

Authority to Collect Pharmacy Acquisition Cost

Effective date: 1/25/12

Pursuant to the authority vested in the Commissioner of Health by sections 201(1)(v) and 206 of the Public Health Law, sections 363-a(2) and 367-a(9)(b) of the Social Services Law and section 111(t) of Part H of Chapter 59 of the Laws of 2011, section 505.3 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to read as follows, to be effective upon filing with the Department of State:

Paragraphs (3) through (6) of subdivision (a) of section 505.3 are renumbered as paragraphs (4) through (7) and new paragraph (3) is added to read as follows:

(3) Drug acquisition cost means the invoice price to the pharmacy of a prescription drug dispensed to a Medicaid recipient, minus the amount of all discounts and other cost reductions attributable to such dispensed drug.

Paragraph (4) is added to subdivision (f) of section 505.3 to read as follows:

(4) Each pharmacy enrolled in the Medicaid program shall provide the department, in such manner, for such periods, and at such times as the department may require, with the drug acquisition cost, as defined in paragraph 505.3(a)(3), of prescription drugs.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Social Services Law (SSL) section 363-a and Public Health Law section 201(1)(v) provide that the Department is the single state agency responsible for supervising the administration of the State's medical assistance ("Medicaid") program and for adopting such regulations, not inconsistent with law, as may be necessary to implement the State's Medicaid program.

Legislative Objective:

On April 1, 2011, the Legislature and Medicaid Redesign Team adopted a proposal to amend Medicaid drug payment methodology, as defined in SSL section 367-a(9)(b), to include average acquisition cost (AAC), when available. To meet Legislative objectives, a rule is needed to require each enrolled pharmacy to report actual acquisition cost of a prescription drug to the Department in a manner specified by the Department. This rule will enable the Department to collect actual acquisition cost, analyze the data and establish a statistically valid and transparent AAC.

Needs and Benefits:

The requirement to report acquisition cost is necessary in order to effectuate the inclusion of AAC in the New York State Medicaid drug reimbursement methodology. Under the fee-for-service pharmacy program, Medicaid reimburses pharmacy services based on a "lower of" methodology that includes the pharmacy's usual and customary charge; Estimated Acquisition Cost (EAC); Federal Upper Limit (FUL); State Maximum Allowable Cost (SMAC); Average

Wholesale Price (AWP) minus a percentage; Wholesale Acquisition Price (WAC) plus a percentage; or AAC, if available.

Once a valid AAC and appropriate dispensing fee is established, the Department intends to seek approval to replace the “lower of” methodology with AAC as the pricing threshold. The rationale for moving to AAC is to establish a transparent pharmacy reimbursement system and to do so with stakeholder involvement and support. There are numerous rulings in both state and federal courts that solidly establish a pattern of inflated, inaccurate or fraudulent pricing resulting from current standard reimbursement benchmarks supplied by drug manufacturers, such as AWP or WAC. Once established, use of AAC allows the State to set reimbursement rates based on an actual acquisition cost (invoice data) and an appropriate dispensing fee. The comprehensive, statewide data collection resulting from the reporting of acquisition cost will allow for a thorough, statistically valid analysis of pricing, including an evaluation of outliers, and the development of a legitimate AAC. Without this data, AAC cannot be established.

COSTS:

Costs for the Implementation of, and Continuing Compliance with this Regulation to the Regulated Entity:

Regulated entities could potentially incur minimal costs related to this amendment; such costs would be limited to administrative costs of identifying acquisition cost and any system updates needed to report such costs.

Costs to State and Local Government:

This amendment will not increase costs to the State or local governments.

Costs to the Department of Health:

The Department could incur minimal administrative costs related to the collection, analysis and maintenance of acquisition costs.

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:

This amendment could potentially impose additional paperwork for regulated entities if collection of acquisition cost is done through the use of a hard copy survey tool rather than electronic submission.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The only potential alternative to requiring the reporting of acquisition cost is a voluntary survey, which is not considered feasible as it would not provide a statistically valid sample of costs.

Federal Standards:

The proposed regulations do not exceed any minimum federal standards.

Compliance Schedule:

The Department will work closely with regulated entities to ensure they are able to comply with the proposed regulation when it becomes effective.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENT

Effect of Rule:

This amendment affects the approximately 4,400 pharmacy providers enrolled in the Medicaid program that actively bill Medicaid for drugs. This amendment will require these businesses, some of which are small, to identify and report the acquisition cost of drugs dispensed to fee-for-service Medicaid beneficiaries. Medicaid will ultimately address additional costs with the development of an increased dispensing fee that regulated entities will participate in establishing.

The fifty-eight local social services districts share in the costs of services provided to eligible beneficiaries who receive Medicaid through their districts and would therefore benefit from a more transparent pharmacy reimbursement benchmark.

Compliance Requirements:

Small businesses will be required to identify the acquisition cost of drugs and report that cost to the Department in a manner to be specified by the Department. This amendment does not impose any new reporting, recordkeeping or other compliance requirements on local governments.

Professional Services:

No new professional services are required as a result of this amendment.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule. However, regulated entities, which include small businesses, could potentially incur minimal costs related to this

amendment; such costs would be limited to administrative costs of identifying acquisition cost and any system updates needed to report such costs. Initial administrative costs and compliance costs for regulated entities will vary and will be dependent on each entity's product wholesalers and/or software vendors. Medicaid will address compliance costs with the development of an increased dispensing fee that regulated small businesses will participate in establishing.

There are no direct costs associated with this amendment for local governments.

Economic and Technological Feasibility:

The amendment requires regulated entities to submit additional information for drugs billed under the fee-for-service Medicaid program but will not affect the way local districts contribute their local share of Medicaid expenses for drugs. Therefore, there should be no technological difficulties associated with compliance with the proposed regulation for local governments and minimal, if any, technological difficulties for small businesses.

Minimizing Adverse Impact:

By engaging regulated entities in the development of procedures for reporting acquisition cost, the Department will minimize any adverse impact on small businesses. Additionally, the Department will work with small businesses to develop an appropriate dispensing fee that accurately reflects the costs associated with this amendment.

Small Business and Local Government Participation:

The Department meets on a regular basis with provider groups representing regulated entities, such as the Pharmacists Society of the State of New York (PSSNY) and the National Association of Chain Drug Stores (NACDS). Both of these groups have been informed of the proposed changes and have expressed concerns over administrative burdens. However, representatives of regulated entities have also welcomed the opportunity to collaborate with the

Department in development of the proposed process. Upon promulgating the regulation, the Department will continue to work with the industry and assist as necessary with implementation of the new requirement.

Local government officials have consistently urged the Department to implement Medicaid cost savings programs.

RURAL AREA FLEXIBILITY ANALYSIS

Effect on Rural Areas:

The proposed amendment will apply to approximately 4,400 Medicaid enrolled pharmacy providers. These regulated entities are located in rural, as well as suburban and metropolitan areas of the State.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

Regulated entities in rural areas will be required to identify the acquisition cost of drugs and report that cost to the Department in a manner to be specified by the Department. No new professional services will be required as a result of this amendment.

Costs:

Regulated entities in rural areas could potentially incur minimal costs related to this amendment; such costs would be limited to administrative costs of identifying acquisition cost and any system updates needed to report such costs. Initial administrative costs and compliance costs will vary and will be dependent on each entity's product wholesalers and software vendors. Medicaid will address compliance costs with the development of an increased dispensing fee that regulated entities in rural areas will participate in establishing.

Minimizing Adverse Impact:

By engaging regulated entities in rural areas in the development of procedures for reporting acquisition cost, the Department will minimize any adverse impact. Additionally, the Department will work with regulated entities in rural areas to develop an appropriate dispensing fee that accurately reflects the costs associated with this amendment.

Rural Area Participation:

The Department meets on a regular basis with provider groups representing regulated entities, such as the Pharmacists Society of the State of New York (PSSNY) and the National Association of Chain Drug Stores (NACDS). While both of these groups have expressed concerns over administrative burdens, representatives of regulated entities have welcomed the opportunity to collaborate with the Department in development of the proposed process and an appropriate dispensing fee. Upon promulgating the regulation, the Department will continue to work with the regulated entities in rural areas and assist as necessary with implementation of the new requirement.

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 regulation, that there will not be a substantial adverse impact on jobs or employment opportunities.

EMERGENCY JUSTIFICATION

Chapter 59 of the laws of 2011 enacted a number of proposals recommended by the Medicaid Redesign Team established by the Governor to reduce costs and increase quality and efficiency in the Medicaid program. The change to SSL section 367-a, which incorporates the use of Average Acquisition Cost (AAC) in the drug reimbursement methodology takes effect April 1, 2011. Without actual acquisition cost data, the Department is unable to move forward with development of AAC. Paragraph (t) of section 111 of Part H of Chapter 59 authorizes the Commissioner to promulgate, on an emergency basis, any regulations needed to implement such law. The Commissioner has determined it necessary to file this regulation on an emergency basis to achieve the savings intended to be realized by the Chapter 59 provisions.