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TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule LSA Document #05-256

DIGEST

Amends 410 IAC 21-3-7 and 410 IAC 21-3-9 to add audiologists as persons required to report to the registry and adds hearing loss conditions to those birth problems that must be reported. Effective 30 days after filing with the Secretary of State.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

The Indiana State Department of Health (ISDH) estimates the current number of pediatric audiologists to be 163 and audiology centers that are providing hearing diagnosis services to infants and children to be 73. Audiologists and audiology centers are classified in the health industry sector. Hospitals that care for infants and children are also impacted, but most hospitals in Indiana are not-for-profit. For-profit hospitals are very large. Hospitals will not be addressed further in this document.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

About 60 percent of the pediatric audiologists have submitted the reporting form voluntarily at least once. So for most of the pediatric audiologist this rule won't add any cost they aren't already incurring. The following are the estimated annual costs resulting from the proposed rule:

Based on the incidence rates for hearing loss, it is anticipated that 150-200 additional confirmatory reports will be received annually if reporting of diagnosed hearing loss is made mandatory. It takes about 10 minutes to complete the form. In total the cost to all audiologists across the state would total approximately \$1,500-\$2,000 per year based on an hourly wage of \$60/hour (or \$6 per infant reported). The cost per audiologist would vary depending on the number of infants they had as clients.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

In total the cost to all audiologists across the state would total approximately \$1,500-\$2,000 per year based on an hourly wage of \$60/hour (or \$6 per infant reported).

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

IC 16-38-4-7 requires the ISDH to establish a birth problems registry to collect epidemiologic data regarding birth defects and to provide resource education and support to parents of children with birth defects. ISDH is given authority to define birth problems and reporting requirements through IC 16-21-2-2.5 as added sets forth the requirements for agency rules. The ISDH believes the proposed rules are within the requirements established at IC 16-38-4-7 and IC 16-21-2.

5. Regulatory Flexibility Analysis

A. Establishment of less stringent compliance or reporting requirements for small businesses.

ISDH has determined that the reporting requirements for audiologists are nearly the same as for physicians who are also required to report. These requirements are minimal.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

ISDH is requiring that reports be submitted as the infants are diagnosed. No annual summary report is being sought. This is the same rule as for physician reporting. It is minimal.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

Because there is variation in the number of reports per audiologist that will need to be submitted, submitting at the time of diagnosis is the simplest and most efficient. When the electronic system is complete, audiologists may choose to submit electronically which would further simplify the reporting.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The best Practice Guidelines for Audiologists and the Early Hearing Detection and Intervention (EHDI) Policy Manual discusses the importance of reporting results of follow-up testing from universal newborn hearing screening via the use of the Diagnostic

Audiology Evaluation (DAE) Form. Both documents were created within the Newborn Screening EHDI Program at ISDH. If reporting of diagnosed hearing loss is made mandatory, the language within these two documents which are currently under revision will only be strengthened.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

No exemption from reporting for audiologists has been made. However, there is currently no fine or repercussions for not reporting. ISDH staff will follow-up to obtain diagnoses.

Conclusion:

Reporting by audiologists of infants diagnosed with hearing loss will not only improve the data in the Indiana Birth Defects and Problems Registry as required in IC 16-39-4 but also will improve the follow-up and tracking data as required in IC 16-41-17 for infants who did not pass the Universal Newborn Hearing Screening in Indiana. This minimal reporting requirement is similar to the reporting requirement of physicians to report diagnoses of birth defects for infants up to three years of age and to report specifically fetal alcohol syndrome and autism in children up to five years. The cost to the audiologist is estimated at \$6 per infant/child and would vary depending on clientele of the pediatric audiologist. Statewide report submission is anticipated at 150-200 reports per year.

410 IAC 21-3-7

410 IAC 21-3-9

SECTION 1. 410 IAC 21-3-7 IS AMENDED TO READ AS FOLLOWS:

410 IAC 21-3-7 Persons required to report

Authority: IC 16-38-4-7

Affected: IC 16-38-4

Sec. 7. The following persons shall report a diagnosed birth problem to the birth problems registry:

- (1) Hospitals.
- (2) Birthing centers.
- (3) Health facilities.
- (4) Physicians.
- (5) Psychiatric hospitals.
- (6) Dentists.
- (7) Oral surgeons.
- (8) Registered or licensed practical nurses.
- (9) Midwives.
- (10) Optometrists.
- (11) Podiatrists.
- (12) Chiropractors.
- (13) Physical therapists.
- (14) Psychologists.
- (15) Local health departments.
- (16) Health maintenance organizations.
- (17) Audiologists.**

(Indiana State Department of Health; 410 IAC 21-3-7; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)

SECTION 2. 410 IAC 21-3-9, AS AMENDED AT 28 IR 2355, SECTION 2, IS AMENDED TO READ AS FOLLOWS:

410 IAC 21-3-9 Reportable birth problems

Authority: IC 16-38-4-7

Affected: IC 16-38-4

Sec. 9. The following categories along with those conditions identified in the International Classification of Diseases – Ninth Revision, Clinical Modification, 1998 (ICD-9-CM) are birth problems:

- (1) A structural deformation.
- (2) A developmental malformation.
- (3) A genetic, inherited, or biochemical disease.
- (4) A condition of a chronic nature, including:

(A) central nervous system hemorrhage; or
 (B) infection of the central nervous system;
 that may result in a need for long term health care.

(5) A pervasive developmental disorder.

(6) A fetal alcohol spectrum disorder.

(7) Any other severe disability that is recognized:

(A) in a child after birth; and

(B) before the child becomes three (3) years of age.

(8)	ICD-9-CM	Name
	Codes	
	155-208	Neoplasms
	216-216.9	Neoplasms
	230-234	Neoplasms
	246.1	Dyshormonogenic goiter
	250	Diabetes mellitus
	257.8	Other testicular dysfunction
	279	Disorders involving the immune mechanism
	282	Hereditary hemolytic anemias
	284.0	Constitutional aplastic anemia
	286.0-286.5	Coagulation defects
	287.3	Primary thrombocytopenia
	288	Diseases of white blood cells
	289.6	Familial polycythemia
	299.00-299.99	Pervasive developmental disorders including autism, childhood disintegrative disorder, Asperger's syndrome, Rett syndrome, and pervasive developmental disorders not otherwise specified
	330	Cerebral degenerations usually manifest childhood
	335	Anterior horn cell disease
	359	Muscular dystrophies and myopathies
	362.21	Retrolental fibroplasia
	362.7	Hereditary retinal dystrophies
	365.14	Glaucoma of childhood
	378	Strabismus and other disorders of binocular eye movement
	379.51	Congenital nystagmus
	389.0-389.9	Hearing loss
	524.0-524.1	Anomalies of jaw
		Congenital anomalies
	740-742	Central nervous system
	743-744	Orofacial
	745-747	Cardiovascular
	748	Respiratory
	749-750.29	Orofacial
	750.3-751	Gastrointestinal
	752-753	Genitourinary
	754-756	Musculoskeletal
	757	Integument
	758	Chromosome and syndromes
	759	Other and unspecified congenital anomalies
	760.71	Fetal alcohol syndrome

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on February 23, 2006 at 11:00 a.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed rule to amend 410 IAC 21-3 to add audiologists as persons required to report to the registry and add hearing loss conditions to those birth problems that must be reported.

This rule amendment does not impose additional requirements that are not expressly allowed by the enabling statute for the birth problems registry.

Copies of these rules are now on file at the Community and Family Health Services Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Sue Uhl
Deputy State Health Commissioner
Indiana State Department of Health