



American Optometric Association

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**Joe E. Ellis, O.D.**  
President

September 17, 2010

The Honorable Kathleen Sebelius  
Department of Health and Human Services  
c/o Office of Consumer Information and Oversight  
Attention: OCIO-9992-IFC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Submitted electronically at Regulations.gov

Re: OCIO-9992-IFC, Group Health Plans and Health Insurance Issuers Coverage of  
Preventive Services under the Patient Protection and Affordable Care Act

Dear Secretary Sebelius,

The American Optometric Association (AOA) appreciates the opportunity to comment on the Interim Final Rule (Rule) (75 FR 41728 et seq) for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act. The AOA generally supports the Rule's approach in interpreting the provisions of the Affordable Care Act (ACA) that are critical to successful implementation of the health insurance market reforms included in the ACA.

By expanding coverage and eliminating cost sharing for the recommended preventive services, Congress, HHS and other Departments expect access and utilization of these services to increase. The extent that individuals increase use of these services Congress and the Departments anticipate several benefits: (1) prevention and reduction in transmission of illnesses as a result of immunization and screening of transmissible diseases; (2) delayed onset, earlier treatment, and reduction in morbidity and mortality as a result of early detection, screening, and counseling; (3) increased worker productivity and fewer sick days; and (4) savings from lower health care costs. Another benefit will be to distribute the cost of preventive services more equally across the broad insured population.

These ACA reforms (e.g. requiring group health plans and health insurance issuers offering group or individual health insurance coverage provide benefits for and prohibit the imposition of cost-sharing requirements with respect to certain preventive services) aim to improve insurance coverage and overall health outcomes for millions of patients across the country.

The AOA supports and views regulations requiring that a group health plan and a health

insurance issuer offering group or individual coverage provide benefits with no imposition of cost sharing as a positive cost effective public health intervention. While this expanded public health approach is necessary, the AOA has concern that the rules relying on US Preventive Services Task Force (USPSTF) ratings/recommendations or Bright Futures guidelines for infants, children and adolescents for decisions regarding coverage and elimination of cost-sharing for preventive services are not in the best interest of the public.

AOA's comments on the Rule specifically focus on the pitfalls of identifying a cursory pediatric vision observation or screening as a preventive measure as well as the need to rethink and rework the currently supported guidelines for preventive glaucoma screening.

### The AOA and Doctors of Optometry

The AOA represents approximately 36,000 doctors of optometry, optometry students and paraoptometric assistants and technicians. Optometrists 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 vision and eye health care in the United States, and provide physician services to millions of American families annually. The AOA and its members have a long history of servicing the vision and eye health care needs of vulnerable populations, including infants, children and adolescents as well as millions of Americans with diabetes or those who are at risk for diabetes.

Optometrists care for the bulk of infants' and children's vision and eye health needs as the predominant providers of primary vision and eye health care services, including early detection and prevention services for infants, children and adolescents as well as other at-risk populations. For patients with age related eye diseases at risk for diabetes, doctors of optometry are often the primary point of care or the "first-contact health care provider" and play an important role in early identification and prevention, educate patients about the disease as well as best management practices, refer those who require the care of other health professionals, and contribute to advancing a proactive, multidisciplinary team approach to care and prevention.

### Vision Observation or Screening as a Preventive Measure for Infants, Children and Adolescents

Vision disorders are the fourth most common disability in the United States and the most prevalent handicapping condition during childhood. Undetected and untreated eye disorders, such as amblyopia, strabismus, binocular problems and uncorrected refractive errors, are major child health problems that are associated with poor reading and other poor school outcomes. In fact, studies indicate that visual factors are better predictors of academic success than race or socioeconomic status. Childhood visual impairments are important causes of developmental disabilities in childhood (Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report [CDC MMWR], 1996) which lead to long term economic and other social concerns (CDC MMWR, 2004).

Other significant vision and eye health concerns and conditions in infants, children and adolescents include retinopathy of prematurity, congenital defects, diabetic retinopathy and cancers such as retinoblastoma. Although there is an urgent need to correct refractive error and diagnose and treat eye disease in preschool as well as school-aged children to prevent the development of amblyopia, strabismus and permanent vision loss, this major public health intervention is not adequately recognized as a current public health and universal health care priority. The AOA believes that preventing and treating vision problems and maintaining healthy eyes for all children from birth through to adulthood must become a public health priority and overall national policy goal in the United States.

Knowing that early detection and timely treatment is essential in preventing and properly managing eye diseases and vision disorders, the AOA worked closely with Congress and a range of other stakeholders committed to advancing the health and wellbeing of this nation to ensure that vision and eye health - especially for America's infants, children and adolescents - received the needed attention as health reform legislation progressed. The AOA fought for inclusion of this provision and was pleased to see the ACA take decisive steps toward making healthy eyes and vision a larger national health care priority by mandating that group health plans and health insurance issuers provide coverage of and limit cost-sharing for certain preventive health care services.

However, AOA has real concerns that the guidelines for vision services implemented in the interim rule are based on a methodology and system that has been failing America's children and families for decades.

As outlined in the Rule, with respect to infants, children, and adolescents, group health plans and health insurance issuers will now be required to cover evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). In the area of vision services for infants, children and adolescents, HRSA currently supports Bright Futures guidelines – a project originally funded by HRSA's Maternal and Child Health Bureau in 1990 then later developed and currently maintained by the American Academy of Pediatrics (AAP).

Bright Futures establishes a periodicity schedule for monitoring eyes and vision from birth through adolescence. Along with the recommended periodicity schedule, these guidelines also make recommendations for age-appropriate interventions. From birth through age two, Bright Futures recommends that vision should be examined (an external inspection that has no demonstrated sensitivity, specificity or positive predictive value) for clearly evident eye health issues and noticeably developed indicators of a vision problem, such as asymmetry. Bright Futures then recommends from age 2 through 4, that pediatricians should continue external inspection and also add vision testing (typically a Snellen visual acuity chart) as well as an attempt at ophthalmoscopy to evaluate the optic nerve and retinal vasculature in the posterior pole of the eye. For ages 5 and older, Bright Futures recommends a continuation of the interventions outlined above.

The AOA opposes the use of Bright Futures guidelines as the foundation for vision-related preventive services for infants, children and adolescents.

Given the asymptomatic nature of eye and vision diseases and disorders and the fact that most childhood vision problems can be prevented through early detection, follow-up and treatment, the AOA believes that it is essential that preventive services programs include prompt vision and eye health examination, as this is the only mechanism available that adequately assures vision and eye health to all children. To this end, AOA believes that infants should receive a comprehensive vision and eye health examination – assessing and treating deficiencies in ocular health, visual acuity, refractive status, oculomotility, and binocular vision – sometime within the first year of life to serve as a baseline preventive measure and then followed by periodic comprehensive exams and potentially complemented with evidence-based screening employing an appropriate sensitivity and specificity and positive predictive values.

A basic public health stipulation is that individuals should not be screened (e.g. not used as a measure or leading indicator of health) unless the methodologies include high sensitivities, specificities and predictive values and are combined with assurances of follow-up and treatment for those who fail. At 27 percent sensitivity, utilizing Snellen Acuity, a methodology developed in 1850 by Dr. Snellen, most vision screenings produce an inordinate number of “false negatives.” As a result, many of these children and their parents are inappropriately told they have “no vision problem.” Many of these children become frustrated by their poor academic performance tied to their undiagnosed vision problems, problems that they and their parents are unaware of, or told don’t exist. Furthermore, these children may inappropriately become labeled as slow learners, become socially isolated and develop behavioral problems.

Appropriate assurance of access to early and timely comprehensive vision care services by a professional eye care provider is therefore essential in addressing this public health emergency in children’s vision and eye health care that exists today. Early identification of vision health problems by a vision care professional (optometrist or pediatric ophthalmologist) can result in better school achievement and health outcomes among children, which lead to more productive and healthier lives across their entire lifespan. Unfortunately, Bright Futures - through a focus on detecting clearly visible eye health conditions and evident disabling vision disorders - and other pieces of the broken children’s vision system of care are letting our children, families and society down with burdens that ultimately add unnecessary costs through increased disability that may otherwise have been prevented.

Today, a quarter of school-aged children suffer from an undiagnosed or untreated vision problem that could have been treated if the child had received proper intervention before entering school. Studies show that while prevalence rates vary between demographic groups, there is an increasing need for eye care among children: a full 25 percent of children aged 5-17 have a vision problem; 79 percent have not visited an eye care provider in the past year; 35 percent have never seen an eye care professional. Additionally, children who are racial and ethnic minorities, those with lower incomes, and those who lack insurance are even less likely than their more affluent counterparts to receive eye care. In fact, only 17 percent of children with families under the federal poverty level have seen an eye care provider.

While it has yet to be conclusively proven why so many children go without needed professional vision and eye health care services, likely explanations include a reliance on pediatricians, family physicians, and school or lay screeners, as well as many uninsured parents' or caregivers' inability to pay for the needed services, and parents' or caregivers' lack of knowledge that early professional eye care is needed to prevent unnecessary loss of vision as well as to improve educational readiness.

Unfortunately, undue reliance on vision screening by pediatricians, family physicians, school-screeners and others may result in the late detection of amblyopia and other vision disorders. And, the evidence clearly indicates that early detection and intervention is essential in successfully treating eye disorders in children and potentially reversing their disabling effects. One study reported that in a sample of 102 private pediatric practices in the United States, vision screening was attempted on only 38 percent of 3-year-old children. The study also showed that only 26 percent of children failing the AAP vision screening guidelines were referred for a professional comprehensive eye examination.

According to the Centers for Disease Control and Prevention, less than 15 percent of all preschool children receive an eye exam and less than 22 percent of preschool children receive some type of vision screening. Because of varying in-school screening requirements, approximately two-thirds of children are not screened before or following enrollment in school. At the end of 2007, sixteen states did not require any vision assessment for children prior to entering school or during the subsequent school years. In states that do require vision screening, it is often a requirement of public school settings only, and they fail to identify or require evidence-based methodologies. Only five states require a follow-up eye examination for those failing the initial screening.

Recently, the Department of Health and Human Services' Office of Inspector General released a report stating that three-quarters of children in nine states did not receive the vision screening services mandated under Medicaid's Early and Periodic Screening, Diagnostic, and Treatment. Another study has shown that even when children do receive these types of cursory vision screenings, more than 40 percent who fail the initial screening do not receive the appropriate follow up care.

So, even when cursory screenings are mandated, they are largely not conducted. When they are conducted, they are lacking in sensitivity and specificity and have high rates of false negatives. And, the children that are lucky enough to be identified as failing the screening often do not receive the follow-up and care they need. Whether conducted in the primary care setting or not, most vision screening models for children fail to require or employ methodologies that meet or exceed the sensitivities and specificities of the National Eye Institute's Vision in Preschoolers Study or programmatic elements that assure necessary follow-up examination.

That's why the American Public Health Association has adopted a policy that recognizes the shortcomings of vision screenings, encourages regular eye examinations at the ages of 6 months, 2 years, and 4 years, and urges pediatricians to recommend that all children receive eye examinations at these intervals. The AOA believes that infants should receive a comprehensive vision and eye health exam – assessing and treating deficiencies in ocular health, visual acuity,

refractive status, oculomotility, and binocular vision sometime within the first year of life to serve as a baseline for further interventions.

Clinical experience and research have shown that at 6 months the average child has reached a number of critical milestones, making this an appropriate age for the first eye and vision examination. At this age the average child can sit up with support and cognitively is concerned with immediate sensory experiences. Visual acuity, accommodation, stereopsis, and other aspects of the infant's visual system have developed rapidly, reaching childhood levels by the age of six months.

While a baseline exam is critical, periodic comprehensive vision and eye health examinations throughout childhood are also extremely important. And, the AOA believes that vision screening could serve to support a system of periodic comprehensive vision and eye health examinations - not the other way around.

### Glaucoma Screening Clinical Preventive Service

Glaucoma is an eye disease that causes damage to the optic nerve resulting in decreased peripheral vision or eventual vision loss. Glaucoma ranks as the leading cause of blindness among African Americans in the United States. Although the major causative factor is elevated intraocular pressure, recent findings show that glaucoma can occur in some individuals with normal eye pressure and that these individuals may also benefit from early detection and screening. The U.S. Centers for Disease Control and Prevention (CDC) has expressed a growing concern that the prevalence of age related eye diseases is expected to double by 2030 with the prevalence of glaucoma among people with diabetes expected to increase twelve fold by 2050.

This increase in the prevalence of preventable adult eye disease is expected to bring with it an exponential rise in associated vision health care expenses, up from its current \$51.4 billion estimated annual cost. (U.S. Centers for Disease Control and Prevention, Improving the Nation's Health; A Coordinated Public Health Approach, 2006) Preventable eye diseases including, diabetic retinopathy, cataracts, age-related macular degeneration, glaucoma and uncorrected refractive error, all add significantly to health disparities of the elderly and represent a growing burden to a group health plan or a health insurance issuer offering group or individual coverage.

It is important to note that most eye disease, including glaucoma, the "sneak thief of sight," is asymptomatic. At this time, most health insurance plans only cover eye examinations for people who have a known vision problem, not for asymptomatic disease or well visits. The best time to intervene and correct problems is at the earliest most treatable asymptomatic stage.

The AOA believes in the value of evidence-based science; however, we disagree with the conclusions drawn by the USPSTF regarding glaucoma and the resulting recommendation for glaucoma screening. The USPSTF findings mean that this critical preventive service will be subject to the imposition of cost-sharing requirements. The AOA believes that this conclusion was based in part on limitations on the types of evidence USPSTF has relied on in the past.

According to the U.S. Centers for Disease Control and Prevention (CDC), exploration of the best

use of clinical preventive services would include “new systems and policy considerations that can be redesigned to fortify vision health goals across the life stages and to integrate or “bundle” vision and eye health goals with pre-existing health protection measures. The CDC reinforces the notion that “vision and health” do not stand alone, and that “implementing policy and systems changes more effectively can ultimately lead to our goal of reduced disparities and improved vision and eye health outcomes for our nation.”

In conclusion, the AOA generally supports the Rule’s approach in interpreting the provisions of the Affordable Care Act (ACA) that are critical to successful implementation of the health insurance market reforms included in the ACA. Specifically, the AOA agrees with a regulatory approach that seeks to increase access and utilization of clinical preventive services. However, unless tied to greater specifics of broadening the evidence base for clinical preventive services beyond USPSTF and Bright Futures the AOA believes that this effort will not fully meet our shared public health goals.

The AOA thus urges that the regulations and rules that enforce the ACA look beyond USPSTF and Bright Futures, particularly for preventive services where the recommendations of the USPSTF and Bright Futures differ from the guidelines promulgated by other pertinent medical/health care and scientific entities. This is certainly the case with both children’s vision screening and glaucoma screening.

Sincerely,

A handwritten signature in black ink that reads "Joe E. Ellis, OD". The signature is written in a cursive, flowing style.

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