

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: SB 46

INTRODUCER: Senator Farmer and others

SUBJECT: Eye Care for Newborns and Infants

DATE: February 10, 2020

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	<b>Pre-meeting</b>
2.			BI	
3.			AP	

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**I. Summary:**

SB 46 requires each child born in a Florida hospital to have an eye examination with a direct ophthalmoscope before being discharged from the hospital. The bill allows a parent to opt out of the eye examination for their newborn by filing a written objection with a signed informed consent with the physician, midwife, or other person in attendance at the birth.

The bill also mandates that health insurers and health maintenance organizations (HMOs) providing certain coverages to cover eye examinations from birth to two weeks, from six to eight weeks, and from six to nine months of age.

The bill has an effective date of July 1, 2020.

**II. Present Situation:**

**Infant and Childhood Eye Disorders and Screenings**

There are many eye conditions and diseases that can affect a child's vision. According to the American Academy of Ophthalmology (AAO), early diagnosis and treatment are critical to maintaining your child's eye health.<sup>1</sup> The AAO states that it is essential to check children's vision when they are first born and again during infancy, preschool and school years. Screening can be performed by a pediatrician, family physician or other properly trained health care provider. It is also often offered at schools, community health centers or community events.<sup>2</sup>

The AAO recommends that for each newborn an ophthalmologist, pediatrician, family doctor or other trained health professional should examine a newborn baby's eyes and perform a red reflex test (a basic indicator that the eyes are normal). An ophthalmologist should perform a

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<sup>1</sup> See <https://www.aao.org/eye-health/tips-prevention/common-childhood-diseases-conditions> (last visited Feb. 7, 2020).

<sup>2</sup> See <https://www.aao.org/eye-health/tips-prevention/children-eye-screening> (last visited Feb. 7, 2020).

comprehensive exam if the baby is premature or at high risk for medical problems for other reasons, has signs of abnormalities, or has a family history of serious vision disorders in childhood.<sup>3</sup>

### ***Amblyopia***

Amblyopia is when vision in one or both eyes does not develop properly during childhood. It is sometimes called lazy eye. Amblyopia is a common problem in babies and young children. A child's vision develops in the first few years of life. It is important to diagnose and treat amblyopia as early as possible. Otherwise, a child with amblyopia will not develop normal, healthy vision.<sup>4</sup>

### ***Retinoblastoma***

Retinoblastoma is a rare type of eye cancer that usually develops in early childhood, typically before the age of five. This form of cancer develops in the retina, which is the specialized light-sensitive tissue at the back of the eye that detects light and color.

In children with retinoblastoma, the disease often affects only one eye. However, one out of three children with retinoblastoma develops cancer in both eyes. The most common first sign of retinoblastoma is a visible whiteness in the pupil called "cat's eye reflex" or leukocoria. This unusual whiteness is particularly noticeable in dim light or in photographs taken with a flash or strobe. Other signs and symptoms of retinoblastoma include crossed eyes or eyes that do not point in the same direction (strabismus), which can cause squinting; a change in the color of the colored part of the eye (iris); redness, soreness, or swelling of the eyelids; and blindness or poor vision in the affected eye or eyes.

Retinoblastoma is often curable when it is diagnosed early. However, if it is not treated promptly, this cancer can spread beyond the eye to other parts of the body. This advanced form of retinoblastoma can be life-threatening.<sup>5</sup> The incidence of retinoblastoma in the United States in children ages 0-14 years is about one in every 250,000 nationwide,<sup>6</sup> or about 15 of the 3,791,712 births in the U.S. in 2018, as estimated by the National Center for Health Statistics.

### ***Dangers of Ocular Medications for Infants***

Ocular medications are sometimes prescribed and used for pediatric patients, but data regarding their safety in this population are sparse. Systemic absorption carries a much greater risk in infants, where higher serum drug concentrations are achieved due to their smaller average blood volume. Caution is required in the application of topical ocular medications in children, especially in infants. Dilating agents, which are frequently used for retinal examination and refraction, are a class composed of sympathomimetics and parasympatholytics. These agents have potentially severe systemic side effects to which premature infants are especially sensitive. Side effects of specific dilating medications are listed below:<sup>7</sup>

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<sup>3</sup> *Id.*

<sup>4</sup> See <https://www.aaio.org/eye-health/diseases/amblyopia-lazy-eye> (last visited Feb. 7, 2020).

<sup>5</sup> See <https://ghr.nlm.nih.gov/condition/retinoblastoma> (last visited Feb. 7, 2020).

<sup>6</sup> See <https://cancerstatisticscenter.cancer.org/#!/data-analysis/module/t2sTupFC?type=barGraph> (last visited Feb. 7, 2020).

<sup>7</sup> Ophthalmic Medications in Pediatric Patients, Teresa M. Myers, MD; David K. Wallace, MD; Sandra M. Johnson, MD, *Compr Ophthalmol Update*. 2005;6(2):85-101.

Medscape® www.medscape.com			
Medication class	Examples	Ocular/Local Side Effects	Systemic Side Effects
<b>Dilating Agents</b>			
Adrenergic agonist	Phenylephrine (Mydrin®) 2.5%/10%	Conjunctival blanching, blurred vision	Hypertension, tachycardia, arrhythmias, headache, hyperhidrosis
Cholinergic antagonists	Cyclopentolate (Cyclogyl®) 0.5%/1% Scopolamine (Isopto® Hyoscine) 0.25% Atropine (Atropisol®) 0.5%/1% Cyclopentolate-phenylephrine (Cyclomydril®) 0.2%–1% Homatropine (Isopto® Homatropine) 2% Tropicamide (Mydracyl®) 0.5%/1%	Ocular irritation, photophobia, follicular conjunctivitis, cutaneous hyperemia, eczematoid dermatitis	Vascular congestion, restlessness, delirium, somnolence, seizures, ataxia, headache, hallucinations, psychosis, gastrointestinal disturbances, temperature elevation, hypotension, bradycardia, respiratory depression, death
<b>Antiglaucoma Medications</b>			
Beta-adrenergic antagonists	Timolol (Timoptic®, Timoptic XE®, Betimolol®) 0.25%/0.5% Betaxalol (Betoptic®) 0.25%/0.5% Levobunolol (Betagan®) 0.25%/0.5% Carteolol (Ocupress®) 1% Metipranolol (Optipranolol®) 0.3%	Ocular irritation, visual disturbances, contact dermatitis, allergic conjunctivitis	Depression, arrhythmias, bronchospasm, masked hypoglycemia in diabetics, behavioral changes, dizziness, bradycardia, apnea, dyspnea
Carbonic anhydrase inhibitor	Dorzolamide (Trusopt®) 2% Brinzolamide (Azopt®) 1%	Ocular irritation, punctate keratitis, blurred vision, headache, contact dermatitis	Bitter taste, headache, nausea, fatigue, skin rash, urinary frequency
Oral carbonic anhydrase inhibitors	Acetazolamide (Diamox Sequels®) 125/250/500 mg (Elixir 250 mg/ 5 ml to 250 mg/ml)	Transient myopia	Hyperpnea, taste alteration, paresthesias in extremities, nausea, vomiting, anorexia, diarrhea, fatigue, urinary frequency, renal calculi, metabolic acidosis, Stevens-Johnson syndrome, aplastic anemia
Adrenergic agonist	Dipivefrin (Propine®) 0.1%	Follicular conjunctivitis, conjunctival deposits, contact dermatitis, stinging, cystoid macular edema (especially in aphakics)	Tachycardia, arrhythmias, hypertension (rare) (Pregnancy category B)
Alpha-adrenergic agonist	Apraclonidine (Iopidine®) 0.5%/1% Brimonidine (Alphagan® P) 0.15%	Allergic reactions (redness, lacrimation, eyelid edema), mydriasis, contact dermatitis, conjunctival blanching, conjunctival follicles, photophobia	Bradycardia, heart palpitations, tachyphylaxis (apraclonidine) depression, asthma, fatigue/drowsiness (brimonidine)
Cholinergic antagonists	Pilocarpine (Isopto®, Carpine, Pilocar®) 0.5%/1%/2%/3%/4%/6%	Induced myopia, miosis, retinal tears and detachment	Headache, diarrhea, nausea, and vomiting (rare)
Prostaglandin analog	Latanoprost (Xalatan®) 0.005% Bimatoprost (Lumigan®) 0.003% Travoprost (Travatan®) 0.004% Unoprostone (Rescula®) 0.15%	Permanent increased iris pigmentation, excessive eyelash growth, punctate keratitis	Rare: muscle/joint/back pain, possible sleep disturbance, sweating, possible headache

## Mandated Health Insurance Coverage

Florida law does not currently mandate that health insurance policies or HMO contracts must provide coverage for eye examinations for children, using a direct ophthalmoscope, in which a child's pupils are dilated to allow for detection of pediatric congenital and ocular abnormalities and developmental abnormalities.

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurance carrier, to submit to the Agency for Health Care Administration and the legislative committees having jurisdiction, a report that assesses the social and financial impacts of the proposed coverage. As of this writing, the Senate Committee on Health Policy has not received such a report.

The Patient Protection and Affordable Care Act (PPACA)<sup>8</sup> does not mandate that health insurance policies or HMO contracts must provide coverage for eye examinations for children, using a direct ophthalmoscope, in which a child's pupils are dilated to allow for detection of pediatric congenital and ocular abnormalities and developmental abnormalities. Under PPACA, individuals and small businesses can shop for health insurance coverage on the federal marketplace. All non-grandfathered plans<sup>9</sup> must include minimum essential coverage (MEC),<sup>10</sup> including an array of services that includes the 10 essential health benefits (EHBs). These 10 EHBs are further clarified or modified each year through the federal rulemaking process and are open for public comment before taking effect. The 10 general categories for the EHBs are:

- Ambulatory services (outpatient care).
- Emergency services.
- Hospitalization (inpatient care).
- Maternity and newborn care.
- Mental health and substance abuse disorder services.
- Prescription drugs.
- Rehabilitative services and rehabilitative services and devices.
- Laboratory services.
- Preventive care and chronic disease management.
- Pediatric services, including oral and vision care.<sup>11</sup>

States are free to modify the EHBs offered in their states by adding coverage; however, because of concerns that federal funds would be used on costly mandated coverages that were not part of

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<sup>8</sup> H.R. 3590 – 111<sup>th</sup> Congress: Patient Protection and Affordable Care Act (March 27, 2009).

<https://www.govtrack.us/congress/bills/111/hr3590> (last visited Feb. 6, 2020).

<sup>9</sup> A “grandfathered health plan” are those health plans, both individual and employer plans, that maintain coverage that were in place prior to the passage of the PPACA or in which the enrollee was enrolled on March 23, 2010, while complying with the consumer protection components of the PPACA. If a group health plan enters a new policy, certificate, or contract of insurance, the group must provide the new issuer the documentation from the prior plan so it can be determined whether there has been a change sufficient to lose grandfather status. *See* 26 U.S.C. 7805 and 26 C.F.R. s. 2590.715-1251(a).

<sup>10</sup> To meet the individual responsibility provision of the PPACA statute, a benefit plan or coverage plan must be recognized as providing minimum essential coverage (MEC). Employer based coverage, Medicaid, Medicare, CHIP (i.e.: Florida KidCare), and TriCare would meet this requirement.

<sup>11</sup> 42 U.S.C. s. 18022(b)(1)(A)-(J).

the required EHBs, PPACA contains a provision requiring that, starting in 2016, the states must pay for the cost of the coverage. As a result, the State of Florida may be required to defray the costs of any additional benefits beyond the required EHBs put in place after 2011.<sup>12</sup> Florida has not enacted any mandated benefits since 2011.<sup>13</sup>

Examples of health insurance benefits mandated under Florida law include:

- Coverage for certain diagnostic and surgical procedures involving bones or joints of the jaw and facial region (s. 627.419(7), F.S.);
- Coverage for bone marrow transplants (s. 627.4236, F.S.);
- Coverage for certain cancer drugs (s. 627.4239, F.S.);
- Coverage for any service performed in an ambulatory surgical center (s. 627.6616, F.S.);
- Diabetes treatment services (s. 627.6408, F.S.);
- Osteoporosis (s. 627.6409, F.S.);
- Certain coverage for newborn children (s. 627.641, F.S.);
- Child health supervision services (s. 627.6416, F.S.);
- Certain coverages related to mastectomies (s. 627.6417, F.S.);
- Mammograms (s. 627.6418, F.S.); and
- Treatment of cleft lip and cleft palate in children (s. 627.64193, F.S.).

### III. Effect of Proposed Changes:

SB 46 amends s. 383.04, F.S., to require that each child born in a hospital receive an examination using a direct ophthalmoscope in which the newborn's pupils are dilated to allow detection of pediatric congenital and ocular and developmental abnormalities.

The bill allows a parent of the newborn to opt out of the examination by filing a written objection along with a signed informed consent explaining the risks associated with opting out of the eye examination with the physician, midwife, or other person in attendance at the birth. The person receiving the objection must maintain a record that reflects that the eye examination was not performed. The bill also amends s. 383.07, F.S., to exclude a failure to perform the eye examination from being subject to criminal penalties associated with s. 383.04, F.S.

The bill amends ss. 627.6416 and 641.31, F.S., to require health insurers and HMOs, respectively, which are required to cover child health supervision services, to also cover such eye examinations for a child from birth to two weeks of age, from six to eight weeks of age, and from six to nine months of age.

The bill provides an effective date of July 1, 2020.

<sup>12</sup> See 42 U.S.C. s. 18031(d)(3)(B)(ii).

<sup>13</sup> Centers for Medicare and Medicaid Services, *Florida – State Required Benefits*, [https://downloads.cms.gov/ccio/State%20Required%20Benefits\\_FL.pdf](https://downloads.cms.gov/ccio/State%20Required%20Benefits_FL.pdf) (last visited Feb. 6, 2020).

**IV. Constitutional Issues:**

## A. Municipality/County Mandates Restrictions:

None.

## B. Public Records/Open Meetings Issues:

None.

## C. Trust Funds Restrictions:

None.

## D. State Tax or Fee Increases:

None.

## E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

## A. Tax/Fee Issues:

None.

## B. Private Sector Impact:

SB 46 may have an indeterminate negative fiscal impact on hospitals that are required to perform eye examinations under the requirements of the bill. The same is true for insurers and HMOs mandated by the bill to provide the new coverage and for insureds whose premiums might rise due to the new mandated coverage.

## C. Government Sector Impact:

As described above, federal law may require the State of Florida to assume the cost of additional benefits that it mandates insurance companies to cover.<sup>14</sup> The potential effect of that requirement in this instance is unknown.

Also unknown is the potential cost to state government regarding state group health insurance.

**VI. Technical Deficiencies:**

None.

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<sup>14</sup> See 42 U.S.C. s. 18031(3)(B)(ii).

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 383.04, 383.07, 627.6416, and 641.31.

**IX. Additional Information:**

**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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