COMMENTS OF THE AMERICAN PILOTS' ASSOCIATION
ON WAIVER REVISIONS FOR CERTAIN MEDICATIONS
AND SUGGESTIONS FOR RISK EVALUATION
[COAST GUARD DOCKET NUMBER USCG-2014-0720]

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Introduction

The American Pilots' Association (APA), on behalf of its nation-wide membership, is pleased to submit the following comments in response to the Notice that appeared in the January 28, 2015 Federal Register, 80 Fed. Reg. 18, requesting public comments on the criteria for granting waivers for certain medications and on suggestions for risk evaluation. According to the Notice, these proposed revisions and policy changes, if approved, will be reflected in a replacement to Enclosure (4) of NVIC 04-08 (Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials).

The APA is the national association of the piloting profession. Virtually all of the more than 1,200 state-licensed pilots working in the 24 coastal states of the United States, as well as all of the U.S. registered pilots operating in the Great Lakes system under authorization by the Coast Guard, belong to APA member pilot groups. These pilots handle nearly 95 percent of large ocean-going vessels moving in international trade in the waterways of the United States. The role and official responsibility of these pilots is to protect the safety of navigation and the marine environment in the waters for which they are licensed. In this regard, the APA and the Coast Guard have the common objective of working to ensure public and maritime safety.

While APA's membership is comprised predominantly of groups of state-licensed pilots, APA has a strong interest in federal regulations and policies that impact credentialied mariners, including the Coast Guard medical review policies that are the subject of this solicitation for comments. The reason for this interest rests in the fact that state-licensed pilots also hold U.S. Coast Guard-issued merchant mariner credentials and officer endorsements as federal first class pilots.
State pilot training, certification, qualification, and recency standards are more stringent than federal requirements, but the federal pilot endorsement does provide some benefit in that it serves as a national minimum standard. In the state pilotage system, obtaining a federal first class pilot endorsement can be either an entry level requirement for selection to a state pilot training or apprentice program or it could be one of the many steps in such a training program preparing an individual for an eventual state pilot license. In addition, state pilots must maintain a valid federal pilot endorsement in order to hold a state license or to work under that license. As a result, the professional career of each state-licensed pilot who belongs to an APA member pilot group, and the welfare of the pilot and his or her family, depends upon how the Coast Guard administers its federal credentialing program, including its medical review program and the issuance of medical waivers.

With this as background, the APA respectfully offers the following comments and suggestions on waivers for certain medications.

Comments

The APA welcomes the Coast Guard’s recognition of the need to provide some detail as to what information the agency expects from mariners when it is considering whether the risks associated with use of certain medications are low enough to warrant the issuance of a medical waiver. It would greatly aid the mariner and the mariner’s examining physician if the Coast Guard published the factors it considers in making medical waiver determinations. Publication of this information would allow examining physicians, when treating and examining a mariner whose use of a medication may raise some questions about fitness, to provide to the Coast Guard a more complete and appropriately focused medical evaluation and associated supporting documents.

The APA would like to take this opportunity to expand on the idea of the Coast Guard making public the criteria it uses in considering waivers for certain medications. The Coast Guard should publish the internal criteria, check-lists, or other “job aids” used by its medical evaluators to review and determine merchant marine medical fitness generally. While publication of factors considered by the Coast Guard in making medication waiver determinations will, as discussed above, be valuable to examining physicians and should facilitate a more effective and timely decision by the Coast Guard, public disclosure of the factors the Coast Guard uses in its broader mariner fitness determinations will provide even more benefit to the overall mariner medical review process.

The APA also supports the Coast Guard’s proposed policy that would specifically “allow for consideration of the treating physician’s formal assessment of impairment” in determining whether there are exceptional circumstances that warrant issuance of a waiver for a mariner’s use of a certain medication. While the APA has long argued that the mariner’s physician – who has the benefit of actually examining and testing (and in some cases treating) the mariner and conducting follow-up interviews – is best suited to make fitness for duty determinations, the Coast Guard, per 46 CFR § 10.302, has nonetheless
continued to reserve the right to make final mariner medical fitness determinations. In the proposed new Enclosure (4) of NVIC 04-08, the Coast Guard also makes clear that it “retains final authority for the issuance of medical waivers.”

Under this system where the Coast Guard makes final medical decisions with regard to mariners, including decisions on granting medical waivers, we think it is important that the Coast Guard not merely consider the examining physician’s formal assessment of impairment, the Coast Guard should give significant deference to the examining physician’s opinion. We also see benefit in the Coast Guard providing the examining physician with a list of items that should be addressed in a physician’s assessment of the mariner’s suitability for a waiver for use of certain medications.\(^1\) A better understanding of what the Coast Guard expects will no doubt aid the examining doctors in their work.

With respect to the Coast Guard’s proposed revision of the “Prescription and Over-the-Counter Medications” section of Enclosure (4) to NVIC 04-08, we believe this to be an unnecessary expansion of the reporting criteria for non-prescription medications. The current version of this section requires mariners to report all prescription medications “prescribed, filled or refilled and/or taken within 30 days prior to the date that the applicant signs the CG-719K,” and all over-the-counter (and prescription medications) “that were used for a period of 30 days or more within the last 90 days prior to the date the applicant signs the CG-719K.” The new text proposed by the Coast Guard now suggests that mariners should disclose not only prescription medications, but also over-the-counter medications, “filled or refilled and/or taken within 30 days prior to the date that the applicant submits the CG-719K.”

The proposed changes to this section are confusing and unnecessarily broad. For example, the revised language suggests that a marine would be expected to disclose to the Coast Guard that he or she took one aspirin, one multivitamin, or one fiber tablet within 30 days of submitting a 719K. Is this really what the Coast Guard intended through this new text or what it needs to make mariner fitness determinations? Furthermore, considering that mariners may be subject to criminal penalties for incomplete submissions on 719K forms, such a stringent reporting requirement for any over-the-counter medication seems unreasonable.

The APA recommends that the Coast Guard not change the guidance on the reporting of prescription and non-prescription medications, but rather use the existing language currently contained in Enclosure (4) of NVIC 04-08.

Finally, the Coast Guard also requested input on five specific questions relating to the use of medical waivers for certain medications. These five questions, along with APA comments follow.

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\(^1\) As detailed in section E. (1) of the proposed new Enclosure (4) to NVIC 04-08.
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?

As already mentioned above, the Coast Guard should give appropriate deference to the opinions and assessments of the licensed medical professionals who actually conduct the examination and evaluation of the mariner. As to this point, one of the most important factors that the Coast Guard should take into account in determining whether or not to grant a waiver for use of a particular medication is the **actual** side effects. If any, a mariner is experiencing as a result of taking the medication. Many medications, and virtually all prescription medications, are accompanied by a long list of possible or theoretical side effects a person might experience while taking the medication. It is also generally true that a significant number of people take these medications without experiencing any, let alone all, of the listed potential side effects. The examining doctors’ assessment as to whether the mariner is experiencing none, some or all of medication’s adverse side effects is perhaps the most significant factor the Coast Guard should consider in making its final determination as to whether or not to grant a waiver for a particular medication.

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?

This question is best suited to be addressed by medical professionals. The Coast Guard’s medical evaluators should be open to the various methods of evaluation proposed by practicing medical professionals who are charged with actually conducting the medical and physical examinations of mariners.

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?

Yes; provided, of course, that the examining physician who provides the opinion conducts a thorough examination and is fully aware of the duties and responsibilities of the mariner. Since the Coast Guard has in place a medical review system in which non-practicing government medical personnel located at the NMC make medical fitness and waiver determinations without ever seeing, let alone examining, the mariner, the agency should — at a minimum — apply great deference to the opinions of the examining physician.

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?

No. As discussed earlier, different people have different reactions to various medications, including medications with potentially impairing effects. As much as practicable, the
Coast Guard should avoid “one-size-fits-all” rigid requirements for specific medical tests, including neuropsychological/neurocognitive evaluations. Examining physicians should have professional discretion to conduct their medical examination and develop their assessment of the impairing effects, if any, a mariner may experience while taking a particular medication. Similarly, the Coast Guard should not lock itself into a policy of always requiring such evaluations for mariners who regularly take a prescription medication that has potentially impairing impacts for some people. These and many other medical evaluations and tests are expensive and should only be ordered if deemed absolutely necessary.

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)?

This question should be addressed by expert medical professionals. Again, though, the Coast Guard’s medical personnel should seek the opinions of recognized experts in this area and then adopt policy as appropriate.

Conclusion

These proposed policy changes are important to the APA and its member pilot groups, and we appreciate the opportunity to offer constructive comments and suggestions.