67-15

14 CFR Part 67

[Docket No. 27890]

RIN 2120–AF42

Medical Standards and Certification

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; disposition of comments.

SUMMARY: On September 9, 1994, the Federal Aviation Administration (FAA) issued an emergency final rule amending the general medical standard for first-, second-, and third-class airman medical certificates. The FAA, in the same document, sought public comment on the final rule. This document disposes of the comments received in response to that rule.

ADDRESSES: Comments submitted in response to this rulemaking may be examined at the Federal Aviation Administration, Office of the Chief Counsel, Rules Docket, room 915–G, 800 Independence Avenue SW., Washington, DC, weekdays (except Federal holidays) between 830 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Tina Lombard, Aeromedical Standards Branch, (AAM–210), Office of Aviation Medicine, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–9655.

SUPPLEMENTARY INFORMATION:

Background

The general medical standard for the three classes of airman medical certificates is detailed in part 67 of Title 14 of the Code of Federal Regulations (14 CFR part 67). A first-class medical certificate is required to exercise the privileges of an airline transport pilot certificate, while second- and third-class medical certificates are required to exercise the privileges of commercial and private pilot certificates, respectively. An applicant who is found to meet the appropriate medical standards is entitled to a medical certificate without restrictions other than the limit of its duration as prescribed in 14 CFR part 67.

An applicant may be ineligible for certification under §§ 67.13(f)(2), 67.15(f)(2), or 67.17(f)(2) if that person has an organic, functional, or structural disease, defect, or limitation that the Federal Air Surgeon finds: (1) makes the applicant unable to safely perform the duties or exercise the privileges of the airman certificate the applicant holds or for which the applicant is applying, or (2) may reasonably be expected within 2 years of Federal Air Surgeon's finding to make the applicant unable to safely perform those duties or exercise those privileges.

Paragraph (f)(2) of §§ 67.13, 67.15, and 67.17 provides the historical basis for denying medical certification in cases where the Federal Air Surgeon has determined that an applicant's medication or other treatment (including prescription, over-the-counter, and nontraditional medication or other treatment remedies) interferes with the applicant's ability to safely perform the duties, or exercise the privileges, of the airman certificate for which the airman is applying or holds.

Notwithstanding the FAA's long-standing medical certification policy and practice regarding medication and other treatment, the U.S. Court of Appeals for the Seventh Circuit determined that paragraph (f)(2) did not provide a basis for denial of medical certification based on medication alone. *Bullwinkel v. Federal Aviation Administration*, 23 F.3d 167, (7th Cir., *reh'g. denied*). The Seventh Circuit's decision that medication alone was not covered by paragraph (f)(2) raised serious safety concerns within the FAA. As a result of those concerns, the FAA on September 9, 1994, promulgated an emergency final rule that was immediately effective to clarify and codify the FAA's policy regarding an individual who holds, or is applying for, an airman medical certificate in a case where medication or other treatment was found to interfere, or may reasonably be expected to interfere, with that individual's ability to safely perform airman duties (57 FR 46706).

The September 9, 1994, emergency final rule amended paragraph (f) of §§ 67.13, 67.15, and 67.17 by adding to each a new paragraph (3), which sets out the standard for certification where medication or other treatment is involved. Each paragraph (f)(3) made ineligible for unrestricted medical certification any applicant whose medication or other treatment is found by the Federal Air Surgeon to make, or may reasonably be expected to make with 2 years after the finding, that applicant unable to safely perform the duties or exercise the privileges of his or her airman certificate. The final rule did not change the FAA's current and long-standing application of the medical certification standards. Rather, its sole purpose was to expressly codify the agency's practice in light of the *Bullwinkel* decision.

Also, for continuity with the current administration of other medical certification procedures, reference to this emergency final rule was added by revising § 67.25, Delegation of authority, and § 67.27, Denial of medical certificate.

The FAA invited public comment on the final rule and established a 60-day comment period, which closed on November 8, 1994.

Discussion of Comments

The FAA received six comments in response to the emergency final rule; four comments opposed and two comments supported the rule. The commenters included five individuals and one association, the Aerospace Medical Association (ASMA).

One commenter states that the FAA was wrong to amend the rules because of a single case. The commenter suggests that a better standard would be to list those drugs in the regulations that would be considered automatically disqualifying or potentially disqualifying.

One commenter characterizes the rule as a major change and objects to it being issued as a final rule without prior public comment. He suggests that the FAA rescind the final rule and schedule the subject for a notice of proposed rulemaking.

One commenter states that his third-class medical certificate was revoked because he was taking a medication to control symptoms of bipolar disorder. He contends that the matter of disqualification should be based solely on the underlying medical condition. He further contends that medication can control symptoms for approximately 80 percent of people with the disorder. The commenter concludes that patients taking certain medications for bipolar disorder are "effectively cured" of the underlying condition and should be eligible for medical certification.

One commenter states that there was no cause for issuing an emergency rule and that the FAA's policy was shown in court to be contrary to law. He contends that the FAA's choice of rulemaking procedure was improper. Further, he objects that the September 9, 1994, final rule does not specify the names of all disqualifying medication or treatment which the rule encompasses. He states that the rule enables the FAA to make judgments which may be arbitrary or unreasonable. The commenter suggests that this rulemaking action should have been contained in an overall revision of parts 61 and 67.

The ASMA states that it strongly supports the final rule. Further, the ASMA concurs with the dissenting opinion in the *Bullwinkel* case in that the general medical standard of the airman medical standards should be viewed as including all elements of medicine, i.e., medication and other treatments.

One commenter agrees with the FAA's action but expresses concern about the change in the rules without benefit of prior public comment.

FAA Response

The FAA's rationale for issuing this emergency final rule is fully set out in the preamble to the rule published at 59 FR 46706 on September 9, 1994.

As stated in the preamble to the final rule, the FAA determined an emergency existed that required immediate action; that determination is unchanged by the comments. A delay could have had an adverse effect on aviation safety. Neither a notice of proposed rulemaking nor incorporation of the amendment into a possible part 67 revision, as proposed by commenters, was determined to be in the public interest.

As to the commenters' call for a "list" of disqualifying medications, the Federal Air Surgeon has determined that an exhaustive "listing" of specific medications or specific treatments to determine an airman's eligibility is not possible. All the positive and negative effects of any medication or treatment are rarely appreciated when first introduced. In some cases, substantial amounts of time may pass before a particular drug or treatment can be judged with confidence, particularly with its application to individuals in the aviation environment. Because of the continuous changes in the field of medicine and pharmacology, the FAA has determined that publishing a static list of disqualifying medication is not appropriate or practical.

In case where an individual has been determined to have a disqualifying condition and/or use a disqualifying medication or other treatment and requests special issuance of a medical certificate, the Federal Air Surgeon considers not only all relevant scientific data on the particular condition and/or medication or other treatment but also the individual's particular situation and the role that he/she will perform in aviation. The case-by-case review can and does result in instances where the particular condition and/or medication or other treatment precludes the affected individual from receiving even an individually tailored special issuance medical certificate. Conversely, with the availability of new data and experience, some similarly affected individuals may, by adjustments in their medication dosage or other treatment, or restrictions in their privileges, for example, receive special issuance of medical certificates.

Because this careful analysis of each special issuance case is frequently not fully appreciated, the perception exists that many conditions and/or medications or other treatment are always disqualifying. In fact, with the availability of new data and experience, the Federal Air Surgeon has found it safe to issue special medical certificates to the majority of those individuals who historically were always denied. But, as there are literally hundreds of diagnoses, medications, and other treatments, as well as thousands of combinations that frequently change over time, the FAA cannot, as a practical matter, produce a "list" of medications and/or treatments that would be considered disqualifying or, conversely, acceptable for airman medical certification.

While at any point in time there may be treatment and medications that preclude the special issuance of a medical certificate, the FAA will continue to seek public comment, when appropriate, as it has done recently concerning insulin-using diabetics (see 59 FR 67426, September 29, 1994), to assist the Federal Air Surgeon in formulating policy on the special issuance of medical certificates.

Finally, the *Bullwinkel* decision highlighted a deficit in FAA procedures that the emergency final rule has now corrected; the agency does not view the decision as finding the policy and practice of the FAA to be "contrary to law" as characterized by one commenter. The rule change clarifies and resolves any previous ambiguity in FAA's medical standards regarding medication and/or other treatment.

Conclusion

Accordingly, after careful consideration of all the comments submitted, the FAA has determined that no further rulemaking action is warranted.

Issued in Washington, DC, on February 23, 1996.

Jon L. Jordan,

Federal Air Surgeon.

[FR Doc. 96–4686 Filed 2–28–96; 8:45 am]

BILLING CODE 4910–13–M

Corrections

Federal Register
Vol. 59, No. 223
Monday, November 21, 1994

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 67

[Docket No. 27890; Amendment No. 67-15]
RIN 2120-AF42

Medical Standards and Certification

Correction

In rule document 94-22207 beginning on page 46706, in the issue of Friday, September 9, 1994, make the following correction:

§ 67.25 [Corrected]

On page 46708, in the second column, in § 67.25 (b), in the eighth line, "an" should read "and".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 67

[Docket No. 27890; Amendment No. 67–15]

Medical Standards and Certification; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final rule, Medical Standards and Certification, published in the **Federal Register** on September 9, 1994.

EFFECTIVE DATE: October 20, 1994.

FOR FURTHER INFORMATION CONTACT: Dennis P. McEachen, (202) 493–4075.

Correction of Publication

In the final rule beginning on page 46706 in the issue of Friday, September 9, 1994, in the second column, on page 46708, amendatory instruction No. 5 is corrected to read as follows:

"5. The first sentence is republished and the second sentence is revised in paragraph (b) of § 67.25 to read as follows:"

Issued in Washington, DC, on October 17, 1994.

Michael E. Chase,

Acting Assistant Chief Counsel, Office of the Chief Counsel.

[FR Doc. 94–26071 Filed 10–19–94; 8:45 am]

BILLING CODE 4910–13–M