

ADOPTIONS SECTION

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF FAMILY HEALTH SERVICES

SPECIAL CHILD HEALTH SERVICES

EARLY IDENTIFICATION AND MONITORING PROGRAM

Notice of Readoption

Birth Defects Registry

Readoption with Technical Changes: N.J.A.C. 8:20

Authority: N.J.S.A. 26:2-103.1 through 103.9, particularly 103.9; 26:2-185 through 188; and 26:8-40.20 through 40.26, particularly 40.26.

Authorized By: Kaitlan Baston, MD, MSc, DFASAM, Commissioner, Department of Health.

Effective Dates: July 17, 2024, Readoption;
August 19, 2024, Technical Changes.

New Expiration Date: July 17, 2031.

Take notice that, pursuant to N.J.S.A. 52:14B-5.1, the rules at N.J.A.C. 8:20, Birth Defects Registry, were scheduled to expire on September 8, 2024.

N.J.A.C. 8:20-1 governs the Birth Defects Registry, which the Department of Health (Department) maintains pursuant to N.J.S.A. 26:8-40.21. The Birth Defects Registry contains a confidential record of all children who have birth defects that are identified within the first five years of a child's life. Subchapter 1 identifies the entities with reporting obligations, the birth defects that are to be reported, and the minimum

content of the required report. N.J.A.C. 8:20-2 governs the Autism Registry, which the Department maintains pursuant to N.J.S.A. 26:2-187. The Autism Registry contains a confidential record of all children diagnosed through age 21 as having any of the autism spectrum disorders. Subchapter 2 identifies the entities with reporting obligations, the diagnoses of autism that are to be reported, and the minimum content of the required report. The Birth Defects and Autism Registries may contain any other information the Department deems necessary and appropriate to conduct thorough and complete epidemiological surveys of birth defects and autism, and to plan for services needed by the children and their families.

N.J.A.C. 8:20 establishes, at Subchapter 1, Live Births, definitions of terms the subchapter uses, and standards for reporting birth defects in newborns to the Department; and at Subchapter 2, Autism, the purpose and scope of the subchapter, definitions of terms the subchapter uses, and standards for reporting autism diagnoses to the Department.

The Department is developing a rulemaking to update the chapter; however, this rulemaking would not be finalized prior to the chapter expiration. Therefore, the Department is readopting the chapter to maintain its effectiveness pending the completion of the rulemaking in development. In addition, the Department is making technical changes throughout the chapter to update cross-references, references to publications incorporated by reference, contact information, and website addresses, and correct references to the name of the Department, pursuant to N.J.S.A. 26:1A-2 and 2.1, and the programs that administer the registries.

The Commissioner has reviewed N.J.A.C. 8:20 and determined that, subject to the technical changes described above, and pending the completion of the rulemaking in development, the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which the Department originally promulgated it, as amended and supplemented over time, and should be readopted. Therefore, pursuant to N.J.S.A. 52:14B-5.1.c(1), N.J.A.C. 8:20 is readopted and shall continue in effect for seven years.

Full text of the technical changes follows (additions indicated in boldface **thus**; deletions in brackets [thus]):

SUBCHAPTER 1. LIVE BIRTHS

8:20-1.1 Definitions

The following words and terms used in this chapter shall have the following meaning unless the context clearly indicates otherwise.

...

"Commissioner" means the Commissioner of the New Jersey Department of Health [and Senior Services].

"Department" means the New Jersey Department of Health [and Senior Services].

...

"International Classification of Diseases, [Ninth] **Tenth** Revision, Clinical Modification" or "[ICD-9-CM] **ICD-10-CM**" means the [document] **clinical modification, issued by the National Center for Health Statistics, of the ICD-10**, published by the World Health Organization, which promotes the international comparability in the

collection, processing, classification, and presentation of mortality statistics, and which is incorporated herein by reference, as amended and supplemented. The [ICD-9-CM] **ICD-10-CM** is available for download at the National Center for Health Statistics' webpage at [http://www.cdc.gov/nchs/products/elec_prods/subject/icd96ed.htm] <https://www.cdc.gov/nchs/icd/icd-10-cm.htm>.

...

8:20-1.2 Reporting requirements

(a) A health care professional shall report any child who is born to a resident of the State of New Jersey, or who becomes a resident of the State prior to and through five years of age, and who is diagnosed as having a defect either at birth or any time through the fifth year of life to the Department, Special Child Health [and Early Intervention] Services Program as follows:

1. The conditions listed as Congenital Anomalies (Diagnostic Codes [740.00] **Q00** through [759.90] **Q99**) in the [most recent revision of the International Classification of Diseases, Clinical Modification (ICD-9-CM)] **ICD-10-CM**, [shall,] except as specified [in] **at** (a)1ii below, **shall** be reported to Special Child Health [and Early Intervention] Services. In addition, there are several other conditions considered to be birth defects that are not listed under Diagnostic Codes [740.00] **Q00** through [759.90] **Q99**, which describe Congenital Anomalies. The birth defects listed [in] **at** (a)1i below shall also, in every case, be reported to Special Child Health [and Early Intervention] Services. The minor conditions listed [in] **at** (a)1ii below shall not be reported to Special Child Health

[and Early Intervention] Services in every case, but only as required [in] **at** (a)1iii, iv, and v below.

i.-iv. (No change.)

v. If a condition or defect listed [in] **at** (a)1ii above accompanies a condition or defect listed in either Diagnostic Codes [740.00] **Q00** through [759.90] **Q99** in the [most recent revision of the International Classification of Diseases, Clinical Modification] **ICD-10-CM**, or [in] **at** (a)1i above, a registration form shall be completed.

(b) Clinical laboratories shall report to the Department any newborn who is a resident of the State of New Jersey, regardless of gestational age, who has a total serum bilirubin (TSB) of 25 milligrams per deciliter (mg/dl) or greater, or who receives an exchange transfusion. For reporting purposes, transcutaneous bilirubin measurements, without validation by TSB laboratory analysis, shall not be accepted.

1.-3. (No change.)

4. The clinical laboratory director shall send the report to the New Jersey Birth Defects Registry in the manner prescribed [in] **at** (g) below [to the Registry website address at: www.nj.gov/health/fhs/sch/schr.shtml].

5. (No change.)

(c)-(f) (No change.)

(g) The reports required by this section shall be sent to the Department [on] **using** the [SCH-O] **SCH-0** form, **which is** available on the [Registry] **Department** website at [<http://www.state.nj.us/health/fhs/sch/schr.shtml>] <https://nj.gov/health/forms>, either electronically, as described on the **Registry** website **at**

<https://www.nj.gov/health/fhs/bdr/moreinfo.shtml#register>, by secure telefacsimile

at (609) 292-8235, or by mail to the following address:

Birth Defects Registry

Early Identification and Monitoring Program

Special Child Health [and Early Intervention] Services

[Early Identification and Monitoring/Birth Defects Registry]

Division of Family Health Services

Department of Health

PO Box 364

Trenton, [New Jersey] **NJ** 08625-0364

(h)-(k) (No change.)

(l) Any agency designated by the Commissioner to receive reports pursuant to this subchapter shall provide to Special Child Health [and Early Intervention] Services any updated diagnostic and/or demographic information.

8:20-1.3 Reporting requirements for hearing loss

Physicians and audiologists shall complete and file a Special Health Services Registration form for any child from birth through 21 years of age diagnosed with any permanent hearing loss, as required [by] **pursuant to** N.J.A.C. 8:19[-1.11].

SUBCHAPTER 2. AUTISM

8:20-2.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Asperger Syndrome" means a disorder defined by **the** DSM [criteria (criteria 299.80) and] **that is** marked by clinically significant impairments in social interaction and the presence of restricted, repetitive, and stereotyped patterns of behavior, interests, and activities. There are no clinically significant delays in the development of language, cognition, self-help skills, or adaptive behavior. These criteria are not met for another specific pervasive developmental disorder.

"Autism" means a developmental disability as defined by [DSM criteria, and diagnosed according to standard] **and diagnosed according to the** DSM [criteria], which is marked by significant impairments in social interaction and communication and the presence of unusual behaviors and interests. Autism includes the following diagnoses commonly known as the Autism Spectrum Disorders: Asperger Syndrome; Autistic Disorder; and Pervasive Developmental Disorder Not otherwise Specified; and the Pervasive Developmental Disorders, including Rett Syndrome and Childhood Disintegrative Disorder, the causes of which are currently not known.

"Autistic disorder" means a disorder **as** defined by **the** DSM [criteria (criteria 299.00) and] **that is** marked by qualitative impairments in social interaction and communication and the presence of repetitive and stereotyped patterns of behavior with onset prior to three years of age [and that], **which** is not better accounted for by Rett Syndrome or Childhood Disintegrative Disorder.

...

"Childhood Disintegrative Disorder" means a disorder as defined by **the** DSM [criteria (criteria 299.10) and] that appears after at least two years of normal development after birth and results in the clinically significant loss of previously acquired skills in at least two areas of functioning (language, social skills, adaptive behavior, bowel/bladder control, play, or motor skills) before age 10. There are abnormalities of functioning in social interaction, communication, and the presence of restricted and stereotyped patterns of behavior [and], **which** is not better accounted for by another pervasive developmental disorder or by schizophrenia.

...

"DSM [criteria]" means the professional standard behavioral criteria for autism (**criterion F84**), published in the [American Psychiatric Association:] Diagnostic and Statistical Manual of Mental Disorders, [Fourth] **Fifth** Edition, **Text Revision** ([DSM-IV] **DSM-5-TR®**) [(criteria 299.0 - 299.90)] (**2022**), [Washington, DC,] **of the** American Psychiatric Association, [2000,] which is incorporated herein by reference, as amended and supplemented[. Copies of DSM-IV may be obtained], **and available** from [the] American Psychiatric Association **Publishing**, [1400 K Street, N.W.] **800 Maine Avenue, SW, Suite 900**, Washington, [D.C., 20005] **DC 20024**.

...

"Pervasive Developmental Disorder Not Otherwise Specified" means a disorder **as** defined by **the** DSM [criteria (criteria 299.80) and] **that is** marked by severe and pervasive impairment in the development of social interaction or verbal and non-verbal communication or when stereotyped behavior, interests, and activities are present, but

the criteria are not met for a specific pervasive developmental disorder. This category includes "atypical autism."

"Rett Syndrome" means a disorder **as** defined by **the** DSM [criteria (criteria 299.80) and] that appears after apparently normal prenatal and perinatal development, [and] which results in severe impairment in expressive and receptive language, loss of social engagement, retardation of psychomotor development, loss of previously acquired purposeful hand skills, and the development of stereotyped hand movements.

8:20-2.3 Reporting requirements

(a) (No change.)

(b) The health care professional shall send the report required by (a) above to the Department [on] **using** the [SCH-0] **SCH-1** form available on the [Registry] **Department** website at [<http://www.state.nj.us/health/fhs/sch/schr.shtml>]

<https://www.nj.gov/health/forms>, either electronically, as described on the **Registry** website at **<https://www.nj.gov/health/fhs/bdr/moreinfo.shtml#register>**, by secure telefacsimile at **(609) 292-8235**, or by mail to the following address:

Early Identification and Monitoring Program

Special Child Health [and Early Intervention] Services

[Early Identification and Monitoring/Autism Registry]

Division of Family Health Services

NJ Department of Health

PO Box 364

Trenton, [New Jersey] **NJ 08625-0364**

(c) (No change.)

(d) The report shall be, in writing, on the [SCH-O] **SCH-1** form and shall include the name, age, race/ethnicity, and address of the person with the diagnosis of autism, registration type, insurance information, child's birth information, diagnosis information, diagnostician's information, and contact information for the person submitting the form.

(e)-(f) (No change.)

(g) Any agency designated by the Commissioner to receive autism reports shall send to the Department, in the manner prescribed [in] **at** (b) above, any updated diagnostic and/or demographic information, in writing, on the [SCH-O] **SCH-1** form.

(h)-(l) (No change.)

(m) In accordance with N.J.S.A. 26:2-188b, a [physician, psychologist or] health care professional providing information to the Department shall not be deemed to be, or held liable for, divulging confidential information.

(n) (No change.)