

**ADOPTED REGULATION OF
THE STATE BOARD OF HEALTH**

LCB File No. R197-07

§§1 and 3 effective April 17, 2008

§2 effective July 1, 2008

EXPLANATION – Matter in *italics* is new; matter in brackets ~~[omitted material]~~ is material to be omitted.

AUTHORITY: §§1-3, NRS 439.150 and 440.120.

A REGULATION relating to the registration of births; revising certain fees charged by the Health Division of the Department of Health and Human Services; and providing other matters properly relating thereto.

Section 1. NAC 440.210 is hereby amended to read as follows:

NEW FIRST
PARALLEL
SECTION

440.210 Each person who is legally responsible for registering the birth of a child shall submit a fee to the Health Division of the Department of *Health and* Human ~~[Resources]~~ *Services* for each birth as follows:

1. If paid on or before the 30th day after the date of the birth of the child, the fee is ~~[\$60.]~~ *\$71.50.*
2. If paid more than 30 days after the date of the birth of the child, the fee is ~~[\$62.]~~ *\$73.50.*

Sec. 2. NAC 440.210 is hereby amended to read as follows:

NEW
SECOND
PARALLEL
SECTION

440.210 Each person who is legally responsible for registering the birth of a child shall submit a fee to the Health Division of the Department of Health and Human Services for each birth as follows:

1. If paid on or before the 30th day after the date of the birth of the child, the fee is ~~[\$71.50.]~~ *\$71.*

2. If paid more than 30 days after the date of the birth of the child, the fee is ~~[\$73.50.]~~ \$73.

Sec. 3. 1. This section and section 1 of this regulation become effective on April 17, 2008.

2. Section 2 of this regulation becomes effective on July 1, 2008.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R197-07

The State Board of Health adopted regulations assigned LCB File No. R197-07 which pertain to chapter 440 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

1. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary.

The public workshops were held on January 2, 2008 via videoconference between Sparks and Elko, and January 3, 2008 in Las Vegas. The Notice of Public Workshop was published in the Reno Gazette Journal on December 13, 2007, Elko Daily Free Press on December 15, 2007 and the Las Vegas Review Journal on December 16, 2007. Notices of the public workshop meetings were mailed on December 7, 2007 to 22 Nevada birthing facilities, 19 main public libraries, nine midwives and 14 specialists/organizations groups.

There was no public in attendance at the Sparks and Elko videoconference workshop. Gretchen Alger Lin, Executive Director, CARES Foundation, and Michelle Gorelow, MAED, Director of Program Services, March of Dimes Nevada Chapter, attended the Las Vegas workshop and presented the following comments:

Ms. Lin expressed support for the fee increase to add Cystic Fibrosis (CF) to the screening panel and to provide Endocrine and Hemoglobinopathy clinics. CARES Foundation provides support to individuals affected by Congenital Adrenal Hyperplasia (CAH). This is a potentially life threatening Endocrine disorder. Ms. Lin provided estimates of approximately 215 individuals living in Nevada with Endocrine disorders (CAH and Congenital Hypothyroidism), and addressed the fact that there are only two board-certified Endocrinologists in the State and that families would benefit from Endocrine clinics. Ms. Lin estimated that 1,000 children with Diabetes Mellitus also need to see Endocrinologists, adding to the workload of the two physicians. Ms. Lin also pointed out that 43 states are committed to testing for CF, (33 states plus Washington DC routinely screen for CF at this time).

Michelle Gorelow provided written testimony in support of the addition of CF to the screening panel and pointed out that Nevada now screens for all but two of the disorders recommended for screening by the March of Dimes, (CF and newborn hearing). Nevada actually screens over 95% of the newborns for hearing, but this is not counted because, in statute, birthing facilities with less than 500 births per year are exempt. Ms. Gorelow cited the American College of Medical Genetics, stating that the incidence of CF is greater than one in 5,000 therefore CF is one of the most common inherited disorders in the United States. Ms. Gorelow indicated that research has shown that early intervention and nutritional therapies provide distinct benefits including improved height, weight and cognitive function

for people with CF. Ms. Gorelow then indicated that new CF therapies have improved the length and quality of life for people with this disease.

2. The number of persons who:

- (a) Attended the hearing;
- (b) Testified at each hearing; and
- (c) Submitted to the agency written statements.

(a) There was no public in attendance at the Sparks/Elko public workshop (January 2, 2008) and two people attended the Las Vegas workshop (January 3, 2008). Approximately 33 individuals attended the State Board of Health Hearing (February 15, 2008).

(b) Eight people testified at the State Board of Health Hearing, two testimonies from medical staff were read, and two testimonies of parents of children with CF were also read.

(c) Two written statements were submitted to the agency prior to the hearing and several others were submitted at the Board of Health hearing.

3. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

Pursuant to NRS 233B.0608(2)(a), the Bureau of Family Health Services (BFHS) requested input from operators of healthcare facilities that are licensed pursuant to NAC 449.0151. BFHS received no responses from these facilities. Questionnaires were sent to the Chief Executive Officer (CEO) of 22 birthing facilities in Nevada (certified mail), and 14 responded by providing the number of individuals employed at their facility; all those responding employed more than 150 individuals and made no comments or suggestions concerning the NBS fee increase. Program staff also met with the President/CEO of the Nevada Hospital Association to discuss the proposed regulation changes.

4. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

The proposed regulation change to amend NAC 440.210 to increase the fees for "Registration of Births" from \$60.00 to \$71.50 until June 30, 2008 and then to \$71.00 after June 30, 2008 was approved without change. However, the State Board of Health supported the concept of a statewide Newborn Screening Coordinator. This increase in the birth registration fee is necessary to accommodate increasing program and personnel costs, add cystic fibrosis (CF) to the newborn screening panel, and to develop six new Endocrine and Hemoglobinopathy follow-up clinics.

Early identification and treatment of CF have been shown to help people with CF to improve lung function as well as increase life expectancy and reduce hospitalizations. With early diagnosis and treatment, people living with CF experience a better quality of life and have a significant delay in the onset of symptoms. This was supported by several testimonies from advocates, doctors, and parents of children with CF. In addition, the Center for Disease Control and Prevention (CDC) also recommends the addition of CF on the newborn screening panel.

The need for Endocrine and Hemoglobinopathy clinics was supported by the State Board of Health. Follow-up is important and generally children with endocrine disorders are seen every two to three months for the first three years. Successful treatment for hypothyroidism depends on life long daily medication and close follow-up of hormone levels. Treatment for CAH is also ongoing, involving periodic medical evaluations and monitoring for medication dose adjustments. These periodic medical check-ups will allow for a full and normal healthy life. Early diagnosis and treatment of Sickle Cell disease can minimize its effect on the individual. These clinics will provide a viable option for families seeking treatment for their child with Sickle Cell disease rather than going out-of-state for services. In a draft report of Nevada's Newborn Screening Program by the National Newborn Screening Center (2007), it was recommended that Nevada establish Endocrine and Hemoglobinopathy clinics because many children with these disorders do not receive appropriate follow-up which can cause avoidable costly hospitalizations.

5. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must Include:
 - (a) Both adverse and beneficial effects; and
 - (b) Both immediate and long term effects.

The adverse economic effect identified as resulting from this proposed regulation change is that the cost to the birthing hospitals providing screening services to infants will increase. The proposed fee increase will have both direct and indirect beneficial economic effects on birthing hospitals in Nevada. Screening for inborn errors of metabolism is mandated by state law. This fee increase will allow facilities to continue providing state-of-the-art newborn screening with the addition of CF. Early diagnosis and treatment of these conditions can reduce medical costs by preventing mental retardation, physical disabilities, and even death. Early preventative treatment of these disorders can also increase life expectancy, reduce hospitalization, and mitigate or delay the onset of symptoms.

The cost of early identification and treatment of congenital abnormalities, identified yearly by routine newborn screening, greatly offsets the cost of future medical expenses incurred if not diagnosed and treated. With many of these disorders the child can experience normal growth and development if detected and treated early; thus, preventing costly medical expenses and tragedies that need not occur in Nevada families. Treatment of many of these disorders is an ongoing process needing periodic medical evaluations and monitoring for medical dose adjustments. A study performed by the University of Colorado Children's Hospital staff, "Medical Consequences of Symptomatic Diagnosis in infants with Cystic Fibrosis", indicates that:

- Symptomatic diagnosis of CF compared to diagnosis by newborn screening was associated with higher complication rates and morbidity.
- No deleterious effect on pulmonary function or Mucoid Pseudomonas colonization could be detected in patients diagnosed through newborn screening compared to the symptomatic diagnosis group.
- The data suggests an advantage for the newborn screened group in pulmonary function and Mucoid Pseudomonas colonization compared to symptomatic diagnosis group.

The proposed fee increase is expected to have both direct and indirect adverse economic effects on Nevada's birthing hospitals. Testing for inborn errors of metabolism and Hemoglobinopathies will cost more than in previous years, and will most likely result in increased cost to families.

6. The estimated cost to the agency for enforcement of the proposed regulation.

Outside the cost of holding the workgroups, newspaper announcements, and expenses related to implementation of specialty clinics (i.e., meetings and correspondence) the cost of enforcement to the agency will not change. Birthing hospitals voluntarily submit payment monthly based on the number of births at each facility.

7. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.

This regulation amendment does not overlap or duplicate regulations of any other state or government agency.

8. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

This regulation amendment does not include provisions which are more stringent than federal regulations; the number of disorders screened in newborn screening programs is left to the discretion of each individual state.

9. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

This regulation change will increase the fee for "Registration of Birth" from \$60.00 to \$71.50 through June 30, 2008 (this will allow for the immediate testing of CF) and will decrease to \$71.00 after June 30, 2008.

The estimate of Nevada's birth rate for Calendar Year (CY) 2006 is 39,573. Estimating a five percent increase for CY 2008, and CY 2009 predicts birth rates of 43,629 and 45,810 respectively. Half of the births for CY 2008 and CY 2009 were added to estimate total births

for State Fiscal Year (SFY) 2009 (44,720). The SFY 2008 proposal of \$71.50 per birth is the driven amount needed to break even for the current fiscal year. The estimated revenue generated from birth registration fees for SFY 2009 is \$3,175,120. The SFY 2009 cost estimate with the proposed fee breakdown is detailed in the table below.

Cost Estimate for SFY 2009 with the Proposed Fee Breakdown

Cost Category	Total Cost	Fee Increase Breakdown	Total Fee Breakdown
Laboratory Costs	\$2,593,760	\$8.00	\$58.00
Personnel Costs	\$424,856	\$1.28	\$9.50
Contracts (Current Clinics)	\$71,600	\$0.48	\$1.60
New Contracts (New Clinics)	\$45,600	\$1.02	\$1.02
Program Costs	\$29,547	\$0.00	\$0.66
Estimate of Total of Cost	\$3,165,363	\$10.78	\$70.78
Variance	\$9,757	\$0.22	\$0.22
Estimate of Total Revenue	\$3,175,120	\$11.00	\$71.00

10. If the proposed regulation is likely to impose a direct and significant economic burden upon a small business or directly restrict the formulation, operation or expansion of a small business. What methods did the agency use in determining the impact of the regulation on a small business?

A small business impact questionnaire was mailed to 22 birthing facilities and no comments were received. A representative of the Nevada Hospital Association did express concern that the fee increase passed down to the public would reflect negatively on hospitals, but he acknowledged the importance of newborn screening and the healthcare cost savings realized through early identification and treatment of inborn errors of metabolism. There was no opposition to the fee increase at either workgroup meetings or the State Board of Health public hearing. This fee increase is not expected to impose a significant burden upon small businesses.