1927 Halifax Road Apt 33
Danville, VA 24540

94832

Richard C. Moore, MD, MPH

October 1, 1998

Docket Clerk
DOT Dockets
Room PL-40 1
400 Seventh Street, SW
Washington, DC 20590-0001

Re: FHWA Docket No. FHWA-98-3 542 -14

Dear Sirs:

I certainly applaud your efforts, especially since it has been 28 years since the last major revision. While not wishing to further delay your efforts, I do still feel compelled to address some areas of concern. While not strictly in the order the issues arise in the NPR, I will try to stay close to that order and to indicate where in the document the language appears.

First is the issue of periodic rest and exercise ECG's. This is a new recommendation, one based upon your 1986 conference report, which I have read. The current regulations certainly permit, if not encourage, an ECG when clinically indicated, e.g., when an irregular pulse is detected. I question whether there is any data supporting a benefit for these studies given the significant increase in cost and whether, as a recommendation rather than a requirement, it will serve any purpose.

The U.S. Preventive Services Task Force addresses screening for asymptomatic coronary artery disease in their 1996 report (U.S. Preventive Services Task Force. Guide to clinical preventive services, 2nd ed. Baltimore: Williams & Wilkins, 1996, pp. 1-14). While they acknowledge that screening may be indicated on public safety grounds, they furnish no data.. . nor do I believe that data supporting a cost benefit exist. The goal, however, is not to detect asymptomatic coronary artery disease, but to prevent sudden incapacitation from that coronary artery disease.

In the discussion in the USPSTF report, they cite a study of 3600 asymptomatic middle aged males with elevated cholesterol subjected to exercise stress testing; only 2% had major cardiac events in over 7 years. Only 11 of 62 events occurred in subjects with an abnormal exercise ECG, a sensitivity of 18%; the positive predictive value of the EST was only 4%. It is generally acknowledged that a resting ECG is an even poorer screening test for coronary artery disease and presumably for incapacitation.

The FAA, in revising their physical examination requirements, cited some data, but my recollection is that it was similar and resulted in requiring fewer, not more, ECG's. I acknowledge that commercial drivers and aircraft pilots are hardly comparable populations from the standpoint of risk factors for coronary artery disease and that the former may be at greater risk. However, the Canadian Aviation Administration stratifies risk using the following factors: age, blood pressure, smoking, diabetes, and ratio of total cholesterol to HDL cholesterol. Their "acceptable" risk for aviation extends up to a 5% risk of a fatal or non-fatal cardiovascular disease event per 5 years; roughly three time the rate seen in the above study.

Piedmont PrimeCare East
1429 South Boston Road
Danville, VA 24540

On the other hand, the incremental cost of a resting ECG is significant. I can only speak for pricing in our practice, but the addition of a resting ECG with interpretation represents a 58% increase in the cost of the examination. Since the majority of examinations we perform are paid for by the employer, this recommendation will either significantly increase their cost of compliance or lead them to say, "It's only a recommendation, not a requirement. Don't do it." If the latter, the recommendation has not had its desired effect.

Thus, if you feel that the data are sufficient to support performing a periodic ECG or EST, it should be a requirement. If the data aren't there to show a benefit, the recommendation won't be followed and should be dropped.

Second is the issue of the "genital-urinary and rectal examination." On page 41773, you propose: "Note hernias or severe hemorrhoids. A condition causing discomfort should be evaluated to determine the extent to which the condition might interfere with the control and safe operation of a commercial motor vehicle."

The common hernias are ventral, umbilical, inguinal and femoral; all involve weakness of containing structures allowing protrusion of abdominal contents and none require a genital-urinary examination to detect. Indeed, in the current form, hernias appear under the "Abdomen" section. This is a logistical rather than a semantic distinction. While most drivers are male, we see an increasing number of female drivers. Inguinal hernias are extremely uncommon (if not rare) in adult females and the presence of the other three types (and arguably, the presence of an inguinal hernia) can be detected without a chaperoned exam, while a "genital-urinary" or rectal examination requires a chaperone.

Presumably, the rectal examination is to detect "severe" hemorrhoids, which are of concern because of the subsequent statement in the proposal. I think **that** statement is certainly valid; but it should be a general statement, applicable to all the body systems. Admittedly it has been a while since I looked at the data, but dental pain and disorders were much more significant for the Armed Forces than hemorrhoids as a cause of mission interference. Likewise, joint and muscle pain, shingles, and headaches are much more common in our clinical practice than painful hemorrhoids.

Thus, I don't think a routine rectal examination is appropriate or relevant to driver safety. I do think the statement about "a condition causing discomfort" is appropriate and relevant, but it belongs elsewhere, probably in the "General Information" section on page 4 1778 .

Third, the last sentence in the instructions (page 41773) and/or section (g) on page 41781 need to be strengthened. It has been your intent for the medical examiner to send **only** the medical certificate to the employer. That is proper; the employer does not have a need to have the entire physical examination form. The actual practice, though has been for the employer to request (and receive, since generally the employer pays the bill) a copy of the entire form. While this may be appropriate for a large concern with a medical department, it is not appropriate for most of our clients, as the confidentiality of the records cannot be assured. Anecdotally, ***they*** say the inspectors ask to see the forms as well as the certificates. This is an even larger concern with the language now appearing in the instructions (bottom of page 41772) to record and discuss with the driver conditions present but not cause for denial.

Assuming I have read your intent correctly, I believe language indicating that **only** the medical examiner's certificate may be released or that the medical examination form **shall not** be released is needed.

Fourth, here are some comments upon the proposed form itself (pp. 41774 - 41776).

Section 3, VISION: The line which says monocular vision yes/no will prove confusing and a source of errors, I fear. Since we test each eye separately as well as both eyes together, I'm not sure what the purpose of this line is. A monocular candidate should be obvious from the recorded vision.

The fact that a monocular driver is not qualified is already stated in the instructions. Please either clarify the purpose and presentation or drop that line.

Section 4, HEARING: Many practices (including ours) employ screening audiometers which present a tone at a fixed level, e.g., 25 dB and the presence or absence of a response is recorded. This is a more reproducible test than the whispered voice test, but does not give a numerical decibel loss to record in block b). If a frequency is not heard, we then do the whispered voice test. I would like you to give consideration to specifically permitting the use of such devices and to address how to record the results (we currently write in "<25" in the frequency/loss box).

Section 5, BLOOD PRESSURE/PULSE RATE: The pulse box needs to be larger.. . there is no room to write in a number.

Section 7, PHYSICAL EXAMINATION: I notice that the height and weight are in metric units. This is likely to be source of problems and errors. While the academic in me applauds that choice, the practical side is that our scale is English. If the intent is to calculate a BMI, that can be accomplished by using a conversion factor in the equation.

Item 9, as it relates to hernias and item 10, rectal exam, were addressed earlier. Hernias should be moved to item 7; items 9 and 10 should either be dropped, or share the language "only if clinically indicated."

MEDICAL EXAMINER'S CERTIFICATE: I'm not sure why the distinction between MD and DO is significant, but if that is retained, for consistency instead of "Chiropractor" you should have DC (the professional degree of chiropractic physicians). I think it should be ADVANCED PRACTICE NURSE, though I think "nurse practitioner" might be better terminology.

Fifth, I support the addition of the language permitting a shortened expiration date for conditions requiring monitoring (page 4 1778). The ex-bureaucrat side of me shudders at the deluge of requests for interpretation that are likely to follow, but it is a good addition, especially in conditions which are known to fluctuate over time frames shorter than two years.

Sixth, the section elucidating the policy on Epilepsy (page 41780) implies, though does not specifically state, that an epileptic controlled on medication is **not** qualified, regardless of how long they have been seizure free, I confess to not having researched the various states' CDL policies, but those states with which I am familiar will restore an epileptic's regular driver's license after a period of time if he/she is controlled on medication. I think this could be more clearly or emphatically worded.

Seventh, the color vision standard is still wide open to problems. I understand very well that signal light recognition and standard tests of color vision involve different skills. I'm not even sure that the requirement for color vision in drivers would stand up to rigorous examination such as the FAA performed for air traffic controllers. But, I would argue that that ability, even if a valid requirement, is better tested by the Department of Motor Vehicles granting the commercial drivers' license than by the medical examiner. "A controlled test using signal red, green and amber" is not a standard piece of medical office equipment; nor is it even standard for an FAA AME's office.. . a pilot is given a practical test at an airport. **This is not a medical standard, it is a performance standard and should be part of the performance testing, not the medical testing.**

And finally, just a typo.. . page 4 1773, Ears, second line, Meuniere's Syndrome should be Meniere's Syndrome (or more properly Meniere Syndrome, as he described it, but didn't suffer from it).

In conclusion, I appreciate the opportunity to comment and again wish to congratulate you on a good job under difficult circumstances. I look forward to the final product and to implementation. It has to be an improvement over the current situation. I hope future revisions will not be decades hence, but will keep pace with changing technology and practices.

Sincerely,

Richard C. Moore, MD, MPH
CAPT, USPHS (RET)