

[4910-13]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 67

[Docket No. FAA-2009-0773

Special Issuance of Airman Medical Certificates to Applicants Being Treated with Certain Antidepressant Medications

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Policy Statement; request for comment

SUMMARY: This policy statement is intended to serve as notice that the Federal Aviation Administration (FAA) will consider for a special-issuance medical certificate applicants for first-, second-, and third-class airman medical certification who are being treated for depression with one of four antidepressant medications. The FAA will evaluate affected applicants on a case-by-case basis and will issue certificates based on a medical finding that an individual's use of such medication will not endanger public safety.

DATES: This policy goes into effect April 5, 2010. Comments must be submitted on or before May 5, 2010.

ADDRESSES: You may send comments identified by Docket Number FAA-2009-0773 using any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- Mail: Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue, SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.
- Hand Delivery or Courier: Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- Fax: Fax comments to Docket Operations at 202-493-2251.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket web site, anyone can find and read the electronic form of all comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the Federal Register published on April 11, 2000 (65 FR 19477-78) or you may visit <http://DocketsInfo.dot.gov>.

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time and follow the online instructions for accessing the docket, or, the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Judi Citrenbaum, Federal Air Surgeon's Office, Office of Aerospace Medicine, Federal Aviation Administration, 800 Independence Avenue S.W., Washington, DC 20591; telephone (202) 267-9689; facsimile (202) 267-5200, e-mail Judi.M.Citrenbaum@faa.gov.

SUPPLEMENTARY INFORMATION:

Availability of the Policy Statement: You can get an electronic copy of this document using the Internet by—

1. Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visiting the FAA's Regulations and Policies web page at http://www.faa.gov/regulations_policies or
3. Accessing the Government Printing Office's web page at <http://www.gpoaccess.gov/fr/index.html>.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue S.W, Washington, DC 20591, or by calling (202) 267-9680. Make sure to identify the docket number.

Background

Under Title 14 of the Code of Federal Regulations (14 CFR) 67.107(c), 67.207(c), and 67.307(c) and 67.113(c), 67.213(c) and 67.313 (c), the FAA generally considers a diagnosis of depression and use of psychotropic medication medically disqualifying for applicants for FAA medical certification. Disqualifying medication generally includes all sedatives, tranquilizers, antipsychotics, antidepressants (including selective serotonin reuptake inhibitors (SSRIs)), analeptics, anxiolytics, and hallucinogens. Aviation Medical Examiners (AMEs) defer medical certificate issuance for any applicant with a disqualifying medical condition, including any

applicant who reveals on a medical certificate application usage of psychotropic medication for treatment of depression.

Under 14 CFR 67.401 the Federal Air Surgeon may, at his discretion, authorize special issuance of airman medical certificates to applicants who are disqualified under the certification standards set forth in subparts B, C, or D of part 67. The FAA, however, has long considered the use of a psychotropic medication for treatment of depression as a basis to deny a special-issuance medical certificate. Current FAA special-issuance practice has been to consider applicants who had taken psychotropic medication only if they had discontinued it for at least 3 months prior to application. Upon careful review and reconsideration, the FAA is modifying its long-standing, special-issuance practice. The FAA has determined that aviators diagnosed with depression taking one of four specific SSRIs may be considered for special issuance of an airman medical certificate. Affected applicants will continue to be considered on a case-by-case basis and in keeping with the conditions and limitations announced in this policy statement.

As reported in the Federal Air Surgeon's Medical Bulletin, Vol. 42, No. 3, 2004-3 (article entitled "Depression and Use of SSRIs in Pilots"), since developed in the 1980s, SSRIs have been used successfully to treat many psychiatric disorders and medical conditions. Because SSRIs have been more effective and better tolerated (fewer side effects) than previous antidepressant medications, they soon became the most frequently prescribed medications for depression. Five of the top 40 medications prescribed in the United States are SSRIs and their usage is increasing.

Some civil aviation authorities have adopted more flexible policies to consider some applicants using SSRIs. Similarly, the International Civil Aviation Organization (ICAO), the aerospace medical community, and the aviation community at large have made recommendations

that suggest more flexibility may be appropriate in some cases. These policies and recommendations may be summarized as follows:

- **Aerospace Medical Association:** in 2004, published a position paper recommending that the FAA allow usage of SSRIs.
- **Aircraft Owners and Pilots Association:** in 2006, proposed a change to policy and offered a protocol for allowing use of certain SSRIs in pilots.
- **Air Line Pilots Association Aeromedical Office:** in 2002, proposed a policy for granting Special-Issuance Medical Certificates for selected SSRIs and with ongoing medical monitoring.
- **Civil Aviation Safety Authority of Australia:** in 1987, allowed use of certain SSRIs. A 10-year follow-up study (1993-2004) of 481 pilots showed no increase in accidents.
- **ICAO:** in 2009, adopted a Recommended Practice that advises that signatory states may certificate applicants on a case-by-case basis who are prescribed (and are taking) an approved SSRI antidepressant medication for an established diagnosis of depression which is in remission.
- **Transport Canada:** in 2004, allowed (with no adverse affect on safety) six pilots holding first-class certificates and serving in multi-crew settings selected use of only three specific medications.
- **U.S. Army:** in 2005, offered a waiver for use of SSRIs in selected pilots.

In keeping with these recommendations and policies, broadening the current special-issuance policy on the use of psychotropic medication to allow certain antidepressants will provide the FAA latitude, on a case-by-case basis, to grant special-issuance medical certificates to applicants determined to be fit for flight. For the FAA, concern regarding applicants who may be reluctant to disclose or who may be masking a struggle with depression remains a safety concern that this policy will serve to address.

Policies and Recommendations the FAA Considered

In 2004, the Aerospace Medical Association (AsMA) [see the docketed copy of the article in the journal *Aviation, Space, and Environmental Medicine* entitled “Aeromedical Regulation of Aviators Using Selective Serotonin Reuptake Inhibitors for Depressive Disorders”

(Vol 75, No. 5)] proposed that aeromedical certifying authorities remove the current absolute prohibition against pilots flying while taking SSRIs and adopt aeromedical protocols that include carefully controlled followup and review. According to AsMA: “Protocols designed to aggressively manage the full spectrum of adverse possibilities related to SSRI use may enable the safe use of SSRIs in formerly depressed aviators who suffer no aeromedically significant side effects. In these closely managed cases of depressive disorders, special issuances or waivers for SSRI use are justified.”

In 2006, the Aircraft Owners and Pilots Association requested the FAA to reconsider its longstanding policy that disallows use of all antidepressant medication. In its request, AOPA states that the FAA should consider those pilots who have a “demonstrated history of continued stability and show no adverse symptoms while using psychotropic medications, specifically SSRIs for a special issuance of a third-class medical certificate.”

AOPA indicates that the Civil Aviation Safety Authority of Australia (CASA) has allowed medical certification of aviators using antidepressants since 1989. “Although CASA’s policy was not formalized until 2001, the compiled data of 481 cases did yield evidence suggesting that the use of antidepressants in carefully screened and well-monitored airmen can safely be undertaken without compromising aviation safety. A smaller study conducted by Transport Canada among military aviators reached a similar conclusion. The results of the Australian and Canadian experience and the conclusion of aviation medical experts clearly favor the use of SSRIs under controlled conditions. Because of these encouraging results, AOPA believes that this is an opportune time for the FAA to change its policy regarding the use of certain SSRIs.”

An August 2007 research article published in the journal *Aviation, Space, and Environmental Medicine* (Vol. 78, No. 8) entitled “Antidepressant Use and Safety in Civil Aviation: A Case-Control Study of 10 Years of Australian Data” followed the impact of SSRI usage on aviation safety. (A copy of this article is placed in the docket.)

According to the article, the aim of the study was “to identify significant safety-related outcomes, such as aircraft accidents or incidents that may be related to the use of antidepressant medication in pilots and air traffic controllers.” The study employed a matched cohort of all holders of Australian aviation medical certificates who were prescribed antidepressants during the period January 1, 1993 to June 30, 2004, and a matched comparison group. No significant differences between the two groups were found in any of the analyses. Provided specific criteria were met and maintained, no evidence of adverse safety outcomes was found arising from permitting individuals to operate as commercial or private aircrew or air traffic controllers while using antidepressants.

In November 2009, the International Civil Aviation Authority (ICAO) adopted a Recommended Practice that advises that signatory states may certificate applicants on a case-by-case basis who are prescribed (and are taking) an approved SSRI antidepressant medication for an established diagnosis of depression which is in remission. The recommendation reads as follows:

6.3.2.2.1, 6.4.2.2.1, 6.5.2.2.1 **Recommendation.**- An applicant with depression, being treated with antidepressant medication, should be assessed as unfit unless the medical assessor, having access to the details of the case concerned, considers the applicant’s condition as unlikely to interfere with the safe exercise of the applicant’s license and rating privileges.

In guidelines provided for assessment of applicants treated with antidepressant medication in its Manual of Civil Aviation Medicine (Doc 8984), ICAO indicates: “Some of these [antidepressant] medications are sedating and some are not, thus offering a therapeutic choice in treating depressed patients who show psychomotor agitation or retardation. Fewer side effects generally result in improved aeromedical safety. However, successful treatment of depression is a dynamic and complex process involving more than just writing a prescription, and the SSRIs can have some aeromedically significant side effects and withdrawal effects that are of little importance in ordinary clinical practice. Aeromedical policies that place an absolute prohibition on operating after a diagnosis of depression may also make it less likely that an aviator or air traffic controller will seek treatment or declare their illness to the licensing authority.”

Forthcoming Notice Related to this Action

FAA studies have shown that certain antidepressants (SSRIs) were found in 61 pilot fatalities of civil aviation accidents that occurred during 1990–2001. (See copies of DOT/FAA/AM-07/19 and DOT/FAA/AM-03/7 placed in this docket.) In conducting these studies, researchers from the FAA Civil Aerospace Medical Institute retrieved medical information on 59 of the 61 pilots from the FAA Medical Certification Database and accident cause/factor information from the National Transportation Safety Board's Aviation Accident Database. (Information on two pilots was not available because one had no medical certificate and one held Canadian certification). Psychological conditions and/or the use of drugs were determined to be the cause or a factor in 19 (31%) of the 61 accidents. Study findings indicated

that SSRIs were used by the aviators but were not reported in their aeromedical examinations. The FAA remains concerned that individuals seen in the study did not disclose a medical history of depression, a related medical condition, or SSRI usage.

According to a May 2004 report published in the journal *Aviation, Space, and Environmental Medicine* (Vol 75, No. 5) entitled “Aeromedical Regulation of Aviators Using Selective Serotonin Reuptake Inhibitors for Depressive Disorders,” pilots would rather risk not taking prescribed antidepressant medication than be grounded. The report (placed in the docket) refers to information about the use of SSRIs available from the Aviation Medicine Advisory Service (AMAS) of Aurora, Colorado which provides consultation to various aviation organizations such as pilot unions and aerospace medicine specialists. This database includes information on approximately 68,000 pilots working at approximately 55 air carriers. According to the report:

“AMAS reviewed its database of telephone inquiries from pilots between 1992 and 1997. It had received 1200 telephone inquiries from pilots who had been diagnosed as having clinical depressions, and who had been advised by their physicians to take antidepressant medications. Under the current FAA policy, these pilots would spend about 9 mo (sic) off flying status. These pilots had called AMAS to discuss the aeromedical implications of their situations.

When advised of the FAA’s policy, that each would be grounded until the depression had cleared and the medication had been discontinued for approximately 3 mo (sic), the pilots indicated their intended responses to the prospect of not flying for 9 mo (sic) or more. Of the 1200 pilots, some 59% (710) told the AMAS that they would refuse the medication and continue to fly. About 15% (180) indicated an intention to take the

medications and continue their flight duties without informing the FAA. The remaining 25% (300) said they would take sick leave, undergo the recommended treatment, and return to work when aeromedically cleared to do so.”

Scenarios involving individuals who might risk flying while taking an antidepressant without medical oversight, or flying without taking an antidepressant when they need to be, are unacceptable. Without condoning what we regard as a serious violation of FAA regulations and a serious breach of the trust on which the aeromedical certification system depends, we want to encourage pilots who are suffering from depression or who are using antidepressants to report this information honestly. We want individuals to be forthcoming about depression and antidepressant usage. We plan, therefore, to announce in a separate Federal Register notice a one-time, limited opportunity to reveal previously undisclosed depression and use of antidepressant medications without being subject to FAA enforcement action. Our intent is to enhance safety by having those individuals suffering from depression and using antidepressants do so with appropriate aeromedical oversight.

Policy Statement

After careful consideration, the FAA has determined that selected individuals who are being treated for depression with one of four specific antidepressant medications may be considered for special issuance of a medical certificate. Individuals granted a special-issuance medical certificate under this policy may take only one type of antidepressant medication limited to the following four medications: Fluoxetine (Prozac), Sertraline (Zoloft), Citalopram (Celexa),

or Escitalopram (Lexapro). All these medications are SSRIs, antidepressants that help restore the balance of serotonin, a naturally occurring chemical substance found in the brain.

The FAA is limiting consideration of special-issuance medical certificates to these four medications. Increasingly accepted and prevalently used, these four antidepressants may be used safely in appropriate cases with proper oversight and have fewer side effects than previous generations of antidepressants. While the focus of this policy statement is on individuals being treated for depression, the FAA realizes that these four medications may be used to treat conditions other than depression. It should be noted, therefore, that, in all instances, the FAA will continue to consider applicants and make determinations on a case-by-case basis under the special-issuance process just as it always has.

In addition to treating psychiatrists, AMEs who have specialized training under a program called the Human Intervention and Motivation Study (HIMS) also will assist the FAA by making recommendations about certification cases to be considered under this new policy. The HIMS program is a safety-critical aviation program established nearly 40 years ago. The program, developed specifically for commercial pilots, was designed as an alcohol and drug assistance program to coordinate the identification, assessment, treatment, and medical certification of pilots in need of help. Under HIMS, pilots who successfully meet rigorous FAA protocols may be returned to duty in accordance with 14 CFR 67.401. The FAA will apply the basic HIMS evaluation and monitoring approach to this new policy and HIMS AMEs will participate in a specialized training program tailored to evaluating and monitoring applicants who wish to be considered under this new policy.

No regulatory changes are being made under this policy. Further, the FAA continues to believe that applicants requiring use of multiple antidepressant medications or use of any other psychotropic medication in conjunction with any one of the four specified in this policy will not

meet the criteria set forth under this policy. The use of psychotropic medication continues to be disqualifying under the medical standards and special-issuance certification will be granted only after thorough analysis of each individual case presented and only when appropriate conditions and limitations are in place so that the applicant may safely be permitted to operate an aircraft. It should be noted that as new information becomes available and recommendations from the medical community change it may be necessary for the FAA to again revise its policy.

The FAA special-issuance policy will include consideration for depression treated with certain antidepressant medication under the guidance set forth as follows:

**CONSIDERATION FOR SPECIAL ISSUANCE OF A MEDICAL CERTIFICATE
WITH REGARD TO DEPRESSION TREATED WITH MEDICATION**

This protocol applies to considerations for special-issuance medical certification for airmen requesting first-, second-, and third-class special-issuance medical certificates, for the exercise of privilege under 14 CFR Parts 121,135, or 91, who are being treated with certain antidepressant medications.

Criteria to be Considered:

Diagnoses:

Mild to moderate depressive disorders, such as

1. Major Depressive Disorder (mild to moderate) either single episode or recurrent episode
2. Dysthymic Disorder
3. Adjustment disorder with depressed mood

Pharmacologic Agents Considered:
(single-agent use only)

1. Fluoxetine (Prozac);
2. Sertraline (Zoloft);
3. Citalopram (Celexa); or
4. Escitalopram (Lexapro)

Specifically Unacceptable diagnoses and or symptoms:

1. Psychosis
2. Suicidal ideation
3. History of electro convulsive therapy (ECT)
4. Treatment with multiple antidepressant medications concurrently
5. History of multi-agent drug protocol use (prior use of other psychiatric drugs in conjunction with antidepressant medications)

Psychiatric status:

1. All symptoms of the psychiatric condition for which treatment is indicated must be ameliorated by the single medication and the condition must be stable with no change in or exacerbation of symptoms for 12 months prior to certification;
2. Airman must be on a stable dosage of medication for a minimum of 12 months prior to certification; and
3. Airman must have no aeromedically significant side effects of prescribed medication.

Required Reports and Consultations:
(initial consideration)

1. A consultation status report (and follow-up reports as required) from a treating psychiatrist attesting to and describing the applicant's diagnosis, length and course of treatment, dosage of the antidepressant medication taken, and presence of any side effects from the antidepressant the applicant takes or has taken in the past;
2. A written statement prepared by the applicant describing his or her history of antidepressant usage and mental health status;
3. A report of the results of neurocognitive psychological tests with provision of the raw test data: including, but not limited to: COGSCREEN AE, Trails A/B; Stroop Test; CCPT, PASSAT, Wisconsin Card Sorting Test;
4. An evaluation and a written report from a HIMS-trained AME who has reviewed items 1., 2., and 3. above and who makes a recommendation for a special-issuance medical certificate; and
5. Any additional information the Federal Air Surgeon may require to make a determination.

Issued in Washington, DC, on March 26, 2010.

Frederick E. Tilton,
Federal Air Surgeon

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