TAB 3

TO: Executive Committee

FR: Helen Burstin, Chief Scientific Officer

Marcia Wilson, Senior Vice President, Quality Measurement

RE: Appeal on Eye Care and Ear, Nose and Throat (EENT) Conditions Measure ***#2721: Screening for Reduced Visual Acuity and Referral in Children***

DA: February 11, 2016

ACTION REQUIRED

The Executive Committee will discuss the appeal deliberations to date and vote to determine whether to ratify the CSAC decision to uphold NQF Approval for Trial Use for eMeasure ***#2721: Screening for Reduced Visual Acuity and Referral in Children***.

Background

The American Optometric Association (AOA) submitted an appeal asking NQF to rescind the Approval for Trial Use for eMeasure #2721: Screening for Reduced Visual Acuity and Referral in Children (see attached letter). The intent of this measure is to encourage early screening for vision impairments in preschool age children in the primary care setting so they can be appropriately referred to eye care specialists. The appeal raises the issue of the effectiveness and appropriateness of vision screening for children in general.

The CSAC considered the issues raised by the appellant, the response by the developer, and the evaluation of the Eye Care and Ear, Nose and Throat (EENT) Standing Committee. The CSAC voted unanimously to uphold the decision to approve the measure for trial use, determining that the Committee had sufficiently discussed and addressed the appellant's concerns during the measure's initial evaluation and post comment period.

Summary of Issues Raised in the Appeal

During the public comment period, the AOA submitted comments that were discussed in detail by the Standing Committee. The appeal raises the additional issue of the effectiveness and appropriateness of vision screening for children in general. AOA states that the "National Eye Institute (NEI) and the Centers for Disease Control and Prevention (CDC) both report that the only way to be assured of healthy eyes and vision is through a comprehensive eye examination. Screenings do not give any such assurance but can certainly mislead children and their parents into believing care has been rendered when it has not." Specific concerns raised in the appeal include:

- Vision screening methodologies fail to identify as many as 73 percent of children with vision issues;

- Children who are identified by screening as having vision issues usually do not receive an eye examination to diagnose the problem and begin treatment; and
- The measure fails to track whether children receive follow-up care and treatment if necessary.

Summary of the EENT Standing Committee's Response to the Appeal Letter

The Eye Care and Ear, Nose and Throat (EENT) Standing Committee reviewed the appeal letter and provided responses via email. All responses supported the EENT Standing Committee's original recommendation to move eMeasure *#2721 Screening for Reduced Visual Acuity and Referral in Children* forward for NQF Approval for Trial Use. While the EENT Standing Committee acknowledged the appellant's concerns, the Committee agreed that those concerns were discussed in detail during the two day in-person meeting and post-comment call. The Committee recognized that, although the measure may not be perfect, by approving it for trial use, the eMeasure will be tested and further developed, which can lead to better eye care screening measures for children.

Letters received in support of the eMeasure during the appeals period are attached to this memo.

AMERICAN OPTOMETRIC ASSOCIATION
1505 PRINCE ST., STE. 300, ALEXANDRIA, VA 22314 | 800.365.2219

December 7, 2015

Bruce Siegel, MD, MPH
Chairman, Board of Directors
National Quality Forum
1030 15th St., Suite 800
Washington, DC 20005

Dear Dr. Siegel,

The American Optometric Association (AOA) represents approximately 33,000 doctors of optometry and optometry students. Doctors of optometry serve patients in nearly 6,500 communities across the country, and in 3,500 of those communities are the only eye doctors. Doctors of optometry provide more than two-thirds of all primary eye and vision health care in the United States. The AOA is a member of the National Quality Forum (NQF) and has been very active in providing input to the NQF's Eye, Ear, Nose and Throat Standing Committee regarding the measures under consideration.

The AOA is very concerned with the actions taken regarding the "Screening for Reduced Visual Acuity and Referral in Children" quality measure and is requesting an appeal of the Board's decision to move forward with initial endorsement and approval of this measure for trial use. This quality measure directly and materially affects one of the most important interests of our members, providing high quality eye care to children. Advocating for a measure that will fail to identify all children in need of eye care will certainly impede their social and academic growth.

When the reduced visual acuity measure was discussed by the EENT committee, the committee had a hearty discussion and identified many flaws and limitations. This measure is questionable in its effectiveness for many reasons, both clinical and practical. For example, there is no universal screening mechanism, there is no screening methodology that is sensitive and specific enough for the task, the qualifications of screeners vary from site to site, and—most importantly—the measure will do nothing to improve quality. Children who are identified by screening as having a potential vision problem usually do not receive an all-important eye examination to diagnose the problem and begin treatment.

The AOA is very concerned that the measure will fail to successfully identify children with vision impairments in need of care. So-called vision screening methodologies fail to identify as much as 73 percent of children with vision issues in need of correction. The only preventive service that adequately identifies vision issues and leads directly to care is an eye examination by an optometrist or ophthalmologist. The National Eye Institute (NEI) and the Centers for Disease Control and Prevention (CDC) both report that the **only** way to be assured of healthy eyes and vision is through a comprehensive eye examination. Screenings do not give any such assurance but can certainly mislead children and their parents into believing care has been rendered when it has not.

The AOA emphasizes this point: Children who fail the proposed screening need an eye examination to determine whether and how to address their vision needs, and children who pass the proposed screening also need an eye examination because screening misses most vision problems that need treatment. Therefore, there is no value to screening children in lieu of an eye examination. The screening measure even fails to track whether screened children receive an eye examination with follow-up care and treatment if necessary. Because screenings are misunderstood by parents to be more diagnostic than they are, screenings actually become a barrier to care instead of promoting access to care.

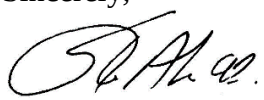
With regard to the measure title itself, it must be noted that visual acuity is not a "condition." Everyone, with the exception of those with no light perception, has "visual acuity" that can be described in a recognizable and accepted term. As such, "Visual Acuity Screening" would not be acceptable public health terminology for a quality measure. "Screening" has a strict public health definition related to finding "conditions" early so that actions can be taken to address the condition or to minimize the risk of progression. One could screen for "Vision Impairment" (e.g., visual acuity of 20/40 or less in the better eye) and use vision acuity testing methods as the testing methodology. However, most eye conditions are better treated before vision impairment occurs. With the exception for the disputed screening measure for amblyopia between ages 3 to 5, which received a grade B,[1] no form of vision screening is recommended at any age by the U.S. Preventive Services Task Force. Thus, the measure title itself requires additional attention for accuracy and relevance.

The AOA believes this measure must be reworked significantly before it is ready to be used even on a limited trial basis and requests that the NQF Board rescind the decision regarding this quality measure.

Thank you for your consideration. If you have additional questions, please contact Jensen N. Jose at jjose@aoa.org.

Sincerely,

Sincerely,



Steven A. Loomis, O.D.
AOA President

[1] U.S. Preventive Services Task Force. "*Visual Impairment in Children Ages 1-5: Screening*." Last accessed November 24, 2015. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/visual-impairment-in-children-ages-1-5-screening.

January 11, 2016

Bruce Siegel, MD, MPH
Chairman, Board of Directors
National Quality Forum
1030 15th Street, Suite 800
Washington, DC 20005

RE: eMeasure #2721: Screening for Reduced Visual Acuity and Referral in Children

Dear Dr Siegel,

On behalf of the American Academy of Pediatrics (AAP), the American Association for Pediatric Ophthalmology and Strabismus (AAPOS), the American Academy of Ophthalmology (AAO), and the American Association of Certified Orthoptists (AACO), we are writing in support of the National Quality Forum's EENT Standing Committee decision to approve eMeasure #2721 (Screening for Reduced Visual Acuity and Referral in Children) for trial use.

We have reviewed the December 7, 2015, letter you received from the American Optometric Association (AOA), appealing the recommendation to endorse eMeasure #2721. While the letter from AOA raises concerns about the complexity and limitations of screening in general, we believe there is a distinction between comprehensive eye examinations and our organizations' shared goal of employing visual acuity critical line testing as a screening mechanism to improve the visual health of America's children. We strongly urge NQF to move forward with endorsing this measure, which will promote vision screening in the pediatric medical home.

The AAP represents 64,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical sub-specialists dedicated to the health and well-being of children. AAPOS has a membership of over 900 actively practicing pediatric ophthalmologists in the United States dedicated to promoting the highest quality eye care for children. The AAO has 32,000 members, representing more than 90% of practicing ophthalmologists in the United States with a mission of ensuring that the public obtains the best possible eye care. AACO is the professional association for orthoptists in the US with a membership of 327 practicing professionals, representing nearly 80% of the field, and its mission is to improve the care of children with disorders of the visual system with emphasis on binocular vision and ocular motility. Our organizations have a long history of partnering to develop policies that promote the best eye care for our pediatric patients.

Pediatricians and ophthalmologists are medical doctors dedicated to child health. We recognize the challenges and complexity of screening for all disorders that affect the well-being of children, including those affecting the developing visual system. The AAP, AAPOS, AAO, and AACO recently published a vision screening Policy Statement and accompanying detailed Clinical Report addressing best recommended practices in screening children for serious vision problems. Among those recommendations is critical line visual acuity testing for children and screening medical evaluation of the eyes by the primary care physician in the medical home at regular intervals throughout childhood. Critical line visual acuity testing is widely acknowledged as

a definitive test for eyesight because it requires all aspects of the visual system, retina, optic nerve, and brain visual pathways to be functional in order to achieve a passing acuity.

As one component of a continuum of comprehensive vision care, HRSA's Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, the U.S. Preventive Service Task Force (USPSTF), and Healthy People 2020 Objectives for the nation recommend that all children be *screened* for detectable vision problems between the ages of 3 and 5 years. The AAP, AAPOS, AAO, AACO and the vast majority of international public health experts support the concept of screening in the medical home, rather than fragmenting care.

The goal of pediatric vision screening is to improve the detection of treatable vision disorders. All screening is a compromise between cost, sensitivity and specificity. We believe electronic data standards for documentation of the performance of critical line visual acuity testing in the medical home provides a simple positive step forward for America's children. Critical line vision testing is a constructive initial starting point upon which future generations of measures and standards can evolve to further refine the challenging process of identifying children in a practical manner with treatable visual problems.

We request NQF move forward with retention of this very positive measure for the health and welfare of America's children. We look forward to continuing to support this vital work with the members of the National Quality Forum.

Thank you for your consideration of this important matter.

Sincerely,

Benard P. Dreyer, MD, FAAP
President, American Academy of Pediatrics

M. Edward Wilson, MD
President, American Association for Pediatric Ophthalmology and Strabismus

William L Rich III, MD, FACS
President, American Academy of Ophthalmology

Laurie Hahn-Parrott, CO, COT, MBA
President, American Association of Certified Orthoptists

January 12, 2016

Bruce Siegel, MD, MPH
Chairman, Board of Directors
National Quality Forum
1030 15th Street, Suite 800
Washington, DC 20005

RE: eMeasure #2721: Screening for Reduced Visual Acuity and Referral in Children

Dear Dr. Siegel,

On behalf of the National Center for Children's Vision and Eye Health at Prevent Blindness (NCCVEH), I am writing in support of the National Quality Forum's EENT Standing Committee decision to approve eMeasure #2721 (Screening for Reduced Visual Acuity and Referral in Children) for trial use. Implementation of this trial measure will provide much-needed data that will drive improvements in vision screening practice, reduce disparities in receipt of preventive vision services, and guide uniform best practices in children's vision health.

Preschool-aged vision screening (PVS) is a national priority (Healthy People 2020[1]; OIG, 2010[2]). Early vision screening is necessary to detect and initiate treatment of vision problems and eye diseases, including amblyopia (1-4%) strabismus (3-4%) and high refractive errors (5-15%). [3-6] Treatment for these conditions is highly successful,[7-9] relatively inexpensive[10] and available, although incomplete utilization is common.[11,12] Adoption of a valid and reliable performance measure is critical to evaluate delivery of eye and vision services.

Vision screening leads to the early detection and the opportunity for prevention and treatment of vision problems in young children including amblyopia. PVS is a cost effective approach to reducing the toll of vision loss on the individual, families, and society as a whole. Economic analysis of amblyopia treatment demonstrates that the benefit to cost ratio for screening leading to early detection and treatment is nearly four to one, a potential savings of more than $12 billion in the U.S.[13]

Vision screening not only plays a role in identifying possible vision problems and encouraging people to seek comprehensive eye care, but screening efforts supported by the medical home are also engaged in helping individuals overcome many of the barriers that have prevented them from maintaining proper vision health, including:

- An inability to afford eye care and necessary treatment
- A lack of education and awareness about eye health
- Cultural aversions to eye care
- Difficulties in access to eye care due to work or lack of transportation
- Language barriers for non-English speaking populations

Simply pushing for an eye exam only approach WILL NOT make these additional barriers to vision health disappear. There is no single approach to eye care that can adequately meet the needs of each age group and the diverse environmental, socio-economic, and cultural values that drive their actions related to receipt of healthcare. At Prevent Blindness and the NCCVEH, we know that a vision screening (whether conducted by a primary care physician, a school nurse, or in a community-based setting) is not a diagnostic process and does not replace a comprehensive examination by an eye doctor; but it is an appropriate and essential element of a comprehensive approach to vision and eye health. The purpose of vision screening is to increase the number of individuals in need of care who ultimately receive comprehensive eye exams and necessary treatment. Vision screening is a critical component in the spectrum of interventions that must be taken to reduce the incidence of eye disease in the United States. The data that will be generated by eMeasure #2721: Screening for Reduced Visual Acuity and Referral in Children will provide the basis upon which we can write the story for improvements in children's visual acuity and reduction of visual impairments in the pediatric health care settings in the U.S.

On behalf of the NCCVEH, I fully support the advancement of this trial eMeasure and welcome opportunities for us to work with the members of the National Quality Forum in its implementation. Thank you for your consideration of this important matter.

Sincerely,

Kira N. Baldonado
Director, National Center for Children's Vision and Eye Health at Prevent Blindness
kbaldonado@preventblindness.org

References

1. US Department of Health and Human Services. Healthy People 2020. Objective Retained As Is From Healthy People 2010. V HP2020–1: Increase the proportion of preschool children aged 5 years and under who receive vision screening. Access verified Jan 12th, 2016: http://www.healthypeople.gov/2020/topics-objectives/topic/vision/objectives
2. Levinson DR. Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services, OEI-05-08-00520 (Washington, DC: U.S. Department of Health & Human Services, Office of Inspector General, May 2010), pp. 2 & 4.
3. The Multi-ethnic Pediatric Eye Disease Study. Prevalence of amblyopia and strabismus in African American and Hispanic children ages 6 to 72 Months. Ophthalmology. 2008 Jul; 115(7):1229-1236.
4. Friedman DS, Repka MX, Katz J, Giordano L, Ibironke J, Hawse P, Tielsch JM. Prevalence of amblyopia and strabismus in white and African American children aged 6 through 71 months the Baltimore Pediatric Eye Disease Study. Ophthalmology. 2009 Nov; 116(11):2128-34.e1-2. Epub 2009 Sep 16.
5. Fozailoff A, Tarczy-Hornoch K, Cotter S, Wen G, Lin J, Borchert M, Azen S, Varma R; Writing Committee of the MEPEDS Study Group*. Prevalence of Astigmatism in 6- to 72-Month-Old African American and Hispanic Children: The Multi-Ethnic Pediatric Eye Disease Study. Ophthalmology. 2010 Sep 29. [Epub ahead of print]
6. Wen G, McKean-Cowdin R, Varma R, Tarczy-Hornoch K, Cotter SA, Borchert M, Azen S; Multi-ethnic Pediatric Eye Disease Study Group. General Health-Related Quality of Life in Preschool Children with Strabismus or Amblyopia. Ophthalmology. 2010 Sep 28.
7. Li T, Shotton K. Conventional occlusion versus pharmacologic penalization for amblyopia. Cochrane Database Syst Rev. 2009 Oct 7;(4):CD006460.
8. Pediatric Eye Disease Investigator Group. A randomized trial of atropine vs. patching for treatment of moderate amblyopia in children. Archives of Ophthalmology 2002;120(3):268–78.

9. Pediatric Eye Disease Investigator Group, Repka MX, Kraker RT, Beck RW, Holmes JM, Cotter SA, Birch EE, et al. A randomized trial of atropine vs. patching for treatment of moderate amblyopia: follow-up at age 10 years. Archives of Ophthalmology 2008; 126(8): 1039–44.
10. Cohen JT and Neumann PJ. The cost savings and cost-effectiveness of clinical primary care. Research Synthesis Report No. 18. Robert Wood Johnson Foundation, Sept 2009. Access verified January 12th 2016: http://www.rwjf.org/content/dam/supplementary-assets/2009/09/Cost-Savings-and-Cost-Effectiveness-Clinical-Preventive-Care-Brief.pdf
11. Castanes MS. Major review: The underutilization of vision screening (for amblyopia, optical anomalies and strabismus) among preschool age children. Binocul Vis Strabismus Q. 2003; 18(4):217-32.
12. Newacheck PW, Hughes DC, Hung YY, Wong S, Stoddard JJ. The unmet health needs of America's children. Pediatrics. 2000 Apr; 105(4 Pt 2):989-97.
13. Gibson, William E. Economic Analysis of the Consequences of Failure to Prevent Childhood Blindness from Amblyopia. Children's Eye Foundation, 2012. Access verified January 12, 2016: http://www.diopsys.com/wp-content/uploads/2013/01/Childrens-Eye-Foundation-Cost-of-Amblyopia.pdf