

November 29, 2011

To Whom It May Concern:

The New York State Department of Health (NYSDOH) is considering a proposal that would modify the regulations governing the reporting of children with birth defects to the Congenital Malformations Registry (CMR)—specifically, 10 NYCRR 22.3. Before NYSDOH proposes these changes, we wish to understand the possible impact they may have on health care providers and facilities.

The CMR was established following the Love Canal crisis in the 1970's, and it now receives reports for over 11,000 children annually from about 160 hospitals. This represents approximately 4.8% of live births. After receiving the reports, DOH provides families with information about local community services, tracks changes in malformation rates over time, monitors geographical disparities, provides information for health planning, and conducts etiological research.

Currently, 10 NYCRR 22.3 requires reporting of certain birth defects by physicians and hospitals for children up to age 2. The proposal would increase the maximum reporting age for the following birth defects to age 10:

- Congenital anomalies of heart
- Genetic syndromes and microdeletions
- Chromosomal anomalies
- Fetal Alcohol Syndrome

Many children with the above malformations are not diagnosed by age 2. In addition, the proposal would require reporting by nurse practitioners and physician assistants that are authorized to diagnose congenital anomalies. The proposed change will support the CMR's ability to enhance epidemiologic surveillance and advance the understanding of birth defects causation.

We are also considering changing the regulation by explicitly adding several diseases and disease categories already reported to the CMR using the International Classification of Diseases (ICD) codes. Because ICD codes are already used for billing purposes in the health field, NYSDOH expects this change will have minimal impact on health care providers and facilities.

We expect that these regulatory changes will only result in a small increase in reports annually. Further, to minimize reporting effort while maximizing convenience, we are considering using the NYSDOH web-based Immunization Information System (NYSIIS), as most reporters are already familiar with this system.

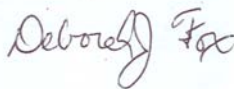
NYSDOH is interested in your thoughts on such a regulation, including its possible economic impact. We have attached a list of questions to help us better understand how such a regulation would affect you. We would appreciate receiving any information you can provide by December 30<sup>th</sup>. Responses can be submitted via email to [djf03@health.state.ny.us](mailto:djf03@health.state.ny.us) or mailed to:

Deborah Fox  
New York State Department of Health  
547 River Street, Room 200  
Troy, NY 12180-2216

Please feel free to share this letter with other individuals and organizations that may have an interest in this regulation. If you have any questions or need additional information, please call me at (518) 402-7760.

Thank you.

Sincerely,

A handwritten signature in black ink that reads "Deborah J. Fox". The signature is written in a cursive style and is positioned above the printed name.

Deborah J. Fox, MPH

**Questions on NYS Department of Health Rulemaking  
Increasing reporting age for certain birth defects  
November 29, 2011**

1. Are you a sole practitioner or are you associated with a business or organization? If you are part of a larger facility, approximately how many employees work there?
2. What is your profession, or what services does your organization or business provide?
3. Do you already report children with birth defects to the Department of Health? If so, about how many annually?
4. If you do not currently report, what is the reason?
5. Do you already have access to the Department of Health's Health Commerce System?
6. What are the estimated costs/economic impacts of complying with these regulatory changes to yourself personally or your business (e.g., estimated additional time required for yourself or your staff, computing expenses, etc.)?
7. Please describe additional measures you or your organization must take to comply with this regulatory change (e.g., record-keeping, software modifications, professional services, etc).
8. Please indicate if the initial and/or continuing compliance with this regulatory change will vary depending on the type or size of an organization.
9. Please describe the economic and technological feasibility of complying with the regulatory change.
10. Please estimate the period of time necessary to come into compliance with this regulatory change.
11. Please describe any anticipated effects of the regulation on jobs or employment opportunities in New York State.
12. Please describe any measure that New York State could take to offset any anticipated adverse economic impacts.
13. Please describe any aspects of the proposed regulatory change that would be considered overly burdensome.
14. Please describe regions of the state or types of professions or organizations that would be disproportionately affected by this regulatory change.
15. Please provide comments on implementation of this regulatory change. Please provide any other relevant information that you would like us to consider. Please include any additional suggestions you have to accomplish our objectives.