

CITY OF BALTIMORE

ORDINANCE NO. 573
APPROVED JUNE 15, 1995

(Council Bill No. 1193)

AN ORDINANCE concerning

PEDIATRIC IMMUNIZATION REGISTRY

FOR the purpose of authorizing the Commissioner of Health to establish a registry of childhood immunization histories.

BY adding to

Article 11 - Health

Section 211A through 211C, inclusive, to be under the new subtitle "Pediatric Immunization Registry"

Baltimore City Code (1983 Replacement Volume, as amended)

SECTION 1. BE IT ORDAINED BY THE MAYOR AND CITY COUNCIL OF BALTIMORE, That Section(s) of the Baltimore City Code (1983 Replacement volume, as amended) be added, repealed, or amended, to read as follows:

ARTICLE 11 - HEALTH

PEDIATRIC IMMUNIZATION REGISTRY

211A. PURPOSE.

(A) INASMUCH AS IMMUNIZATIONS ARE A PROVEN PREVENTIVE MEASURE TO REDUCE THE MORBIDITY AND MORTALITY ASSOCIATED WITH CHILDHOOD COMMUNICABLE DISEASES, IT IS HEREBY DECLARED TO BE NECESSARY FOR THE SAFEGUARDING OF PUBLIC HEALTH AND WELFARE THAT THE CITY ATTAIN AND SUSTAIN AN IMMUNIZATION COVERAGE RATE OF AT LEAST 90% FOR AGE-APPROPRIATE VACCINATIONS AMONG INFANTS AND PRE-SCHOOL CHILDREN RESIDING IN BALTIMORE CITY.

(B) FOR THIS PURPOSE THE COMMISSIONER OF HEALTH SHALL PROMULGATE REGULATIONS TO IMPLEMENT A REGISTRY OF VACCINATION HISTORY FOR CHILDREN RESIDING IN BALTIMORE CITY.

211B. REPORT OF IMMUNIZATIONS.

WITHIN 14 DAYS AFTER ADMINISTERING AN IMMUNIZING AGENT TO ANY CHILD UNDER 5 YEARS OF AGE RESIDING IN BALTIMORE CITY, EACH PEDIATRIC, FAMILY, AND GENERAL HEALTH CARE PROVIDER SHALL SUBMIT A REPORT TO THE COMMISSIONER OF HEALTH IN WRITING IN A FORMAT DESIGNATED BY THE COMMISSIONER.

211C. PENALTY PROVISIONS.

ANY PERSON WHO VIOLATES A PROVISION OF THIS SUBTITLE OR A REGULATION ADOPTED UNDER IT IS SUBJECT TO A CIVIL PENALTY NOT TO EXCEED \$1,000 FOR EACH VIOLATION. IN ADDITION TO IMPOSING A FINE, A JUDGE MAY ISSUE AN ORDER FOR THE WITHHOLDING OF PUBLICLY DISTRIBUTED VACCINES AND/OR PEDIATRIC PRIMARY CARE FUNDING, AND MAY ORDER THE BALTIMORE CITY HEALTH DEPARTMENT TO CONDUCT A MEDICAL RECORDS AUDIT OF THE HEALTH CARE PROVIDER, THE COST OF THE AUDIT BEING A DEBT DUE AND OWING TO THE CITY FROM THE HEALTH CARE PROVIDER.

SEC. 2. AND BE IT FURTHER ORDAINED, That this ordinance shall take effect on the 30th day after the date of its enactment.

EXPLANATION: CAPITALS INDICATE ADDED TO EXISTING LAW.
[BRACKETS] indicate deletion from existing law
Underline indicates amendment to bill

~~Strikeout~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

REGULATIONS FOR BALTIMORE'S PEDIATRIC IMMUNIZATION REGISTRY

Pursuant to Ordinance #573 (enacted June 15, 1995) amending Baltimore City Code Article 11, Sections 215A, 215B AND 215C, the Commissioner of Health of the Baltimore City Health Department hereby adopts and promulgates the following Regulations supporting the establishment and maintenance of the Baltimore City Pediatric Immunization Registry.

I. Definitions:

- A. The "Department" or "Department of Health" shall mean the Baltimore City Health Department.
- B. The "Commissioner" shall mean the duly appointed Commissioner of the Baltimore City Health Department.
- C. "Preschool Child" or "Preschool Children" shall mean any person who has not reached their fifth birthday.
- D. "Child" or "children" shall mean anyone who has not reached their nineteenth birthday.
- E. For purposes of Immunization Registry reporting, "Provider" shall mean any medical doctor, doctor of osteopathy, nurse practitioner, physician assistant, registered or licensed nurse, other individual who is licensed, certified, or otherwise authorized by the state of Maryland to administer an immunization to a preschool child, and whose practice is based within Baltimore City. For reporting purposes, "Provider" shall also include the officers and administrative directors of a health care facility within Baltimore City.
- F. "Report" shall mean both the act or process of collecting, verifying the accuracy of and conveying, or otherwise transmitting to the Department of Health the information required to be reported to the Registry by the Commissioner, in a format designated by the Commissioner, concerning the administration of a dose or doses of vaccine to a preschool child by a provider, and the product of such act or process.
- G. "Parent/Guardian" or "Parental" shall mean any individual with legal custodial rights for a child.
- H. "Day" shall mean any 24 hour period including Saturdays, Sundays and holidays.
- I. "Child Identifier" shall mean any data field which helps to uniquely identify a child which may include but is not limited to child first, middle and last name, date of

birth, birth hospital, mother's maiden name, social security number, health care facility/provider, medical record number, and parent/guardian name.

- J. "Demographic Locator" shall mean the address of residence, telephone number, emergency contact information or other information utilized by the provider or by the Department to conduct outreach on preschool children delayed for age-appropriate immunizations.
- K. "Immunization Information" shall mean vaccine type(s), date(s) of vaccination, name of health care provider and vaccine administrator, anatomical site of administration, and vaccine manufacturer and lot number.
- L. "Pediatric Immunization Registry" or "Registry" shall mean the central computerized database which collects, stores and selectively re-discloses all data and reports containing child identifiers, demographic locators, and immunization information which is maintained by the Department of Health.
- M. "On-line" shall mean having an electronic connection to the Registry through a provider-based computer and modem linked to the Registry's remote client / server metropolitan area network.

II. Duty to Report:

- A. Each provider shall report to the Registry the following child identifiers and demographic locators to the Registry regarding all preschool children who have been administered a vaccine containing one or more antigens defined in section II.B upon the first report of vaccine administration or upon any known changes in information:
 - Child last name, first name, middle name, name suffix (e.g.; "Jr.," "III"), and alternate name(s).
 - Child's date of birth.
 - Child's gender.
 - Mother's maiden name.
 - Child's birth hospital (if known).
 - Current parent/guardian last name, first name, middle name, and relationship to the child.
 - Child's address of residence including house number, street name, apartment number, city, postal zip code and telephone number(s).
- B. Each provider shall report to the Registry each vaccine injection or oral dose and the date of vaccine administration of the following antigens which are administered singly or in combination to a preschool child:

Diphtheria
Haemophilus influenzae type B ("Hib")

Hepatitis B
Measles
Mumps
Pertussis
Polio
Rubella
Tetanus
Varicella

- C. Each provider shall report to the Registry the following information regarding provider identification for each vaccine administered:
- Name of the health care facility, and/or,
 - Provider name
- D. Each provider shall send to the Department for inclusion in the Registry copies of vaccine adverse event ("VAERS") reporting for a preschool child as defined by the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-25).
- E. Each provider shall report to the Registry any medical contraindication to the administration of one or more antigens for any preschool child. The report shall indicate if the contraindication is temporary or permanent. If the contraindication is temporary, the report shall be accompanied by a date after which the contraindication will no longer exist or will be reassessed.
- F. Each provider shall report as an exemption any parent/guardian's religious belief and practice or other parent/guardian refusal which precludes a vaccine's administration to a preschool child.
- G. Each provider is strongly encouraged, not required, to report to the Registry the following additional identifiers or data elements:
- Vaccines and dates of vaccine administration for non-reportable antigens or other immunizing agents including those found on historical records (i.e., documented immunizations administered by a previous health care provider).
 - Vaccines and dates of vaccine administration to children up to and including the nineteenth birthday.
 - Anatomical site of vaccine's administration.
 - Vaccine manufacturer and lot number.
 - Name or initials of person administering vaccination(s).
 - Child's medical record number (or parsed component thereof).
 - Child's social security number.
 - Child's ethnicity
 - Child's health insurer.

- H. The report shall be prepared and verified by the provider for accuracy, and transmitted to the Registry within fourteen (14) days following the administration of vaccine(s).
- I. Health Care Providers shall have the duty to distribute, or otherwise make available the information contained in the Department provided "Parent Information Sheet" as defined in Section VIII.A. of these regulations.

III. Methods of Reporting:

- A. Providers may submit reports electronically either by on-line single transaction or by batch (records accumulated by the provider and submitted in quantity).
- B. Providers who do not possess the means to submit electronic reports may use other Registry reporting mechanisms defined by the Commissioner or his/her designee. Other reporting mechanisms may include but not be limited to mailed or facsimile documentation (e.g.; data entry forms/logs, photocopy of provider's vaccination administration record or Maryland "Shot Book"), or voice reporting through an integrated touch-tone telephone voice response system.

IV. Responsibility of the Department:

- A. The Department of Health is charged with the design, implementation, maintenance and evaluation of the Pediatric Immunization Registry as a central repository for child identifiers, demographic locators, and immunization information. Data contained within the Registry shall be defined by the Commissioner or his/her designee as necessary for public health surveillance and intervention.
- B. The Department of Health is charged with establishing a communications network enabling both the electronic and non-electronic transmission of provider reports to the Registry, as well as the re-disclosure of Registry records to providers and other authorized users and agencies.
- C. The Department of Health is charged with the data entry and validation of reports transmitted to the Registry by providers.
 - (1) Provider reporting received by the Department shall be entered into the Registry no later than fourteen (14) days after its receipt.
 - (2) Validation shall include but not be limited to assuring the accuracy and completeness of Registry collected information from primary and secondary (non-provider) sources, record de-duplication and reconciliation and periodic audits of provider medical records.

- D. The Department of Health is charged with the storage of collected immunization information for Baltimore City children until the child turns nineteen (19) years old or for another period of time in accordance with Maryland State Department of Health standards.
- E. The Department will develop, implement and evaluate appropriate safeguards to assure the integrity and confidentiality of Registry data.
- F. The Department shall develop and distribute, or otherwise make available, to health care providers a "Parent Information Sheet" as defined in Section VIII.A. of these regulations.

V. Phase-In of Reporting Requirements:

- A. By December 31, 1997, compliance with sections II and III of these regulations shall universally and without exception be required by pediatric primary care providers practicing within Baltimore City limits. The Commissioner may in his/her discretion rule an earlier date for universal compliance.
- B. Early compliance with sections II and III of these regulations may be required of providers administering immunizations to preschool children in health care settings that serve patients at risk for immunization delay. Such settings will be defined by the Commissioner based upon indicators including, but not limited to, census information, community immunization coverage levels and health care practice patterns.

VI. Authorized Access to Registry Information:

- A. In accordance with Maryland's Health-General Code §4-305(b)(3) and pursuant to the Baltimore City Health Department's mission to conduct both public health surveillance and intervention to control childhood vaccine preventable diseases, the Department shall receive identifiable provider based records without parent/guardian consent.
- B. The Department, acting as an information conduit, may re-disclose Registry identifiable reports from one pediatric primary care provider to a subsequent provider and other authorized agencies for the sole purpose of medically treating the subject of said immunization records. Therefore, under Maryland's Health General Code §4-301 et seq, such re-disclosure without parental consent is permissible.
- C. A parent/guardian may request and receive identifiable immunization information for his/her child from the Registry upon signed consent for release of medical information presented to the Department.

- D. Outside (the "Registry-Provider network") users or agencies authorized by law to have access to Registry records may receive such information upon receipt by the Department of a signed interagency agreement defining and governing said information transfers.
- E. Unless additional identifiers are defined by an institutional review board ("IRB") for purposes or research, released information from Registry records shall be limited to:
- Child name and date of birth.
 - Immunization history including vaccine type(s) and date(s) of administration.
 - Recorded contraindications and exemptions, as well as observed adverse reactions to immunizing agents.
- F. Subject to the approval of the Commissioner or his/her designee, aggregate information excluding all identifiers may be disclosed by the Department to outside requestors who demonstrate a legitimate and tangible interest in said immunization information. Release of aggregate information must comply with federal, state and local laws governing medical confidentiality and duty of parental notification.
- G. The Department shall forward notification to primary care provider(s) when aggregate reporting for their practice and/or patients is generated from Registry records. Copies of said reporting will be made available to said provider(s) upon request.

VII. Confidentiality of Registry Information:

- A. The collection and re-disclosure of Registry collected records shall follow all federal, state and local laws governing the privacy and confidentiality of medical records.
- B. Each provider shall sign an agreement with the Department which shall affirm the provider's commitment to follow the terms and conditions set forth herein.

VIII. Parent/Guardian Rights:

- A. In accordance with standards developed in the Federal Freedom of Information Act ("FOIA") 5 U.S.C. Section 552 and the Maryland Public Information Act (Maryland Annotated Code Sections 10-611 - 10-628), the Department of Health shall draft and distribute a "Parent Information Sheet" to providers. Providers will be charged with the distribution of the "Parent Information Sheet" to parents/guardians. Said information shall include an abbreviated explanation of:

(1) definition of the Immunization Registry activities, (2) what information is being collected and why, (3) who has access to Registry records, (4) parent/guardian's rights to both view and correct, erase or amend inaccurate, obsolete or irrelevant Registry information, and (5) how parents/guardians may prohibit re-disclosure of their child's Registry record.

- B. A parent/guardian maintains the right to decline ("opt-out") their child's participation in Registry activities. The desire to "opt-out" shall be communicated by the parent/guardian in writing and in person in a format and procedure designated by the Commissioner or his/her designee.
- (1) A signed and dated statement of declination shall prevent the re-disclosure of the child's Registry record including identifiers, demographic locators and immunization information to all but authorized Department staff.
 - (2) A parent/guardian may return their child to an "active" Registry status by submitting a signed and dated statement of re-enrollment in writing and in person in a format and procedure designated by the Commissioner or his/her designee.
 - (3) Providers seeking vaccination histories for children whose parent/guardian have declined to participate in Registry re-disclosure must provide the Department of Health with a signed and dated parental consent for release of medical records.
 - (4) A parent/guardian's decision to decline Registry participation does not exclude nor suspend their child's health care provider's obligation to report to the Registry.

IX. Penalties:

- A. A person or organization who willfully violates any provision of City Ordinance #573 or these regulations governing Baltimore's Immunization Registry is subject to a civil penalty not to exceed \$1,000 for each violation, to be collected in a civil action brought by the Commissioner or his/her designee in the District Court.
- B. In addition to imposing a fine, a judge may issue an order for the withholding of publicly administered pediatric primary care funding and/or may order the Department to conduct a medical records audit of the provider, the cost of the audit being a debt due and owing to the City from the Provider.
- C. If the person or organization in violation is a City employee, progressive disciplinary action may be imposed in addition to, or in place of, civil penalties, including disciplinary action up to and including termination.

Commissioner, Baltimore City Health Department

Date

Attachments: - City of Baltimore Ordinance No. 573 (Council Bill No. 1193), June 15, 1995
- "Notice to Health Care Providers, Baltimore's Pediatrics Immunization Registry Program"