

Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda and Informational Announcements

*April 6, 2017
10:00 AM*

- *Empire State Plaza, Concourse Level, Meeting Room 6, Albany*
- *New York State Department of Health Offices at 584 Delaware Avenue, 3rd Floor Video Conference Room, Buffalo, NY 14202*

A. Agenda

For Adoption

Amendment to Subpart 5-1 of Title 10 –
Public Water Systems

**TO BE DISTRIBUTED UNDER SEPARATE
COVER**

Program Area

Center for
Environmental
Health

Unit Representative

Dr. Roger Sokol

Amendment to Parts 86, 425 and 759 of Title 10 –
Adult Day Health Care Services for Registrants
with AIDS

**TO BE DISTRIBUTED UNDER SEPARATE
COVER**

AIDS Institute

Dr. Franklin Laufer

Amendment to Part 405 of Title 10 NYCRR –
Federal Conditions of Participation

Division of
Hospitals and
Diagnostic and
Treatment Centers

Ruth Leslie

For Discussion

Amendment to Part 710 of Title 10 – Certificate of
Need Review Thresholds

**TO BE DISTRIBUTED UNDER SEPARATE
COVER**

Program Area

Division of Health
Facility Planning

Unit Representative

George Macko

B. Information Announcements

1. Anyone wishing to make oral comments at this meeting should contact the Bureau of Policy and Standards Development by 11:00 A.M. on Wednesday, April 5, at 518-402-5914 to arrange for placement on the speakers' list. Please give your name, affiliation, if any and the agenda item(s) you wish to address. To ensure that all commenters have an opportunity to address the Committee, speakers should limit their comments to 3-4 minutes maximum.
2. All meeting attendees including Committee members are requested to sign the Attendance Sheet, which will be circulated in the meeting room.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval of the Commissioner of Health by Section 2803 of the Public Health Law, Part 405 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph (4) of subdivision (f) of section 405.2 is amended to read as follows:

(4) a physician, or a [registered physician's] licensed physician assistant under the general supervision of a physician, or a nurse practitioner in collaboration with a physician, is on duty at all times in the hospital except that the commissioner may approve substitute coverage, for all or part of each day, by each patient's attending physician when these physicians are immediately available to the hospital by telephone, and available in person or by telemedicine within [20] 30 minutes as needed, upon a hospital demonstrating to the commissioner that:

- (i) all patients are medically stable and patients who become medically unstable are promptly transferred to an appropriate receiving hospital in accordance with section 400.9 of this Title;
- (ii) the hospital does not operate an emergency service; and
- (iii) the entire hospital has less than 25 approved beds[;].

Paragraph (10) of subdivision (b) of section 405.3 is amended to read as follows:

(10) the provision for a physical examination and recorded medical history for all personnel including all employees, members of the medical staff, contract staff, students and volunteers, whose activities are such that a health impairment would pose a potential risk to patients. The examination shall be of sufficient scope to ensure that no person shall assume his/her duties unless he/she is free from a health impairment which is of potential risk to the patient or which might interfere with the performance of his/her duties, including the habituation or addiction to depressants, stimulants, narcotics, alcohol or other drugs or substances which may alter the individual's behavior. The hospital is required to provide such examination without cost for all employees who are required to have such examination. For personnel whose activities are such that a health impairment would neither pose a risk to patients nor interfere with the performance of his/her duties, the hospital shall conduct a health status assessment in order to determine that the health and well-being of patients are not jeopardized by the condition of such individuals. The hospital shall require the following of all personnel, with the exception of those physicians who are practicing medicine [from] from a remote location [outside of New York State], as a condition of employment or affiliation:

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Paragraph (3) of subdivision (b) of section 405.5 is amended to read as follows:

(3) Written nursing care plans shall be kept current. Such plans shall indicate what nursing care is needed, how it is to be provided, and the methods, approaches and mechanisms for ongoing modifications necessary to ensure the most effective and beneficial results for the patient. Patient education and patient/family knowledge of care requirements shall be included in the nursing plan. The nursing care plan may be integrated into the overall interdisciplinary plan of care.

Subdivision (c) of section 405.5 is amended to read as follows:

(c) *Administration of drugs.* All drugs and biologicals shall be administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care as specified under section 405.2 of this Part, and generally accepted standards of practice. They shall be administered by a licensed physician or registered professional nurse, or other personnel in accordance with applicable licensing requirements of title 8 of the New York State Education Law, except for the self-administration of medications as set forth in paragraphs (4) and (5) of this subdivision, and in accordance with [approved] hospital policies and procedures. For purposes of this subdivision, "self-administration" means administration by the patient or the patient's caregiver, including but not limited to a caregiver pursuant to section 2994-ii(3) of the Public Health Law, or a designated caregiver pursuant to section 3360(5) of the Public Health Law.

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(4) Hospitals, in accordance with hospital policies and procedures, may authorize hospital-issued prescription and non-prescription medications to be self-administered, provided that:

(i) a practitioner responsible for the care of the patient in the hospital has issued an order permitting self-administration;

(ii) the capacity of the patient or the patient's caregiver to administer the medication has been assessed;

(iii) the patient or the patient's caregiver has been given instructions for the safe and accurate administration of the medication;

(iv) the security of the medication is addressed; and

(v) documentation is made of the administration of each medication in the patient's record, as reported by the patient or the patient's caregiver.

(5) Hospitals, in accordance with hospital policies and procedures, may authorize a patient to bring in his or her own medications, including prescription medications, non-prescription medications and medical marihuana as defined in section 3360(8) of the Public Health Law, and self-administer such medications, provided that:

(i) a practitioner responsible for the care of the patient in the hospital has issued an order permitting self-administration of the medication the patient brought into the hospital, and in the case of medical marihuana, upon presentation of the patient or designated

caregiver's registry identification card issued pursuant to section 3363 of the Public Health Law;

(ii) the capacity of the patient or the patient's caregiver to administer the medication has been assessed;

(iii) a determination is made concerning whether the patient or the patient's caregiver needs instruction on the safe and accurate administration of the medication;

(iv) the medication is identified and visually evaluated for integrity;

(v) the security of the medication is addressed;

(vi) documentation is made of the administration of each medication in the patient's record, as reported by the patient or the patient's caregiver; and

(vii) if a patient dies in the hospital, any unused prescription medication shall be destroyed or disposed of in accordance with all applicable state and federal laws and regulations. Such prescription medications may not be turned over to the patient's caregiver. In the case of medical marihuana, it may be turned over to the deceased patient's designated caregiver or to appropriate law enforcement for destruction or disposal.

Paragraph (8) of subdivision (c) of section 405.10 is amended to read as follows:

(8) The hospital shall implement policies and procedures regarding the use and authentication of verbal orders, including telephone orders. [Such orders shall be used sparingly, shall be accepted, recorded and authenticated only in accordance with

applicable scope of practice provisions for licensed, certified or registered practitioners, consistent with Federal and State law, and with hospital policies and procedures and shall be authenticated by the prescribing practitioner or, until January 26, 2012, by another practitioner responsible for the care of the patient and authorized to write such an order, within 48 hours, also in accordance with such policies and procedures and Federal and State law.] Such policies and procedures must:

- (i) Specify the process for accepting and documenting such orders;
- (ii) Ensure that such orders will be issued only in accordance with applicable scope of practice provisions for licensed, certified or registered practitioners, consistent with Federal and State law; and
- (iii) Specify that such orders must be authenticated by the prescribing practitioner, or by another practitioner responsible for the care of the patient and authorized to write such orders and the time frame for such authentication.

Subparagraph (ii) of paragraph (1) of subdivision (d) of section 405.19 is amended to read as follows:

405.19 Emergency services.

- (ii) There shall be at least one emergency service attending physician on duty 24 hours a day, seven days a week. For hospitals that exceed

15,000 unscheduled visits annually, the attending physician shall be present and available to provide patient care and supervision in the emergency service. As necessitated by patient care needs, additional attending physicians shall be present and available to provide patient care and supervision. Appropriate subspecialty availability as demanded by the case mix shall be provided promptly in accordance with patient needs. For hospitals with less than 15,000 unscheduled emergency visits per year, the supervising or attending physician need not be present but shall be available within 30 minutes of patient presentation, in person or by telemedicine, provided that at least one physician, nurse practitioner, or licensed physician assistant shall be on duty in the emergency service 24 hours a day, seven days a week. The hospital shall develop and implement protocols specifying when physicians must be present.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the promulgation of this regulation is contained in Public Health Law (PHL) section 2803. Section 2803 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 and promotion of the health of the residents of New York State by requiring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

This regulation amends Sections 405.2 (Governing Body), 405.3 (Administration), 405.5 (Nursing Services), 405.10 (Medical Records), and 405.19 (Emergency Services).

The Centers for Medicare and Medicaid Services (CMS) requires hospitals to meet specified Conditions of Participation (CoPs) in order to participate in the federal Medicare and Medicaid programs. The CoPs outline the basic requirements related to a

hospital's structure, operations and delivery of patient care. The intent is to protect the health and safety of patients. CMS reviewed the existing CoPs and made numerous changes effective on July 16, 2012. 77 Fed. Reg. 29034 (May 16, 2012). As a result, New York State general hospital regulations are being revised to reflect the federal changes.

Sections 405.2(f)(4) and 405.19(d)(1)(ii) are being amended to create a consistent 30 minute timeframe for a physician to be available to patients, and to clarify that such availability may be provided in person or by telemedicine. Current regulations require this to occur in 20 minutes and do not mention telemedicine. Section 405.3(b)(10) is amended to provide that the existing exemption for immunization requirements applies to remote locations within New York State.

Section 405.5(b)(3) permits a nursing care plan to be integrated into the overall interdisciplinary plan of care.

Consistent with changes to the federal CoPs, section 405.5(c) allows patients to self-administer certain medications. Federal regulations at 42 CFR § 482.23(c)(6) allow hospitals the flexibility to develop and implement policies and procedures for a patient and his or her caregivers/support persons to self-administer specific medications (such as non-controlled drugs and biologicals). See 77 Fed. Reg. 29048 (May 16, 2012). In addition, section 405.10(c)(8) changes the requirements for verbal orders by removing the requirement that verbal orders be authenticated within 48 hours. In addition, these

regulations permit self-administration of medical marijuana, subject to appropriate conditions and restrictions.

Costs:

Allowing the supervising or attending physician to be available by telemedicine rather than in person, and within 30 minutes instead of 20 minutes, should not cause hospitals to incur additional costs. No additional costs should be incurred from the provision clarifying that the existing exemption for immunization requirements applies to remote locations within New York State. The provision to permit the nursing care plan to be integrated into the overall interdisciplinary plan of care should incur no additional costs. Authorization for the use and authentication of verbal orders including telephone orders may require updating policies and procedures. The provision authorizing hospitals to develop policies and procedures regarding self-administration is permissive rather than mandatory.

Local Government Mandates:

This provision does not impose any additional mandates on local governments.

Paperwork:

As noted above, policies and procedures will need to be developed and/or updated for authorization for the use and authentication of verbal orders, including telephone orders. Hospitals that authorize medications to be self-administered will need to document the administration of each medication in the patient's record.

Duplication:

This regulation does not duplicate any other State or federal regulation.

Alternatives:

The Department reviewed the federal Conditions of Participation (CoPs) against what is currently in the Part 405 regulations. The related amendments to Part 405 are needed to make State regulation consistent with federal regulation. An alternative of not including medical marijuana as a medication that can be self-administered was considered; however, the Department determined that its inclusion would help facilitate the administration of medical marijuana products in healthcare facilities and ensure continued access for patients.

Federal Standards:

This proposal does not conflict or duplicate federal provisions. These amendments amend the general hospital provisions to reflect the federal CoP.

Compliance Schedule:

This proposed amendment will become effective upon publication of a Notice of Adoption in the *New York State Register*.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulation amends Part 405 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, to reflect changes made by the Centers for Medicare and Medicaid Services' (CMS) Conditions of Participation (CoPs) in order to participate in the federal Medicare and Medicaid programs. The proposed regulatory amendments will impact small businesses and local governments that operate hospitals pursuant to Part 405.

Compliance Requirements:

Sections 405.2(f)(4) and 405.19(d)(1)(ii) are being amended to create a consistent 30 minute timeframe for a physician to be available to patients, and to clarify that such availability may be provided in person or by telemedicine. Current regulations require this to occur in 20 minutes and do not mention telemedicine. Section 405.3(b)(10) is amended to provide that the existing exemption for immunization requirements applies to remote locations within New York State.

Section 405.5(b)(3) permits a nursing care plan to be integrated into the overall interdisciplinary plan of care.

Consistent with changes to the federal CoPs, section 405.5(c) allows patients to self-administer certain medications. Federal regulations at 42 CFR § 482.23(c)(6) allow hospitals the flexibility to develop and implement policies and procedures for a patient and his or her caregivers/support persons to self-administer specific medications (such as non-controlled drugs and biologicals). See 77 Fed. Reg. 29048 (May 16, 2012). In addition, section 405.10(c)(8) changes the requirements for verbal orders by removing the requirement that verbal orders be authenticated within 48 hours. In addition, these regulations permit self-administration of medical marijuana, subject to appropriate conditions and restrictions.

Professional Services:

Practitioners who are responsible for the care of patients and the nursing staff will need to adhere to the policies and procedures regarding the use and authentication of verbal orders, including telephone orders, in accordance with applicable scope of practice provisions for licensed, certified or registered practitioners consistent with Federal and State law. To the extent a hospital adopts policies and procedures allowing for medications to be self-administered, practitioners and nursing staff will also need to adhere to such policies and procedures.

Compliance Costs:

Allowing the supervising or attending physician to be available by telemedicine rather than in person, and within 30 minutes instead of 20 minutes, should not cause hospitals to incur additional costs. No additional costs should be incurred from the

provision clarifying that the existing exemption for immunization requirements applies to remote locations within New York State. The provision to permit the nursing care plan to be integrated into the overall interdisciplinary plan of care should incur no additional costs. Authorization for the use and authentication of verbal orders including telephone orders may require updating policies and procedures. The provision authorizing hospitals to develop policies and procedures regarding self-administration is permissive rather than mandatory.

Economic and Technological Feasibility:

This proposal is economically and technologically feasible. The amendments provide greater flexibility or require only modest updating to policies and procedures. The provisions regarding self-administration are permissive, rather than mandatory.

Minimizing Adverse Impact:

For the reasons stated above, there is no adverse impact.

Small Business and Local Government Participation:

Outreach to the affected parties is being conducted. Organizations who represent the affected parties and the public can also obtain the agenda of the Codes, Regulations and Legislation Committee of the Public Health and Health Planning Council (PHHPC) and the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes, Regulations and Legislation Committee meeting.

Dear Chief Executive Officer (CEO) letters will be sent to affected parties explaining the changes proposed as a result of the federal CoPs.

RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed amendment that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administration Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment, that it will have no impact on jobs and employment opportunities.