

Potentially Preventable Negative Outcomes

Effective date: 12/6/11

Pursuant to the authority vested in the Commissioner of Health by section 2807-c(35) of the Public Health Law, Subpart 86-1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, effective on or after July 1, 2011, by adding a new section 86-1.42 to read as follows:

86-1.42 Potentially preventable negative outcomes.

(a) Effective for discharges occurring on or after July 1, 2011, payments pursuant to this Subpart shall be denied with regard to the following potentially preventable negative outcomes if they are acquired during a patient's inpatient stay at the hospital seeking such payments:

- (1) A foreign object retained within a patient's body after surgery.
- (2) The development of an air embolism within a patient's body.
- (3) A patient blood transfusion with incompatible blood.
- (4) A patient's development of stage III or stage IV pressure ulcers.
- (5) Patient injuries resulting from accidental falls and other trauma, including, but not limited to:
 - i. Fractures
 - ii. Dislocations
 - iii. Intracranial injuries
 - iv. Crushing injuries

v. Burns

vi. Electronic shock

(6) A patient's manifestations of poor glycemic control, including, but not limited to:

i. Diabetic ketoacidosis

ii. Nonketotic hyperosmolar coma

iii. Hypoglycemic coma

iv. Secondary diabetes with ketoacidosis

v. Secondary diabetes with hyperosmolarity

(7) A patient's development of a catheter-associated urinary tract infection.

(8) A patient's development of a vascular catheter-associated infection.

(9) A patient's development of a surgical site infection following:

i. a coronary artery bypass graft – mediastinitis;

ii. bariatric surgery, including, but not limited to, laparoscopic gastric bypass, gastroenterostomy, and laparoscopic gastric restrictive surgery; or

iii. orthopedic procedures, including, but not limited to, such procedures performed on the spine, neck, shoulder and elbow.

(10) A patient's development of deep vein thrombosis or a pulmonary embolism in connection with a total knee replacement or a hip replacement, excluding pediatric patients, defined as patients under eighteen years of age, and also excluding obstetric

patients, defined as patients with at least one primary or secondary diagnosis code that includes an indication of pregnancy.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The requirement to deny reimbursement for hospital acquired conditions, which are avoidable hospital complications and medical errors that are identifiable, preventable, and serious in their consequences to patients, is set forth in section 2807-c(35)(b)(v) of the Public Health Law, as amended by section 35-a of Part H of Chapter 59 of the Laws of 2011. Further, section 111(a) of Part H of Chapter 59 of the Laws of 2011 permits such regulations to be implemented retroactively.

Legislative Objectives:

The Legislature chose to address the issue of patient safety and quality of care through this proposal, which denies reimbursement for hospital acquired conditions. The proposal is also the result of a federal requirement and recommendations submitted by the Medicaid Redesign Team.

Needs and Benefits:

The Patient Protection & Affordable Care Act (HR 3590) requirement, effective on or after July 1, 2011, mandates states to implement a policy for Medicaid that prohibits federal payments for any costs of providing medical assistance for hospital acquired conditions (HACs). This proposal appropriately implements those requirements. HACs are conditions deemed to be reasonably preventable in accordance with evidence-based guidelines. Healthcare providers, patients and payers are all adversely impacted by the occurrence of HACs.

This proposal offers more direct and accountable reimbursement of healthcare services, thereby incentivizing providers to improve quality and provide higher valued healthcare for Medicaid beneficiaries.

COSTS:

Costs to State Government:

Section 2807-c(35)(b)(v) of the Public Health Law requires that the rates of payment for hospital inpatient services do not include, for APR-DRG assignment purposes, any conditions as a secondary diagnosis that were not present on admission and are therefore deemed a HAC. Since less than 0.1% of total Medicaid discharges (2009 data) were found to include a HAC, the denial in reimbursement results in an insignificant decrease in aggregate Medicaid payments.

Costs of Local Government:

There will be no additional cost to local governments as a result of these amendments.

Costs to the Department of Health:

There will be no additional costs to the Department of Health as a result of this amendment.

Local Government Mandates:

The proposed amendment does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

There is no additional paperwork required of providers as a result of this amendment.

Duplication:

These regulations do not duplicate existing State and federal regulations.

Alternatives:

No significant alternatives are available. New York State is required by federal regulations to implement a policy, and the Department is required by the Public Health Law sections 2807-c(35)(b)(v) to promulgate implementing regulations.

Federal Standards:

This amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

Section 86-1.42 requires reimbursement for hospital acquired conditions, which are avoidable hospital complications and medical errors that are identifiable, preventable, and serious in their consequences, to be denied effective on or after July 1, 2011; there is no period of time necessary for regulated parties to achieve compliance.

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**REGULATORY FLEXIBILITY ANALYSIS
FOR
SMALL BUSINESS AND LOCAL GOVERNMENTS**

Effect on Small Business and Local Governments:

For the purpose of this regulatory flexibility analysis, small businesses were considered to be general hospitals with 100 or fewer full time equivalents. Based on recent financial and statistical data extracted from the Institutional Cost Report, seven hospitals were identified as employing fewer than 100 employees.

Health care providers subject to the provisions of this regulation under section 2807-c(35)(b)(v) of the Public Health Law will not be reimbursed for any cost associated with the ten identified categories of hospital acquired conditions. Using 2009 Medicaid data, a total of 728 HACs were identified, accounting for less than 0.1% of total Medicaid discharges.

This rule will have no direct effect on local governments.

Compliance Requirements:

No new reporting, record keeping or other compliance requirements are being imposed as a result of these rules. Affected health care providers will bill Medicaid using procedure codes and ICD-9 codes approved by the American Medical Association, as is currently required.

The rule should have no direct effect on local governments.

Professional Services:

No new or additional professional services are required in order to comply with the proposed amendments.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule, nor will there be an annual cost of compliance. As a result of this proposal there will be a minimal decrease in hospital Medicaid revenues for hospital inpatient services that include HACs.

Economic and Technical Feasibility:

Small businesses will be able to comply with the economic and technological aspects of this rule. The proposed amendments are technologically feasible because it requires the use of existing technology. The overall economic impact to comply with the requirements of this regulation is expected to be minimal.

Minimizing Adverse Impact:

The proposed amendments reflect statutory intent and requirements.

Small Business and Local Government Participation:

Hospital associations participated in discussions and contributed comments through the State's Medicaid Redesign Team process regarding these changes.

RURAL AREA FLEXIBILITY ANALYSIS

Effect on Rural Areas:

Rural areas are defined as counties with a population less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 150 persons or less per square mile. The following 43 counties have a population less than 200,000:

Allegany	Hamilton	Schenectady
Cattaraugus	Herkimer	Schoharie
Cayuga	Jefferson	Schuyler
Chautauqua	Lewis	Seneca
Chemung	Livingston	Steuben
Chenango	Madison	Sullivan
Clinton	Montgomery	Tioga
Columbia	Ontario	Tompkins
Cortland	Orleans	Ulster
Delaware	Oswego	Warren
Essex	Otsego	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming
Genesee	St. Lawrence	Yates
Greene		

The following 9 counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Erie	Oneida
Broome	Monroe	Onondaga
Dutchess	Niagara	Orange

Compliance Requirements:

No new reporting, record keeping, or other compliance requirements are being imposed as a result of this proposal.

Professional Services:

No new additional professional services are required in order for providers in rural areas to comply with the proposed amendments.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule, nor is there an annual cost of compliance.

Minimizing Adverse Impact:

The proposed amendments reflect statutory intent and requirements.

Rural Area Participation:

This amendment is the result of federal requirement, effective on or after July 1, 2011, that requires states to implement a policy for Medicaid that prohibits federal payments for any costs of providing medical assistance for hospital acquired conditions (HACs).

JOB IMPACT STATEMENT

A Job Impact Statement is not required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature and purpose of the proposed rules, that they will not have a substantial adverse impact on jobs or employment opportunities. The proposed regulations establish quality-related measures pertaining to the reimbursement for hospital acquired conditions. The proposed regulations have no implications for job opportunities.

EMERGENCY JUSTIFICATION

It is necessary to issue the proposed regulations on an emergency basis in order to meet the statutory timeframes prescribed by Section 2807-c(35)(b)(v) of the Public Health Law, as amended by Chapter 59 of the Laws of 2011 related to the reimbursement for hospital acquired conditions. The Centers for Medicare and Medicaid Services (CMS) issued a final rule prohibiting Medicaid payments to providers for conditions that are reasonably preventable, referred to as hospital acquired conditions, effective on or after July 1, 2011. The proposed regulations will comply with CMS regulations.

Public Health Law section 2807-c(35), as amended by Chapter 59 of the Laws of 2011, Part H, §35-a, specifically provides the Commissioner of Health with authority to issue these emergency regulations.

Further, there is compelling interest in enacting these regulations immediately in order to secure federal approval of the associated Medicaid State Plan Amendment.