Accreditation of General Hospitals and Diagnostic and Treatment Centers

Effective date: 2/22/12

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval of the Commissioner of Health by paragraph (2) of section 2803 of the Public Health Law, Sections 405.1, 700.2, 720.1 and 755.2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, Section 751.11 of Title 10 (Health) is renumbered 751.12 and a new Section 751.11 (Health) of Title 10 is added to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph (2) of Subdivision (a) of Section 405.1 of Part 405 is amended to read as follows:

(2) the commissioner may accept as evidence of compliance with the minimum operational standards of this Part, accreditation by an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that hospitals so accredited are in compliance with such operational standards. The Commissioner can choose to enter into collaborative agreements with such accreditation agencies so that the accreditation agency’s accreditation survey can be used in lieu of a Departmental survey. A list of accreditation agencies with which the
Department has a collaborative agreement will be posted on the department’s website.

Hospitals shall notify the commissioner in writing within seven days after receipt of notice of [the accreditation decision or notification of a tentative nonaccreditation by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association.] failure to be accredited, re-accredited or the loss of accreditation by the accreditation agency.

Subdivision (b) of Section 405.1 of Part 405.1 is amended to read as follows:

(b) The provisions of Parts 700, except for paragraphs (a) (1), (a)(21-22), (b)(25) and (c)(7), (35)-(41) of section 700.2; 702; 703, except for section 703.6; 706; and 707 of Article 1 of this Chapter shall not apply to general hospitals.

Paragraph (1) of Subdivision (a) of Section 700.2 is amended to read as follows:

(1) Accredited hospital or other accredited medical facility, as defined in article 28 of the Public Health Law, shall mean a hospital or facility which has been accredited by [the Joint Commission on Accreditation of Hospitals, or an osteopathic hospital which has been accredited by the Committee of Hospitals of the American Osteopathic Association.] an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that hospitals or facilities so accredited are in compliance with operational standards under this Chapter.
Section 720.1 is amended to read as follows:

Section 720.1 [Standards of Joint Commission on] General Hospital Accreditation [of Hospitals or American Osteopathic Association].

(a) General [H] hospitals must comply with the operational standards set forth in Part 405 of this Title. The commissioner may[, if he so desires,] accept as evidence of compliance with the minimum operational standards of Part 405 of this Title accreditation by [of the Joint Commission on Accreditation of Hospitals or American Osteopathic Association] an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that hospitals so accredited are in compliance with such operational standards. The Commissioner can choose to enter into collaborative agreements with such accreditation agencies so that the accreditation agency’s accreditation survey can be used in lieu of a Departmental survey. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department’s website. [that such hospitals meet the standards of such organization as set forth in the Accreditation Manual of Hospitals of the Joint Commission on Accreditation of Hospitals, 1976 Edition, as amended or the Accreditation Requirements of the American Osteopathic Association, 11th edition, February 1976, as amended, provided that, in addition to complying with Part 405 of this Title] These provisions shall apply provided that:
[(1)] a copy of the survey report and the certificate of accreditation of the Joint Commission on Accreditation of Hospitals or the certificate of accreditation of the American Osteopathic Association is submitted to the commissioner within seven days of receipt from the hospital;

(2) the Joint commission on Accreditation of Hospitals’ plan of correction and interim self-evaluation or the American Osteopathic Association notice of noncompliances and progress report on correction of noncompliances are submitted to the commissioner simultaneous with the mailing or the receipt as the case may be;

[(1) [(3)] there are no constraints placed upon release of the Joint Commission on Accreditation of Hospitals’ accreditation agency survey report, plan of correction, interim self-evaluation report, or the American Osteopathic Association certificate of accreditation, notice on noncompliances, progress report on correction of noncompliances or such other material which the commissioner has accepted under this section; [or] and

(2) [(4)] the hospital is at all times subject to a survey for compliance with Part 405 of this Title as deemed necessary by the commissioner.

(b) The hospital shall notify the commissioner immediately upon receipt of notice in writing within seven days of failure to be accredited, re-accredited or the loss of accreditation by the [Joint Commission on Accreditation of Hospitals or the American
Osteopathic Association] accreditation agency with Centers for Medicare and Medicaid Services deeming status.


Section 751.11 is renumbered Section 751.12 to read as follows:

751.12 Validity

If any clause, sentence, paragraph or section of this Part shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph or section thereof directly involved in the controversy in which such judgment shall have been rendered.

A new Section 751.11 is added to read as follows:

751.11 Center Accreditation.
(a) Centers must comply with the operational standards set forth in this Article 6 of Subchapter C of Chapter V of this Title. The commissioner may accept as evidence of compliance with the minimum operational standards of this Article 6 of Subchapter C of Chapter V of this Title, accreditation by an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that centers so accredited are in compliance with such operational standards. The Commissioner can choose to enter into collaborative agreements with such accreditation agencies so that the accreditation agency’s accreditation survey can be used in lieu of a Departmental survey. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department’s website. These provisions shall apply provided that:

(1) there are no constraints placed upon release of the accreditation agency survey report, plan of correction, interim self-evaluation report, certificate of accreditation, notice on noncompliances, or such other material which the commissioner has accepted under this section; and

(2) the center is at all times subject to a survey for compliance with Article 6 of Subchapter C of Chapter V of this Title as deemed necessary by the commissioner.

(b) The center shall notify the commissioner in writing within seven days of failure to be accredited, re-accredited or the loss of accreditation by the accreditation agency.
Subdivision (f) of Section 755.2 is amended to read as follows:

When ambulatory surgery services are provided, the operator shall ensure that:

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(f) evidence of compliance with operational standards, as set forth in Section 751.11 of this Title, shall apply. [accreditation is obtained from either the Accreditation Association for Ambulatory Health Care (AAAHC) or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).] New facilities shall obtain accreditation from an accreditation agency to which the Centers for Medicare and Medicaid Services has granted deeming status and which the Commissioner has determined has accrediting standards sufficient to assure the Commissioner that ambulatory surgery services so accredited are in compliance with ambulatory surgery services operational standards under this Chapter within two full years of operation. [Facilities operational upon the effective date hereof shall obtain accreditation within one full year of such effective date.]
REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Sections 2800 and 2803(2) of the Public Health Law (PHL). Section 2800 of PHL Article 28 (Hospitals) specifies that “Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

PHL Section 2803(2) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.
Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

Section 720.1 of 10 NYCRR specifically requires hospitals to comply with operational standards set forth in Part 405 of 10 NYCRR and specifies that such hospitals are at all times subject to a survey for compliance with Part 405. Section 720.1 currently authorizes the Commissioner to accept as evidence of compliance with the minimum operational standards of Part 405, accreditation of The Joint Commission (TJC) or the American Osteopathic Association (AOA). Sections 405.1 and 700.2 of 10 NYCRR also refer to The Joint Commission and to the American Osteopathic Association as the national accreditation organizations that are authorized to issue certificates of accreditation to facilities certifying compliance with operational standards. Diagnostic and Treatment Centers (DT&Cs), whose provisions are set forth in 10 NYCRR Subchapter C, Article 6, are, like general hospitals, also Public Health Law Article 28 facilities that are surveyed for compliance with their operational standards. In addition to the TJC, Section 755.2 specifies that accreditation can be obtained for Free-Standing and Off-Site Hospital Based Ambulatory Surgery Centers from the Accreditation Association for Ambulatory Health Care (AAAHC).
Although the TJC and the AOA have been the 2 accrediting organizations predominantly used over the years, and in the case of Free-Standing and Off-Site Hospital Based Ambulatory Surgery Centers, also the AAAHC, additional accrediting organizations have come into existence and have been granted deeming status by the federal Centers for Medicare and Medicaid Services (CMS). Newer accrediting agencies are being utilized by hospitals and other facilities more and more, and recognized by CMS for federal surveillance purposes. At the same time more facilities are dropping their affiliation with the TJC, and various sections of Title 10 NYCRR limit the accreditation agencies for purposes of compliance with Department regulations to just the TJC, AOA, or the AAAHC. The Department of Health enters into collaborative agreements with approved accrediting agencies with the intent to reduce duplication of surveys.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity

This proposal is intended to reduce duplicative surveys, resulting in costs savings to the regulated parties. The regulated parties will also need to devote less staff time to the survey process.
Cost to State and Local Government:

The regulatory changes being sought could actually produce a cost savings for state and local governments. Any state or local government Article 28 general hospital or diagnostic and treatment center that chooses to be accredited by an accreditation agency with CMS deeming status for Medicare compliance would have the ability to select a more cost efficient option for accreditation with the expansion of approved agencies. Currently, when a facility drops its accreditation to TJC or AOA the state must perform routine surveys for that facility. This regulation may reduce the need for such surveys by the State because it broadens the number of accredited agencies for which the Department may accept accreditation as compliance with Department regulations.

Cost to the Department of Health:

These regulatory changes will be a cost savings as they will allow the Department to reduce duplicative surveys which require additional staff and resources.

Local Government Mandates:

None. The provisions do not add any additional mandates to local governments.
Paperwork:

No additional new paperwork will be required.

Duplication:

This proposal is intended to reduce duplicative surveys, saving costs and staff time for the Department and the regulated parties. These sought after regulatory changes for hospitals would eliminate the need for hospitals to notify the Department when successfully obtaining accreditation or re-accreditation from a CMS approved agency. The revised regulations will require diagnostic and treatment centers to notify the Department of any adverse accreditation decisions in order to bring consistency to the accreditation notification process for both hospitals and centers.

Alternative Approaches:

There are no other viable alternative approaches. Current provisions limit the accreditation agencies with which the State can enter into collaborative agreements. This proposal would allow for additional accreditation agencies whose accreditation would be acceptable evidence of compliance with Department standards. The proposed regulation would require such agencies to have CMS deeming status for Medicare compliance and be acceptable to the Commissioner. Agencies that meet those requirements will no longer be prohibited from being utilized by hospitals and diagnostic
and treatment centers in lieu of State routine surveys and the Commissioner can choose to enter into additional collaborative agreements which will reduce duplicative surveys. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department’s website.

**Federal Requirements:**

This regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas. This proposal is intended to reduce duplicative surveys, saving costs and staff time for the Department and the regulated parties.

**Compliance Schedule:**

This proposal will go into effect upon publication of a Notice of Adoption in the New York State Register.

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Effect of Rule:

General hospitals and diagnostic and treatment centers (DT&Cs) would be affected by this rule. Small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule would include: 3 hospitals and 234 diagnostic and treatment centers.

Compliance Requirements:

There will be no additional requirements for general hospitals. Centers must now notify the Department of accreditation decisions consistent with requirements for hospitals.

Professional Services:

This proposal does not require any additional professional services.

Compliance Costs:

There are no additional costs required to comply with this measure. It would reduce the cost of duplicative routine surveys for both the Department and the regulated parties. Staff time would also be saved.
Economic and Technological Feasibility:

This proposal is economically and technically feasible. As said above, it will eliminate the cost of duplicate surveys to determine compliance with operational standards. Facility and Department staff time will also be saved.

Minimizing Adverse Impact:

There will be no adverse impact to small businesses or local governments from this regulation. The revisions merely allow the Commissioner to accept as evidence of compliance with minimum operational standards, a facility’s accreditation from a Centers for Medicare and Medicaid Services (CMS) approved accreditation agency. Current regulations specify that such accreditation must be from TJC, AOA or the AAAHC in order to show evidence of compliance. This rule will allow other accreditation agencies to be utilized as long as they are CMS approved. Many facilities choose such other agencies for their accreditation and these regulatory changes recognize CMS expansion of approved agencies.

Small Business and Local Government Participation:

Outreach to the affected parties is being conducted. They include general hospitals, diagnostic and treatment centers and accreditation agencies. Organizations representing the affected parties can access notice of this proposal on the Department’s
website by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). The public, including any affected party, is invited to comment during the PHHPC Codes and Regulations Committee meeting.
RURAL AREA FLEXIBILITY ANALYSIS

Pursuant to section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural facilities defined within PHL Articles 28, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.
A Job Impact Statement is not included in accordance with Section 201-a (2) of the State Administrative Procedure Act (SAPA), because it will not have a substantial adverse effect on jobs and employment opportunities.
ASSESSMENT OF PUBLIC COMMENT

The public comment period ended on November 12, 2011 and the Department received one comment from the Clinton County Health Department. They recommended that this proposal be extended to Local Health Departments that have achieved national accreditation status with the Public Health Accreditation Board. Any accreditation agency that CMS has granted deeming status and which the Commissioner has determined that their accrediting standards are sufficient to assure that facilities so accredited are in compliance with the operational standards, can be authorized. The Public Health Accreditation Board has not been granted deeming status.

A change will not be made to these provisions.