA's primary mission is public safety, and the agency should not be pressured to change its policy by special interest groups. In addition to those physicians, eight AME's opposed the policy change.

Many pilots and individual commenters who opposed the policy change stated that the proposed monitoring system is unwieldy and will detract from the pilot's ability to control the aircraft. They considered the proposed guidelines too complex. Some pilots contended that it would be extremely difficult to carry out the proposed monitoring protocol in the best visual flight rules conditions and

that it would be impossible to comply in adverse flight conditions. Concern was expressed regarding the danger of the combined effects of hypoglycemia and hypoxia in flight.

Some of the above commenters also suggested that the implementation of the proposed guidelines relies too heavily on the applicant's objectivity and honesty in assessing his or her medical situation.

The majority of commenters who opposed a policy change stated that controlled diabetics are always in jeopardy of insulin reactions and that the risk of hypoglycemia is not satisfactorily reduced or eliminated by the proposed protocol.

Finally, although the FAA has recently changed its policy to allow medical clearance of ATCS's under some circumstances, many individual commenters pointed out that pilots and ATCS's cannot be compared since ATCS's are subjected to close supervision and prohibited from solo duty.

FAA Response

In its comment, the ADA stressed the need to restrict some ITDM individuals from consideration for special issuance of a medical certificate. It advocated excluding ITDM individuals at risk of hypoglycemia, i.e., "individuals with a history of severe hypoglycemic reactions resulting in the loss of consciousness or seizure, recurrent severe hypoglycemic reactions requiring intervention by another party, or recurrent hypoglycemia without warning symptoms." The panel of endocrinologists who served at the request of the Federal Air Surgeon and whose recommendations were included in FAA's notice of December 29, 1994 (59 FR 6724) also recognized the need to restrict ITDM individuals at risk of hypoglycemia from consideration for special issuance of a medical certificate. The recommendation of the panel proposed restricting consideration of eligibility for special issuance to ITDM individuals who "have had no recurrent (two or more) severe hypoglycemic reactions requiring intervention by another party during the past 3 years and have no current history of hypoglycemia resulting in impaired cognitive function without warning symptoms (hypoglycemia unawareness)."

In its new policy, the FAA developed eligibility criteria to consider only those ITDM individuals who have had no recurrent hypoglycemic reactions resulting in a loss of consciousness or seizure within the past 5 years; had no recurrent hypoglycemic reactions

requiring intervention by another party within the past 5 years; and had no recurrent hypoglycemic reactions resulting in impaired cognitive function which occurred without warning symptoms in the past 5 years. The agency has determined that this 5-year time frame and the requirement for a period of 1 year of demonstrated stability following the first episode of hypoglycemia in each of the above instances provides an adequate basis for a medical determination of the applicant's eligibility. By restricting consideration for special issuance of a medical certificate to those individuals who meet these eligibility criteria, the FAA will ensure that only those individuals at low risk of hypoglycemia are considered under this protocol.

Some individual commenters and pilots stated that the proposed blood glucose monitoring guidelines to be followed during flight are complex, unwieldy, and detract from a pilot's ability to control the aircraft. Under this policy, blood glucose monitoring guidelines to be followed during flight require an individual with ITDM to monitor his or her blood glucose concentration at hourly intervals. An individual may, if he or she is unable to perform an hourly measurement of blood glucose concentration during flight, ingest a 10 gm glucose snack. One hour after ingestion of this glucose snack, an individual must measure his or her blood glucose concentration. If, at this time, the individual is unable to perform the blood glucose measurement, he or she must ingest a 20 gm glucose snack and land as soon as possible. The decision as to the appropriateness of performing a blood glucose test or ingesting a glucose snack at the prescribed test interval will be made by the pilot, taking into consideration all factors pertaining to the safety of his or her flight. Compliance with these monitoring guidelines during flight should not detract from an individual's ability to concentrate on flight operations given that the pilot can make a judgment of the appropriate action to be taken as his or her flight conditions warrant. The FAA also notes that several commenters point out the ease with which a trained ITDM individual can accomplish a glucose determination. One commenter provided a video tape demonstrating his use of a glucometer during actual flight with a safety pilot.

Many pilots commenting on the protocol stated that the blood glucose monitoring system would be extremely difficult to carry out in VFR conditions and would be impossible to comply with in adverse conditions. The FAA

shares the concern of the commenters that aviation safety be maintained at all times and that adherence to this protocol not interfere with the safe operation of an aircraft. However, compliance with these monitoring guidelines during flight allows a pilot, after taking into consideration the existing flight conditions, to determine the appropriateness of performing a blood glucose test or, at the required test interval, ingesting a glucose snack to ensure that an appropriate blood glucose level is maintained. This procedure allows a pilot to comply with the monitoring guidelines while ensuring the safe operation of his or her aircraft.

Some individual commenters stated that special issuance of a medical certificate should be offered for all classes of airman medical certificates. The FAA has determined that special issuance to ITDM individuals will be limited to applicants for third-class airman medical certificates. By restricting ITDM individuals to a third-class medical certificate, the FAA policy allows a student, recreational, or private pilot to accept reasonable risks to his or her person or property that are not acceptable in the exercise of commercial or airline transport pilot privileges.

Many individual commenters compared ITDM air traffic control specialists to ITDM pilots operating under this policy, citing the success of the ATCS program and the willingness of the FAA to consider ITDM ATCS's on a case-by-case basis. These commenters urged the FAA to extend these privileges to ITDM pilots also. Other individual commenters pointed out the dissimilar aspects of the two programs, specifically in that ITDM ATCS's are supervised at all times while on duty. The FAA is aware of the differences between the two programs and has considered the responsibilities and the medical certification and operational requirements of both ITDM ATCS's and ITDM pilots. An ATCS has daily responsibility for public safety through the operation of the air traffic control system. In addition to meeting the conditions of the protocol, the FAA requires that ITDM ATCS's, as do all ATCS's, hold a medical clearance which is equivalent to the second-class airman medical certificate required for commercial pilot privileges. And, as an extra measure of safety, the FAA does not permit solo duty by an ITDM ATCS. In contrast, ITDM pilots would fly infrequently, at their own convenience, and would be responsible primarily for the safe operation of one aircraft. Under this new policy, an ITDM individual may be considered for a third-class

airman medical certificate but be restricted to exercise only the privileges of a student, recreational, or private pilot certificate. The FAA believes that, under this protocol for individuals with ITDM, a further restriction from solo flight is not necessary.

The FAA has closely monitored the ITDM ATCS program, and it has been incident-free since its inception in 1991. This incident-free record has been maintained although an ITDM ATCS works a 40-hour week, often on a rotating schedule, which is a significantly longer period of time than ITDM pilots would operate under the conditions of this protocol. The FAA believes that the success of its ITDM ATCS program is an indicator of the feasibility of its new policy concerning ITDM pilots.

Summary

The FAA has reevaluated the proposed medical evaluation and monitoring protocol for ITDM individuals published in its 1994 Federal Register notice (docket no. 26493). After consideration of all the comments received, the FAA has determined that ITDM individuals following the conditions and requirements of the protocol described above will be able to safely perform their airman duties, thus permitting the special issuance of airman medical certificates to selected ITDM individuals who agree to and are capable of following the FAA-prescribed protocol.

International Civil Aviation Organization (ICAO) and Joint Aviation Regulations (JAR)

The FAA has determined that a review of the ICAO Standards and Recommended Practices and JAR's is not warranted because there are no existing comparable rules, and any waiver under this policy would be limited to the territory of the United States.

Regulatory Evaluation

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs Federal agencies to promulgate new regulations or modify existing regulations only if the expected benefits to society outweigh the expected costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Office of Management and Budget directs agencies to assess the effect of regulatory changes on international trade. In conducting these analyses, the FAA has determined that

this policy: (1) would generate benefits exceeding costs; (2) is not "significant" as defined in the Executive Order and DOT's Regulatory Policies and Procedures; (3) would not have a significant impact on a substantial number of small entities; and (4) would not constitute a barrier to international trade.

Cost Benefit Analysis

The FAA expects that this policy will impose additional costs on those insulin-using diabetics who seek special issuance of a third-class medical certificate. While the medical records and examinations required for consideration should be readily available to most applicants, the specific evaluation requirements of the protocol will impose those additional requirement costs for all such applicants. Also, additional costs will be incurred if the applicant is required to undergo a medical flight test prior to final consideration of a waiver request. The FAA intends to require most initial ITDM applicants for student pilot privileges to undergo such testing.

Once an individual has been selected for special issuance under this policy, additional costs will also be incurred in meeting the general conditions of the protocol, as well as the individual conditions, if any, imposed for the term of the special issuance. With the exceptions of the quarterly and annual examinations and reporting by appropriate medical specialists of the applicant's diabetes status to the FAA, the medical requirements of the protocol are already met by many insulin-using diabetics. Frequent daily blood glucose measurements using a digital measuring device are a routine activity for many diabetic individuals that may meet the requirements of the protocol and impose no additional cost. However, the protocol may require some to purchase an approved measuring device (approximately \$150), perform more tests (especially while flying), and purchase additional glucose snacks. The FAA believes that there will be little additional cost beyond that identified above for appropriate blood glucose management prior to and during flight.

The FAA believes that this protocol will not have an adverse impact on safety. The protocol will permit those insulin-using diabetics who voluntarily apply for and who are found eligible for special issuance of a third-class medical certificate the opportunity to exercise pilot privileges in a manner that protects the individuals as well as the public. Additionally, those individuals receiving special issuance under this protocol may benefit from the required

increased disease surveillance. The FAA has no data available from which to estimate the number of individuals who may seek special issuance or the number of special issuances that would be granted and thus cannot estimate the total overall cost of this policy. However, the FAA has determined that the benefits to the individual offered by this policy exceed the additional cost voluntarily undertaken by individual applicants. If an individual considers the cost too great, the applicant will not seek the waiver.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily or disproportionately burdened by government regulations. The RFA requires a Regulatory Flexibility Analysis if a rule is expected to have a significant (positive or negative) economic impact on a substantial number of small entities. Based on the standards and thresholds specified in FAA Order 2100.14A, Regulatory Flexibility Criteria and Guidance, the FAA has determined that this policy would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act

This policy does not contain any Federal intergovernmental or private sector mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 does not apply.

International Trade Impact

The Office of Management and Budget directs agencies to assess the effects of regulatory changes on international trade. The policy would not have any impact on international trade.

Federalism Implications

The policy herein would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12866, October 4, 1993, it is determined that this policy would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Conclusion

For the reasons discussed above, including the findings in the Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this policy is

not significant under Executive Order 12866, Regulatory Planning and Review, issued October 4, 1993. In addition, the FAA certifies that this policy does not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This policy is not considered significant under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979) and Order DOT 2100.5, Policies and Procedures for Simplification, Analysis, and Review of Regulations, of May 22, 1980.

The Federal Air Surgeon, for the reasons set out above, has determined that the FAA will consider selected

ITDM individuals for special issuance of a third-class airman medical certificate on a case-by-case basis with the conditions and restrictions set forth in this policy statement. Individuals will be closely monitored to determine the effectiveness of this policy. The performance and medical condition of an ITDM individual will be monitored through the review of medical evaluations, records of daily blood glucose measurements, reports of hypoglycemic episodes, and reports of involvement in any accidents or incidents. The Federal Air Surgeon, at his discretion, may modify or terminate this policy at any time. If substantive change is made to this policy, it will be

published in the Federal Register. Publication of this policy statement disposes of the petition submitted by ADA in 1991.

Individuals interested in applying for special issuance of an airman medical certificate should contact: Federal Aviation Administration, AAM-300, Civil Aeromedical Institute, 6500 South MacArthur, Oklahoma City, OK 73125.

Issued in Washington, DC, on November 5, 1996.

Jon L. Jordan,

Federal Air Surgeon.

[FR Doc. 96-29739 Filed 11-18-96; 10:58 am]

BILLING CODE 4910-13-M