

**DEPARTMENT OF HEALTH AND SOCIAL SERVICES**  
**DIVISION OF PUBLIC HEALTH**  
**Statutory Authority: 16 Delaware Code, Section 223 (16 Del.C. §223)**  
**16 DE Admin. Code 4108**

**FINAL**

**108 Autism Surveillance and Registration Program**

**ORDER**

**Nature of the Proceedings**

Delaware Health and Social Services (“DHSS”) initiated proceedings to adopt the State of Delaware Autism Surveillance and Registration Program Regulations. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Delaware Code**, Section 223.

On January 1, 2005 (Volume 8, Issue 7), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Delaware Code** Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by January 31, 2005, or be presented at a public hearing on January 24, 2005, after which time DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying “Summary of Evidence.”

**Summary of Evidence**

A public hearing was held on January 24, 2005, at 10:00 a.m. in the Third Floor Conference Room of the Jesse Cooper Building located on Federal and Water Streets, Dover, Delaware before David P. Walton, Hearing Officer. The purpose of the hearing was to discuss the proposed Department of Health and Social Services (DHSS) Autism Surveillance and Registration Program Regulations. Announcements regarding the public hearing were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations* in accordance with Delaware Law. Dennis Rubino, of the Community Health Care Access Branch of the Division of Public Health (DPH) made the agency’s presentation. One individual attended and offered comments at the hearing on the proposed Regulations. Written comments were also received on the proposed regulations during the public comment period (January 1, 2005 through January 31, 2005). Organizations represented at the hearing and those offering comments included:

- Autism Society of Delaware
- State Council for Persons with Disabilities (SCPD)
- Delaware Developmental Disabilities Council (DDDC)
- Governor’s Advisory Council for Exceptional Citizens (GACEC)
- Delaware Healthcare Association

Public comments and the DHSS (Agency) responses are indicated below:

**Section 3.2:** This section states, “The Department shall have access to information in the medical records of children with suspected autism.” It is unclear if the Department will have access to the entire medical records of the children or only the portion of the medical record pertaining to the diagnosis of autism. This should be clarified prior to publication of final regulations.

**Agency Response:** After careful review of the law and Section 3.2 of the regulations, the intent is to have access to all information in the medical record. While the Agency may not always require information from the entire medical record, based on the goals and purpose of the Autism Registry it may as the situation dictates require access to the entire medical record. The Agency is satisfied that section 3.2 is clear enough to gain access to required information

**Section 3.5.2:** This section requires that, “the designated representative of any clinical laboratory conducting assessment, evaluation or research that performs any test which identifies a child or children under age 18 with confirmed autism” to report this to the Division of Public Health within 30 days. Medical professionals have stated that there are no laboratory tests that would be performed in a clinical laboratory that would identify a child with confirmed autism. It is unclear why this section is included in the proposed regulations as the related Statute does not make any references to clinical laboratories being required to report occurrences of autism.

*Agency Response:* The Agency agrees that there currently is no laboratory test that could be performed to identify a child with confirmed autism. However, Section 221 of the law refers to health care practitioners and all hospitals and ‘clinical laboratories’. It is the intent of the Agency to have confirmed autism reported from assessments, evaluations, and research as conducted by the health care practitioners in any clinical laboratory setting.

**Although the definition of autism is taken directly from the Statute there are some concerns that the definition is incorrect. Specifically, the portion of the definition referring to structural or biochemical abnormalities that may be diagnosed prior to the birth of a child. At this time there are no tests that are performed on a child prior to birth that would allow for the diagnosis of autism.**

*Agency Response:* The Agency has maintained the definition of autism as per the law but has further refined the definition according to ICD 9 and DSM IV. Additionally, to add further clarity, a list of diagnoses is contained in the Appendix.

**It is recommended that occupational and physical therapists be included in the regulations since motor functioning is part of the diagnostic criteria for autism. For example, the definition of “confirmed autism or diagnosed autism” in section 2.0 includes “stereotyped and repetitive motor mannerisms (e.g. hand and finger flapping or twisting or complex whole-body movements)”.**

*Agency Response:* The Agency agrees and maintains that occupational and physical therapists are included under the term ‘health care practitioners’ (Section 3.5.1).

**The statutory [16 Del.C. Section 223(b)(c)] exemptions for 1) health care providers who treat with prayer alone and 2) caretakers of infants who oppose reporting on religious grounds should be included in the regulations.**

*Agency Response:* The Agency agrees and language from the law has been incorporated into the final Regulations.

**Section 5.1:** There is a concern that the first sentence could be construed to mean that reporting agencies identified in section 3.5 should be reporting information without personally identifiable information. It is inferred that DPH intended the first sentence of this section to only apply to disclosure of information already obtained by the Division. To obviate any ambiguity, the phrase “received by Division” could be inserted after the word “autism”.

*Agency Response:* The Agency agrees with this comment and this section has been amended for clarity purposes.

**It was recommend that DPH include a voluntary registration process whereby parents or guardians of Delaware citizens, regardless of age, may of their own free will, register their dependent child after the point of original diagnosis of autism. To that end, the following wording should be considered for inclusion in the regulations.**

**“Section 3.7 Voluntary Reporting: For the purposes of fulfilling the intent of this act, specifically to collect and reflect accurate and complete census data on citizens with autism in Delaware, a voluntary registration process has been established. Individuals may report their autistic dependent of any age by completing from**

**XYZ. Having it attested by means of a signature of the autistic individual's attending physician and submitting this form to DHSS, DPH, at the following address. Individuals identified using this voluntary process will become part of the Delaware registry."**

**Agency Response:** The Agency has investigated the recommendation and found that: 1) the statute does not give the authority to collect information for persons over the age of 18; and 2) the Division is requiring that health care practitioners confirm and report the children with an autism diagnosis. Accordingly, any parent can therefore request that their health care provider submit the report. In this way, the accuracy of the report is guaranteed.

In addition to written comments made above, positive comments were shared about Delaware enacting such a regulation to capture information in order to better understand autism.

The public comment period was open from January 1, 2005 to January 31, 2005.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

### **Findings of Fact**

The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware. The proposed regulations include minor modifications from those published in the January 1, 2005, *Register of Regulations*, based on public comment. These modifications are deemed not to be substantive in nature.

**THEREFORE, IT IS ORDERED**, that the proposed State of Delaware Autism Surveillance and Registration Program Regulations are adopted and shall become effective May 10, 2005, after publication of the final regulation in the *Delaware Register of Regulations*.

Vincent P. Meconi, Secretary, 3/14/2005

## **4108 Autism Surveillance and Registration Program**

### **1.0 Purpose**

1.1 Autism is a severe neurodevelopmental disorder whose prevalence appears to be increasing in Delaware and across the United States. An Autism Surveillance and Registration, or an Autism Registry, will enable the Department of Health & Social Services (DHSS), Division of Public Health (DPH) to collect basic descriptive information on the individuals with autism, to track changes in prevalence over time, to inform the planning of service delivery to children with autism and their families, and to facilitate autism research.

1.2 The purpose of the Autism Registry is to provide an accurate and continuing source of data concerning autism to provide information to Public Health officials to help to ultimately decrease the autism morbidity burden associated with the disorder. The Autism Registry will gather data to assist with: prevalence estimation, cluster investigation, risk factor identification, and outcome assessment.

1.3 The usefulness of the data collected in the Autism Registry will depend upon the full and accurate reporting of the confirmed diagnosis of autism by health care practitioners, hospitals, and clinical laboratories.

1.4 The Autism Registry will be a separate component of the Newborn Screening Management System.

### **2.0 Definitions**

The following words shall have the meanings indicated:

"Autism" means any structural or biochemical abnormality, regardless of cause, diagnosed at any time before or after birth, that requires medical or surgical intervention or that interferes with normal growth or development. Reportable autism diagnoses are listed in Appendix A of these Regulations.

"Confirmed Autism Or Diagnosed Autism" means an abnormality characterized by each of the following symptoms:

- Impaired social behavior:
  - marked impairment in the use of multiple nonverbal behaviors, such as eye-to-eye gaze, facial expression, body postures, and gestures to regulate social interaction
  - failure to develop peer relationships appropriate to developmental level
  - a lack of spontaneous seeking to share enjoyment, interest, or achievements with other people (e.g., by a lack of showing, bringing, or pointing out objects of interest)

- lack of social or emotional reciprocity
- Abnormal development of communication skills:
  - delay in, or total lack of, the development of spoken language (not accompanied by an attempt to compensate through alternative modes of communication such as gesture or mime)
  - in individuals with adequate speech, marked impairment in the ability to initiate or sustain a conversation with others
  - stereotyped and repetitive use of language or idiosyncratic language
  - lack of varied, spontaneous make-believe play or social imitative play appropriate to developmental level
- Lack of awareness of the need for emotional support and little emotional response to family members:
  - encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus
  - apparently inflexible adherence to specific, nonfunctional routines or rituals
  - stereotyped and repetitive motor mannerisms (e.g., hand or finger flapping or twisting or complex whole-body movements)
  - persistent preoccupation with parts of objects

"Division" refers to the Division of Public Health under the Department of Health and Social Services.

"Infant" refers to a newborn from birth to 1 year of age.

"Registry" means a central data bank containing collected, classified, coded, and sorted data relating to confirmed autism in children from birth through age 17, as reported by health care practitioners, hospitals and clinical laboratories.

"Surveillance" means the process of identifying and investigating confirmed autism in children under age 18.

"Suspected Autism" is a term used for an infant or young child who is showing some developmental variations that do not meet the criteria for autism but whose variations have been shown to be associated with a risk of eventually developing all of the traits of autism.

### **3.0 Reporting Requirements**

The provisions of this section shall apply to the Delaware Health and Social Services, Division of Public Health, Autism Registry:

3.1 The registry shall collect information on any child under the age eighteen (18) who is a resident of the state of Delaware, or whose parent is a resident of Delaware, and who is diagnosed at any time prior to age eighteen (18) as having confirmed autism. For the purposes related to the registry the Department shall have access to any medical record of the child with confirmed autism.

3.2 The Department shall have access to information in the medical records of children with suspected autism. On request of the Department all mandated reporting sources should identify children who have suspected autism. The Department shall have access to records of such children.

3.3 Any diagnosis of confirmed autism shall be reported for all infants and children up to age 18, including those who have since died (if the data is still available).

3.4 For purposes of these reporting requirements, reportable diagnoses are those diagnoses, from the International Classification of Diseases (ICD) and DSM IV as listed in Appendix A of these regulations; as well as the 6-digit modified Pediatric Association system (BPA/ICD-9). The reportable diagnoses listed in Appendix A may be revised, upon notice, to reflect changes in publications accepted for use by the Centers for Disease Control and Prevention.

3.5 The following persons and organizations are required to report occurrences of autism within 30 days of diagnosis to the Division of Public Health.

3.5.1 Any physician, surgeon, dentist, podiatrist, or other health care practitioner who diagnoses a child with autism under age 18 who is not known to be previously reported. Other health care practitioners will include but not be limited to: psychiatrists, clinical and school psychologists, speech and language pathologists, licensed clinical social workers, and nurses including school nurses;

3.5.2 The designated representative of any clinical laboratory conducting assessment, evaluation or research that performs any test which identifies a child or children under age 18 with confirmed autism not known to be previously reported; and

3.5.3 The designated representative of any hospital that diagnoses a child or children under age 18 with confirmed autism.

3.6 The administrative officer of every health care facility shall be responsible for establishing reporting procedures at that facility, using the identified Autism Registry Reporting Form. Reporting procedures must ensure that, on the effective date of these regulations, each child up to the age of 18 diagnosed as having confirmed autism or currently under care with a diagnosis of confirmed autism must be reported to the Division.

3.7 Reporting sources shall complete the Division of Public Health Autism Surveillance Form for each reported case, and forward the completed form to the Division of Public Health Director or designee within 30 days of the diagnosis.

#### **4.0 Follow-up Information from Reporting Sources**

Any follow-up information, including family, physician, hospital or clinical laboratory contact deemed necessary by the Department, shall be submitted to the Department at least 1 time each year by those required to report occurrences of autism. The required follow-up information for the Autism Surveillance and Registry system will be sent to the same address as the Autism Registry Report Form.

#### **5.0 Exemption Based on Religious Grounds**

5.1 **The provisions of these regulations shall not apply to any person or private institution that, as an exercise of religious freedom, treats the sick or suffering by spiritual means through prayer alone.**

5.2 **A parent, custodian or guardian of an infant having autism may refuse disclosure to surveillance system and registry of the infant's name and identifying information on the grounds that such autism identification is contrary to the religious tenets and practices of the infant's parent, custodian or guardian.]**

#### **5.0 6.0 Confidentiality of Reports**

~~[5.1 6.1]~~ No report of a diagnosis or treatment of confirmed autism [received by the Division] shall be disclosed in such a way as to identify the child who is the subject of the report, or as to identify the child's family. However, patient-identifying information may be exchanged among authorized entities as approved by the Department and upon receipt by the Department of satisfactory assurances by those entities of the preservation of the confidentiality of such information. Those entities will maintain the confidentiality of any information exchanged for the purpose of delivery of program services, evaluation, early intervention and epidemiological investigation.

~~[5.2 6.2]~~ No individual or organization providing information pursuant to these regulations shall be held liable for divulging such information to the Division.

~~[5.3 6.3]~~ Inclusion on the registry does not determine the eligibility for services through any state agency.

#### **6.0 7.0 Penalties**

Any person or organization required to report the diagnosis or treatment of confirmed autism pursuant to these regulations, and who violates these regulations, shall be subject to a fine of up to \$100 for each violation, pursuant to 16 Del.C. Sec. 226. Justices of the Peace Courts have jurisdiction over such violations.

#### **7.0 8.0 Severability**

In the event any particular clause or section of the regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effective.

### **APPENDIX A**

#### **DELAWARE AUTISM REGISTRY REPORTABLE DIAGNOSES**

| <b><u>Broad Categories</u></b>               | <b><u>Specific Categories</u></b>        | <b><u>Codes</u></b> |
|--|--|---------------------|
| <b><u>Autism spectrum disorder (ASD)</u></b> | <u>ICD-9</u>                             |                     |
|  | <u>Infantile autism</u>                  | <u>299.0</u>        |
|  | <u>Infantile autism, active state</u>    | <u>299.00</u>       |
|  | <u>Infantile autism, residual state</u>  | <u>299.01</u>       |
|  | <u>DSM-IV</u>                            |                     |
|  | <u>Autistic disorder</u>                 | <u>299</u>          |
|  | <u>Childhood disintegrative disorder</u> | <u>299.1</u>        |
|  | <u>Rett's Disorder</u>                   | <u>299.8</u>        |
|  | <u>Asperger's Disorder</u>               | <u>299.8</u>        |

Pervasive developmental  
disorder NOS      299.8  
**8 DE Reg. 1481 (4/1/05)**