STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

JESSICA AND JOSH MALOY, on behalf of and as parents and natural guardians of LAYTON MALOY,

Petitioners,

vs. Case No. 14-3466N

FLORIDA BIRTH-RELATED NEUROLOGICAL INJURY COMPENSATION ASSOCIATION,

Respondent,

and

WOMEN'S CARE OF FLORIDA, LLC, JEFFREY L. PURETZ, M.D., AND LAKELAND REGIONAL MEDICAL CENTER, INC.,

Intervenors.
_____/

FINAL ORDER

Pursuant to notice, a final hearing was held in this case on October 4, 2016, via video teleconference with sites in Tampa and Tallahassee, Florida, before Barbara J. Staros, an Administrative Law Judge of the Division of Administrative Hearings (DOAH).

APPEARANCES

For Petitioners: Charles T. Moore, Esquire
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For Respondent: Brooke M. Gaffney, Esquire
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For Intervenors Women's Care of Florida, LLC, and Jeffrey L. Puretz, M.D.:

Justine D. Adamski, Esquire
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501 East Kennedy Boulevard
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For Intervenors Lakeland Regional Medical Center, Inc.:

Paula J. Lozano, Esquire
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1819 Main Street, Suite 1110
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STATEMENT OF THE ISSUE

The issue in this case is whether Layton Maloy suffered an injury for which compensation should be awarded under the Florida Birth-Related Neurological Injury Compensation Plan (Plan).

PRELIMINARY STATEMENT

On July 9, 2014, Jessica and Josh Maloy, on behalf of and as parents and natural guardians of Layton Maloy (Layton), a minor, filed a Petition for Benefits Pursuant to Florida Statute Section 766.301 et seq. (Petition), with DOAH. The Petition alleged that Layton suffered brain damage as a result of a birth-related neurological injury, and sought a determination as to compensability under the Florida Birth-Related Neurological Injury Compensation Association (NICA) statutes.

The Petition named Jeffrey L. Puretz, M.D., as the physician who provided obstetric services at Layton's birth at Lakeland Regional Medical Center, Inc., in Lakeland, Florida, on September 4, 2012.

DOAH served NICA with a copy of the Petition on July 25, 2014, and served Lakeland Regional Medical Center, Inc., with a copy of the Petition on July 29, 2014. DOAH'S docket reflects that a copy of the Petition was mailed to Jeffrey L. Puretz, M.D, on July 24, 2014.

On September 11, 2014, Women's Care of Florida, LLC, and Jeffrey L. Puretz, M.D., filed a Petition to Intervene, which was granted. Lakeland Regional Medical Center, Inc., filed a Petition for Leave to Intervene on January 13, 2015, which was granted.

On October 16, 2014, NICA filed a response to the Petition, giving notice that the alleged injury did not "meet the definition of a 'birth-related neurological injury' as defined in section 766.3021(2), Florida Statutes." NICA requested that a hearing be scheduled to resolve whether the claim was compensable.

Following discovery, an abatement of the case at the request of the parties, and three continuances, a final hearing was scheduled for October 4, 2016. The case was heard as scheduled. On September 28, 2016, the parties filed a Pre-hearing Stipulation in which they agreed to certain facts as set forth in section E of

the Pre-hearing Stipulation. These facts have been incorporated into this Final Order.

Petitioners presented the live testimony of Samantha Lineberger and Petitioner, Jessica Maloy, at the final hearing. Petitioners' Exhibits 1 through 3 and 5 were admitted into evidence, including the deposition testimony of Dr. James Balducci, Dr. Paul Kornberg, and Dr. Ena Andrews. The record was left open to allow the limited deposition testimony of Dr. Daniel Adler. Respondent presented the live testimony of Dr. Michael Duchowny. Respondent's Exhibits 1 through 7 were admitted into evidence, including the deposition testimony of Dr. Donald Willis, Dr. Michael Duchowny, Dr. Jay Goldsmith, Dr. Jeffrey Puretz, and Petitioners. Joint Exhibits 1 through 10 were admitted into evidence.

A Transcript of the Final Hearing was filed on October 19, 2016. A transcript of Dr. Adler's deposition was filed on November 21, 2016, which is admitted into evidence as Petitioners' Exhibit 6. On December 8, 2016, Respondent filed a Motion to Sustain Objections Made During Testimony of Dr. Adler. No response was filed to the Motion. The Motion is granted in part.[1/]

Petitioners and Respondent timely filed their Proposed Final Orders on December 8, 2016, which have been carefully considered in the preparation of this Final Order.

FINDINGS OF FACT

1. Jessica and Josh Maloy are the natural parents of Layton Maloy.

2. Layton was born on September 4, 2012, at Lakeland Regional Medical Center, Inc. (Lakeland Regional), which is a hospital located in Lakeland, Florida.

3. Layton was a single gestation and weighed in excess of 2,500 grams at birth.

4. Obstetrical services at Layton's birth were provided by Dr. Jeffrey L. Puretz, who was a physician participating in the NICA program.

5. Notice of NICA participation was provided to Petitioners by Dr. Puretz and by Lakeland Regional.

6. Petitioners contend that Layton suffered a birth-related neurological injury and seek compensation under the NICA Plan. More specifically, Petitioners contend that Layton suffered a stroke during labor and delivery, which resulted in a brain injury, rendering Layton permanently and substantially mentally and physically impaired. Respondent contends that there was no event during labor and delivery which resulted in oxygen deprivation to Layton, and that any medical conditions suffered by Layton are not birth-related neurological injuries as defined in section 766.302(2), Florida Statutes. Respondent further contends that Layton is not permanently and substantially mentally and

physically impaired. Intervenors take no position as to whether Layton suffered a birth-related neurological injury.

7. Layton was born at approximately 9:22 p.m., via cesarean section secondary to non-reassuring fetal heart rate tracing following six hours of labor. Following receiving an epidural, Mrs. Maloy experienced hypotension for which she received two doses of Ephedrine to raise her blood pressure. Following the second dose of Ephedrine, the baby's fetal heart tracing became non-reassuring and the mother and baby's heart rate became tachycardic. Mrs. Maloy also received an amnioinfusion during labor.

8. Layton was born crying, pink and vigorous. Layton's one-minute Apgar score was 8, and his five-minute Apgar score was 9. He did not require resuscitation at birth, and was sent to the regular newborn nursery with "routine NB orders" where he was noted to be active, awake, with normal rooting and sucking reflexes. Layton was discharged from the hospital with his mother on day two of life.

9. After returning home, Mrs. Maloy noticed what she believed to be Layton having abnormal movements described as episodes of arms and/or legs shaking. His two-week old check-up was normal. However, two or three days after that check-up, she returned to the pediatrician's office where "Layton had an episode in front of Dr. Leviten." Dr. Leviten admitted Layton to Lakeland

Regional for evaluation and a neurological consultation. A VEEG obtained was interpreted to reveal frontal central spike and wave on a few occasions from the left hemisphere suspicious for seizure activity. Layton was subsequently placed on Phenobarbital. Layton was noted at this time to be clinically very stable, doing well, eating well, happy and alert, and interactive.

10. Layton was transferred to All Children's Hospital. Upon admission, he was noted to be bottle feeding, had normal tone and no focal deficits. Dr. Ena Andrews, a pediatric neurologist, first saw Layton on September 26, 2012, at All Children's Hospital, where she reviewed his medical records from Lakeland Regional. Her impression included a history of focal seizures and a finding on MRI that "is suspicious for intrauterine stroke." She conducted a neurological examination of Layton. There were no abnormal findings from her neurological examination. She also reviewed a CT performed at Lakeland Regional that was read as normal by a radiologist. However, she ordered an MRI to rule out an intrauterine stroke.

11. The MRI was conducted and Dr. Andrews reviewed the results with Mrs. Maloy on September 27, 2012:

> IMAGING STUDIES: I reviewed images of the MRI with mom at the bedside. As suspected, after reviewing the head CT, there is an area on the right frontal lobe with hypodensity on T2 weighted images. The area is also hypodense on diffusion, indicating it is not an acute ischemic lesion. Ventricles

> enlarged on the left compared to the right. There is also a hypodense area on the right parietal. Finding appears to be limited to the white matter without clear involvement of the cortex. There is no enhancement.
>
> LABORATORY STUDIES: Phenobarbital level is 22.9 this morning.
>
> IMPRESSION:
>
> 1. History of focal seizures, doing well without seizure recurrence. Phenobarbital is in low-therapeutic range.
>
> 2. Hypodense lesion in the right frontal and parietal white matter, unclear etiology. Given prior investigations at outside hospital, including blood cultures and CSF cultures, infection is unlikely. No evidence of diffusion change to suggest acute stroke; however, this does not rule out the possibility of prenatal stroke. Differential also includes some other type of inflammatory lesion with edema.

12. In her deposition which was taken on June 23, 2015, when Layton was less than 3 years old, Dr. Andrews explained that her use of the word "prenatal" referenced a stroke occurring before birth, and her use of the term "acute stroke" referenced a stroke occurring within 14 days of the September 26, 2012, MRI.

13. Dr. Andrews was asked about the comments she wrote in her September 27, 2012, notes:

> Q: So by "acute stroke" in your September 27th note, do you mean no stroke occurring within 14 days?
>
> A: Yes.
>
> Q: Is that 9/26 MRI?

A: Correct.

Q: Is that your testimony?

A: Yes.

Q: Now, you have -- you did not -- you did not diagnose Layton Maloy with having suffered a stroke during labor and delivery, correct?

A: That's correct.

Q: Based on your notes here, would you agree with me that the imaging that you looked at was suggestive potentially for -- or rather you weren't able to rule out a stroke occurring just before -- sometime before birth, correct?

A: Correct. I was not able to rule that out.

* * *

Q: So one -- you actually reviewed not only the MRI that was done on September 26, 2012, but you also reviewed the CT scan that was done prior to that, correct?

A: Yes.

Q: Okay. And when you reviewed the CT scan, even though the radiologist didn't note some abnormality, you felt that there was a possible abnormality on that CT scan, correct?

A: Correct.

Q: And you felt there was an area on the right frontal lobe that caused you some concern, correct?

A: Yes.

Q: And . . . you felt that the area is also hypodense on diffusion, indicating it is not an acute ischemic lesion; is that correct?

A: Yes.

Q: And so by that you mean that it wasn't an ischemic event, whether it's a stroke or something else, that caused this lesion occurring within two weeks of the study being done, correct?

A: Correct.

Q: And so that acute ischemic lesion that you saw on the CT scan and then correlated on the MRI, that is something that could have occurred during labor?

Ms. Gaffney: Form

A: Yes.

14. Layton was discharged from All Children's Hospital on September 29, 2012, but Dr. Andrews and another pediatric neurologist, Dr. Joseph Casadonte, followed up the medical management of Layton's seizures in their offices beginning on October 10, 2012. Layton continues to see Dr. Andrews for management of his seizures, and has had additional brain diagnostic testing and imaging through the years.

15. A November 28, 2012, brain MRI was read to reveal the following findings in pertinent part:

Findings:

The previously seen signal abnormality in the right frontal and right parietal lobes is no longer identified.
Lateral ventricles and third ventricle are mildly prominent, more so then on prior examination. There is persistent asymmetry with the left lateral ventricle being larger

> than the right lateral ventricle. The subarchachnoid spaces are increased in size when compared to prior examination. There is no mass effect or midline shift. No abnormal fluid collections are identified.
> The pons is decreased in size. The vermis also appears smaller than expected. It is also noted that the corpus callosum is thinned in appearance.

16. Layton was admitted to St. Joseph's Hospital in January 2013, for acute vomiting and rash, with a history of seizures. Radiology results from an MRI conducted at St. Joseph's Hospital revealed the following:

> IMPRESSION:
>
> 1. Generalized volume loss in the brain with prominence of the subarachnoid space in the lateral ventricles.
>
> 2. No transependymal fluid migration to suggest increased intracranial pressure.
>
> 3. No intracranial hemorrhage or mass effect.

17. While at St. Joseph's Hospital, Layton had an 18-hour video EEG monitoring which was normal. He also had a consultation with Dr. Jose Ferreira. Dr. Ferreira's impression included history of suspected neonatal seizures; mild degree of hypotonia of unclear significance; suggestion of mild volume loss on MRI which he believed was borderline; and the possibility of disorders associated with seizures of continued concern. He noted that the MRI showed no signs of ischemia or hemorrhage.

18. Dr. Andrews attributes Layton's balance and coordination issues to his mild to moderate developmental delay. Her records reflect that Layton continues to improve with function overall, and her testimony is consistent with her records. Significantly, Dr. Andrews testified that she has not seen evidence of a mental impairment, but that he suffers from physical or motor impairment for which physical therapy was prescribed. She further explained that some of the factors, e.g., social interactions, language development, and higher cognitive functions, which she would use to evaluate any mental impairment cannot be determined until he is older. She also testified that he is improving from physical therapy. When asked whether Layton's physical impairments were permanent, she answered that she "wouldn't be able to say whether his impairment is permanent" at this time, as she does not know to what extent he will continue to make progress and at what point he may or may not plateau. Layton also has had difficulty feeding and is being seen by a gastroenterologist for that.

19. Layton's most recent brain MRI was conducted on February 9, 2015. The report from the MRI contained the following:

> IMPRESSION:
>
> Continued somewhat slightly dysmorphic appearance of the brain as discussed in detail with mildly prominent ventricles, left greater than right. The findings may suggest some degree of volume loss, potentially involving

> the left basal ganglia and thalamus with question for decreased white matter volume. While nonspecific, these may be the sequela of prior insult.

20. Dr. Andrews agrees with the above impression. She believes that his epilepsy to be symptomatic from brain abnormalities that were seen on MRI. However, when specifically asked whether the seizure disorder that Layton has is consistent with a perinatal stroke, she responded, "his epilepsy, we believe to be symptomatic from brain abnormalities that we've seen on MRI." She did not specifically testify that these brain abnormalities were consistent with a perinatal stroke.

21. Petitioners retained James Balducci, M.D., to review Layton's medical records. Dr. Balducci practices in obstetrics and gynecology and maternal fetal medicine in Arizona. In his deposition taken on April 13, 2015, Dr. Balducci stated his opinion that Layton did sustain a brain injury caused by oxygen deprivation during labor. Specifically, Dr. Balducci is of the opinion that Layton suffered oxygen deprivation to his brain shortly after a second dose of ephedrine was administered to his mother during labor and delivery, and that this caused Layton to have a stroke. He reached this opinion by examining the fetal heart tracings.

22. Dr. Balducci explained the basis for his opinion as follows:

A: This baby suffered oxygen deprivation to the brain shortly after the second dose of Ephedrine. So the effects of the Ephedrine caused a vasoconstriction in the fetal vessels in the brain, caused an intrapartum stroke to the baby's brain, which was the source and the cause of this baby's neurologic sequela which the baby suffers from today.

Q: And is the basis for that opinion, Dr. Balducci, the fetal heart tracings that you've just gone over with me?

A: Yes. The fact that the baby was completely reassuring prior to the two doses of Ephedrine, and the fact that the baby became completely non-reassuring after the second dose of the Ephedrine, with the maternal pulse raising up to 140, trying to get the mother's blood pressure up, the Ephedrine had the effect, in the fetal physiology, of causing a fetal stroke in the kid's brain.

Q: And sir, are you able to say within a reasonable degree of medical probability that that is diagnosable from these fetal heart tracings?

A: Yes, ma'am. And the reason is --

Q: And the timing of the -- I'm sorry. I didn't mean to speak over you.

A: Yes ma'am, because the tracing prior to the second dose of ephedrine was reassuring, and the -- the fetal heart rate tracing post Ephedrine was completely non-reassuring, and nothing else had changed.

Q: Sir, would you agree with me that you can have a non-reassuring tracing and still deliver a viable infant with no hypoxic brain injury?

A: Yes, ma'am. That happens a lot.

23. Dr. Balducci is of the opinion that a local area of Layton's brain was devoid of oxygen secondary to the administration of Ephedrine to his mother. According to Dr. Balducci, the effects of this type of stroke may not show up until a week or two later so the baby is not depressed at birth.

24. At the request of Petitioners, Paul Kornberg, M.D., reviewed Layton's medical records and performed a medical examination of Layton. Dr. Kornberg is a specialist in physical medicine and rehabilitation, specifically pediatric rehabilitation. He serves as Medical Director for Tampa General Hospital's Pediatric Rehabilitation Program and works in an outpatient clinic. His practice includes treatment of children with Cerebral Palsy and who have had intrapartum strokes. He examined Layton and evaluated him on April 7, 2015, when Layton was approximately 2 1/2 years old.

25. Dr. Kornberg believes that Layton is permanently and substantially neurologically and physically impaired. This opinion is based on Layton's daily seizures and that, at the time of his examination, Layton was dependent on a feeding tube. Based upon the history he was given, he noted that Layton dragged his left leg when fatigued.

26. Upon examination, however, Dr. Kornberg found that Layton's tone and strength appeared to be normal. At the time of his examination, Layton was walking and putting words together at

the level that would be expected at his age at the time of the examination. Dr. Kornberg has no opinion as to whether Layton's impairments are related to oxygen deprivation occurring during labor and delivery. He noted that there are causes other than an event during labor and delivery that could cause Layton's symptoms (e.g., seizures, functional neurologic impairments, sensory processing issues), including a variety of developmental abnormalities of the brain.

27. Layton's school records from the Polk County Public Schools contain an initial Individualized Education Plan (IEP) which was developed at an IEP meeting on September 1, 2015, just three days before Layton's third birthday. In the domain of Curriculum and Learning, Layton scored in the mild developmental delay range in cognitive development and scored average in communication development. In the Social Emotional Behavior domain, Layton scored in the mild developmental delay range in personal-social development. In the Independent Functioning domain, Layton scored in the significant delay range in adaptive developmental quotient and average in the motor development quotient. The initial IEP indicates that the educational setting for Layton would be in an ESE Pre-K classroom. The IEP noted that he needed a health care plan but did not need assistive technology devices or strategies and did not need specially designed or adaptive physical education (PE).

28. A physical therapy (PT) evaluation was performed by Polk County Public Schools on November 12, 2015. It reveals that Layton's ESE teacher reported that, at that time, Layton was able to go up and down the steps to the portable classroom with one railing and close supervision; he pedaled a small tricycle on the playground sidewalk; and he was able to drink a can of Pediasure from a straw. The physical therapist notes that although a wooden chair with armrests was available in the classroom, Layton was sitting in a standard classroom chair at the time and appears to have functional balance. He was noted to walk independently within the classroom and needed verbal cuing to remind him not to run in the classroom which, apparently, he liked to do. By observation and teacher report, Layton was noted to want to run in the classroom and to need verbal cuing to slow down. Although observed to be mildly off balance at times, falls appeared to be rare. He was reported to be able to put away his lunchbox and was eating well. He was observed walking and running on the playground without falling. Nonetheless, the PT report recommended that Layton continue to wear his soft helmet for safety when playing on the playground or transitioning on campus, due to his history of seizures and falling.

29. Layton's most recent PT report, dated August 30, 2016, from his school states in pertinent part:

Layton should be watched closely when he is outdoors to be sure he does not get overheated. Mother had previously noted that he had a high incidence of falling (greater than 10x) per day, however by teacher report, and undersigned therapist's observation, his falls are currently rare. Layton has been wearing a soft helmet when he is outdoors at school (on the playground and in the halls).

Layton has been able to walk with the undersigned PT from his classroom, to the far end of school and back, with supervision to handheld assistance. Layton is able to walk on the yellow lines (with helmet on) with minimal verbal cuing. He is able to walk at a good pace, and has only had rare stumbles (primarily when he stumbled on a doormat, but did not fall). Layton is able to ascend steps to the portable reciprocally with one railing, and is emerging in ascending the steps reciprocally without using the railing. He is able to descend the steps in a step to fashion, both with and without the railing. Layton is able to ascend and descend the ramp without the railing with verbal cuing to slow down by teacher report for ascent and observation of PT for descent. By Mrs. Stambaugh's report, he is able to ride the tricycle independently with the helmet on. She reported that he has not had falls on the playground.

Within the classroom, Layton does not wear the helmet. He sits in a wooden toddler chair with armrests to give some additional protection if he should have a seizure while sitting in his chair in the classroom.

By teacher report, Layton is potty trained, and uses the standard toilet. She noted that he wears regular underwear, but still needs assistance with hygiene. Mrs. Stambaugh reported that he feeds himself with utensils. By report, Layton is a car rider in the am and pm, and does not currently need to negotiate bus steps. By Mrs. Stambaugh's report, they

> go to the field at the front of the school for fire drills, and they hold Layton's hand when they walk there. Mrs. Stambaugh reported that Layton only climbs on playground equipment with direct, close adult supervision.

30. The PT report suggested that Layton continue to wear his soft helmet when on the playground or walking on campus, that he should be closely supervised on any playground equipment, and that he should not get overheated.

31. His most recent IEP dated September 7, 2016, notes that Layton loves to dress up as a police officer or fireman, and loves to play with Legos and blocks. The IEP reflects that Mrs. Maloy has Layton on a waiting list for a regular Pre-K program. It also reflects that he no longer receives G-tube feedings at school because he is eating well. However, school staff has been trained to provide G-tube feedings to him in case Layton will not eat or drink his Pediasure.

32. Testimony of Layton's parents is consistent with the mental and physical abilities detailed in the school records. Mrs. Maloy is able to understand Layton and attend to his needs when he communicates with her. Although Layton tends to prefer a certain food repetitively for breakfast, lunch, and dinner, he eats regular food and his G-tube is used as a supplemental feed. Layton continues to have a seizure disorder for which he continues to be followed by Dr. Andrews and continues to take medicine. Mr. Maloy plays catch with Layton, and takes him to the water

park. Mr. Maloy sometimes feeds Layton food from his own plate including meats and vegetables.

33. NICA retained Dr. Donald Willis, a physician who is board-certified in maternal fetal medicine and obstetrics and gynecology. Dr. Willis reviewed the medical records related to Layton's birth to determine whether Layton sustained an injury to the brain or spinal cord caused by oxygen deprivation or mechanical injury in the course of labor, delivery, or resuscitation in the immediate post-delivery period. In a report dated September 2, 2014, Dr. Willis referenced relevant parts of Layton's records and stated in pertinent part:

> The mother was admitted at 39 weeks in labor with spontaneous rupture of the membranes. Amniotic fluid was clear.
>
> The fetal heart rate (FHR) monitor during labor was reviewed. The FHR had a normal baseline rate of 130 bpm on admission and normal heart rate variability. Late and variable FHR decelerations began about 90 minutes prior to delivery. This pattern was followed by a period of exaggerated FHR variability with some improvement in the overall pattern prior to delivery.
>
> Cesarean section was done for "intolerance to labor." Birth weight was 3,319 grams (7 lbs 5 oz's). The baby was not depressed at birth. Apgar scores were 9/9. The baby came out crying and required no resuscitation. The baby was taken to the normal newborn nursery after delivery. Umbilical cord blood gas was not done.

> Newborn hospital course was uneventful. The baby was discharged home with the mother two days after delivery.
>
> The baby apparently did well until about two weeks after birth, when some twitching movements were noted. Seizure activity was diagnosed. Head MRI at four months of age showed generalized volume loss.
>
> In summary, Cesarean section was done for a non-reassuring FHR pattern during labor. The baby was not depressed at birth and had a normal hospital course with discharge home two days after birth. Medical records suggest the baby did not suffer a birth related injury.
>
> There was no apparent obstetrical event that resulted in loss of oxygen or mechanical injury to the baby's brain during labor, delivery or the immediate post delivery period.

34. In a deposition on February 24, 2015, Dr. Willis testified as to typical findings in an infant who suffered oxygen deprivation. If a stroke is caused by hypoxic injury to the baby during labor and delivery, then the entire brain is going to be affected by the hypoxia. "I mean, we don't see an isolated stroke in a baby like of one small, little area in the brain due to hypoxic injuries during labor and delivery." Normally, babies born with hypoxic brain injury are depressed at birth. Layton's Apgar score was 9 at one minute and 9 at 5 minutes, and was not depressed at birth. He noted that the hospital progress notes stated that the baby came out crying and was vigorous, and went to the normal nursery. Two days after birth, the hospital notes

stated that the newborn was progressing as expected. And, he noted that the baby was discharged home after two days, which is a routine time for discharge. When asked whether the fetal heart tracing was consistent with an in utero stroke, Dr. Willis testified that "well I don't know that a tracing can tell me if a baby had a stroke in utero."

35. He further explained:

> A: I have been reviewing cases for NICA for 14, 15 years, and what I look at is oxygen deprivation that occurs during labor or delivery that results in brain injury. And those babies, as we said, are going to have problems at birth and be depressed.
>
> I have not considered a stroke that occurs spontaneously during labor as a hypoxic event resulting in brain injury.
>
> Q: Well --
>
> A: I am not the judge. I'm just -- I'm just the doctor that's reviewing the cases here, but that's how I review them and that's what -- and that's how I reviewed the NICA case and that's my interpretation of what it means by oxygen deprivation with brain injury.
>
> Q: Well, I want to go over that again then. An ischemic stroke occurring in utero during labor will cause oxygen deprivation to the part of the brain that's affected by the ischemia, correct?
>
> A: That's correct.
>
> Q: Okay. And as you sit here today, you're not familiar with any such pathology, an intrauterine stroke occurring during labor not caused by hypoxia?

> A: I'm sure all things can occur, but for NICA, I read it as I stated. I mean, if you had a stroke due to the -- that wasn't due to oxygen deprivation, again, where would you place when that stroke occurred if there's no event to show you that here's where the stroke occurred?
>
> I can't say that the baby had a stroke during labor because an MRI afterwards shows the baby had brain injury. I don't know where that stroke occurred. The only thing I can do is look at the fetal heart rate tracing and the baby after birth and the newborn course and try to determine if that baby had oxygen deprivation sufficient enough to cause brain injury. And that's what I've done on my report.
>
> If baby had a stroke that you're talking about, who knows -- you know, how would you -- I have no way of telling where or when that would have occurred if you have a stroke that leaves a baby without symptoms, because all the ones we see due to oxygen deprivation, those babies are depressed at birth.

36. When asked whether Ephedrine poses a risk of harm to a baby, he replied "no." When asked whether tachycardia can cause a stroke, he replied, "Tachycardia does not cause stroke as far as I'm aware." When asked whether there is any way from reviewing an MRI to be able to tell when an injury occurred, he replied, "no."

37. Dr. Willis' opinion that there was no apparent obstetrical event that resulted in loss of oxygen or mechanical trauma to the baby's brain during labor or delivery is credited.

38. NICA also retained Dr. Michael Duchowny to evaluate Layton. Dr. Duchowny is board-certified in pediatrics, neurology, with special qualifications in child neurology, and in clinical neurophysiology. He is a senior staff attending at Nicklaus Children's Hospital, and directs the neurology training program. Dr. Duchowny reviewed Layton's medical records and performed an independent medical examination on Layton on January 7, 2015. In a medical report dated January 11, 2015, Dr. Duchowny expressed the following opinions:

> In Summary, Layton's neurological examination is only significant for mild generalized hypotonia with oromotor dysfunction and an indwelling G-tube. His motor and cognitive development are both in the 18-24 months range which places him at a mild level of disability. He is doing well from the social and behavioral domains with no specific focal or lateralizing findings of significance. This examination therefore does not provide support for the presence of either a substantial mental or motor impairment.
>
> Review of the medical records reveals that Layton was born at 39 weeks gestation at Lakeland Regional Medical Center. He weighed 3320 grams at birth and had Apgar scores of 8 & 9 at 1 and 5 minutes. He was ultimately discharged in stable condition on day 3 of life. As documented by his mother, he was diagnosed with neonatal seizures which have persisted to the present time. Most of his current issues are related to a chronic medically resistant seizure disorder. Of note, Layton has never received pyridoxine, pyridoxal-5-phosphate or biotin.
>
> Layton's MRI scan on January 3, 2013 was significant for prominent extra-axial spaces

> and generalized volume loss. There is no mention of a right frontal infarct pattern. I have not personally reviewed the scan.
>
> In view of Layton's overall developmental progress, I do not believe he should be considered for inclusion within the NICA program.

39. Dr. Duchowny routinely reviews and interprets brain imaging studies as a daily part of his practice. He explained that the MRI is the gold standard in terms of diagnosis of stroke, and that FHR tracings are of no clinical significance in diagnosing a stroke. Had Layton suffered a stroke during labor and delivery or at any time, Dr. Duchowny would expect to see findings of that on the neuroimaging studies performed on Layton's brain. He did not see any clinical evidence of a stroke on any of the brain MRIs he reviewed. Dr. Duchowny attributes Layton's seizure disorder to developmental abnormalities in his brain which were acquired in utero. He attributes Layton's mild generalized hypotonia (low muscle tone) and oral-motor dysfunction (which has necessitated a G-tube for supplemental feeding) to prenatally acquired Cerebral Palsy.

40. When asked about Dr. Ferreira's use of the term "volume loss" regarding the January 2013 MRI, Dr. Duchowny disagrees that there was volume loss and noted an asymmetry of the ventricles. "It certainly is not a stroke."

41. Regarding his physical examination of Layton, Dr. Duchowny described Layton's motor and cognitive development to be in the mild range of delay. He noted that there were "no local or lateralizing findings as one might expect to see in a stroke." He described his findings to be consistent with a toddler with developmental delay.

42. Dr. Duchowny described Layton as very sociable, noting his behavior to be "appropriate." He described Layton as a "very cute boy" who is very interactive and progressing well in the social and behavioral domains. He noted that while Layton was poorly coordinated, he could take steps and walked into the examination room. He had a "button" on the left side of his abdomen for the G-tube.

43. He also noted that in reviewing Dr. Andrews' records, she initially noted "suspicion of perinatal or prenatal stroke" but that notation did not carry throughout her notes over time. That is, while she considered it, she did not diagnose Layton with a stroke. This is consistent with Dr. Andrews' testimony. Moreover, when asked about Dr. Casadonte's notation of "concern for intrauterine stroke," Dr. Duchowny understands that to mean prenatally acquired.

44. When asked if it is medically probable that based on his records review, his examination of Layton, and his review of the imaging studies, whether Layton suffered a stroke during

labor and delivery, Dr. Duchowny replied, "No, I don't believe so." Dr. Duchowny's opinion in this regard is credited.

45. Dr. Duchowny wrote a supplemental report dated September 19, 2016, which addressed Layton's February 9, 2015, MRI study. This report was one page in length and reads as follows:

> Pursuant to your request, I reviewed the MR imaging study on Layton Maloy performed on February 9, 2015, at All Children's Hospital. As you know, Layton has been imaged extensively in the past including head CT studies on September 24, 2012, March 7, 2013, and September 13, 2013, brain MR Imaging on Sept. 26, 2012, November 28, 2013 and February 9, 2015, and head ultrasound on October 18, 2012.
>
> The brain MR imaging study of February 9, 2015 is the most recent imaging performed to date and was obtained when Layton was 2 ½ years old. This study reveals no areas of abnormality in the cerebral cortex or subcortical white matter. The deep gray matter structures (basal ganglia and thalami) are also normal. The hippocampi demonstrate no abnormality. The lateral ventricles are enlarged and dysmorphic in appearance. The occipital horns are larger than the frontal horns and evidence a colpocephalic configuration. There is a ventricular asymmetry favoring greater enlargement on the left. The corpus callosum is borderline thin. The posterior fossa contents are abnormal and reveal ponto-cerebellar hypoplasia and vermian hypoplasia with compensatory enlargement of the fourth ventricle.
>
> In summary, these imaging findings are consistent with prenatally acquired brain malformations and provide no evidence for acquired brain injury due to either intra-partum mechanical injury or oxygen deprivation.

46. In response to Dr. Duchowny's one-page supplemental report, Petitioners requested Dr. Daniel Adler review the February 9, 2015, MRI report, as well as his earlier imaging reports. Dr. Adler is a pediatric neurologist who practices in New York City. It is Dr. Adler's opinion that the images from the February 9, 2015, MRI report demonstrate a progressive loss of tissue in the white matter of Layton's brain and are not the result of a congenital problem. He concludes that the images reflect brain injury that happened to the fetus due to intrauterine hypoxia, of a type not manifested by encephalopathy.

47. At NICA's request, Jay Goldsmith, M.D., reviewed Layton's medical records and the reports of all diagnostic and neuroimaging studies performed on Layton, as well as Mrs. Maloy's labor and delivery records. Dr. Goldsmith is a neonatologist who is board-certified in Pediatrics and Neonatal-Perinatal Medicine. He practices neonatology and is a professor of pediatrics at Tulane University Medical School. He diagnoses strokes in babies as part of his clinical practice and has been practicing neonatology for approximately 40 years.

48. In his deposition which took place on September 26, 2016, Dr. Goldsmith noted that at birth, Layton was a fairly vigorous baby with good Apgar scores. No abnormal brain

function, or encephalopathy, was noted in the newborn period, and Layton went home with his mother after two days.

49. Dr. Goldsmith explained:

> That's, probably, the most important thing to rule out; an intrapartum deprivation of oxygen; if there's no encephalopathy, for the most part, there's no injury that occurred during labor and delivery; the person who is injured, or a baby who is injured in -- a fetus who was injured in labor and delivery will, certainly, in the overwhelming number of cases, show signs of that injury as a newborn; and demonstrate it as an encephalopathy.
>
> The one exception to that is perinatal arterial stroke; and so that's what, basically, this case has come down to; Layton came back at two to three weeks of age with seizures; had a work-up; and subsequently, I think, seven brain imaging studies, none of which showed arterial stroke.
>
> Now, perinatal arterial stroke is a neuroradiological diagnosis, pure and simple; you can think about it; you can put it on your differential diagnosis; but if you don't see a stroke on the images, there's no stroke; and, in fact, as this process evolved, over two and a half years or so, the MRIs showed that Layton has a developmental, or genetic, anomaly of his brain that has, certainly, defined itself on the brain imaging.

50. Dr. Goldsmith considers MRI to be the gold standard in diagnosing a stroke, which is consistent with Dr. Duchowny's testimony. He further noted that Layton transitioned well from intrauterine to extrauterine, and explained that babies injured in the womb during labor and delivery do not make this transition

well, would not be vigorous at birth, would be acidotic, and may need resuscitation.

51. Dr. Goldsmith is also of the opinion that the findings of the 2015 MRI suggest a developmental anomaly of the brain, showing that his brain was slightly dysmorphic with no evidence of stroke. When asked whether he would expect to see evidence of a stroke on the MRI findings, he answered, "Yes; unfortunately, the brain does not regenerate," noting that with an ischemic stroke, that area of the brain will die and will not regenerate. "We will see a hole in the brain in that area."

52. It is Dr. Goldsmith's ultimate opinion "to an extraordinary high degree of certainty" that Layton did not suffer a stroke during labor and delivery, and that his injuries were not a result of a neurological injury caused by oxygen deprivation that occurred during labor and delivery. Dr. Goldsmith's opinion in this regard is credited.

53. While Dr. Goldsmith is of the opinion that Layton is permanently and substantially mentally and physically impaired, he would defer to a neurologist, especially one who has examined Layton, to make that determination.

54. The dispute in this case centers on what, more likely than not, was the primary cause of Layton's impairments. That is, did Layton suffer a stroke during his mother's labor that resulted in oxygen deprivation to a specific portion of Layton's

brain which caused his disabilities or is it more likely than not that they were caused by a prenatally acquired congenital or genetic disorder acquired in utero. Secondly, did any such injury result in Layton becoming permanently and substantially mentally and physically impaired.

55. The undersigned finds the testimony of NICA's experts to be compelling. The greater weight of the evidence establishes through the opinions of Dr. Willis and Dr. Goldsmith, together with Dr. Duchowny, that there was not an apparent obstetrical event that resulted in loss of oxygen to Layton's brain during labor and delivery that resulted in brain injury.

56. Moreover, the record evidence does not support a finding that Layton is permanently and substantially mentally and physically impaired. His treating physician, Dr. Andrews, noted Layton's improvements over time and was not of the opinion that Layton has a mental impairment. Moreover, Dr. Kornberg's opinion that Layton is substantially impaired, while deferring to the pediatric neurologists, was based in large part on Layton's required use of the G-tube for feeding. He has clearly improved in this regard and now uses the G-tube to supplement his eating and use of Boost or Pediasure. Dr. Duchowny's opinion that Layton's disabilities are in the mild range, and not considered to be substantial, is consistent with Dr. Andrews' assessment, and is credited.

CONCLUSIONS OF LAW

57. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. §§ 766.301-766.316, Fla. Stat. (2011).

58. The Plan was established by the Legislature "to provide compensation on a no-fault basis, for a limited class of catastrophic injuries that result in unusually high costs for custodial care and rehabilitation." § 766.301, Fla. Stat. (emphasis added). The Plan applies only to a birth-related neurological injury, which is defined in section 766.302(2) as follows:

> 'Birth-related neurological injury' means injury to the brain or spinal cord of a live infant weighing at least 2,500 grams for a single gestation or, in the case of a multiple gestation, a live infant weighing at least 2,000 grams at birth caused by oxygen deprivation or mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate postdelivery period in a hospital, which renders the infant permanently and substantially mentally and physically impaired. This definition shall apply to live births only and shall not include disability or death caused by genetic or congenital abnormality. (emphasis added).

59. The injured infant, her or his personal representative, parents, dependents, and next of kin, may seek compensation under the Plan by filing a claim for compensation with DOAH. §§ 766.302(3), 766.303(2), and 766.305(1), Fla. Stat. NICA, which administers the Plan, has "45 days from the date of service of a

complete claim . . . in which to file a response to the petition and submit relevant written information relating to the issue of whether the injury is a birth-related neurological injury." § 766.305(4), Fla. Stat.

60. If NICA determines that the injury alleged in a claim is a compensable birth-related neurological injury, it may award compensation to the claimant, provided that the award is approved by the Administrative Law Judge to whom the claim has been assigned. § 766.305(7), Fla. Stat. If, on the other hand, NICA disputes the claim, as it has in the instant case, the dispute must be resolved by the assigned Administrative Law Judge in accordance with the provisions of chapter 120, Florida Statutes. §§ 766.304, 766.309, and 766.31, Fla. Stat.

61. In discharging this responsibility, the Administrative Law Judge must make the following determinations based upon all available evidence:

> (a) Whether the injury claimed is a birth-related neurological injury. If the claimant has demonstrated, to the satisfaction of the administrative law judge, that the infant has sustained a brain or spinal cord injury caused by oxygen deprivation or mechanical injury and that the infant was thereby rendered permanently and substantially mentally and physically impaired, a rebuttable presumption shall arise that the injury is a birth-related neurological injury as defined in s. 766.302(2).
>
> (b) Whether obstetrical services were delivered by a participating physician in the

> course of labor, delivery, or resuscitation in the immediate postdelivery period in a hospital; or by a certified nurse midwife in a teaching hospital supervised by a participating physician in the course of labor, delivery, or resuscitation in the immediate postdelivery period in a hospital.

§ 766.309(1), Fla. Stat. An award may be sustained only if the Administrative Law Judge concludes that the "infant has sustained a birth-related neurological injury and that obstetrical services were delivered by a participating physician at birth." § 766.31(1), Fla. Stat.

62. In the instant case, Petitioners filed a claim alleging Layton did sustain oxygen deprivation resulting in brain injury rendering him permanently and substantially physically and mentally impaired. As the proponent of the issue of compensability, the burden of proof is upon Petitioners. § 766.309(1)(a), Fla. Stat. See also Balino v. Dep't of Health & Rehab. Servs., 348 So. 2d 349, 350 (Fla. 1st DCA 1977)("[T]he burden of proof, apart from statute, is on the party asserting the affirmative of an issue before an administrative tribunal.").

63. The parties have stipulated that Layton was born a live infant in a hospital licensed in Florida and weighed in excess of 2,500 grams. There is no dispute that the physician who provided obstetric services at Layton's birth was a participating physician in the NICA program. The parties disagree as to whether Layton's impairments were caused by oxygen deprivation during labor or

whether they were more likely caused by prenatally acquired abnormalities. This is particularly significant in that the above-quoted statutory definition of a birth-related neurological injury expressly excludes those caused by genetic or congenital abnormalities. § 766.302(2), Fla. Stat.

64. The undersigned finds Dr. Willis' expert opinion that there was no apparent obstetrical event that resulted in loss of oxygen to Layton's brain during labor or delivery that resulted in brain injury more compelling than the opinions of Drs. Balducci and Adler. Moreover, while Layton's treating physician, Dr. Andrews, initially considered that there was a possibility that Layton suffered an intrauterine stroke, she never made that diagnosis.

65. Even if the undersigned were persuaded that Layton suffered a stroke during labor that resulted in his disabilities, it must be established that those disabilities are permanent and substantial in nature as both are required to establish compensability. Fla. Birth-Related Neurological Injury Comp. Ass'n v. Div. of Admin. Hearings, 686 So. 2d 1349 (Fla. 1997). While Dr. Goldsmith and Dr. Kornberg testified that they considered Layton to be permanently and substantially mentally and physically impaired, the greater weight of the evidence, together with Dr. Duchowny's opinion, establishes otherwise. That is, Petitioners established that Layton has certain disabilities.

However, his school and physical therapy records, as well as his treating physician, reflect that he has improved in several areas, especially since attending school. Additionally, while not minimizing his disabilities, the evidence does not establish that these disabilities are "substantial" as contemplated by the NICA statutes. Thus, Layton is not entitled to benefits under the NICA Plan.

CONCLUSION

Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED that the Petition filed by Jessica and Josh Maloy, on behalf of and as parents and natural guardians of Layton Maloy, is dismissed with prejudice.

DONE AND ORDERED this 19th day of January, 2017, in Tallahassee, Leon County, Florida.

BARBARA J. STAROS
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Filed with the Clerk of the
Division of Administrative Hearings
this 19th day of January, 2017.

ENDNOTE

[1/] Petitioners were permitted to file, after the final hearing, a deposition of their expert, Dr. Daniel Adler, for the limited purpose of addressing Dr. Duchowny's supplemental one-page report dated September 19, 2016, which was written after his deposition, and two weeks prior to the scheduled Final Hearing. Any reference to Dr. Adler's testimony in this Order will be limited to matters specifically related to Dr. Duchowny's supplemental report dated September 19, 2016.

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NOTICE OF RIGHT TO JUDICIAL REVIEW

Review of a final order of an administrative law judge shall be by appeal to the District Court of Appeal pursuant to section 766.311(1), Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original notice of administrative appeal with the agency clerk of the Division of Administrative Hearings within 30 days of rendition of the order to be reviewed, and a copy, accompanied by filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal. See § 766.311(1), Fla. Stat., and Fla. Birth-Related Neurological Injury Comp. Ass'n v. Carreras, 598 So. 2d 299 (Fla. 1st DCA 1992).