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**Comments for proposed HHS Clinical Quality Measure:
“Non-Recommended Prostate-Specific Antigen (PSA)-Based Screening”**

Submitted by: Men’s Health Network

Men's Health Network (MHN) is a national non-profit organization whose mission is to reach men, boys, and their families where they live, work, play, and pray with health awareness and disease prevention messages and tools, screening programs, educational materials, advocacy opportunities, and patient navigation.

MHN appreciates the opportunity to provide comments on the draft clinical quality measure developed by Mathematica Policy Research regarding “unnecessary screening for prostate cancer using prostate-specific antigen (PSA).”

We have serious concerns about this proposed measure and the impact it would have on men who would benefit from early detection of prostate cancer. We thank you for considering the comments outlined below.

We understand that the development of this clinical quality measure is based in large part on the “D” recommendation given to PSA screening by the United States Preventive Services Task Force (USPSTF) in 2012. This recommendation has been very controversial and is not supported by the majority of professional associations and prostate cancer advocacy organizations. Also, notably, prostate cancer screening is currently under review again by the USPSTF, making CMS consideration of this clinical quality measure seemingly premature.

<http://www.uspreventiveservicestaskforce.org/Page/Document/draft-research-plan/prostate-cancer-screening1>

The use of the PSA as an early indicator that the individual’s prostate may have or be developing abnormal conditions is too often mischaracterized as a cancer test. It is not, but is useful in detecting non-symptomatic prostate cancer, as well as other abnormalities in the prostate. The PSA is also useful in tracking the progress of prostate cancer, or lack of progress, once detected. The medical community understands these limitations, and does not use the PSA as a stand-alone cancer test, instead using it as an indication of prostate health, and in combination with other tests to determine if prostate cancer might be present.

The risk of “harms” associated with the test are minimal, and no different from any other blood draw, procedures that are used to determine cholesterol and glucose levels daily in every medical setting across the country.

This is a simple test that has helped diagnose thousands of men who had potentially life-threatening prostate cancer, but had no idea they might be at risk. It has also helped discover many more prostate cancers that would never be life threatening, and that might

never be treated, but, instead, may be carefully monitored to ensure that the cancer does not progress.

The decision to treat prostate cancer, once identified – or to engage in either active monitoring (active surveillance) or passive monitoring (watchful waiting) – is a decision to be made by a man in consultation with his physician and his family. This process is entirely separate from the screening decision.

Leading organizations including the American Urological Association, the American Cancer Society, and the National Comprehensive Cancer Network have each issued their own, more nuanced, guidance recommending discussions between patients and providers on PSA and other screening tools in the early detection of prostate cancer.

New technologies are now being used in conjunction with PSA testing to help determine the likelihood of aggressive prostate cancer and guide treatment decisions, and while PSA may eventually be replaced by more precise screening tools, it is currently an essential option for patients and providers in the early diagnosis of clinically significant prostate cancer.

The effect of this quality measure would be to discourage the important conversation between a health care provider and the patient to determine if the patient might benefit from prostate cancer screening, a screening which may include a PSA. This would discourage discussions with men who know they might be at high risk for prostate cancer because of race, ethnicity, family history, age, or exposure to certain carcinogens such as Agent Orange and the dust and debris from the World Trade Center disaster.

It would also discourage similar talks with men who do not know their family medical history.

Failure to have those discussions will mean many of these men are diagnosed with later stage prostate cancer, condemning them to painful, perhaps life-threatening, experiences in their fight for survival.

We agree with one physician who states that the quality measure is misdirected and that the treatment (and decision to treat or not) should be the quality metric, rewarding appropriate care, and not rewarding inappropriate care:

“Instead of using PSA screening (or lack thereof) as a quality metric, how about using treatment as a quality metric? Why not use the EHR to see who is treating low-risk prostate cancer inappropriately? Or use the EHR to see who is ordering inappropriate CT scans or bone scans? Let’s monetize appropriate care, not monetize the wholesale disruption of PSA screening.” Benjamin Davies MD, Urologic Oncologist and Associate Professor of Urology at the University of Pittsburgh. Chief of Urology at UPMC Shadyside Hospital and Director of the Urologic Oncology Fellowship at the University of Pittsburgh.

<http://www.forbes.com/sites/benjamindavies/2015/11/15/the-governments-war-against-mens-health-its-about-to-get-worse>

Thank you for your thoughtful consideration of these comments.