

Pursuant to the authority vested in the Commissioner of Health by sections 363-a(2) of the Social Services Law and section 201(1)(v) of the Public Health Law, section 505.5 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended to read as follows, effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (4) of subdivision (a) of section 505.5 is amended to read as follows:

(4) *Orthopedic footwear* means shoes, shoe modifications, or shoe additions which are used [as follows: in the treatment of children,] to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; [in the treatment of children,] or to support a weak or deformed structure of the ankle or foot [; as a component of a comprehensive diabetic treatment plan to treat amputation, ulceration, pre-ulcerative calluses, peripheral neuropathy with evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace]. Orthopedic shoes must have, at a minimum, the following features:

Subdivision (g) of section 505.5 is amended to read as follows:

(g) Benefit limitations. The department shall establish defined benefit limits for certain Medicaid services as part of its Medicaid State Plan. The department shall not allow exceptions to defined benefit limitations. The department has established defined benefit limits on [the following services: (1) Compression and surgical stockings are limited to coverage during pregnancy and for venous stasis ulcers.

(2) Orthopedic footwear is limited to coverage in the treatment of children to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or

injured part of the ankle or foot; in the treatment of children to support a weak or deformed structure of the ankle or foot; as a component of a comprehensive diabetic treatment plan to treat amputation, ulceration, pre-ulcerative calluses, peripheral neuropathy with evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace.

(3) enteral nutritional formulas. Enteral nutritional formulas are limited to coverage for:

[(i)] (1) tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube;

[(ii)] (2) individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means;

[(iii)] (3) children under age 21 when caloric and dietary nutrients from food cannot be absorbed or metabolized; and

[(iv)] (4) persons with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed and who:

[(a)] (i) require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; or

[(b)] (ii) require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 22 as defined by the Centers for Disease Control and a documented, unintentional weight loss of five percent or more within the previous six month period, up to 1,000 calories per day; or

[(c)] (iii) require total nutritional support, have a permanent structural limitation that prevents the chewing of food, and the placement of a feeding tube is medically contraindicated.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Social Services Law (“SSL”) § 363-a(2) and Public Health Law § 201(1)(v) empower the Department to adopt regulations, not inconsistent with law, necessary to implement the State’s Medical Assistance (“Medicaid”) program.

Legislative Objectives:

The proposed regulations would amend the Department’s regulations governing Medicaid coverage of orthopedic footwear and compression and support stockings (collectively referred to as “compression stockings”) consistent with recent judicial case law: the permanent injunction order in the federal class action, Davis et al. v. Shah (“Davis”), W.D.N.Y. (12-CV-6134-CJS-MWP, July 1, 2016.). The proposed regulations are thus consistent with the Legislature’s objective in enacting the statutory authority for the State’s Medicaid program.

Needs and Benefits:

The proposed regulations are necessary to align the Department’s regulations to the July 1, 2016, permanent injunction order in Davis.

Prior to April 2011, the Medicaid program covered orthopedic footwear for any physical deformity, range of motion malfunction, or foot or ankle weakness. It also covered compression stockings to treat clinically significant medical conditions, such as open wounds, and complications in pregnancy as well as for relatively less serious purposes, such as circulatory improvement and wound prevention.

As part of the Medicaid Redesign Team initiatives adopted in April 2011, the Legislature limited the Medicaid program’s coverage of orthopedic footwear and compression

stockings. Under the new State law, Medicaid payment for these items could be made only for orthopedic footwear and compression stockings furnished to Medicaid recipients who had certain specified medical conditions or diagnoses. Orthopedic footwear was covered only when used as an integral part of a lower limb orthotic appliance, as part of a diabetic treatment plan, or to address growth and development problems in children. [Social Services Law (“SSL”) § 365-a(2)(g)(iii)]. Compression stockings were covered only for pregnancy or treatment of venous stasis ulcers. [SSL § 365-a(2)(g)(iv)]. The Department adopted conforming amendments to its Medicaid regulations at 18 NYCRR § 505.5.

The Legislature adopted the benefit limitations on orthopedic footwear and compression stockings during a period of State and national fiscal crisis. It was felt that the State must establish priorities for Medicaid coverage, particularly with regard to optional Medicaid services, such as orthopedic footwear and compression stockings, that federal law permits, but does not require, states to include in their Medicaid programs. Accordingly, the Legislature determined to give priority, in the allocation of public Medicaid monies, to the intensive medical needs of recipients with serious medical conditions, including children; pregnant women; and persons afflicted with serious conditions such as venous stasis ulcers and complications related to diabetes. A consequence of these benefit limits, however, was that Medicaid recipients with non-covered medical conditions or diagnoses could no longer obtain these items through Medicaid, even when these items were medically necessary for their particular conditions or diagnoses.

In 2012, a proposed class of Medicaid recipients sued in Davis to overturn the 2011 benefit limitations as violating various provisions of the federal Medicaid Act and the Americans with Disabilities Act. In January 2013, the federal district court certified the case as a class

action and, in December 2013, permanently enjoined the Department from enforcing the new State law and regulations. In March 2016, the U.S. Court of Appeals for the Second Circuit affirmed the district court's ruling that the State's benefit limits violated the Medicaid Act's comparability provisions (requiring that any services to any categorically needy recipient are not less in amount, duration and scope than services available to any categorically or medically needy recipients), while remanding the matter to the district court for further proceedings. (Davis et al. v. Shah, 821 F.3d. 231). The district court's July 1, 2016 order permanently enjoins the Department from enforcing the benefit limits on orthopedic shoes and compression stockings set forth in SSL § 365-a(2)(g)(iii) and (iv) and in 18 NYCRR § 505.5. The Department is further directed to make necessary amendments to such regulations consistent with the July 1, 2016, permanent injunction order.

The proposed regulations would amend the Department's regulations governing reimbursement for orthopedic footwear and compression stockings consistent with the court-ordered July 1, 2016, permanent injunction in Davis.

Costs to Regulated Parties:

Regulated parties include enrolled providers that actively bill the Medicaid program for orthopedic footwear and enrolled providers that actively bill the Medicaid program for compression stockings. The proposed regulations would not affect these providers' costs. During the approximately 20 months that the Department applied these benefit limits (April 2011 to December 2013), these Medicaid providers could not claim Medicaid reimbursement for orthopedic footwear and compression stockings sought by Medicaid recipients with non-covered conditions or diagnoses. However, after the district court enjoined the Department's enforcement of these benefit limits in December 2013, Medicaid providers were able to resume

claiming for orthopedic shoes and compression stockings pursuant to the standards in effect prior to April 2011.

Costs to State Government:

The proposed regulations will not affect the State's share of Medicaid costs. They merely amend the Department's regulations so that these regulations are consistent with the federal district court's July 1, 2016, permanent injunction order in Davis. In April 2011, when the benefit limits were adopted, it was anticipated that State share Medicaid savings would be approximately \$14.6 million for State Fiscal Year 2011-12. However, the Department has not realized such savings since on or about December 2013, when the federal district court first enjoined the Department from enforcing the benefit limits.

Costs to Local Government:

Social services districts would not incur any additional expense as a result of the proposed regulations. State law limits the amount that districts must pay for Medicaid services provided to district recipients.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

The proposed regulations do not impose any mandates on social services districts or any other unit of local government.

Paperwork:

The proposed regulations do not impose any reporting or paperwork requirements.

Duplication:

The proposed regulations do not duplicate any existing federal, state or local regulations.

Alternatives:

There are no alternatives to the proposed regulations. The Department's regulations governing orthopedic shoes and compression stockings must be consistent with the district court's permanent injunction in Davis.

Federal Standards:

The proposed regulations do not exceed any minimum federal standards.

Compliance Schedule:

Regulated parties will be able to comply with the regulations when they become effective.

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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

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed regulations, that they would not have a substantial adverse impact on jobs and employment opportunities.