DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 10

[Docket No. USCG–2016–0029]

Change-2 to Navigation and Vessel Inspection Circular 04–08: Medical Certification Standards, Medications, and Medical Review Process

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy; availability.

SUMMARY: The Coast Guard announces the availability of Change-2 to Navigation and Vessel Inspection Circular (NVIC) 04–08, “Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials” (NVIC 04–08). Change-2 to NVIC 04–08 contains revisions to Enclosure (1) Medical Certification Standards, Enclosure (4) Medications, and Enclosure (6) Medical Review Process. The revisions to Enclosures (1) and (6) reflect process and procedural changes related to centralization of the evaluation of credential applications at the National Maritime Center and implementation of the final rule that aligned Coast Guard regulations with amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers and made changes to national endorsements. The revisions to Enclosure (4) provide more detailed guidance on medications that are subject to further review, and address comments received in response to a notice published in the Federal Register on January 28, 2015 seeking input from the public on this issue.

DATES: Change-2 to NVIC 04–08 is in effect on June 3, 2016.

ADDRESSES: Submit comments online at http://www.regulations.gov in accordance with Web site instructions.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email LCDR Ian Bird, Office of Commercial Vessel Compliance (CG–CVC), 202–372–1255, email MMCPolicy@uscg.mil.

SUPPLEMENTARY INFORMATION:

Viewing Documents


Background

Coast Guard regulations contained in 46 CFR part 10, subpart C, contain the medical and physical standards that merchant mariner applicants must meet prior to being issued a merchant mariner medical certificate. NVIC 04–08 provides guidance to the regulated community on how to comply with the regulations pertaining to medical and physical qualifications for merchant mariners. On December 24, 2013, the Coast Guard published a final rule in the Federal Register (78 FR 77706) entitled “Implementation of the Amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, and Changes to National Endorsements.” It amended 46 CFR parts 1, 10, 11, 12, 13, and 15 to implement the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978 (STCW Convention), including the 2010 amendments to the STCW Convention, and the Seafarers’ Training, Certification and Watchkeeping Code, as well as updating requirements for national endorsements. The final rule also established the merchant mariner medical certificate as a document issued independently of the merchant mariner credential. Merchant mariner credentials issued after January 24, 2014, and that require a general medical examination are not valid for service unless accompanied by a valid medical certificate. Enclosures (1) and (6) of NVIC 04–08 required revision to reflect changes implemented with the final rule and a reorganization of the mariner credentialing function.

Guidance on medication use contained in Enclosure (4) to NVIC 04–08 prior to Change-2 noted that use of certain medications was considered disqualifying for issuance of credentials. The guidance did not provide details on the types of medications that might lead to denial of a medical certificate, nor did it provide discussion of the information and criteria that the Coast Guard considers in determining whether to issue a waiver for certain medications.

In developing this policy, the Coast Guard sought recommendations from the Merchant Mariner Medical Advisory Committee (MEDMAC) on waiver considerations for mariner applicants whose conditions require the use of potentially impairing medications while operating under the authority of the credential. In response to Coast Guard Task Statement 14–09, Medical Evaluation of Merchant Mariner Treated with Potentially Impairing Medications, MEDMAC recommended that medications with central nervous depressant effects, such as opioid, benzodiazepine, or non-benzodiazepine medications, be considered disqualifying and generally not waiverable. They also recommended that the following medications be determined disqualifying: medications that impair vision, anticoagulants, anti-metabolites and cancer treatments, sedating anti-histamines, antipsychotics, opioid-like analgesics, anti-seizure medications, and stimulant medications, such as amphetamine and methylphenidate. MEDMAC’s recommendations did not include specific criteria for waiver consideration for mariners whose conditions require the use of potentially impairing medication while operating under the authority of the credential.

On January 28, 2015, the Coast Guard published a notice in the Federal Register requesting public comments on a proposed revision to Enclosure (4) that would provide more in-depth guidance on these issues (80 FR 4582).

We summarize the policy contained in Change-2 to NVIC 04–08 and address the public comments received on the proposed revision to Enclosure (4) below.

Discussion

Enclosure (1) and Enclosure (6). The revised Enclosure (1) Medical Certification Standards summarizes the medical and physical requirements for mariner endorsements and provides additional guidance regarding the medical certificate. The revision to Enclosure (6) provides guidance on the medical review process used to determine if a mariner meets the medical and physical standards for issuance of a medical certificate.

Enclosure (4)—Medications. The revision to Enclosure (4) provides guidance to the regulated community on medications that may be deemed disqualifying for issuance of a medical certificate due to risks of impairment or other safety concerns. The new guidance also clarifies the extenuating circumstances related to the use of potentially impairing medications that the Coast Guard weighs in evaluating risks to public and maritime safety, and
in determining suitability for a medical waiver. The revised enclosure additionally provides a safety warning to mariners advising them to refrain from operating under the authority of the credential when they are under the influence of any medication that can cause drowsiness, or impair cognitive ability, judgment, or reaction time. The revised guidance for mariners seeking a waiver to use potentially impairing medications while operating under the authority of the credential follows.

I. Medication Waivers Requiring Special Consideration

Medications that may impair cognitive ability, judgment or reaction time are considered disqualifying for issuance of credentials. The underlying condition, as well as the effects of the medications, may lead to denial of a medical certificate or may result in issuance of a waiver.

Due to the documented risks of impaired cognition, judgment, and reaction time associated with the use of certain legally prescribed controlled substances; the Coast Guard has determined that use of these medications while acting under the authority of the credential generally will not be waived. These medications include, but are not limited to opioid/opiate medications, benzodiazepine medications, non-benzodiazepine sedative hypnotic medications, and barbiturate medications. However, waivers may be considered, on a case-by-case basis, if the Coast Guard determines that there are exceptional circumstances that warrant consideration for a waiver.

Exceptional Circumstances. The criteria for waiver consideration for applicants seeking to use, or be under the influence of, medications that may impair their cognitive ability, judgment, or reaction time, while acting under the authority of the credential, are listed below. Applicants unable to meet all of the criteria are only considered for a waiver under extraordinary circumstances, if the Coast Guard deems the risk of impairment to be sufficiently low. The criteria follow.

1. The mariner was previously granted a waiver allowing use of the same medication while working under the authority of the credential, where the credential was of the same scope of authority.

2. The mariner demonstrated compliance with all terms of the prior waiver.

3. There were no accidents or other safety concerns related to medication, judgment, cognitive ability, or reaction time during the course of the prior waiver period(s).

4. The mariner has been on a stable medication regimen for a minimum of 2 years, as documented by the treating physician and pharmacy records.

   a. Mariners who have required periodic increases in medication dosing during the preceding 2-year period would not meet this criterion.

   b. Mariners who have consistently or periodically supplemented their medication regimen with other disqualifying medications during the 2-year period are not likely to be considered as meeting this criterion. For example, an individual who has been on a stable dose of one opioid pain medication for 2 years, but has also periodically taken or filled prescriptions for an opioid cough medication during that same time period, would not be considered as being on a stable dose of medicine.

   c. Mariners whose medication dose has been decreased or tapered off, without subsequent dose increase, may be considered as meeting this criterion.

5. The mariner is not seeking to use, or be under the influence of, more than one medication with risk for impairment while working under the authority of the credential.

6. The mariner’s treating physician provides written assessment that adequately addresses all information requested in the section on Recommended Evaluation Data for Medication Waivers requiring Special Consideration, and that supports a determination that the mariner is at low risk for medication impairment based upon objective testing and standard evaluation tools.

7. When requested, formal neuropsychological/neurocognitive testing, performed as outlined in the section providing guidance on formal neuropsychological/neurocognitive evaluation, documents the absence of significant medication impairment.

8. The mariner does not use any other medications or have any other medical conditions, which may alone, or in combination, adversely affect the mariner’s fitness.

9. Use of methadone may not be waived under any circumstances.

The risk presented by the mariner’s position may be considered in determining whether to grant a waiver. Because of the wide-range of operational conditions, it is impossible to set out in advance which positions may be suitable for a waiver. The Coast Guard retains final authority for the issuance of waivers. Waivers may include restrictions and/or operational limitations on the credential.

Recommended Evaluation Data for Medication Waivers Requiring Special Consideration. Applicants seeking consideration for a medication waiver for the use of medications that may impair cognitive ability, judgment, or reaction time, while acting under the authority of the credential, should submit the additional information detailed below, for each medication.

1. A letter from the prescribing and/or treating physician that includes the following:

   a. Whether the physician has familiarized himself/herself with the detailed guidelines on medical conditions and medications contained in NVIC 04–08.

   b. Whether the physician understands the safety-sensitive nature of the credential and the specialized shipboard environment.

   c. A detailed discussion of the condition that requires the use of the potentially impairing medication.

   d. A description of any known complications experienced by the mariner from the use of a particular medication, level of current stability, and prognosis of the underlying condition. The physician should also provide his or her professional opinion on whether the condition is suitable for safety-sensitive work.

   e. A description of the dosage and frequency of use of the medication (this description should be very specific; “as needed” is not sufficient information).

   The description should also reflect that the physician has reviewed the mariner’s pharmacy records for documentation of the number of pills dispensed for use each month and documentation of the length of time that the mariner has been on the medication.

   f. A detailed statement about whether the mariner is taking the medication as directed, and if there are any concerns of misuse or overuse of the medication.

   g. A statement about whether the mariner is compliant with therapy and follow-up appointments.

   h. A statement about whether the mariner requires use of this medication while at work, or while aboard the vessel. If the mariner requires use of the potentially impairing medication while at work or while aboard the vessel, the physician should provide a detailed explanation and rationale for the use.

   i. A statement about whether the physician has advised the mariner of the risks of impairment related to the medication. The physician should also discuss any risks advised, as well as any instructions discussed with the mariner for mitigating risk.

   j. A statement about whether the mariner’s other medications, medical
conditions, and work/sleep conditions might compound the impairing effects of this medication. This discussion should reflect that the physician has knowledge of the specifics of the mariner’s medications, medical conditions, and work/sleep schedule.

k. A statement about whether the physician has formally evaluated the mariner for the presence of any impairing medication effects. This discussion should include a description of the method of evaluation utilized, as well as the findings.

l. A medical opinion of whether the mariner has any medication effects that would impede safe operation of a vessel or interfere with work in a safety sensitive position. This discussion should include the rationale for the physician’s opinion.

m. A statement of whether the physician has advised the mariner that it is safe to operate a vessel, operate hazardous machinery, and perform safety sensitive functions while under the influence of this medication.

2. When specifically requested by the reviewing authority, additional amplifying information, to include a formal neuropsychological/neurocognitive evaluation.

a. In particular, mariners seeking waivers to use or be under the influence of potentially impairing opioid/opiate, benzodiazepine, sedative hypnotic, and/or barbiturate medications, while acting under the authority of the credential, may be asked to submit the results of a formal neuropsychological/neurocognitive evaluation.

b. The Coast Guard will not normally request a neuropsychological/neurocognitive evaluation unless the applicant meets all other requirements for waiver consideration. This is to prevent mariners from undergoing costly testing when issuance of a waiver is unlikely.

c. Mariners are advised that submission of neuropsychological/neurocognitive evaluation results does not guarantee issuance of a waiver.

d. When a formal neuropsychological/neurocognitive evaluation is requested, the assessment should include objective assessment of the following functions, at a minimum:

(1) Alertness, arousal, and vigilance;
(2) Attention (focused, shifting, and divided), processing speed, and working memory;
(3) Reaction time (choice and complex), psychomotor function, upper motor speed, and coordination;
(4) Sensory perceptual function;
(5) Executive function: mental flexibility, adaptive problem solving, abstract reasoning, impulse control, risk taking/risk assessment, organizational ability (including visual spatial organization), and planning;
(6) Memory; and
(7) Communication skills.

e. When a formal neuropsychological/neurocognitive evaluation is requested, the evaluation and narrative interpretation must be provided by a neuropsychologist who is board-certified and licensed in the United States.

f. The report of the formal neuropsychological/neurocognitive evaluation should also include:

(1) Documentation of witnessed administration of the medication in question by a licensed medical provider; and

(2) Documentation of the time interval between ingestion of the medication and administration of the neuropsychological/neurocognitive testing battery.

II. Safety Warning for Mariners

Certain medications, whether prescription or over-the-counter, have known impairing effects and their labels warn about the risk of drowsiness and caution against use while driving or operating hazardous machinery. The nature of shipboard life and shipboard operations is such that mariners may be subject to unexpected or emergency response duties associated with vessel or crew safety, and prevention of pollution and maritime security at any time while aboard a vessel.

In the interest of safety of life and property at sea, the Coast Guard views shipboard life and the attendant shipboard duties that can arise without warning, as safety sensitive duties that are analogous to operating hazardous machinery. As such:

1. Mariners are advised to discuss all medication use with their treating providers and to inform them of the safety sensitive nature of their credential; and

2. Mariners are cautioned against acting under the authority of their credential while under the influence of medications that:

a. Can cause drowsiness; or

b. Can impair cognitive ability, judgment, or reaction time; or

c. Can carry warnings that caution against driving or operating heavy machinery.

3. Mariners are advised that they are considered to be acting under the authority of the credential anytime they are aboard a vessel in a situation which 46 CFR 5.57(a) applies, even when off-watch or while asleep.
impairment. Because of the safety sensitive nature of the medical certificate, the Coast Guard contends that neither mariner self-assessment, nor provider limited office-based assessment, is sufficient to rule out the risk of significant cognitive impairment in cases where the mariner seeks to use medications with known risk of impairment while operating under the authority of their credential. The Coast Guard notes that this opinion was also shared by all of the medical professionals who provided comment on the policy. They all agreed that the treating provider’s office assessment would not be sufficient to ensure that a mariner applicant was free of impairing medication effects when using medications of this type.

Three commenters opposed the proposed policy clarification, arguing that the Coast Guard should never issue waivers for mariners who require the use of potentially impairing medications, while operating under the authority of the credential, regardless of the circumstances. The Coast Guard acknowledges that individuals who use potentially impairing medications may suffer impairment, but finds that there is no evidence to support a conclusion that all individuals will uniformly suffer impairment. On this basis, the Coast Guard disagrees with imposing a new, blanket exclusion against all mariners who require the use of potentially impairing medication while operating under the authority of the credential. The merchant mariner medical regulations in 46 CFR part 10, subpart C, do not prohibit the use of legally prescribed medications, to include opioids, benzodiazepines, and non-benzodiazepine sedative hypnotics; and NVIC 04–08 has always provided for an individualized assessment of mariner applicants.

The Coast Guard additionally emphasizes that the proposed policy clarification is not a change in policy; rather, it provides the regulated community with specificity and clarifies that the Coast Guard will consider during the individualized assessment of mariner applicants who require the use of potentially impairing medications, while operating under the authority of the credential. The individualized assessment considers whether the specifics of an applicant’s medical condition, medical history, medication use, and cognitive functioning indicate a low likelihood of impairment, or indicate findings that suggest impairment. The Coast Guard contends that the policy clarification contained in Change 2 to NVIC 04–08 adequately strikes a balance between potentially impairing medications when operating under the authority of the credential, such testing may not be necessary in all cases. Therefore, the Coast Guard has retained the wording from the proposed policy indicating that a neuropsychological/neurocognitive evaluation need only be provided when requested by the Coast Guard, as part of the individualized assessment.

Another commenter argued that the Coast Guard would not be able to implement a process to request neuropsychological/neurocognitive evaluation on the basis that testing is time-consuming and expensive, and that there are no objective neuropsychological evaluation tools that are readily available to primary care providers. The Coast Guard disagrees that neuropsychological/neurocognitive evaluation may be expensive and time consuming and that the associated evaluation tools are not readily available to primary care providers. However, we disagree with the assertion that their use is not warranted in certain situations. Such a situation may occur during the course of conducting an individualized assessment. Without information from a neuropsychological/neurocognitive evaluation, the evaluator is left to presume the presence or absence of medication impairment based upon limited information. To presume that an applicant is impaired by their medication and deny them medical certification when no impairment truly exists, may result in extraordinary costs for the mariner applicant, including loss of employment, with resultant loss of home and healthcare. Alternatively, to assume that no medication impairment exists when a mariner applicant is actually experiencing impairment, may result in unacceptable high costs to public and maritime safety, should a maritime casualty result. It is important to note that this section of the proposed policy describes the information that the Coast Guard will consider when determining whether extenuating circumstances exist that warrant consideration for a medical waiver for mariners seeking to use potentially impairing medications, while operating under the authority of the credential. As is often the case for any medical condition that is disqualifying and generally not approved for waiver, the evaluation to determine extenuating circumstances may often require assessment and testing that is beyond the scope of the primary care provider. When formal neuropsychological/
elements of the neuropsychological/ neurocognitive evaluation, when such testing is requested by the Coast Guard. The current policy also specifies that medication administration should be witnessed and documented by a provider prior to the conduct of neuropsychological/neurocognitive evaluation, when such testing is requested by the Coast Guard.

Authority

V.B. Gifford,
Captain, U.S. Coast Guard, Director of Inspections & Compliance.

[F.R. Doc. 2016–13158 Filed 6–2–16; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 16–29; RM–11758; DA 16–543]

Television Broadcasting Services; Scottsbluff, Nebraska and Sidney, Nebraska

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: At the request of Gray Television License, LLC, licensee of station KDUH–TV, Channel 7, Scottsbluff, Nebraska, and New Rushmore Radio, Inc., former licensee of KDUH–TV (collectively, Petitioners), the Commission has before it an unopposed Notice of Proposed Rulemaking seeking to amend the Post-Transition Table of DTV Allotments to delete channel 7 at Scottsbluff, Nebraska and to substitute channel 7 at Sidney, Nebraska. Petitioners further request modification of KDUH–TV’s license to specify Sidney as the station’s community of license. Petitioners assert that their proposal to reallocate channel 7 to Sidney is based on the technical specifications currently authorized for KDUH–TV and, therefore, the new allotment will be mutually exclusive with the station’s existing allotment. Petitioners further state that their proposal would meet the Commission’s allotment priorities by providing Sidney with its first local television service and that Scottsbluff would remain well-served after the proposed reallocation because full-power television station KSTF(TV), channel 29, would remain licensed to that community.

DATES: Effective July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Adrienne Denysyk, Adrienne.Denysyk@fcc.gov, Media Bureau, (202) 418–2651.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission’s Report and Order, MB Docket No. 16–29, adopted and released May 16, 2016. The full text of this document is available for public inspection and copying during normal business hours in the FCC’s Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC, 20554. This document will also be available via ECFS (http://fjallfoss.fcc.gov/ecfs/). To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to fcc50@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).


The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,
Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows: