

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to approval by the Commissioner of Health by Section 2816 of the Public Health Law, Section 400.18 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 400.18 is amended to read as follows:

10 NYCRR § 400.18 Statewide Planning and Research Cooperative System (SPARCS).

(a) Definitions. For the purposes of this section, these terms shall have the following meanings:

(1) Health care facilities shall mean facilities licensed under Article 28 of the Public Health Law.

(2) Identifying data elements shall mean those SPARCS [and Patient Review Instrument (PRI)] data elements that, if disclosed without any restrictions on use or re-disclosure would constitute an unwarranted invasion of personal privacy. A list of identifying data elements shall be specified by the Commissioner and will be made available publicly.

(3) Inpatient hospitalization data shall mean SPARCS data submitted by hospitals for patients receiving inpatient services at a general hospital that is licensed under Article 28 of the Public Health Law and that provides inpatient medical services.

(4) Outpatient data shall mean emergency department data, ambulatory surgery data, and outpatient services data.

(i) Emergency department data shall mean SPARCS data submitted by a facility licensed to provide emergency department services under Article 28 of the Public Health Law.

(ii) Ambulatory surgery data shall mean SPARCS data submitted by a facility licensed to

provide ambulatory surgery services under Article 28 of the Public Health Law.

(iii) Outpatient services data shall mean all data submitted by licensed Article 28 facilities excluding inpatient hospitalization data, emergency department data, and ambulatory surgery data.

(5) [Patient Review Instrument (PRI) data shall mean the data submitted on PRI forms by residential health care facilities, pursuant to section 86-2.30 of this Title.

(6) SPARCS Administrator shall mean a person in the SPARCS program designated by the Commissioner to act as administrator for all SPARCS activities.

[(7)] (6) SPARCS data shall mean the data collected by the Commissioner under section 2816 of the Public Health Law and this section, including inpatient hospitalization data and outpatient data.

[(8)] (7) SPARCS program shall mean the program in the New York State Department of Health (NYSDOH) that collects and maintains SPARCS data and discloses SPARCS [and Patient Review Instrument (PRI)] data.

(b) Reporting SPARCS data.

(1) Health care facilities shall report data as follows:

(i) Health care facilities shall submit, or cause to have submitted, SPARCS data in an electronic, computer-readable format through [NYSDOH's] a secure electronic network [according to the requirements of section 400.10 of this Part and the] designated by the Department according to specifications provided by the Commissioner.

(ii) All SPARCS data must be supported by documentation in the patient's medical and billing records.

(iii) Health care facilities must submit on a monthly basis to the SPARCS program, or cause to have submitted on a monthly basis to the SPARCS program, data for all

inpatient discharges and outpatient visits. Health care facilities must submit, or cause to have submitted, at least 95 percent of data for all inpatient discharges and outpatient visits within sixty (60) days from the end of the month of a patient's discharge or visit. Health care facilities must submit, or cause to have submitted, 100 percent of data for all inpatient discharges and outpatient visits within one hundred eighty (180) days from the end of the month of a patient's discharge or visit.

(iv) The SPARCS program may conduct an audit evaluating the quality of submitted SPARCS data and issue an audit report to a health care facility listing any inadequacies or inconsistencies in the data. Any health care facility so audited must submit corrected data to the SPARCS program within 90 days of the receipt of the audit report.

(2) Content of the SPARCS data.

(i) Health care facilities shall submit, or cause to have submitted, uniform bill data elements as required by the Commissioner. The data elements required by the Commissioner shall be based on those approved by the National Uniform Billing Committee (NUBC) or required under national electronic data interchange (EDI) standards for health care transactions and shall be published on the NYSDOH website to the extent allowed by copyright law.

(ii) Health care facilities shall submit, or cause to have submitted, additional data elements as required by the Commissioner. Such additional data elements shall be from medical records or demographic information maintained by the health care facilities.

(iii) The list of specific SPARCS data elements and their definitions shall be maintained by the Commissioner, will be made available publicly, and may be modified by the Commissioner.

(c) Maintenance of SPARCS data.

The Commissioner shall be responsible for protecting the privacy and security of the health care information reported to the SPARCS program.

(d) Requests for SPARCS [and PRI] data.

(1) SPARCS [and PRI] data may be used for medical or scientific research or statistical or epidemiological purposes approved by the Commissioner.

(2) The Commissioner may determine that additional purposes are proper uses of SPARCS [and PRI] data.

(3) In determining the purpose of a request for SPARCS [and PRI] data, the SPARCS program shall not be limited to information contained in the data request form and may request supplemental information from the applicant.

(4) The Commissioner shall charge a reasonable fee to all persons and organizations receiving SPARCS [and PRI] data based upon costs incurred and recurring for data processing, platform/data center and software. The Commissioner may discount the base fee or waive the fee upon request to the SPARCS program. The fee may be waived in the following circumstances:

(i) Use by a health care facility of the data it submitted to the SPARCS program.

(ii) Use by a health care facility that is licensed under Article 28 of the Public Health Law for the purpose of rate determinations or rate appeals and for health care-related research.

(iii) Use by a Federal, New York State, county or local government agency for health care-related purposes.

(5) The SPARCS program shall follow applicable federal and state laws when determining whether SPARCS [and PRI] data contain identifying data elements may be

shared and whether a disclosure of SPARCS [and PRI] data constitutes an unwarranted invasion of personal privacy.

(6) All entities seeking SPARCS [and PRI] data must submit a request to the SPARCS program using standard data request forms specified by the SPARCS program. Data users shall take all necessary precautions to prevent unwarranted invasions of personal privacy resulting from any data analysis or release. Data users may not release any information that could be used, alone or in combination with other reasonably available information, to identify an individual who is a subject of the information. Data users bear full responsibility for breaches or unauthorized disclosures of personal information resulting from use of SPARCS [or PRI] data. Applications for SPARCS [or PRI] data must provide an explicit plan for preventing breaches or unauthorized disclosures of personal information of any individual who is a subject of the information.

(7) Each data request form must include an executed data use agreement in a form prescribed by the SPARCS program. Data use agreements are required of: a representative of the requesting organization; a representative of each other organization associated with the project; and all individuals who will have access to any data including identifying data elements.

(8) The SPARCS program shall publish and make publicly available the name of the project director, the organization, and the title of approved projects.

(9) The SPARCS Administrator shall review and make recommendations on requests for SPARCS [and PRI] data containing identifying data elements to a data release committee established by the Commissioner. The data release committee shall have at least three members, including at least one member not otherwise affiliated with NYSDOH. The members of the data release committee shall be posted on the NYSDOH website.

Requests will be granted only upon formal, written approval for access by a majority of

the members of the data release committee. The Commissioner has the final authority over the approval, or disapproval, of all requests. Requests for identifying data elements shall be approved only if:

- (i) The purpose of the request is consistent with the purposes for which SPARCS [and PRI] data may be used;
- (ii) The applicant is qualified to undertake the project; and
- (iii) The applicant requires such identifying data elements for the intended project and is able to ensure that patient privacy will be protected.

(10) The SPARCS Administrator may recommend approval of a request in which future SPARCS data is to be supplied on a periodic basis under the following conditions:

- (i) SPARCS data may be requested for a predetermined time not to exceed three years beyond the current year provided that the organization and uses of the data remain as indicated in the data request form submitted to the SPARCS program.
- (ii) During the period of retention of SPARCS [or PRI] data, no additional individuals may access SPARCS [or PRI] data without an executed data use agreement on file with the SPARCS program.

(11) The Commissioner may rescind for cause, at any time, approval of a data request.

(e) Penalties.

(1) Any person or entity that violates the provisions of this section or any data use agreement may be liable pursuant to the provisions of the Public Health Law, including, but not limited to, sections 12 and 12-d of the Public Health Law.

(2) Any person or entity that violates the provisions of this section or any data use agreement may be denied access to SPARCS [or PRI] data.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Statewide Planning and Research Cooperative System (SPARCS) is a comprehensive health care data reporting system established in 1979 through cooperation between the health care industry and government. The enabling legislation for SPARCS is Section 2816 of the Public Health Law (PHL). The regulations pertaining to SPARCS are under Section 400.18 of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York (NYCRR).

Legislative Objectives:

In 2001, the Legislature codified the Department's authority to collect SPARCS data by adding PHL § 2816. In 2011, the Legislature expanded this authority by authorizing the Department to develop and implement an All Payer Database for New York State. In doing so, the Legislature referenced the Department's need for greater flexibility in the forms of data submission.

The enactment of Public Health Law § 2816(6) authorized the Department to describe data elements by reference to information reasonably available to regulated parties, as such material may be amended in the future. This provision recognizes the Department's need for flexibility when determining data elements by authorizing the Department to adjust such data elements administratively.

Needs and Benefits:

The current regulation directs data to be submitted to SPARCS through the Health Commerce System (HCS). This rule making revises Section 400.18 to grant the SPARCS program the flexibility to explore other data intake options, consistent with Public Health

Law § 2816. This rule making also removes all references to Patient Review Instrument (PRI) data, which is an obsolete data source.

This rule making clarifies that input data dictionary elements are protected by copyright law. The Department will continue to precisely identify and publish a description of what data elements must be submitted to the extent it may do so under copyright law.

The proposed regulation changes will enhance the SPARCS program by modernizing the program's technology and functionality. Currently, HCS users regularly experience bandwidth issues, poor network performance, and slow data transfer speeds. These issues hinder the ability of data submitters to submit SPARCS data in a timely fashion. By leveraging new technology for SPARCS data intake, the SPARCS program will operate more efficiently.

Lastly, the proposed regulation specifies that data elements required by the Commissioner shall be based on those approved by the National Uniform Billing Committee (NUBC) or required under national electronic data interchange (EDI) standards for health care transactions and shall be published on the NYSDOH website to the extent allowed by copyright law. The SPARCS program is in the process of changing its data format to require data to be submitted in the X12 837R ("X12") format, which is to some extent proprietary intellectual property owned by X12 Incorporated. See <http://www.x12.org/>, <http://members.x12.org/policies-procedures/cap01v3-bylaws.pdf>, <http://store.x12.org/store/ip-use>. Consistent with past practice, the Department will publish the data elements with specificity so that regulated parties will know exactly what data elements must be submitted, with the caveat that the Department will not publish intellectual property that it does not have a right to publish.

Costs:

Costs to Regulated Parties:

The rule change levies minor additional costs to health care facilities licensed under Article 28 of the PHL that may need to, in some cases, change their existing contracts with vendors to submit data, if they utilize a vendor. These minor additional costs would be solely related to changes needed to submit data to the Department's contractor rather than submitting data directly to the Department using the HCS. Data will continue to be submitted in the standard claims data format that all Article 28 facilities have already adopted under federal regulations in 42 CFR Part 162 as authorized by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Costs to the NYSDOH:

The costs associated with this change will be offset by savings from no longer having to finance a mainframe system and changes needed to the HCS maintained by the NYS Office of Information Technology Services. This change will also allow for the reallocation of NYSDOH staff to areas needing additional resources.

Costs to State and Local Governments:

There are no anticipated costs to local governments as a result of this rule change, except that any PHL Article 28 facilities that are operated by local governments will incur the same costs as any other Article 28 facilities subject to this regulation.

Local Government Mandates:

This rule change imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

Paperwork:

The rule change imposes no significant reporting requirements, forms, or other paperwork upon regulated parties.

Duplication:

There will be no duplication of reporting efforts to New York State for health care facilities licensed under Article 28 of the PHL.

Alternatives:

There are no reasonable alternatives that could serve as a substitute, because the Department will no longer be able to collect data using the HCS. The Department's mainframe system for SPARCS was scheduled to sunset when key staff retired. The Office of Information Technology Services would no longer support COBOL/mainframe SPARCS translation. Likewise, the Office of Information Technology Services was sunsetting support for a key technology used to support the SPARCS application on the HCS.

Federal Standards:

The rule change does not exceed any minimum standards of the federal government for the same or similar subject area, as the federal government does not operate a national program like SPARCS.

Compliance Schedule:

The rule change will not alter SPARCS compliance schedules. Health care facilities licensed under Article 28 of the PHL will continue to submit data to SPARCS at the same frequency and levels they currently do.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

The rule change will have no impact on jobs and employment opportunities on the part of regulated parties (health care facilities licensed under Article 28 of the Public Health Law). The regulated health care facilities already have an existing data reporting infrastructure and are required to report SPARCS data. The way facilities submit data to SPARCS would not change. It would not be more burdensome or costly for data submitters as their data submission process would be very similar to what currently is in place. There will be no job impacts in any other segments or sectors of the job market. With regards to adverse employment effects, there is no expectation of job losses as a result of the rule.