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Attention: DOCKET NO. USCG 2006-25080

1. INTRODUCTION

These comments are submitted on behalf of the Marine Engineers' Beneficial Association (MEBA). MEBA represents U.S. Coast Guard licensed deck and engine officers as well as unlicensed personnel serving in the United States merchant marine. Our members serve in areas of the maritime industry including both domestic and international shipping (bulk cargo, containerships, tankers, cruise ships, tugs, barges and ferry systems). In addition MEBA provides shipboard officers to vessels owned by the United States that support national defense and the global war on terrorism-- vessels that are under the control of the U.S. Navy's Military Sealift Command; U.S. Maritime Administration; Army Corps of Engineers and the National Oceanographic and Atmospheric Administration.

MEBA commends the United States Coast Guard (USCG) for opening the process of implementing a proposed Navigation and Inspection Circular (NVIC) to the public. Given that the USCG is not required to issue a notice and comment for the purpose of issuing a NVIC, MEBA appreciates the Coast Guard's recognition of the valuable input it will receive from the maritime industry in clarifying the issue of medical and physical evaluations.

We are hopeful that the USCG understands any NVIC issued may need to be revised from time to time based on the impact that the NVIC will have on seafarers' ability to crew vessels.

The USCG states in its proposed NVIC: "The information contained in this NVIC does not change current Coast Guard practices with respect to the physical and medical evaluation process. It reduces the current practices to writing, making them transparent for all to see. As such, it is not anticipated that this NVIC will result in higher rates of disqualification for service, nor in increased processing time for credential applications with physical and/or medical issues. To the contrary . . . the Coast Guard expects the process to be fairer and less subjective, and we anticipate application processing time to be reduced because all parties will know precisely what information is needed at the outset of the application process."

The aforementioned statement is very difficult to square considering that under the current process there are approximately 45 disqualifying medical conditions, and under this proposed NVIC the Coast Guard has listed approximately 200 disqualifying medical conditions.

2. Professional Medical Advice and Counsel

The Marine Engineers' Beneficial Association is a member of the Maritime Trades Department of the AFL-CIO. As a member of the Maritime Trades Department, MEBA has taken medical counsel and advice from Dr. Kenneth B. Miller. Kenneth Miller, MD, has been a Board Certified specialist in occupational medicine for over 25 years. He has had numerous opportunities to design and implement many medical protocols in a wide variety of occupational settings. During the past 14 years as the Medical Director for the Seafarers Health and Benefit Plan, Dr. Miller has developed the capability to implement the required USCG and MSC medical evaluations through a network of contracted clinics throughout the nation which perform almost 2,000 USCG medical evaluations and 4,000 MSC evaluations per year.

Dr. Miller also serves on the informal Medical Standards Work Group constituted under the auspices of the Merchant Marine Personnel Advisory Committee (MERPAC). MERPAC's purpose is to advise the Secretary, via the Commandant, U.S. Coast Guard, on matters relating to the training, qualification, licensing, certification and fitness of seamen in the U.S. merchant marine. The Committee acts in

an advisory capacity in accordance with 5 U.S.C. App. I (1976), the Federal Advisory Committee Act.

Unless otherwise specified herein, the two categories of comments that immediately follow have been derived from the advice and counsel of Dr. Kenneth B. Miller. The two categories are (1) general comments reflecting overall processes; and (2) procedures and more specific technical comments regarding individual elements within the NVIC.

3. GENERAL COMMENTS

Privacy and Employment Provisions Pursuant to Federal Law

In the opening section of the draft NVIC, the USCG puts forward the purpose of the NVIC, discusses the background of its development and implementation and, under the heading entitled "Discussion", describes a number of what can best be described as "guiding principles" (a-n) for the proper implementation of the requirements which follow the introduction. There is no statement concerning the mariner's right to privacy, no assurances that the medical information obtained will be handled in accordance with the principles set forth in Federal law for the safeguarding of protected health information (termed PHI under HIPPA regulations) or any other guarantees that the PHI will be appropriately utilized and protected from unwarranted intrusion. To the extent that the USCG is issuing a document which is required for maritime employment, it is critical that privacy policies and procedures be developed and stated in this section. We would also request that the USCG provide a statement that complies with the general principles that are stated in Federal law under the employment provisions of the Americans with Disabilities Act (ADA), in that mariners should not be discriminated against on the basis of a disability which may be present. Inasmuch as the USCG expects that medical providers in the private sector will perform the medical examinations in compliance with "guidance" from the USCG utilizing USCG forms and medical qualifications, such a statement is a critical guiding principle that merits inclusion.

Medical Examination and Review Procedures

Under section #5, "Discussion", items (a-n) put forward important general principles which set forth the guidance under which the medical examinations are to be performed.

Many of these principles are critical to a complete understanding of the process and the proper performance of the examinations. However, most of the important concepts regarding the complete Medical Review Process resulting in the certification of the mariner as "competent, not competent or needing further review" on the USCG Form 719K are relegated to "Enclosure #5" at the very end of the NVIC.

It is critically important that medical providers, who are the initial gatekeepers, be provided with as much relevant information in a concise manner at the very beginning of the document. It is vitally important that medical providers (who are often performing these examinations with little time or recompense) be seen as the most important first line of review and be provided with as much information as possible regarding the medical review and certification process and their role within that process. It is also quite likely that the initial examining medical provider may become the physician whom the mariner relies upon for the required referrals and follow-up documentation during the waiver and appeal procedures. Stating the process in its entirety early on should assist both the mariner, medical provider, and the USCG in the timely processing of the requested credential.

For these reasons, it is recommended that the Discussion section be merged with Enclosure #5, in its entirety, and be re-titled "Medical Examination and Review Procedures". Such a merger would provide an examining physician with all of the critical examination policies and procedures in one location at the outset of the process.

Appeals Procedures

The most basic elements of the appeals procedure must be stated somewhere in the NVIC. Currently, the NVIC refers the applicant (and the examining physician who might assist in the appeal) to 46 CFR Subpart 1.03.

It is important for mariners and their physicians to know, at the outset, that any appeal must be filed in writing within 30 days, that the timeframe may be extended upon written request with good cause and that the initial action (denial) stands while the appeal is reconsidered, unless the denial is stayed by the USCG. Given the unusually short timeframe for filing an appeal,

it is unnecessarily burdensome to expect that a mariner or a physician be required to search for the critical information which may determine whether or not a mariner can retain his credential to be employed.

General Comments on Enclosure #3

As a result of the efforts of MERPAC, the National Maritime Center (NMC) and the Workgroup on Medical Standards mentioned above, many improvements in the current process are being implemented or contemplated. These include the centralization of all waivers (except vision and hearing) at the NMC, enhanced medical review resources for timely processing of credentials and the vastly increased transparency of the process. We further support the ability of mariners to certify that they can perform the Physical Ability Standards through a "suitable practical demonstration" of their physical abilities by physical or occupational therapists, and to obtain a waiver for certain visual requirements through the attestations of their co-workers or employers.

Nonetheless, the vast increase in the number and scope of the "Potentially Disqualifying Conditions and Medications" (Encl. #3) has created a significant and ongoing concern among many reviewers of the document.

- Inasmuch as the genesis and basis for Encl. #3 was the rather detailed and comprehensive standards contained in the FAA regulations rather than a more traditional set of maritime related standards (i.e., MSC physical for pre-positioning vessels), there is a persistent concern that items in Encl. #3 will generate large numbers of waiver requests, and increase costs and delays in medical follow-up. Since everyone involved in the process up until this point has invested significant efforts in adapting the FAA standards to the maritime work environment, it is critical that the USCG recognize that a significant amount of discretion must be exercised in the adherence to such a detailed set of standards. Discretion must be exercised at all levels of review including the initial examining physician, the initial and final medical reviewers at the NMC and the reviews that may take place in the appeals process.

In accordance with the general principles as outlined in the employment provisions of the Americans with Disabilities Act (ADA), each case must be handled on a

case-by-case basis without application of absolute or inflexible automatic disqualifications. For example, the NMC should not necessarily require that, in all cases, all of the evaluation data items listed in Encl. #3 for a specific medical condition be completed. It is likely that a competent medical reviewer may be able to determine whether or not an individual is eligible for a waiver if sufficient documentation exists to satisfy the reviewer that such a waiver should be granted. Assurances within the document that the final medical reviewer has such discretion will help alleviate both the real number of waiver denials for "inadequate documentation" and the perception that all of the elements listed in Encl. #3 for a specific medical condition are required. Perhaps such a statement might be included under item #6 on the cover sheet to Encl. #3 entitled "Alternate Evaluation Data". Unnecessary costs and duplicative and invasive medical interventions should be avoided; they have attendant costs and risks associated with them that may not be trivial.

- As Encl. #3 is rather long and overly complex, WE would recommend that the USCG review the enclosure for repetitive and duplicative requirements for similar conditions. For example, many of the diseases of the visual system require exactly the same evaluation data; this is true for most, if not all, of the bodily systems that the enclosure summarizes. Many diseases within a specific bodily system with exactly the same evaluation criteria should be "collapsed", merged together and listed as separate, but related conditions. This will greatly shorten the enclosure, avoid repetition, duplication and unnecessary confusion when an examining physician is looking for guidance when performing an examination. An index or table of contents (by page number, for example) should be attached as a cover sheet to the enclosure or some other approach should be included which would provide a quick reference guide to the examining physician.

Medical Recordkeeping

As the draft NVIC states in section 5(m) "marine employers shall maintain the medical records required by 46 CFR 15.1107". Section 46 CFR 15.1107 states in subsection (a) that marine employers should maintain documentation which would ensure "medical fitness (such as results of a recent evaluation by a medical

professional certifying that the mariner is physically able to perform the tasks and duties normally associated with a particular shipboard position or does not have an apparent medical condition that disqualifies him or her from the requirements of a particular shipboard position)." It is unclear whether or not a marine employer who employs a mariner whose medical condition is waived by the USCG is, by definition, in compliance with this recordkeeping requirement simply by retaining a copy of the MMC. Legal clarification of this requirement in the NVIC would be helpful.

4. TECHNICAL COMMENTS

Comments on Enclosure #3

Many of the conditions listed in this enclosure could be determined to either represent a "significant impairment of functional status" or present "a risk of sudden incapacitation". Unfortunately, very little actual data exists in the medical literature to support such theoretical assumptions for many of the listed conditions. Therefore, it is even more critical that the NMC and the USCG be very thoughtful in their justification that such risks actually exist to the extent that a waiver should be denied.

Dr. Miller strongly recommends that all medical reviewers adopt a multifactorial, case-by-case functional assessment of an individual's ability to perform the essential job functions typically associated with the credential that may be issued.

Item #3: Strike reference to radiation therapy "significantly impair chances for waiver". This pre-supposes that mariners who have undergone such therapy will not be able to function adequately. The whole section is overly broad and should simply focus on documentation as to the impairment (or lack thereof) of essential job functions listed in the item.

Item #10: Duplicative to item #5

Items #11-34: Given the genesis of this enclosure derived from the FAA standards, the presence of any of the 22 separate and rather arcane ocular pathologies (consuming 5 of the 32 pages of the enclosure) may be relevant for pilots and others covered by FAA regulations. It is

difficult to see how many of these chronic ocular conditions relate to the risk for sudden incapacitation or safety onboard a vessel. The evaluation criteria for many of these conditions repeat themselves over and over again. We recommend merging to avoid duplication and elimination of those conditions which cannot be defended as a safety risk in the maritime environment. General visual acuity standards are also covered in Encl. #4.

Item #48a: Unclear as to relevance to safety and sudden incapacitation.

Items #52-81: While many of the items in this section present potential risks of sudden incapacitation or functional impairment, many are overly duplicative requiring the same evaluation criteria. The criteria for many of these conditions require a GXT (stress test) that achieves 10 METS. Unfortunately, in the real world, there are many reasons that individuals may not achieve this level of effort that are not cardiac related (i.e. leg fatigue, general de-conditioning, shortness of breath, etc.). Achieving target heart rates, normal blood pressure responses and the lack of ischemia even at 8-10 METS are generally accepted in clinical practice as sub-optimal, but acceptable test results to rule out significant heart disease. Once again, the need for discretion and flexibility in a case-by-case analysis is critical to the issuance of a waiver.

Item #77: The use of an ejection fraction of <40% as an absolute denial of a waiver is not supported by the medical literature. The ejection fraction can be measured by both echocardiogram and/or cardiac catheterization and they often differ by a wide margin depending upon a variety of factors. Furthermore, the ejection fraction can be improved with appropriate treatments and cardiac rehabilitation. There is significant debate in the medical literature as to the correlation between ejection fraction and functional capabilities. While it is important to consider ejection fraction in the overall picture, reliance upon this single variable as an absolute exclusion while allowing consideration of heart transplants and implantable defibrillators as "generally not waivable" appears to be inconsistent and may run afoul of the ADA for examiners who utilize the absolute exclusion of an EF<40% as a reason for denial of employment.

Items #87-96: There is no mention in this section of any forms of colitis (ulcerative, Crohn's, etc.) in this section. Evaluation criteria for these diseases may be similar to those for GI bleeding or gastrointestinal infections.

Items #101-115: There is no mention of chronic renal failure, a common clinical endpoint of both diabetes and hypertension. Evaluation criteria similar to those for #109-112 would be appropriate.

Items #131&134: Relating to the requirement that the mariner be asymptomatic and on no medications is overly restrictive and does not correspond to the clinical realities in the field. Minor or occasional symptoms or the use of "entry-level" medications (as outlined in the evaluation criteria for arthritis, i.e. NSAIDS or other analgesics) would be more appropriate.

Item #185: Although many psychotic disorders impair functional abilities, it is quite clear from the psychiatric literature that many individuals who carry a diagnosis of "psychotic disorder" can be employed quite safely and effectively if their condition is well-controlled and monitored over time. It appears to be discriminatory in nature to treat this class of medical conditions differently from any other class of conditions, as an apparent absolute exclusion, without consideration as to whether or not a mariner can safely perform the essential job functions without significant risk. MEBA suggests expanding the evaluation criteria (as in the related diagnoses of items #183 & 184), perhaps including the traditional markers of safety and function widely utilized in the psychiatric community (such as, certification that the mariner "does not represent a threat to self or others" is compliant with a medication regimen over time and has a history of functional employment in the industry). Once again, discretion is advised for this very common group of disorders.

Items #189-192: No mention is made of disorders of platelet adequacy or function. Low platelets can represent a significant risk of bleeding and is a common complication of a diverse group of conditions (liver disease, hematological disorders such as idiopathic

thrombocytopenic purpura, hematological malignancies, bone marrow suppression etc.). Evaluation criteria should be developed to address a suitable level of platelet numbers and function in association with a hematology consultation.

Comments on Medications in Enclosure #3

- Anti-psychotics: Waivers should be considered in conjunction with certification for a waiver for the underlying condition (see above).
- Legally prescribed controlled substances: These drugs include a large and diverse group of treatments (from Tylenol with codeine up to opiates and related drugs). Many of the conditions for which these medications are prescribed already require waivers and supporting documentation as to side-effects, dosages required and whether or not use is episodic or continuous. Many individuals who take these medications can develop tolerance and suffer no adverse side-effects if taken episodically and appropriately. Waivers should be considered on a case-by-case basis.
- Sumatriptin (Imitrex): Already covered under anti-migraine category—We recommend deletion

Comments on Vision and Hearing Standards in Enclosure #4

Item #5: The NVIC proposes to change the current average audiometric standards from an unaided average threshold of 70db down to 20 db and an aided threshold of 40 db down to 20 db. If these rather restrictive thresholds cannot be met, the NVIC authorizes the use of the functional speech discrimination test of 90% at 55 db. While we support the use of the speech discrimination test as a better measure of functional capacity, the 20db threshold will probably generate a large number of waivers without achieving any meaningful gain in safety.

A 30db average threshold is our recommendation (both aided and unaided—the current MSC standard) with the same speech discrimination requirements.

5. CONCLUSION

The new USCG draft NVIC represents a major departure from current practice which may have far-reaching effects upon the entire maritime community. Many reviewers of the document have expressed concerns regarding the potential impacts while others feel confident that adequate procedures and practices will prevent adverse outcomes. While we recognize that the NVIC is only one part of the overall process and is viewed by the USCG as only "guidance", many in the maritime industry will undoubtedly begin to interpret the criteria embodied within the document as a medical standard for employment.

The challenge for medical reviewers at the NMC will reside in the application of the medical guidelines in the NVIC in a fair and consistent manner in accordance with generally accepted principles within current medical practice. These principles, which include the recognition of privacy rights and the utilization of case-by-case determinations with discretion and flexibility in the application of the guidance provided in the NVIC, will greatly contribute to a safer maritime working environment while preserving the health, well-being and livelihood of the larger maritime community.

We look forward to our continuing involvement in the review process and the successful implementation of these guidelines to achieve these goals.

Sincerely,

/s/

Bill Van Loo
Secretary-Treasurer