Dated: January 22, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–01486 Filed 1–27–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2014–0720]

Request for Public Comment on Waiver Revisions for Certain Medications and Suggestions for Risk Evaluation

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed policy clarification and request for comments.

SUMMARY: The Coast Guard is seeking public comment on the policy clarification proposed in this Notice regarding the criteria for granting medical waivers to mariners who require the use of potentially impairing prescription medications. The Coast Guard is also seeking input regarding effective methods of risk evaluation of such mariners. Current Coast Guard guidance states that the ''use of certain medications is considered disqualifying for the issuance of credentials,'' and that ''the underlying cause or need for use of these medications and potential side effects may result in denial of a credential application or require a waiver.'' Current guidance specifically identifies that use of benzodiazepine medications, opioid and opiate medications, non-benzodiazepine sedative hypnotic medications, and barbiturate medications require a waiver, but does not specify the factors that the Coast Guard will consider in making its determination on whether the risks associated with use of these medications are low enough to warrant consideration for a waiver.

The Coast Guard is proposing additions to the current medication policy that will clarify the circumstances that the Coast Guard will consider when determining whether to grant a medical waiver for use of these medications. Additionally, the Coast Guard is proposing to include a safety warning to mariners advising them to refrain from use of impairing medications while operating under the authority of their credential. The Coast Guard is seeking comments from the public on whether the proposed policy adequately addresses safety concerns regarding merchant mariners whose medical conditions require the use of medications that have the potential to impair cognitive ability, judgment or reaction time.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before March 30, 2015 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2014–0720 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice, call or email Lieutenant Ashley Holm, Mariner Credentialing Program Policy Division (CG–CVC–4), U.S. Coast Guard, telephone 202–372–2357, email *MMCPolicy@uscg.mil.* If you have questions on viewing material in the docket, call Docket Operations at 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation

You may submit comments and related material regarding whether the policy clarifications proposed in this Notice should be incorporated into a final policy on issuing medical waivers to mariners whose medical conditions require use of benzodiazepine medications, opioid and opiate medications, non-benzodiazepine sedative hypnotic medications, or barbiturate medications. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this notice (USCG–2014–0720) and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number (USCG–2014–0720) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this notice.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing the comments: To view comments, go to *http://www.regulations.gov,* type the docket number (USCG–2014–0720) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Open Docket Folder'' on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use their Docket Management Facility.

Privacy Act: Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act system of records notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Background and Purpose

Coast Guard regulations in 46 CFR 10.302 contain the medical standards that merchant mariners must meet prior to being issued a merchant mariner credential (MMC). In cases where the mariner does not meet the medical standards in 46 CFR 10.302, waivers may be granted when extenuating circumstances exist that warrant special consideration. 46 CFR 10.303. Additionally, 46 CFR 10.304 specifies

the scope of the general medical exam required for receiving an MMC and directs that ''this exam must also document any condition requiring medication that impairs cognitive ability, judgment, or reaction time.''

On September 8, 2008, the Coast Guard issued Navigation and Vessel Inspection Circular (NVIC) 04–08, ''Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials'' (NVIC 04–08). In Enclosure (4) of NVIC 04–08, the Coast Guard identifies medications that may be disqualifying or may require a medical waiver. (NVIC 04–08 is available on the Internet at: *http://www.uscg.mil/hq/cg5/nvic/pdf/2008/NVIC%2004-08%20CH%201%20with%20Enclosures%2020130607.pdf.*)

The medications identified have a documented potential to impair cognitive ability, judgment and/or reaction time. In many instances, the medication labels also warn against driving or operating heavy machinery while under the influence of these medications. Because of the documented potential for impairment associated with these medications, the Coast Guard considers the use of these medications to be generally disqualifying. In some cases, waivers are granted to allow for limited use of the medication; while in other cases, the mariner is denied medical certification. When waivers are granted for use of these potentially impairing medications, the conditions of the waiver usually stipulate that the mariner must refrain from use of the medication for a specified time period, in order to decrease the likelihood that the mariner will be under the influence of the medication while working. However, such waiver stipulations cannot be applied to mariners who are medically required to take their potentially impairing medications prior to, and while working. As a result, mariners in this situation often have to change their medical treatment plan or risk denial of medical certification.

Enclosure (4) to NVIC 04–08 lists benzodiazepine medications, opioid and opiate medications, non-benzodiazepine sedative hypnotic medications, and barbiturate medications as requiring a waiver. Since the issuance of NVIC 04–08, there have been several instances where mariners sought waivers for use of these specific medications. However, NVIC 04–08 does not provide any guidance on the circumstances that will warrant consideration for a medical waiver. Published guidance on the circumstances that will be considered in determining whether the use of these medications warrant consideration for a medical waiver will support Coast Guard efforts to consistently evaluate merchant mariners whose medical condition requires the use of these medications and to assess whether an applicant's use of one of these medications warrants a medical waiver under 46 CFR 10.303.

The proposed policy changes seek to clarify the extenuating circumstances related to use of potentially impairing medications that the Coast Guard weighs in evaluating risk to public and maritime safety and in determining suitability for a medical waiver. Additionally, the policy would allow for consideration of the treating physician's formal assessment of impairment in determining whether the risk associated with the mariner's medication use is acceptable for a safety sensitive position.

The Coast Guard recognizes that there are instances when a mariner may take a medication or start a prescription for a medication outside of the timeframe of the MMC application process, and thus the medication use has not been included in the Coast Guard's review of the mariner's MMC application. Because a number of prescription medications and over-the-counter medications have effects that may impair cognitive ability, judgment and reaction time, it is critical that each mariner consider the effects of his or her medication before deciding to operate under the authority of his or her credential. Between 1987 and 2000, the National Transportation Safety Board investigated a significant number of accidents across all modes of passenger transportation that involved the use of potentially impairing prescription and over-the-counter medications, and their analysis determined that ''prescription and over-the-counter medications continue to be factors in transportation accidents and incidents.'' [1]

The current Coast Guard guidance advises mariners that certain medications may be considered disqualifying for the issuance of credentials, but the policy does not provide guidance on whether it is appropriate to operate under the authority of the credential while under the effects of a potentially impairing medication. As such, one of the proposed changes to the medication policy includes 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 Coast Guard is proposing to include these policy changes in a replacement to Enclosure (4) to NVIC 04–08.

In addition to seeking comments from the public about whether the proposed policy adequately addresses safety concerns regarding merchant mariners whose medical conditions require use of potentially impairing medication, the Coast Guard is also seeking public input on five specific questions relating to the medical waivers for the use of such medications.

Questions for the Public

1. What factors, if any, should the Coast Guard consider in determining whether to grant a waiver for mariners whose conditions require them to use (or be under the effects of) a potentially impairing medication while operating under the authority of the merchant mariner credential?

2. What methods of objective evaluation are available to reliably assure that a mariner is free of any impairing medication effects, specifically effects that would interfere with the safe operation of the vessel?

3. Should the treating physician's opinion that the mariner has no medication impairment be considered sufficient to mitigate risk to public and maritime safety?

4. Should formal neuropsychological/neurocognitive evaluation be required of all mariners who require chronic use of potentially impairing medications, or use of potentially impairing medications while operating under the authority of the credential? If so, what functions should be measured/evaluated, and what would be the appropriate standard for a test's outcome?

5. Under what circumstances, if any, should the Coast Guard consider granting waivers for mariners whose conditions require use of opioid maintenance therapy (for example, methadone or buprenorphine)?

The Proposed Policy

The proposed replacement to Enclosure (4) to NVIC 04–08, provided below, outlines more specific guidance for each class of medication discussed above. Additionally, the guidance advises mariners to carefully consider manufacturers' warnings for any medication(s) they may be taking, whether prescription or over-the-counter, before acting under the authority of the credential. The proposed replacement for Enclosure (4) to NVIC 04–08 follows:

[1] National Transportation Safety Board Safety Recommendation I–00–5, January 13, 2000. *http://www.ntsb.gov/doclib/recletters/2000/I00_5.pdf.*

Medications

Definitions

A. *Acting under the authority of the credential.* The definition of ''acting under the authority of a credential'' is found in 46 CFR 5.57. It states that

(a) A person employed in the service of a vessel is considered to be acting under the authority of a credential or endorsement when the holding of such credential or endorsement is:

(1) Required by law or regulation; or

(2) Required by an employer as a condition for employment.

(b) A person is considered to be acting under the authority of the credential or endorsement while engaged in official matters regarding the credential or endorsement. This includes, but is not limited to, such acts as applying for renewal, taking examinations for raises of grade, requesting duplicate or replacement credentials, or when appearing at a hearing under this part.

(c) A person does not cease to act under the authority of a credential or endorsement while on authorized or unauthorized shore leave from the vessel.

B. *Alcohol* means any form or derivative of ethyl alcohol (ethanol). *See* 33 CFR 95.010.

C. *Controlled substance* has the same meaning assigned by 21 U.S.C. 802 and includes all substances listed on Schedules I through V as they may be revised from time to time (21 CFR part 1308). *See* 33 CFR 95.010.

D. *Dangerous drug* means a narcotic drug, a controlled substance, or a controlled-substance analog (as defined in section 102 of the Comprehensive Drug Abuse and Control Act of 1970 (21 U.S.C. 802)). *See* 46 CFR 16.105.

E. *Drug* means any substance (other than alcohol) that has known mind or function-altering effects on a person, specifically including any psychoactive substance, and including, but not limited to, controlled substances. *See* 33 CFR 95.010.

F. *Intoxicant* means any form of alcohol, drug or combination thereof. *See* 33 CFR 95.010.

Prohibitions

A. *Illegal Substances:* Use of illegal or illegally obtained substances, including all illegal or illegally obtained dangerous drugs (as defined in 46 CFR 16.105), is incompatible with maritime service and is not waiverable under any circumstances.

B. *Intoxicants:* Operation of vessels while under the influence of drugs or alcohol is regulated under 33 CFR part 95. Issuance of a credential does not authorize a mariner to operate a vessel in contravention of 33 CFR part 95. *See also* 46 U.S.C. 2302.

Important Safety Warning

Certain medications, whether prescription or over-the-counter, have known impairing effects and their labels warn about 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, 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:

A. 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

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

(a) Can cause drowsiness, or

(b) can impair cognitive ability, judgment or reaction time, or

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

C. 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 to which 46 CFR 5.57(a) applies, even when off-watch or while asleep.

Prescription and Over-the-Counter Medications

Credential applicants who are required to complete a general medical exam should disclose on the Merchant Mariner Credential Medical Evaluation Report, CG–719K, all prescription and over the counter medications, filled or refilled and/or taken within 30 days prior to the date that the applicant submits the CG–719K to the Coast Guard. 46 CFR 10.302(a) and 10.304(a).

In addition, credential applicants who are required to complete a general medical exam should disclose on the CG–719K all prescription medications and over-the-counter medications, including dietary supplements and vitamins, that were used for a period of 30 days or more within the 90 days prior to the date the applicant submits the CG–719K to the Coast Guard. 46 CFR 10.302(a) and 10.304(a).

Medications which may impair cognitive ability, judgment or reaction time are considered disqualifying for issuance of credentials. Additionally, the underlying condition requiring use of the potentially impairing medication and/or the possible side-effects of these medications may result in denial of a credential application. Mariners who require the use of disqualifying medications may seek consideration for a waiver in accordance with 46 CFR 10.303.

The following is a non-exhaustive list of medications that may be deemed disqualifying due to risk of impaired cognitive ability, judgment or reaction time. Mariners on these medications are subject to further medical review, in accordance with enclosure (6) of NVIC 04–08, to determine whether the applicant's use of the medication is disqualifying. If the applicant's medication use is deemed disqualifying by the Coast Guard, then the Coast Guard will determine whether the mariner qualifies for a waiver under 46 CFR 10.303. Please refer to the section on Medication Waivers that follows.

A. *Anti-Depressants:*

(1) Conditions which require Selective serotonin reuptake inhibitors (SSRI), serotonin and norepinephrine reuptake inhibitors (SNRIs), or Wellbutrin (bupropion) do not require a waiver unless the underlying condition is deemed disqualifying.

(2) Conditions which require the use of other anti-depressants will be evaluated for stability of the underlying condition and the absence of impairing medication side-effects.

(3) A waiver is not required when used as a smoking cessation aid and with Premenstrual Dysphoric Disorder (PMDD).

B. *Anti-Motion Sickness Agents:* Use is approved and a waiver is not required when used in accordance with manufacturers' warnings and directions.

C. *Anti-Psychotics:* The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303.

D. *Anti-Convulsives:* The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303. See enclosure (8) for guidance on evaluating waivers of underlying conditions that may require anti-convulsives.

E. *Anti-Histamines:*

(1) Non-sedating medications, such as loratadine (Claritin), fexofenadine (Allegra) and desloratadine (Clarinex), are acceptable when used in accordance with manufacturers' warnings and directions.

(2) Sedating medications—The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303.

F. *Barbiturate Medications:* Due to the risk of impaired cognitive ability, judgment, and reaction time, use of barbiturate medications is disqualifying. The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303. Waivers for use within 48 hours prior to, or while acting under the authority of the credential will only be approved on a case-by-case basis if the Coast Guard determines that there are exceptional circumstances that mitigate risk to public safety. See medication waiver discussion below.

G. *Benzodiazepines:* Due to the risk of impaired cognitive ability, judgment, and reaction time, use of benzodiazepine medications is disqualifying. The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303. Waivers for use within 48 hours prior to, or while acting under the authority of the credential will only be approved on a case-by-case basis if the Coast Guard determines that there are exceptional circumstances that mitigate risk to public safety. See Medication Waivers discussion below.

H. *Cough Preparations with Dextromethorphan, Codeine, or other Codeine-Related Analogs:*

(1) Use of over-the-counter medications is approved when used in accordance with manufacturers' warnings and directions.

(2) For prescription medications containing opioid or opiate ingredients, see section K, Legally Prescribed Controlled Substances.

I. *Diet Aids (e.g. Dexatrim, Metabolife, etc.) and Stimulants (e.g. modafinil, amphetamines, etc.):*

(1) Use of over-the-counter medications is approved when used in accordance with manufacturers' warnings and directions.

(2) Prescription medications—The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303.

J. *Non-benzodiazepine Sedative Hypnotic Medications:* Due to the risk of impaired cognitive ability, judgment, and reaction time, use of non-benzodiazepine sedative hypnotic medications is disqualifying. The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303. Waivers for use within 12 hours prior to, or while acting under the authority of the credential will only be approved on a case-by-case basis if the Coast Guard determines that there are exceptional circumstances that mitigate risk to public safety. See medication waiver discussion below.

K. *Legally Prescribed Controlled Substances* (including legally prescribed narcotics, opiates, opioids and legally prescribed medications which contain narcotics or opioids such as Tylenol with codeine): Due to the risk of impaired cognitive ability, judgment, and reaction time, use of legally prescribed controlled substances is disqualifying. The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303. Waivers for use within 12 hours prior to, or while acting under the authority of the credential will only be approved on a case-by-case basis if the Coast Guard determines that there are exceptional circumstances that mitigate risk to public safety. See medication waiver discussion below.

L. *Medical Use of Hallucinogens (e.g. medical marijuana, peyote or ecstasy):* Even if legalized by a state, is disqualifying and not waiverable under any circumstances.

M. *Muscle Relaxants:* Centrally acting (*e.g.* carisoprodol, meprobamate, cyclobenzaprine, methocarbamol, orphenadrine citrate, anti-muscarinics and phenyltoloxamine, etc.): The medication and the underlying condition will be reviewed to determine whether the mariner qualifies for a waiver under 46 CFR 10.303. Waivers for use within 12 hours prior to, or while acting under the authority of the credential will only be approved on a case-by-case basis if the Coast Guard determines that there are exceptional circumstances that mitigate risk to public safety. See medication waiver discussion below.

Medication Waivers

A. As stated previously, medications which 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 credential application or may result in issuance of a waiver.

B. Due to the documented risks of impaired cognition, judgment and reaction time associated with the use of centrally acting opioid/opiate medications, benzodiazepine medications, non-benzodiazepine sedative hypnotic medications, and barbiturate medications, the Coast Guard has determined that use of these medications while acting under the authority of the credential is generally not waiverable. 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.

C. The Coast Guard retains final authority for the issuance of waivers.

D. Waivers may include restrictions and/or limitations on the credential.

E. Applicants seeking consideration for waivers for the use of medications that may impair cognitive ability, judgment, or reaction time 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 him/herself with the detailed guidelines on medical conditions and medications contained in Navigation and Vessel Inspection Circular 04–08.

b. Whether the physician understands the public-safety sensitive nature of the merchant mariner credential.

c. A detailed discussion of the condition which requires 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 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 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 requested, additional amplifying information, to include 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. When formal neuropsychologic or neurocognitive evaluation is requested, the assessment should include objective evaluation of the following functions, at a minimum: [2]

i. Alertness, arousal and vigilance

ii. Attention (focused, shifting and divided), processing speed,and working memory

iii. Reaction time (choice and complex), psychomotor function, upper motor speed and coordination

iv. Sensory perceptual function

v. Executive function: Mental flexibility, adaptive problem solving, abstract reasoning, impulse control, risk taking/risk assessment, organizational ability (including visual spatial organization), and planning

Authority

Ths notice is issued under the authority of 5 U.S.C. 552(a) and 46 U.S.C. 7101 *et seq.*

Dated: January, 16, 2015.

J.C. Burton,

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

[FR Doc. 2015–01623 Filed 1–27–15; 8:45 am]

BILLING CODE 9110–04–P

[2] Kay, GG and Logan BK, (2011). Drugged Driving Expert Panel report: A consensus protocol for assessing the potential of drugs to impair driving. (DOT HS 811 438). Washington, DC: National Highway Traffic Safety Administration.