ORAL ARGUMENT NOT YET SCHEDULED

No. 20-1443

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

CHARLES ERWIN,

Petitioner,

v.

FEDERAL AVIATION ADMINISTRATION,

Respondent.

On Appeal from the Federal Aviation Administration
Petition for Review of Final Order Dated September 11, 2020

PETITIONER CHARLES ERWIN'S FINAL BRIEF

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April 29, 2021

CERTIFICATE AS TO PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

Pursuant to D.C. Cir. Rule 28(a)(1) Petitioner Charles Erwin hereby certifies as follows:

I. The Parties

The Petitioner is Charles Erwin ("Mr. Erwin"), an individual.

The Respondent is the Federal Aviation Administration ("FAA").

There are no intervenors or amici to date.

II. Rulings Under Review

The ruling under review is the FAA's final decision issued on September 11, 2020 denying Mr. Erwin's request for reconsideration of the withdrawal of his Authorization for Special Issuance of an Airman Medical Certificate that was issued on May 17, 2017.

III. Related Cases

This case has not previously been before this Court. Mr. Erwin, however, did file a writ of mandamus on July 8, 2020 in the United States District Court for the Western District of Oklahoma, styled *Erwin v. FAA, et al.*, Case No. CIV-20-661-D, in which he requested that the FAA's Federal Air Surgeon issue a final decision regarding his request for reconsideration. After Mr. Erwin filed the writ of mandamus, the FAA issued a final decision on September 11, 2020 addressing Mr. Erwin's request for reconsideration pursuant to 14 C.F.R. § 67.401(i)(3). The FAA

and Mr. Erwin agreed to a joint stipulation of dismissal without prejudice of the case on October 14, 2020, because the FAA's final decision issued on September 11, 2020 rendered the writ of mandamus moot.

Counsel for Mr. Erwin is not aware of any related case pending before this Court or any other Court.

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JURISDICTIONAL STATEMENT

The Court has subject-matter jurisdiction in this case pursuant to 49 U.S.C. § 46110. The FAA issued its Final Order on September 11, 2020 affirming the withdrawal of Mr. Erwin's Authorization for Special Issuance of an Airman Medical Certificate dated May 17, 2017 ("Authorization"). Mr. Erwin timely appealed the FAA's Final Order by filing his Petition for Review on November 10, 2020, which was "not later than 60 days after the order [was] issued." 49 U.S.C. § 46110(a). Mr. Erwin's appeal of the Final Order disposes of all the parties' claims.

STATEMENT OF ISSUES TO BE RAISED

The issues to be raised are:

1. Whether the administrative record fails to support the FAA's denial of Mr. Erwin's request for reconsideration of his Authorization, thus making the denial arbitrary, capricious, and/or an abuse of discretion.

2. Whether the FAA's failure to provide Mr. Erwin with any basis for its denial of his request for reconsideration of his Authorization is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

3. Whether the FAA's practice of allowing individual air carriers to use ethyl glucuronide (EtG) and ethyl sulfate (EtS) testing methodologies or define ethyl glucuronide (EtG) testing thresholds without publishing, articulating, or

promulgating any rules that permit this delegation of responsibility or explain how ethyl glucuronide (EtG) testing methodology or thresholds should be used in the airline industry is arbitrary, capricious, an abuse of discretion, or an improper delegation of the FAA's responsibilities.

STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the Addendum to this brief.

INTRODUCTION

The Final Order issued by the Federal Air Surgeon is contrary to the FAA's own conclusions as to the cause of Mr. Erwin's positive test for alcohol use.

Over three years ago, the livelihood and passion of Mr. Erwin was placed in jeopardy because a little known—and often misunderstood—ethanol biomarker showed as 'positive' on a random, unannounced drug screening. Mr. Erwin is a career aviator who has flown commercially most of his adult life and has experience working for regional, domestic, and international air carriers. He is currently a First Officer with a major air carrier and flies the Airbus 330 internationally. But because an ethanol biomarker surpassed some arbitrary and undisclosed threshold, Mr. Erwin's career as an aviator was nearly erased simply because he ate pulled pork that, unbeknownst to him, was cooked in beer.

The science of ethanol biomarkers ethyl glucuronide (EtG) and ethyl sulfate (EtS) is murky at best. Clinicians, courts, counselors, and others have struggled on how best to utilize a tool that 'looks back' to detect alcohol use in patients undergoing abstinence-based sobriety treatment. The FAA is no different. While ethyl glucuronide (EtG) and ethyl sulfate (EtS) testing is a commercially available tool to monitor alcohol misuse, it is not a panacea for abstinence-based alcohol monitoring. Numerous studies, experts, courts, and U.S. government agencies have cautioned against relying too heavily on these emerging tools, precisely because they are highly susceptible to environmental influences and must be interpreted through the lens of individual physiological factors. Yet, the FAA apparently relies exclusively on 'positive' ethyl glucuronide (EtG) and ethyl sulfate (EtS) tests—without promulgating a single standard on their use—when making the determination to end an aviation career.

And even when presented with this evidence, along with a reasonable explanation for the true cause of a 'positive' ethyl glucuronide (EtG) / ethyl sulfate (EtS) test, the FAA arbitrarily disregarded its own agency's conclusions and ignored the substantial evidence in the record. Thus, Mr. Erwin respectfully appeals the decision of the FAA to deny his request for reconsideration that withdrew his Authorization for Special Issuance of an Airman Medical Certificate dated May 17, 2017.

BACKGROUND

I. Facts

Mr. Erwin began his career as a commercial airline-pilot in 2008. In the fall of 2016, Mr. Erwin was evaluated for alcohol dependency because of an "unknown caller to the Delta flight [Human Intervention and Motivational Study] staff who said the pilot was drinking too much and was depressed." R. at 521; J.A. at 064.[1] The FAA later determined that Mr. Erwin was disqualified from holding an Airman First-Class Medical Certificate due to alcohol dependency. Because of this diagnosis, Mr. Erwin completed inpatient treatment at Talbott Recovery Center in Atlanta, Georgia. After completion of his inpatient treatment and based on the recommendation of his then Aviation Medical Examiner, Dr. Charles Harper, the FAA issued Mr. Erwin an Authorization for Special Issuance of an Airman Medical Certificate ("Authorization") on May 17, 2017. R. at 521; J.A. at 064.[2] This Authorization allowed Mr. Erwin to continue as a commercial airline pilot, subject to numerous conditions, including aftercare monitoring through the Human

[1] The evaluation had nothing to do with suspected alcohol misuse related to Mr. Erwin's job duties as a commercial airline pilot, and Mr. Erwin voluntarily completed the evaluation at the request of his employer.

[2] The FAA will issue a Special Issuance Letter to accompany the Special Issuance Medical Certificate, which lists stipulations the Federal Air Surgeon has placed on the pilot. References to Mr. Erwin's Authorization refer to his Special Issuance Letter and its restricting conditions.

Intervention and Motivational Study program.[3] As pertinent here, the Authorization required Mr. Erwin to: (1) submit to random, unannounced drug and/or alcohol testing at least fourteen times annually; and (2) maintain total abstinence from alcohol. R. at 527–28; J.A. at 069-70.

On December 13, 2017, Mr. Erwin and his girlfriend (now wife) Amy Alford had a late lunch at the restaurant South 55 located in Franklin, Tennessee. Mr. Erwin had a glass of tea and the BBQ Brisket Queso (*i.e.*, pulled pork), and Ms. Alford had a glass of wine and a BLT sandwich. Because Mr. Erwin underwent lap-band surgery years prior, he didn't consume his entire meal, but took the leftovers home with him for dinner that evening. Ms. Alford paid for their meal at 3:31 pm CST on December 13, 2017, and she and Mr. Erwin went home for the evening. R. at 352; J.A. at 192. Mr. Erwin later ate his pulled pork leftovers from South 55 that evening. *Id*.

Approximately nineteen hours later, at 11:00 am EST on December 14, 2017, Mr. Erwin was selected for a random urinalysis as part of the on-going drug and alcohol monitoring required under his Authorization. Quest Diagnostic

[3] "[Human Intervention and Motivational Study] is an occupational substance abuse treatment program, specific to commercial pilots, that coordinates the identification, treatment, and return to work process for affected aviators. It is an industry-wide effort in which managers, pilots, healthcare professionals, and the FAA work together to preserve careers and enhance air safety." Human Intervention and Motivational Study website, *available at* https://himsprogram.com/about-hims/

Incorporated Forensic Toxicology ("Quest") tested Mr. Erwin's urine sample for, among other substances, the presence of ethyl glucuronide (EtG) and ethyl sulfate (EtS) biomarkers. Quest determined that Mr. Erwin had 144 ng/mL of ethyl glucuronide (EtG) in his sample, which was above the 100 ng/mL threshold established by the client (*i.e.*, Mr. Erwin's employer). Quest contacted Mr. Erwin on December 17, 2017 to determine if he had "used any hair products or taken a different medicine because the results indicated a possible incidental exposure." R. at 124; J.A. at 267. Because of Quest's inquiry, Mr. Erwin contacted the restaurant and learned (for the first time) that his meal had been prepared in beer. R. 349–50; J.A. 193-94. Mr. Erwin was unaware of this fact because the restaurant's menu did not indicate that the meal would be prepared or cooked in alcohol. R. 337–43; J.A. 195-201.

Quest ultimately provided the results of the ethyl glucuronide (EtG) / ethyl sulfate (EtS) test to Mr. Erwin's employer and Dr. Harper, who as a result, wrote to the FAA to request a withdrawal of Mr. Erwin's Authorization. R. at 425; J.A. at 033.

Mr. Erwin—adamant that he did not knowingly consume any alcohol—underwent confirmatory tests on December 28, 2017 for phosphatidyl ethanol (PEth) in his blood and ethyl glucuronide (EtG) in his hair and nails. All tests were negative for alcohol. R. at 344–46; J.A. at 224-26.

II. Procedural History

On January 9, 2018, Mr. Erwin received a letter from the FAA stating that it had withdrawn his Authorization due to the positive alcohol test on December 14, 2017. Because of this withdrawal, Mr. Erwin's employer gave him two options: (1) attend inpatient treatment at the Metro Atlantic Recovery Residences and sign a new employment contract (the so-called "last chance contract"); or (2) terminate his employment. R. at 124; J.A. at 267. Mr. Erwin signed the last chance contract and attended a ninety-day in-patient treatment program at Metro Atlantic Recovery Residences beginning on January 9, 2018.

On March 9, 2018, Mr. Erwin requested reconsideration of the withdrawal of his Authorization pursuant to 14 C.F.R. § 67.401(i). R. at 353–56; J.A. at 187-90. On March 21, 2018, Mr. Erwin supplemented his reconsideration request with an expert report prepared by Thomas Kupiec, Ph.D. R. at 295–304; J.A. at 232-41. The FAA confirmed receipt of the reconsideration request and expert report and stated that everything would be sent to the reviewing doctor. On April 10, 2018, the FAA confirmed receipt of the letter for reconsideration and other data and requested additional information. Mr. Erwin timely provided the numerous reports and completed the additional evaluations that the FAA requested. *See* R. at 168–75; J.A. at 248-55.

On August 16, 2018, the FAA sent Mr. Erwin a letter requesting additional information. On August 23, 2018, the FAA acknowledged Mr. Erwin's request for reconsideration and stated that the items in the August 16, 2018 letter were "expected to be all that is necessary at this time for review and reconsideration…." R. at 167; J.A. at 264. Mr. Erwin timely supplied the information requested in the August 16, 2018 letter and patiently awaited the decision of his reconsideration request.

Unbeknownst to Mr. Erwin, the FAA had decided to issue him a second Special Issuance of an Airman Medical Certificate (the "Second Authorization") to allow him to continue flying commercially based on his Metro Atlantic Recovery Residences treatment records and Dr. Steven Lynn's psychiatric evaluation from July 31, 2018. *See* R. at 2; J.A. at 304. This Second Authorization is dated January 31, 2019 and expires on January 31, 2024. R. at 150; J.A. at 276.

But even with the Second Authorization, Mr. Erwin continued to request a final decision regarding his March 9, 2018 request for reconsideration. Despite numerous follow-up emails and telephone calls, the FAA failed to issue a final decision until Mr. Erwin filed a writ of mandamus on July 8, 2020 in the United States District Court for the Western District of Oklahoma, styled *Erwin v. F.A.A.*,

et al., Case No. CIV-20-661-D, in which he requested that the FAA's Federal Air Surgeon issue a final decision regarding his request for reconsideration.[4]

After the writ of mandamus was filed, the FAA issued a final decision on September 11, 2020 (the "Final Order") addressing Mr. Erwin's request for reconsideration pursuant to 14 C.F.R. § 67.401(i)(3). R. at 1; J.A. at 303.[5]

Mr. Erwin now appeals the Final Order because it is arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law under the Administrative Procedure Act and thus must be set aside.[6]

ARGUMENT AND AUTHORITIES

I. Summary of the Argument

Mr. Erwin raises four grounds for appeal. First, in withdrawing Mr. Erwin's Authorization, the FAA arbitrarily disregarded its own findings that Mr. Erwin's 'positive' alcohol test resulted from his consumption of food cooked in alcohol and

[4] The FAA Administrator has delegated authority to the Federal Air Surgeon to issue or deny an authorization for a special issuance of a medical certificate. 14 C.F.R. § 67.407(a).

[5] The FAA and Mr. Erwin agreed to a joint stipulation of dismissal without prejudice of the action filed in *Erwin v. F.A.A., et al.*, Case No. CIV-20-661-D on October 14, 2020 because the FAA's Final Order rendered the writ of mandamus moot.

[6] The National Transportation Safety Board ("NTSB") lacks jurisdiction to review the FAA Administrator's determination denying the authorization for a special issuance of a medical certificate. *See, e.g.*, Pet. of Bartel, NTSB Order No. SM-5186 at 2 (2012); Pet. of Reder, NTSB Order No. EA-4438 (1996); Pet. of Peterson, NTSB Order No. EA-4216 at 5 (1994); Pet. of Doe, 5 NTSB 41, 43 (1985). Mr. Erwin is thus seeking review of the FAA's Final Order before this Court pursuant to 49 U.S.C § 46110.

not because he failed to maintain his abstinence. Second, the FAA failed to consider the evidence in the record that Mr. Erwin maintained his alcohol abstinence, that consuming food prepared in alcohol can lead to positive ethyl glucuronide (EtG) and ethyl sulfate (EtS) tests, and that low-level positive ethyl glucuronide (EtG) tests are not reliable. Third, the FAA has failed to promulgate rules, methodologies, or thresholds for ethyl glucuronide (EtG) and ethyl sulfate (EtS) testing, and instead arbitrarily delegated this authority to third parties, which leads to differing results for similarly situated Airmen. Fourth, the FAA failed to provide any rationale for its decision to affirm the withdrawal of Mr. Erwin's Authorization in its Final Order and instead simply recounted the procedural events that resulted in the withdrawal of Mr. Erwin's Authorization.

II. Standing

Although the FAA has intimated that Mr. Erwin has suffered no harm because he was issued the Second Authorization allowing him to continue flying commercially, nothing could be farther from the truth. Initially, Mr. Erwin's Second Authorization requires continued aftercare monitoring and other requirements until January 31, 2024. Mr. Erwin's Authorization would have expired on May 31, 2020 and, thus, ended his monitoring requirements.

Further, the FAA has suggested that it may begin lifelong monitoring for Airmen diagnosed with substance-use disorders currently under special issuance authorizations. *See* NTSB Safety Recommendation A-07-43.

Moreover, Mr. Erwin's employer required him to sign a last chance contract as a result of the December 14, 2017 positive test result. This last chance contract contains onerous termination provisions not in his previous contract. Without the withdrawal of his Authorization on January 9, 2018, Mr. Erwin would have his previous employment contract in place, and he would not be required to continue aftercare monitoring—now possibly lifelong monitoring requirements—and the other conditions of the Second Authorization.

III. Standard of Review

"When reviewing an order of the FAA, the Courts of Appeals will apply the standard of review articulated in the Federal Aviation Act. 49 U.S.C. § 46110(c). The standards articulated in the Administrative Procedure Act apply only where the Federal Aviation Act does not provide the appropriate standard." *Dickson v. F.A.A.*, 480 Fed. Appx. 263, 266 (5th Cir. 2012) (citing *Flamingo Exp., Inc. v. F.A.A.*, 536 F.3d 561 (6th Cir. 2008)). Under the Federal Aviation Act, the "[f]indings of fact by the…Federal Aviation Administration…if supported by substantial evidence, are conclusive." 49 U.S.C. § 46110(c).

Other decisions of the FAA are governed by the Administrative Procedure Act and must be set aside or reversed if arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law. 5 U.S.C. § 706. "Under this standard, we 'may reverse only if the agency's decision is not supported by substantial evidence, or the agency has made a clear error in judgment.'" *Safe Extensions, Inc. v. F.A.A.*, 509 F.3d 593, 604 (D.C. Cir. 2007) (internal citations omitted).

IV. The Final Order is Contrary to the FAA's Internal Recommendations

The Final Order issued by the Federal Air Surgeon is contrary to ***the FAA's own conclusions*** as to the cause of Mr. Erwin's positive test. Specifically, Dr. Alan Sager, an Aerospace Medicine psychiatry consultant with the FAA, stated in an internal FAA memorandum that:

> It is apparent that the pilot had negative hair and blood tests approximately two weeks following his positive testing in December 2017. The pilot states that he did not drink any alcohol but in all likelihood consumed food at a restaurant that was cooked in beer. ***We believe that this is the most likely explanation***, however since we are not in receipt of the pilot's complete hospital record from [Metro Atlantic Recovery Residences], we would like to review that record before making a final determination.
>
> R. at 148; J.A. at 273 (emphasis added).

Approximately a month later and after reviewing the Metro Atlantic Recovery Residences records, Dr. Sager concluded that "[w]e continue to believe

that the pilot's positive PEth [sic] test was inadvertent and secondary to his ingestion of food prepared with beer." R. at 155; J.A. at 275.

There is nothing in the record that refutes or discounts Dr. Sager's conclusions. It is clear that the FAA itself believed that Mr. Erwin maintained his sobriety and, thus, satisfied the requirements of his Authorization. Because Mr. Erwin maintained his abstinence from alcohol, his Authorization should never have been withdrawn. But despite the FAA's own internal conclusions from its subject-matter experts that it believed Mr. Erwin had an accidental and extraneous exposure to alcohol from the consumption of pulled pork prepared in beer, the Federal Air Surgeon issued a Final Order contrary to this conclusion. This decision should not stand because it is arbitrary and capricious, not supported by substantial evidence, and is a clear error of judgment.

V. The Record Fails to Support the Final Order's Conclusion

The record fails to support the Final Order's conclusion that Mr. Erwin did not remain totally abstinent from alcohol. Quite the opposite. The record supports Mr. Erwin's contention from the start—he had an accidental and extraneous exposure to alcohol from the consumption of pulled pork prepared in alcohol that resulted in a very low positive ethyl glucuronide (EtG) / ethyl sulfate (EtS) test.[7]

[7] R. at 12; J.A. at 289, Deborah Bright ("[the] airman…claimed a positive monitoring test was due to pulled pork cooked with alcohol…."); R. at 14; J.A. at 291, Matthew Dumstorf ("[Mr. Erwin] had a very low positive EtG/EtS, [he]

Further, the record contains an affidavit from Mr. Erwin's Human Intervention and Motivational Study aftercare counselor (who was treating Mr.

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believes this is realted [sic] to consuming pulled pork that was cook[ed] in beer the night prior to his positive EtG/EtS, approx two weeks later he had additional testing, the results were all hnegative [sic]…."); R. at 16; J.A. at 293, Ahmad Kennedy ("we ahve [sic] rec'd the medical certificate back and a letter from his Attorney Evan Way along with the alcohol test, a letter regarding his lap-band-surgery previously, a letter from the lady he had lunch with that day and seh [sic] says he had nothing but watter [sic] to drink, a letter from the restaurant owner explaining that the BBQ Brisket was cooked in beer and other Misc. info. sending to Dr. D[umstorf] for review[.]"); R. at 39; J.A. at 280, Dr. Steven Lynn ("He adamantly denied drinking...he believes he ate some pulled pork that was cooked in beer."); R. at 90; J.A. at 180, Metro Atlantic Recovery Residences History and Physical Exam ("[Mr. Erwin] [s]tates he ate some Pork cooked In Beer the night prior to the test and that he was not drinking. Peth and Hair Follicle test both negative"); R. 97; J.A. 243, Metro Atlantic Recovery Residences Discharge Summary ("[Mr. Erwin] claimed that he has not been drinking but tested positive on a PEth [sic] test on 12/14/17 after eating pulled pork that was cooked in beer. He claimed that he has not drank alcohol since 11/21/2016"); R. at 98; J.A. at 244, Metro Atlantic Recovery Residences Discharge Summary ("States he ate some Pork cooked in Beer."); R. at 100; J.A. at 246, Metro Atlantic Recovery Residences Discharge Summary ("I haven't drank since November 21, 2016"); R. at 107; J.A. at 256, Steven M. Lynn, M.D., P.C. ("Airman Erwin denies that he drank alcohol and over the subsequent days he determined that he had ate pulled pork that was cooked in beer that probably resulted in his positive EtG and EtS…[h]e is adamant that he did not drink alcohol"); R. at 122; J.A. at 265, Thomas B. Faulkner, M.D., Aviation Medical Examiner ("Mr. Erwin is adamant that he didn't drink alcohol"); R. 124; J.A. 267, Mr. Erwin ("I have not relapsed and maintained my sobriety…."); R. at 139; J.A. at 269, Thomas B. Faulkner, M.D., Aviation Medical Examiner ("This Airman was been involved in the [Human Intervention and Motivational Study] program at Delta Air Lines, and ***due to questionable results on a screening*** was removed from certification.") (emphasis added); R. at 145–48; J.A. at 270-73, Alan Sager, M.D., Psychiatric Consultant ("The pilot is adamant that he did not drink alcohol."); and R. at 234; J.A. at 114, Metro Atlantic Recovery Residences Phase 1 Review ("I know I'm sober and haven't had a drink since November 21, 2016.").

Erwin for his continued progress and participation in abstinence-based sobriety before and after the positive test as a condition of his Authorization) who states:

> In my professional experience, training, and education, I noticed no indications during my treatment of Mr. Erwin that he had ever relapsed in his alcohol-abstinence program. Based on all my professional encounters with Mr. Erwin, he continues to maintain abstinence from alcohol.
>
> R. at 306; J.A. at 242.

Moreover, the record also contains Mr. Erwin's formal request for reconsideration that details the facts, legal authority, and an expert opinion that supports Mr. Erwin's assertion that he had an accidental and extraneous exposure to alcohol from the consumption of pulled pork cooked in beer. R. at 353–56; J.A. at 187-90.[8] For example, the submitted expert report concluded ***"within a reasonable degree of scientific certainty, that the result of Mr. Erwin's urine analysis does not represent conclusive evidence of intentional alcohol consumption."*** R. at 302; J.A. at 239 (emphasis added).

Despite the overwhelming evidence in the record that Mr. Erwin had an accidental and extraneous exposure to alcohol, the Federal Air Surgeon determined

[8] Curiously, and unfortunately, the exhibits referenced in Mr. Erwin's reconsideration letter are spread throughout the record. Exhibit 1 is located at R. at 351; J.A. at 191; Exhibit 2 is located at R. 352; J.A. 192; Exhibit 3 is located at R. 349–50; J.A. 193-94; Exhibit 4 is located at R. 337–43; J.A. 195-201; Exhibit 5 is located at R. at 321–36; J.A. at 202-17; Exhibit 6 is located at R. 347–48; J.A. 218-19; Exhibit 7 is located at R. at 317–20; J.A. at 220-23; Exhibit 8 is located at R. at 344–45; J.A. at 224-25; and Exhibit 9 is located at R. 312–16; J.A. 227-31.

"that the additional information and documentation [was] not sufficient to reverse the determination [to withdraw his Authorization]." R. at 1; J.A. at 303. Not so. The record includes (1) Mr. Erwin's repeated assertions that he did not voluntarily consume alcohol; (2) an affidavit from a Human Intervention and Motivational Study aftercare healthcare provider that Mr. Erwin has maintained his sobriety since 2016; (3) an expert opinion finding Mr. Erwin did not intentionally consume alcohol; (4) the FAA's own internal memoranda concluding it believed unintentional consumption of alcohol was the most likely explanation for the very low positive ethyl glucuronide (EtG) / ethyl sulfate (EtS) test; and (5) a reconsideration letter and supporting exhibits cautioning against reliance on ethyl glucuronide (EtG) / ethyl sulfate (EtS) abstinence testing.

The record contains no support for the Final Order's conclusion. In fact, ***the December 14, 2017 test results do not appear in the record.***[9] The only evidence of a positive test in the record are circumstantial and fleeting references to a purported 'positive' ethyl glucuronide (EtG) / ethyl sulfate (EtS) test. Because the test results are not part of Mr. Erwin's official Airman medical record, it implicitly means the Federal Air Surgeon did not even review the test results when he withdrew Mr. Erwin's Authorization or when he denied Mr. Erwin's request for reconsideration. *See* R. at 1; J.A. 303 ("I have reviewed your agency medical file….").

[9] The record, however, does contain at least eighteen other test results.

Had the Federal Air Surgeon evaluated the evidence actually contained in the record, he would have reached a different conclusion.

First, Mr. Erwin's reconsideration letter contained scientific support that his 'positive' test was from an extraneous, incidental exposure.

> "Clinical study and analysis in peer-reviewed literature continue due to recognized concern that the EtG test may give false positive results and is not fully understood." *Johnson v. State Med. Bd. of Ohio*, 2008-Ohio-4376, ¶ 3, 147 Ohio Misc. 2d 121, 124, 893 N.E.2d 565, 568. Indeed, the substance abuse community recognizes that a small environmental exposure to ethanol can lead to a false positive of alcohol consumption. This leads some researchers to advocate for a 200 ng/mL cutoff to reduce false positives and increase identifying alcohol consumption. Lowe J., *Determining Ethyl Glucuronide Cut-Offs When Detecting Self-Reported Alcohol Use in Addiction Treatment Patients*, ALCOHOL CLIN. EXP. RES., May 2015, at 39:905-10. Regardless, "research is needed to build consensus regarding an acceptable EtG cutoff level . . . ." *Id.*
>
> Even the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration ("SAMHSA") has stressed that the use of EtG and EtS for abstinence testing should be approached with caution because this test is still very much in its scientific infancy and that "more research is warranted." SAMHSA Advisory, 2012 (attached as Exhibit 5). That is the case here. Mr. Erwin's tests do not indicate that he consumed alcohol. Rather, his results are consistent with extraneous, incidental exposure to ethanol from a meal—not identified as containing alcohol—less than 19 hours prior. Numerous researchers have supported the conclusion that "consuming foodstuffs that contain alcohol cause positive urine EtG results including samples taken 5 h[ours] after eating sauerkraut and 3.5 h[ours] after consuming matured bananas. Similarly, *in vivo* fermentation of baker's yeast to ethanol with subsequent formation of EtG and EtS has been reported." Natalie E. Walsham, R. A., *Ethyl Glucuronide and Ethyl Sulfate*, ADVANCES IN CLINICAL CHEMISTRY, 2014, at 62. Mr. Erwin's positive

> EtG and EtS tests are clearly from the consumption of a meal prepared—unbeknownst to him—with alcohol.
>
> R. at 354; J.A. at 188.

Second, Mr. Erwin's reconsideration letter explained that the 'positive' ethyl glucuronide (EtG) test failed to account for his physiology.

> Further, the December 14, 2017, test failed to account for Mr. Erwin's age, metabolism, medical history, hydration level, and current medical conditions. Any one of these factors combined with the incidental exposure to ethanol in his meal the previous afternoon could account for the levels of EtS and EtG. Indeed, Mr. Erwin underwent lap-band surgery years prior and an ulcer was recently discovered in his digestive tract. (*See* Exhibit 6). This implies that consumed meals are staying in his digestive system longer and thus EtG and EtS levels will be elevated and present for a longer period of time. This comports with the findings of Dr. Gregory Skipper who stated: "A positive EtG is not necessarily proof of intentional alcoholic beverage consumption. Low level positive tests are known to occur due to incidental exposure. The cutoff for possible incidental exposure vs. intentional use has not been accurately established, due to many factors including; amount of 'incidental' exposure, individual metabolism, hydration, kidney function, etc." Gregory E. Skipper, Memo to Alabama State Board of Medical Examiners, 2005, at 1 (attached at Exhibit 7).
>
> R. at 354–55; J.A. at 188-89.

Lastly, Mr. Erwin's reconsideration letter contained his follow-up, confirmatory tests which established that he had remained abstinent.

> Mr. Erwin adamantly denies breaching his abstinence agreement in his Authorization. A 2013 study found positive EtG and EtS results should be followed by a PEth test to determine if the ethanol exposure was incidental. "EtG and EtS can be considered to be highly sensitive in detecting alcohol intake. However, to overcome the dilemma in interpreting low positive EtG/EtS results, the use of

> PEth testing seems to be effective in providing additional information on potential recent drinking or extraneous EtOH exposure." Gregory E. Skipper, *Phosphatidylethanol: The Potential Role in Further Evaluation Low Positive Urinary Ethyl Glucuronide and Ethyl Sulfate Results*, ALCOHOLISM: CLINICAL AND EXPERIMENTAL RESEARCH, 2013, at 4 (attached as Exhibit 9). Further, the use of 100 ng/mL as the cutoff is "not as a conclusive value, but only as a place to start further investigation with the subject, with the subject's family or co-workers who might observe a relapse, or through additional chemical testing." *Johnson v. State Med. Bd. of Ohio*, 2008-Ohio-4376, ¶ 51, 147 Ohio Misc. 2d 121, 140, 893 N.E.2d 565, 580. After notification of the December 14, 2017, positive test result, Mr. Erwin was tested again on December 28, 2017. (December 28, 2017 tests, attached as Exhibit 8). These tests were for phosphatidyl ethanol in blood and EtG ethanol biomarkers in hair and nail samples. All samples tested negative for ethanol. Mr. Erwin clearly did not breach his abstinence contract because the inconclusive EtG and EtS tests were not supported by further investigative tests: specifically, the negative results of PEth testing.
>
> R. at 355; J.A. at 189.

It's difficult to imagine how the Federal Air Surgeon reached the conclusion in his Final Order given that the December 14, 2017 test and documentation package were unavailable for review, there are no statements by the FAA—or anyone else—that Mr. Erwin was being less than truthful about his sobriety, the FAA's own internal memoranda support Mr. Erwin's assertion that the 'positive' ethyl glucuronide (EtG) test was from eating pulled pork prepared in beer, and the scientific community cautions against relying on low-level positive ethyl glucuronide (EtG) tests for abstinence-based sobriety treatment or confirmation of relapse. The FAA's decision here to deny Mr. Erwin's reconsideration request is

arbitrary and capricious because the Final Order is not supported by the evidence on which it relies—much less substantial evidence. *See Flyers Rights Educ. Fund, Inc. v. F.A.A.*, 864 F.3d 738, 743 (D.C. Cir. 2017).

VI. The FAA Has Failed to Establish Ethyl Glucuronide (EtG) / Ethyl Sulfate (EtS) Testing Methodologies or Thresholds

The FAA has impermissibly delegated its authority to third parties to use and establish thresholds for ethyl glucuronide (EtG) and ethyl sulfate (EtS) testing. In evaluating Mr. Erwin's urine test, Quest used the ethyl glucuronide (EtG) level of 100 ng/mL as the threshold for a 'positive' test. But it only did so because Delta Airlines—Quest's client—requested this particular cutoff. Mr. Erwin's Authorization requires random testing for alcohol. The Authorization, however, does not specify an alcohol cutoff level for these random tests. Indeed, the Authorization's only mention of alcohol testing is that Mr. Erwin will "undergo random, unannounced drug and/or alcohol testing administered either directly by [his Human Intervention and Motivational Study Aviation Medical Examiner] or coordinated through an independent third-party testing facility." R. at 528; J.A. at 070. Notably, Mr. Erwin's Authorization does not specify even the type of testing he will undergo. Under the FAA's undefined standards, every Airman with an authorization for a special issuance of a medical certificate that requires alcohol abstinence (and therefore alcohol monitoring tests) could be subject to a different cutoff level or a different test altogether.

The FAA determines if an authorization for a special issuance of a medical certificate is warranted. Yet it allows private, third parties—air carriers in this case—to determine the type of testing and subsequent cutoff levels. This is arbitrary and capricious even if *all* air carriers utilized Quest's ethyl glucuronide (EtG) testing methodology because individual results would vary depending on the air carriers' cutoff levels. In fact, the FAA would take drastically different actions against an Airman depending on the air carriers' established cutoff level. For example: Consider if an Airman's authorization required alcohol abstinence, used random ethyl glucuronide (EtG) testing, and the Airman tested at ethyl glucuronide (EtG) 144 ng/mL:

Air Carrier	**Cutoff Level of Ethyl Glucuronide (EtG) for a Positive Test Result**	**Action Taken by the FAA**
Air Carrier "Delta"	100 ng/mL	Withdraw of authorization
Air Carrier "Echo"	150 ng/mL	No violation
Air Carrier "Foxtrot"	200 ng/mL	No violation
Air Carrier "Gulf"	250 ng/mL	No violation

As the table above illustrates, allowing an air carrier to determine the ethyl glucuronide (EtG) cutoff level allows differing results for identical situations. Under the above scenario, an Airman could be subject to adverse employment actions, withdrawal of his or her authorization by the FAA, and possibly the loss of

their livelihood simply because his or her employer set a lower ethyl glucuronide (EtG) testing threshold.

This arbitrary cutoff level for alcohol is inconsistent with the other published cutoff levels for the FAA's drug and alcohol testing program. *See* 49 C.F.R. § 40.87 (establishing and mandating that laboratories "must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests"); 14 C.F.R. § 120.203(b) (requiring the FAA to comply with the provisions of 49 C.F.R. § 40.87). Further, regulations direct "all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use. [This regulation] concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents." 49 C.F.R. § 40.1. The regulation also states that "other types of alcohol tests (*e,g.*, blood and urine) are not authorized for testing done under this part. Only saliva or breath for screening tests and breath for confirmation tests using approved devices are permitted." *Id.* § 40.277.

Because the FAA has not promulgated guidance directing air carriers to apply a uniform ethyl glucuronide (EtG) cutoff level, the cutoff level chosen by Mr. Erwin's air carrier employer should be rejected. Instead, the FAA should

promulgate a standardized drug-testing policy that details the testing methodology and establishes uniform cutoff levels. This will ensure fairness and give Airmen notice of the drug-testing standards. Failure to apply a uniform standard to all Airmen results in an arbitrary decision by the FAA.

Mr. Erwin's Authorization must be reinstated now because the current non-uniform standard is arbitrary and capricious and denies him fair notice of the testing methodology and corresponding cutoff levels.

VII. The Final Order Fails to Provide Rationale for its Decision

By either design or oversight, the Final Order is thin on findings of fact and devoid of conclusions of law. Besides a recitation of the events that led to the withdrawal of his Authorization, Mr. Erwin is simply told that a review of his agency medical file and the documentation he submitted was not sufficient to reverse the withdrawal. R. at 1; J.A. at 303. There is absolutely no explanation of how a single positive test overcame all other documentation that supported Mr. Erwin's contention that he had an accidental, extraneous ethanol exposure. Also absent is any mention of what documentation was reviewed, weighed, or assigned credibility, or why the Federal Air Surgeon ignored the conclusions reached by the FAA itself that "[w]e continue to believe that the pilot's positive [ethyl glucuronide (EtG) test in December 2017] was inadvertent and secondary to his

ingestion of food prepared with beer." R. at 155; J.A. at 275. It is nothing but a hollow agency decision.

Tellingly, the Final Order finds that Mr. Erwin (although initially determined to endanger public safety) may continue as a commercial airline pilot because he had been granted the Second Authorization dated January 31, 2019. R. at 2; J.A. at 304. This finding was based on Mr. Erwin's Metro Atlantic Recovery Residences treatment records and Dr. Lynn's psychiatric evaluation from July 31, 2018. *Id.* But, inexplicably, the Metro Atlantic Recovery Residences records contain no contradiction of Mr. Erwin's contention that he consumed food cooked in alcohol.

Instead, the Metro Atlantic Recovery Residences records are replete with Mr. Erwin's assertion that he had an accidental and extraneous exposure to ethanol and that his follow-up tests all came back negative for alcohol consumption. Even Dr. Lynn's records reflect an identical recitation of Mr. Erwin's explanation and never state that he relapsed and consumed alcohol (Dr. Lynn's records also list a "Sobriety Date [of] November or December 2016"). R. at 107; J.A. at 256.

What we're left with is a Final Order which rubber-stamped its previous decision to withdraw Mr. Erwin's Authorization without any basis to support that decision. Unfortunately, the FAA was more concerned with Mr. Erwin reapplying for a new authorization than actually determining if his previous Authorization

should have been withdrawn in the first place. This lack of attention to detail ultimately required Mr. Erwin to complete additional mental and physical examinations; enter into a last chance contract with his employer; and complete ongoing aftercare monitoring requirements. If this isn't arbitrary and capricious action by an agency, it's hard to imagine what is.

CONCLUSION

Mr. Erwin respectfully requests that the FAA's Final Order be set aside and that his Authorization for Special Issuance of an Airman Medical Certificate dated May 17, 2017 be retroactively reinstated.

Respectfully Submitted,

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ORAL ARGUMENT NOT YET SCHEDULED

No. 20-1443

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

CHARLES ERWIN,

Petitioner,

v.

FEDERAL AVIATION ADMINISTRATION,

Respondent.

On Appeal from the Federal Aviation Administration
Petition for Review of Final Order Dated September 11, 2020

ADDENDUM TO PETITIONER CHARLES ERWIN'S FINAL BRIEF

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April 29, 2021

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United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

Addendum 1

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (4865)

5 U.S.C.A. § 706, 5 USCA § 706
Current through P.L. 116-259. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 49. Transportation (Refs & Annos)
Subtitle VII. Aviation Programs
Part A. Air Commerce and Safety (Refs & Annos)
Subpart IV. Enforcement and Penalties (Refs & Annos)
Chapter 461. Investigations and Proceedings

49 U.S.C.A. § 46110

§ 46110. Judicial review

Effective: October 5, 2018
Currentness

(a) Filing and venue.--Except for an order related to a foreign air carrier subject to disapproval by the President under section 41307 or 41509(f) of this title, a person disclosing a substantial interest in an order issued by the Secretary of Transportation (or the Administrator of the Transportation Security Administration with respect to security duties and powers designated to be carried out by the Administrator of the Transportation Security Administration or the Administrator of the Federal Aviation Administration with respect to aviation duties and powers designated to be carried out by the Administrator of the Federal Aviation Administration) in whole or in part under this part, part B, or subsection (l) or (s) of section 114 may apply for review of the order by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit or in the court of appeals of the United States for the circuit in which the person resides or has its principal place of business. The petition must be filed not later than 60 days after the order is issued. The court may allow the petition to be filed after the 60th day only if there are reasonable grounds for not filing by the 60th day.

(b) Judicial procedures.--When a petition is filed under subsection (a) of this section, the clerk of the court immediately shall send a copy of the petition to the Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration, as appropriate. The Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration shall file with the court a record of any proceeding in which the order was issued, as provided in section 2112 of title 28.

(c) Authority of court.--When the petition is sent to the Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration, the court has exclusive jurisdiction to affirm, amend, modify, or set aside any part of the order and may order the Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration to conduct further proceedings. After reasonable notice to the Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration, the court may grant interim relief by staying the order or taking other appropriate action when good cause for its action exists. Findings of fact by the Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration, if supported by substantial evidence, are conclusive.

(d) Requirement for prior objection.--In reviewing an order under this section, the court may consider an objection to an order of the Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration only if the objection was made in the proceeding conducted by the Secretary, Administrator of the Transportation Security Administration, or Administrator of the Federal Aviation Administration or if there was a reasonable ground for not making the objection in the proceeding.

Addendum 2

(e) Supreme Court review.--A decision by a court under this section may be reviewed only by the Supreme Court under section 1254 of title 28.

CREDIT(S)

(Pub.L. 103-272, § 1(e), July 5, 1994, 108 Stat. 1230; Pub.L. 107-71, Title I, § 140(b)(1), (2), Nov. 19, 2001, 115 Stat. 641; Pub.L. 108-176, Title II, § 228, Dec. 12, 2003, 117 Stat. 2532; Pub.L. 115-254, Div. K, Title I, § 1991(f)(1) to (4), Oct. 5, 2018, 132 Stat. 3642.)

Notes of Decisions (196)

49 U.S.C.A. § 46110, 49 USCA § 46110
Current through P.L. 116-259. Some statute sections may be more current, see credits for details.

End of Document

Code of Federal Regulations
Title 14. Aeronautics and Space
Chapter I. Federal Aviation Administration, Department of Transportation
Subchapter D. Airmen
Part 67. Medical Standards and Certification (Refs & Annos)
Subpart E. Certification Procedures

14 C.F.R. § 67.401

§ 67.401 Special issuance of medical certificates.

Effective: July 20, 2012
Currentness

(a) At the discretion of the Federal Air Surgeon, an Authorization for Special Issuance of a Medical Certificate (Authorization), valid for a specified period, may be granted to a person who does not meet the provisions of subparts B, C, or D of this part if the person shows to the satisfaction of the Federal Air Surgeon that the duties authorized by the class of medical certificate applied for can be performed without endangering public safety during the period in which the Authorization would be in force. The Federal Air Surgeon may authorize a special medical flight test, practical test, or medical evaluation for this purpose. A medical certificate of the appropriate class may be issued to a person who does not meet the provisions of subparts B, C, or D of this part if that person possesses a valid Authorization and is otherwise eligible. An airman medical certificate issued in accordance with this section shall expire no later than the end of the validity period or upon the withdrawal of the Authorization upon which it is based. At the end of its specified validity period, for grant of a new Authorization, the person must again show to the satisfaction of the Federal Air Surgeon that the duties authorized by the class of medical certificate applied for can be performed without endangering public safety during the period in which the Authorization would be in force.

(b) At the discretion of the Federal Air Surgeon, a Statement of Demonstrated Ability (SODA) may be granted, instead of an Authorization, to a person whose disqualifying condition is static or nonprogressive and who has been found capable of performing airman duties without endangering public safety. A SODA does not expire and authorizes a designated aviation medical examiner to issue a medical certificate of a specified class if the examiner finds that the condition described on its face has not adversely changed.

(c) In granting an Authorization or SODA, the Federal Air Surgeon may consider the person's operational experience and any medical facts that may affect the ability of the person to perform airman duties including—

(1) The combined effect on the person of failure to meet more than one requirement of this part; and

(2) The prognosis derived from professional consideration of all available information regarding the person.

(d) In granting an Authorization or SODA under this section, the Federal Air Surgeon specifies the class of medical certificate authorized to be issued and may do any or all of the following:

Addendum 3

(1) Limit the duration of an Authorization;

(2) Condition the granting of a new Authorization on the results of subsequent medical tests, examinations, or evaluations;

(3) State on the Authorization or SODA, and any medical certificate based upon it, any operational limitation needed for safety; or

(4) Condition the continued effect of an Authorization or SODA, and any second- or third-class medical certificate based upon it, on compliance with a statement of functional limitations issued to the person in coordination with the Director of Flight Standards or the Director's designee.

(e) In determining whether an Authorization or SODA should be granted to an applicant for a third-class medical certificate, 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 safety of persons and property in other aircraft and on the ground.

(f) An Authorization or SODA granted under the provisions of this section to a person who does not meet the applicable provisions of subparts B, C, or D of this part may be withdrawn, at the discretion of the Federal Air Surgeon, at any time if—

(1) There is adverse change in the holder's medical condition;

(2) The holder fails to comply with a statement of functional limitations or operational limitations issued as a condition of certification under this section;

(3) Public safety would be endangered by the holder's exercise of airman privileges;

(4) The holder fails to provide medical information reasonably needed by the Federal Air Surgeon for certification under this section; or

(5) The holder makes or causes to be made a statement or entry that is the basis for withdrawal of an Authorization or SODA under § 67.403.

(g) A person who has been granted an Authorization or SODA under this section based on a special medical flight or practical test need not take the test again during later physical examinations unless the Federal Air Surgeon determines or has reason to believe that the physical deficiency has or may have degraded to a degree to require another special medical flight test or practical test.

(h) The authority of the Federal Air Surgeon under this section is also exercised by the Manager, Aeromedical Certification Division, and each Regional Flight Surgeon.

(i) If an Authorization or SODA is withdrawn under paragraph (f) of this section the following procedures apply:

(1) The holder of the Authorization or SODA will be served a letter of withdrawal, stating the reason for the action;

(2) By not later than 60 days after the service of the letter of withdrawal, the holder of the Authorization or SODA may request, in writing, that the Federal Air Surgeon provide for review of the decision to withdraw. The request for review may be accompanied by supporting medical evidence;

(3) Within 60 days of receipt of a request for review, a written final decision either affirming or reversing the decision to withdraw will be issued; and

(4) A medical certificate rendered invalid pursuant to a withdrawal, in accordance with paragraph (a) of this section, shall be surrendered to the Administrator upon request.

(j) [Reserved by 77 FR 16668]

Credits
[Amdt. 67–20, 73 FR 43066, July 24, 2008; Amdt. 67–21, 77 FR 16668, March 22, 2012; 77 FR 39389, July 3, 2012]

SOURCE: 61 FR 11256, March 19, 1996, unless otherwise noted.

AUTHORITY: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45303.

Notes of Decisions (3)

Current through Feb. 11, 2021; 86 FR 9252.

End of Document

14 C.F.R. § 67.407

§ 67.407 Delegation of authority.

Currentness

(a) The authority of the Administrator under 49 U.S.C. 44703 to issue or deny medical certificates is delegated to the Federal Air Surgeon to the extent necessary to—

(1) Examine applicants for and holders of medical certificates to determine whether they meet applicable medical standards; and

(2) Issue, renew, and deny medical certificates, and issue, renew, deny, and withdraw Authorizations for Special Issuance of a Medical Certificate and Statements of Demonstrated Ability to a person based upon meeting or failing to meet applicable medical standards.

(b) Subject to limitations in this chapter, the delegated functions of the Federal Air Surgeon to examine applicants for and holders of medical certificates for compliance with applicable medical standards and to issue, renew, and deny medical certificates are also delegated to aviation medical examiners and to authorized representatives of the Federal Air Surgeon within the FAA.

(c) The authority of the Administrator under 49 U.S.C. 44702, to reconsider the action of an aviation medical examiner is delegated to the Federal Air Surgeon; the Manager, Aeromedical Certification Division; and each Regional Flight Surgeon. Where the person does not meet the standards of §§ 67.107(b)(3) and (c), 67.109(b), 67.113(b) and (c), 67.207(b)(3) and (c), 67.209(b), 67.213(b) and (c), 67.307(b)(3) and (c), 67.309(b), or 67.313(b) and (c), any action taken under this paragraph other than by the Federal Air Surgeon is subject to reconsideration by the Federal Air Surgeon. A certificate issued by an aviation medical examiner is considered to be affirmed as issued unless an FAA official named in this paragraph (authorized official) reverses that issuance within 60 days after the date of issuance. However, if within 60 days after the date of issuance an authorized official requests the certificate holder to submit additional medical information, an authorized official may reverse the issuance within 60 days after receipt of the requested information.

(d) The authority of the Administrator under 49 U.S.C. 44709 to re-examine any civil airman to the extent necessary to determine an airman's qualification to continue to hold an airman medical certificate, is delegated to the Federal Air Surgeon and his or her authorized representatives within the FAA.

SOURCE: 61 FR 11256, March 19, 1996, unless otherwise noted.

Addendum 4

AUTHORITY: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45303.

Current through Feb. 11, 2021; 86 FR 9252.

End of Document

Code of Federal Regulations
Title 14. Aeronautics and Space
Chapter I. Federal Aviation Administration, Department of Transportation
Subchapter G. Air Carriers and Operators for Compensation or Hire: Certification and Operations
Part 120. Drug and Alcohol Testing Program (Refs & Annos)
Subpart F. Alcohol Testing Program Requirements

14 C.F.R. § 120.203

§ 120.203 General.

Effective: July 13, 2009
Currentness

(a) Purpose. The purpose of this subpart is to establish programs designed to help prevent accidents and injuries resulting from the misuse of alcohol by employees who perform safety-sensitive functions in aviation.

(b) Alcohol testing procedures. Each employer shall ensure that all alcohol testing conducted pursuant to this subpart complies with the procedures set forth in 49 CFR part 40. The provisions of 49 CFR part 40 that address alcohol testing are made applicable to employers by this subpart.

(c) Employer responsibility. As an employer, you are responsible for all actions of your officials, representatives, and service agents in carrying out the requirements of the DOT agency regulations.

SOURCE: Amdt. 120–0, 74 FR 22653, May 14, 2009; Amdt. 120–1, 78 FR 42003, July 15, 2013, unless otherwise noted.

AUTHORITY: 49 U.S.C. 106(f), 106(g), 40101–40103, 40113, 40120, 41706, 41721, 44106, 44701, 44702, 44703, 44709, 44710, 44711, 45101–45105, 46105, 46306.

Current through Feb. 11, 2021; 86 FR 9252.

End of Document

Addendum 5

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart A. Administrative Provisions

49 C.F.R. § 40.1

§ 40.1 Who does this regulation cover?

Currentness

(a) This part tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use.

(b) This part concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents.

(c) Nothing in this part is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006; 82 FR 52243, Nov. 13, 2017, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 et seq.

Notes of Decisions (49)

Current through Feb. 11, 2021; 86 FR 9252.

End of Document

Addendum 6

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart F. Drug Testing Laboratories

49 C.F.R. § 40.87

§ 40.87 What are the cutoff concentrations for drug tests?

Effective: January 1, 2018
Currentness

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff[1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA)[2]	50 ng/mL[3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL[3]	Benzoylecgonine	100 ng/mL.
Codeine/	2000 ng/mL	Codeine	2000 ng/mL.
Morphine		Morphine	2000 ng/mL.
Hydrocodone/	300 ng/mL	Hydrocodone	100 ng/mL.
Hydromorphone		Hydromorphone	100 ng/mL.
Oxycodone/	100 ng/mL	Oxycodone	100 ng/mL.
Oxymorphone		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.

Addendum 7

Amphetamine/	500 ng/mL	Amphetamine	250 ng/mL.
Methamphetamine		Methamphetamine	250 ng/mL.
MDMA[4]/MDA[5]	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

(e) [Reserved by 77 FR 26473]

Credits

[75 FR 49862, Aug. 16, 2010; 77 FR 26473, May 4, 2012; 77 FR 60319, Oct. 3, 2012; 82 FR 52244, Nov. 13, 2017]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006; 82 FR 52243, Nov. 13, 2017, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 et seq.

Notes of Decisions (1)

Current through Feb. 11, 2021; 86 FR 9252.

Footnotes

1 For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

2 An immunoassay must be calibrated with the target analyte, &b.Delta;-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

3 Alternate technology (THCA and Benzoylecgonine): When using an alternate technology initial test for the specific target analytes of THCA and Benzoylecgonine, the laboratory must use the same cutoff for the initial and confirmatory tests (i.e., 15 ng/mL for THCA and 100ng/mL for Benzoylecgonine).

4 Methylenedioxymethamphetamine (MDMA).

5 Methylenedioxyamphetamine (MDA).

End of Document

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart N. Problems in Alcohol Testing

49 C.F.R. § 40.277

§ 40.277 Are alcohol tests other than saliva or breath permitted under these regulations?

Currentness

No, other types of alcohol tests (e,g., blood and urine) are not authorized for testing done under this part. Only saliva or breath for screening tests and breath for confirmation tests using approved devices are permitted.

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006; 82 FR 52243, Nov. 13, 2017, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 et seq.

Current through Feb. 11, 2021; 86 FR 9252.

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Addendum 8