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¦ LOCAL COMMISSIONERS MEMORANDUM ¦
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Transmittal No: 91 LCM-13

Date: January 31, 1991

Division: Commissioner's Office

TO: Local District Commissioners

SUBJECT: Filed Regulation 505.3, 505.5 and 505.16

ATTACHMENTS: Attachment Listed Below (available on-line)

The following changes to the Official Regulations of the State Department of Social Services have been filed for adoption with the Secretary of State.

18 NYCRR 505.3, 505.5 and 505.16 relating to medical assistance coverage of drugs, durable medical equipment and hearing aid services and products and audiology services.

The final rule - Filed: 1/31/91 - Effective: 2/20/91.

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Michael J. McNaughton
Director, Local District
Policy Communications

STATE DEPARTMENT OF SOCIAL SERVICES

ALBANY, NEW YORK

Pursuant to the provisions of Sections 20(3)(d),34(3)(f) and 363-a.2, of the Social Services Law, I, Cesar A. Perales, Commissioner of Social Services, do hereby repeal sections 505.3 and 505.5 and Parts 522 and 524 and add new sections 505.3, 505.5 and 505.31 to the Official Regulations of the State Department of Social Services, being Chapter II of Title 18 NYCRR, effective when the Notice of Adoption is published in the New York State Register.

Dated: January 30, 1991

Signed:_____
Commissioner

This is to certify that this is the original of an order of the State Department of Social Services made on, January 30, 1991
repealing sections 505.3 and 505.5 and Parts 522 and 524 and adding new sections 505.3, 505.5 and 505.31 to the Official Regulations of the State Department of Social Services, being Title 18 NYCRR, a summary of which was published in the New York State Register on June 20, 1990

Dated: January 30, 1991

Signed:_____
Commissioner

Paragraph (4) of subdivision (a) of section 505.3 is redesignated subdivision (i) of new section 505.3. Existing section 505.3 is repealed.

505.3 Drugs.

(a)Definitions.

(1) Compounded prescription means one in which two or more ingredients are mixed by the dispensing pharmacist. Medical assistance reimbursement for compounding is limited to the following:

(i) a combination of any two or more legend drugs found on the list of medicaid reimbursable prescription drugs; or

(ii) a combination of any legend drugs included on the list of medicaid reimbursable prescription drugs and any other item(s) not commercially available as an ethical or proprietary product(s); or

(iii) a combination of two or more products which are labeled 'Caution: For Manufacturing Purposes only.' The reconstitution of a commercially available drug is not a compounded prescription.

(2) Drug means both prescription and nonprescription drugs.

(3) Nonprescription drug means any drug for which a prescription is not required under section 6810 of the Education Law, including over the counter, pre-packaged items.

(4) Practitioner means a physician, physician's assistant, dentist, podiatrist or nurse practitioner.

(5) Prescription drug means any drug for which a prescription is required under section 6810 of the Education Law.

(6) Written order or fiscal order are terms which are used interchangeably in this section and refer to any original, signed written order of a practitioner which requests a pharmacy to provide a drug to a medical assistance recipient.

(b) Written order required. (1) Drugs may be obtained only upon the written order of a practitioner, except for telephone orders for prescription drugs filled in compliance with this section.

(i) The ordering/prescribing of drugs is limited to the practitioner's scope of practice.

(ii) The ordering/prescribing of drugs is limited to practitioners not excluded from participating in the medical assistance program.

(2) All orders for drugs must show the ordering practitioner's name, address, telephone number, United States Drug Enforcement Agency (DEA) number (if applicable), and either the practitioner's MMIS provider identification number, the practitioner's license number or the certification number of the facility in which the drugs were ordered. All orders must also contain the name and identification number of the recipient for whom ordered.

(3) When used in the context of an order for a prescription drug, the order must also meet the requirements for a prescription under section 6810 of the Education Law. When used in the context of a nonprescription drug, the order must also contain the following information: name of the drug; quantity ordered; strength or dosage; ingredient information, as necessary; directions for use; date ordered; and number of refills, if any.

(4) Telephone orders for prescription drugs permitted to be filled by subdivision (4) of section 6810 of the Education Law are permitted; however, refills of telephone orders are not permitted unless supported by written order.

(5) A telephone order must be recorded by the pharmacy in the format required by subdivision (6) of section 6810 of the Education Law, recording the time of the call and the initials of the person taking the call and the dispenser, prior to dispensing the drug. The pharmacist must label the drug as he/she would a written prescription, and make a good faith effort to verify the practitioner's identity, if the practitioner is unknown to the pharmacist. The practitioner must expressly state whether substitution is permitted or prohibited.

(6) Telephone orders are not permitted for nonprescription drugs nor for prescription drugs not permitted to be filled by subdivision (4) of section 6810 of the Education Law.

(c) Where obtained. Drugs may be obtained only from pharmacies which are properly registered by the state in which the pharmacy is located, or from the ordering practitioner. A pharmacy must keep on file the signed written order of the practitioner for audit by the department, or other authorized agency, for six years from the date of payment for any drug dispensed. A practitioner must annotate the patient record to reflect the dispensing of the drug and the quantity, dose, directions for use and number of refills, if any.

(d) Prescription refills. (1) A written order may not be refilled unless the practitioner has indicated the number of allowable refillings on the order. Drugs which require the official New York State triplicate prescription cannot be refilled.

(2) No written order for drugs may be refilled more than six months after the date of issuance, nor more than five times within a six month period.

(3) Refills must bear the prescription number of the original written order.

(e) Prescribed quantities. (1) Drugs must be ordered in a quantity consistent with the health needs of the patient and sound medical practice.

(2) Dispensing limits for drugs. The maximum quantity of drugs dispensed is limited to the larger of:

(i) a 30 day supply; or

(ii) 100 doses. One hundred doses is 100 units of a solid formulation.

(3) Exception. The dispensing limit does not apply to long-term maintenance drugs. Long-term maintenance drugs are identified as drugs considered by the department to be anticonvulsants, antidiabetics, antifungal agents, cardiac drugs, hormones, hypotensive agents, anticholinergic and parasympatholytic agents for treatment of ulcers, thyroid preparations, diuretics, antihyperlipidemics; or prescriptions written and dispensed on the official New York State Triplicate Prescription form for up to a three month supply when written in conformity with the Controlled Substance Act (Title IV of Article 33 of the Public Health Law).

(f) Payment for drugs. (1) The reimbursement amounts are payment in full.

(2) Payment for drugs will only be made for prescription drugs listed in 10 NYCRR 85.25

(3) Payment will only be made for nonprescription drugs listed in Part 528 of this Title. Payment must not exceed the maximum reimbursable price for the package size listed in the fee schedule for pharmacy services. The fee schedule for pharmacy services is available from the department and is also contained in the department's Medicaid Management Information System (MMIS) Provider Manual (Pharmacy). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, New York 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manuals are provided free of charge to every pharmacy at the time of enrollment in the MA program. If a lesser amount than the package size listed in the fee shedule is dispensed, the amount charged is determined by multiplying the unit price by the number of units dispensed. The unit price is the listed maximum reimbursable price of the drug divided by the listed package size.

(4) Drugs provided by a practitioner and billed separately will be paid for at the actual cost to the practitioner.

(5) The ingredient cost of drugs dispensed by a pharmacy will be paid for as follows:

(i) The maximum payment for multiple source prescription drugs for which an upper payment limit has been set by the federal Health Care Financing Administration (HCFA) must not exceed the aggregate of the specified upper limit set by HCFA for the particular multiple source prescription drug, plus a dispensing fee or the provider's usual and customary price charged to the general public, whichever is lower.

(ii) The maximum payment for multiple source prescription drugs and brand name prescription drugs for which no upper limit has been set by HCFA is the lower of the estimated acquisition cost to the pharmacy plus a dispensing fee or the provider's usual and customary price charged to the general public.

(iii) The maximum payment for nonprescription drugs is the lowest of the usual and customary charge to the general public, not exceeding the lowest sale price on the date of service, or the price established under Part 528 of this Title.

(iv) The upper limit for payment of a multiple source drug for which a specific upper limit of reimbursement has been established does not apply if a prescriber certifies "brand medically necessary" or "brand necessary" in his or her own handwriting directly on the face of the prescription in addition to writing "d a w" in the box provided for such purpose on the prescription form. A handwritten statement that is transferred to a rubber stamp or other mechanical device and then stamped onto the prescription form is not acceptable. Reimbursement for these drugs will be made under the provision of subparagraph (ii) of this paragraph. In order to be reimbursed under subparagraph (iv) of this paragraph, a prescription ordered by telephone must be followed within five business days by a written prescription containing the information required by this subparagraph.

(6) The department will pay a dispensing fee to a pharmacy for dispensing prescription drugs and an additional fee for compounded prescriptions. The amount of the fee is contained in the fee schedule for pharmacy services. The fee schedule for pharmacy services is available from the department and is also contained in

the department's Medicaid Management Information System (MMIS) Provider Manual (Pharmacy). Copies of the manual may be obtained by writing to the Computer Sciences Corporation, Health and Administrative Services, 800 North Pearl St., Albany, New York 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manuals are provided free of charge to every pharmacy at the time of enrollment in the MA program.

(g) Limitations. (1) The department will pay for therapeutic vitamins and specific vitamin preparations only when ordered by a physician for the treatment of deficiency states or pathological conditions requiring increased vitamins.

(2) The department will pay for amphetamine and amphetamine-like substances (congeners) only when used in outpatient treatment of conditions other than obesity or weight reduction.

(3) No payment will be made for any drug which has weight reduction as its sole clinical use.

(4) From time to time the department may limit the frequency or the amount of drugs which may be ordered. The department may require prior approval or prior authorization of drugs. The department may allow for exceptions to prior approval or prior authorization requirements in emergency circumstances. Emergency circumstances for purposes of this paragraph means any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated. The department will advise practitioners and pharmacies in writing

before any reduction in frequency or amount, prior authorization or prior approval is imposed on any drug.

(h) Utilization threshold.

(1) This subdivision describes the utilization threshold that the department has established for pharmacy services. Part 503 of this Title authorizes the department to establish a utilization threshold for specific provider service types, including pharmacy services. Part 503 also describes the application of the utilization threshold, services and procedures excluded from the utilization threshold for all provider service types subject to a threshold, the method for obtaining an exemption from or increase in the utilization threshold, notices, and the right to a fair hearing in certain situations.

(2) General rules. (i) Federally nonparticipating persons. Payment will be made for up to 43 pharmacy service formulary codes in a benefit year for persons who belong to a group listed in sections 360-3.3(a)(1) or 360-3.3(b)(7) of this Title.

(ii) Federally participating persons. Payment will be made for up to 60 pharmacy service formulary codes in a benefit year for persons who belong to a group listed in sections 360-3.3(a)(2)-(6), 360-3.3(b)(l)-(6) or 360-3.3(b)(3) of this Title.

(3) Formulary codes. As used in this subdivision, a formulary code is defined as follows:

(i) for prescription drugs, the first time a prescription is filed is one formulary code; each refill of the original prescription is also one formulary code; and

(ii) for nonprescription drugs and medical and surgical supplies, each initial fiscal order for the drug or supply is one formulary code; each refill of the fiscal order is also one formulary code.

Section 505.5 and Part 522 are repealed and a new Section 505.5 is added to read as follows:

505.5 Durable medical equipment; medical/surgical supplies; orthotic and prosthetic appliances; orthopedic footwear.

(a) Definitions.

(1) Durable medical equipment means devices and equipment, other than prosthetic or orthotic appliances, which have been ordered by a practitioner in the treatment of a specific medical condition and which have all of the following characteristics:

(i) can withstand repeated use for a protracted period of time;

(ii) are primarily and customarily used for medical purposes;

(iii) are generally not useful to a person in the absence of an illness or injury; and

(iv) are usually not fitted, designed or fashioned for a particular individual's use. Where equipment is intended for use by only one person, it may be either custom-made or customized.

(2) Medical/surgical supplies means items for medical use other than drugs, prosthetic or orthotic appliances, durable medical equipment, or orthopedic footwear which have been ordered by a practitioner in the treatment of a specific medical condition and

which are usually:

(i) consumable;

(ii) non-reusable;

(iii) disposable;

(iv) for a specific rather than incidental purpose; and

(v) generally have no salvageable value.

(3) Orthotic appliances and devices mean those appliances and devices which are used to support a weak or deformed body member; or to restrict or eliminate motion in a diseased or injured part of the body.

(4) Orthopedic footwear means shoes, shoe modifications, or shoe additions which are used to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; to support a weak or deformed structure of the ankle or foot, or to form an integral part of a brace. Orthopedic shoes must have, at a minimum, the following features:

(i) Blucher or Bal construction;

(ii) leather construction or synthetic material of equal quality;

(iii) welt construction with a cement attached outsole or sewn on outsole;

(iv) upper portion properly fitted as to length and width; no unit sole; bottom sized to the last;

(v) closure appropriate to foot condition. Velcro strap or lace closure preferred except in circumstances when a patient is unable to use them;

(vi) full range of width, not just narrow, medium, wide; and

(vii) extended medial counter and firm heel counter.

(5) Prosthetic appliances and devices mean those appliances and devices (excluding artificial eyes and dental prostheses) ordered by a qualified practitioner which replace any missing part of the body.

(6) Practitioner means a physician, dentist, podiatrist, physician assistant, or nurse practitioner.

(7) Provider, for purposes of this section, means a pharmacy, certified home health agency, medical equipment and supply dealer, hospital, residential health facility, or clinic enrolled in the medical assistance program as a medical equipment dealer.

(8) The terms written order or fiscal order are used interchangeably in this section and mean any original, signed written order of a practitioner which requests durable medical equipment, prosthetic or orthotic appliances and devices, medical/surgical supplies, or orthopedic footwear.

(9) Acquisition cost means the line item cost to the provider. Shipping and handling charges are not reimbursable under the medical assistance program.

(b) Written order required.

(1) All durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear may be furnished only upon a written order of a practitioner.

(i) The ordering of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear is limited to the practitioner's scope of practice.

(ii) The ordering of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear is limited to practitioners not excluded from participating in the medical assistance program.

(2) All orders must show the name, address, telephone number of the practitioner and the name and identification number of the recipient for whom ordered.

(3) When used in the context of an order for a prescription item, the order must also meet the requirements for a prescription under section 6810 of the Education Law. When used in the context of a nonprescription item, the order must also contain the following information: name of the item, quantity ordered, size, catalog number as necessary, directions for use, date ordered, and number of refills, if any.

(4) An original fiscal order for medical/surgical supplies must not be filled more than 14 days after it has been written by the practitioner unless prior approval or prior authorization is required for the item.

(i) An order for medical/surgical supplies will not be refilled unless the ordering practitioner has indicated the number of refills on the order. All refills must reference the original order.

(ii) The maximum number of refills permitted for medical/surgical supplies is found in the fee schedule for durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear. The fee schedule for such equipment and supplies is available from the department and is also contained in the department's Medicaid Managment Information

System (MMIS) Provider Manual (Durable Medical Equipment, Medical and Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, New York 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program.

(iii) No order can be refilled more than 180 days from the original date ordered.

(c) Review of claims.

(1) The identity of the practitioner who ordered the durable medical equipment, medical/surgical supply, prosthetic or orthotic appliance or device, or orthopedic footwear must be recorded by the provider on the claim for payment by entering in the license or MMIS provider identification number of the practitioner where indicated.

(2) Written orders for durable medical equipment, medical/surgical supplies, prosthetic or orthotic devices, or orthopedic footwear must be maintained by the provider submitting the claim for audit by the department or other authorized agency for six years from the date of payment.

(3) The financial liability of the ordering practitioner as well as the provider of any durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances or devices or orthopedic footwear determined on audit not to be medically necessary is set forth in Part 518 of this Title.

(d) Payment.

(1) General payment policy.

(i) Payment for durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear is limited to providers enrolled in the medical assistance program as medical equipment dealers. Payment for medical/surgical supplies is also available to providers enrolled in the medical assistance program as pharmacies.

(ii) Reimbursement amounts are payment in full. No separate or additional payments will be made for shipping, handling, delivery or necessary fittings and adjustments.

(iii) Payment will not be made for items provided by a facility or organization when the cost of these items is included in the rate.

(iv) Payment for items provided by a not-for-profit provider will be made at the acquisition cost.

(v) Any insurance payments including Medicare must be applied against the total purchase price of the item.

(vi) All items not listed in the department's fee schedule for durable medical equipment, medical/surgical supplies, prosthetic and orthotic appliances and orthopedic footwear require prior approval from the New York State Department of Health. The fee schedule for such equipment and supplies is available from the department and is also contained in the department's MMIS Provider Manual (Durable Medical Equipment, Medical/Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, New

York 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program. Reimbursement amounts for unlisted items are determined by the New York State Department of Health and must not exceed the lower of:

(a) the acquisition cost to the provider plus 50 percent; or

(b) the usual and customary price charged to the general public.

(vii) The provider is responsible for any needed replacements or repairs that are due to defects in quality, or workmanship.

(2) Payment for durable medical equipment.

(i) Payment for purchase of durable medical equipment must not exceed the lower of:

(a) the acquisition cost to the provider plus 50 percent; or

(b) the usual and customary price charged to the general public.

(ii) All rentals of durable medical equipment, except those subject to partial reimbursement under the Medicare program, require prior approval from the New York State Department of Health. The rental payment must not exceed the lower of the monthly rental charge to the general public or the price determined by the New York State Department of Health. The total accumulated monthly rental

charges may not exceed the actual purchase price of the item. Rental payment includes all necessary equipment, delivery, maintenance and repair costs, parts, supplies and services for equipment set-up, maintenance and replacement of worn essential accessories or parts.

(3) Payment for medical/surgical supplies.

(i) Payment for medical/surgical supplies listed in the fee schedule for durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear must not exceed the lower of:

(a) the price as shown in the fee schedule for durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear ; or

(b) the usual and customary price charged to the general public.

(ii) The fee schedule for medical/surgical supplies is available from the department and is also contained in the department's MMIS Provider Manual (Durable Medical Equipment, Medical/Surgical Supplies, Orthotic and Prosthetic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, New York 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program.

(4) Payment for orthotic and prosthetic appliances and devices.

(i) Payment for prosthetic and orthotic appliances and devices must not exceed the lower of:

(a) the price as shown in the fee schedule for durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear, or

(b) the usual and customary price charged to the general public.

(ii) Payment for orthotists and prosthetists for home visits is set forth in the fee schedule for durable medical equipment, medical/surgical supplies, prosthetic and orthotic appliances and orthopedic footwear.

(iii) The fee schedule for orthotic and prosthetic appliances and devices is available from the department and is also contained in the department's MMIS Provider Manual (Durable Medical Equipment, Medical and Surgical Supplies, Prosthetic and Orthotic Applicances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St.,Albany, New York, 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program.

(5) Payment for orthopedic footwear.

(i) Payment for orthopedic footwear must not exceed the lower of:

(a) the acquisition cost to the provider plus 50 percent; or

(b) the usual and customary charge to the general public.

(ii) Orthopedic shoes must be provided by a provider who has submitted proof of certification or approval from the American Board for Certification in Orthotics and Prosthetics.

(6) Payment for oxygen must not exceed the lower of:

(i) the acquisition cost to the provider plus 50 percent; or

(ii) the usual and customary price charged to the general public.

(7) Payment for hearing aid batteries is reimbursed at retail less 20 percent updated on a periodic basis.

(8) Payment for enteral therapy must not exceed the lower of:

(i) the acquisition cost to the provider plus 50 percent; or

(ii) the usual and customary charge to the general public.

(e) Service limitations.

(1) The following items of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear are limited in their amount and

frequency and require prior authorization.

Item	Limit
Cane	1 every 3 yrs.
Cane, Quad or three prong	1 every 3 yrs.
Flare heels (each)	2 pair per yr.
Cork lifts	2 pair per yr.
Steindler heel corrections	2 pair per yr.
Spenco Insert	2 pair per yr. per child
Heel wedge	2 pair per yr.
Foot, insert, removable, molded to patient model, longitudinal arch support, each	2 per yr. per adult
Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each	2 per yr. per adult
Foot, arch support, removable, premolded, longitudinal, each	2 per yr. per adult
Foot, arch support, removable, premolded, longitudinal/metatarsal, each	2 per yr. per adult
Longitudinal arch support	1 pair per yr. per adult
Foot, arch support	2 pair per yr. per adult
Removable mold/Levi mold	1 pair per yr. per adult
Elastic stocking/below knee medium wt.	4 pair per yr.
Elastic stocking/below knee heavy wt.	4 pair per yr.

Elastic stocking/above knee medium wt.	4 pair per yr.
Elastic stocking/above knee heavy wt.	4 pair per yr.
Elastic stocking/full length medium wt.	4 pair per yr.
Elastic stocking/full length heavy wt.	4 pair per yr.
Elastic stocking/leotards	4 pair per yr.
Elastic stocking/garter belt	4 pair per yr.
Surgical stocking/below knee	4 pair per yr .
Surgical stocking/thigh length	4 pair per yr.
Surgical stocking/full length	4 pair per yr.
Corset, Sacroiliac	2 per yr.
Corset, Lumbar	2 per yr.
Handheld shower head	1 every 3 yrs.
Bed pan, fracture	1 every 3 yrs.
Urinary suspensory	1 every 5 yrs.
Emesis basin	1 every 5 yrs.
Sitz bath	1 every 5 yrs.
Urinal, female, any material	1 every 5 yrs.
Urinal, male, any material	1 every 5 yrs.
Commode pail	1 every 5 yrs.
Flotation pad	1 per yr.
Humidifier, cold air	1 every 3 yrs.
Vaporizer, room type	1 every 3 yrs.
Standard adult wheelchair	1 every 3 yrs.
Electric heating pad standard	1 every 3 yrs.

Hot fomentation heating pads	1 every 3 yrs.
Orthopedic shoes	2 pair per yr.

(2) From time to time the department may impose additional service limitations on items of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices or orthopedic footwear. The department will notify providers in writing before it implements additional limitations.

(3) The department may allow exceptions to the limitations established under this paragraph where the ordering practitioner attests to medical necessity and the item must be replaced because it is worn or has been lost or stolen.

(f) Prior approval and prior authorization requirements. (1) Orthopedic shoes can be provided only on the basis of an examination by and a signed, original written fiscal order of, a qualified physician or podiatrist and upon the prior authorization of the department.

(2) From time to time the department may require the prior authorization of items of durable medical equipment, medical/surgical supplies, orthotic or prosthetic appliances and devices, or orthopedic footwear. When prior authorization is required for these items, the items can be provided only on the basis of an examination by, and a signed, original written fiscal order of, a qualified practitioner and upon the prior authorization of the department. Providers will be notified in writing by the department before it implements requirements for the prior authorization of any item.

(3) When an appliance or device is recommended by a qualified practitioner on the staff of a state mental hygiene facility for a medical assistance recipient in the family care program, prior approval or authorization is not required.

Part 524 is repealed and a new section 505.31 is added to read, as follows:

505.31 Audiology, hearing aid services and products.

(a) Definitions.

(1) Hearing aid services means services that are provided in compliance with Article 37 of the General Business Law. These services include the selecting, fitting and dispensing of hearing aids, hearing aid checks following dispensing, and hearing aid repairs. Hearing aid products means hearing aids, earmolds, batteries, special fittings and replacement parts.

(2) Audiology services mean audiometric examinations or testing, hearing aid evaluations, conformity evaluations and hearing aid prescriptions or recommendations if indicated.

(3) Qualified audiologist means an audiologist that is licensed and currently registered to practice audiology in the State by the State Education Department.

(4) Qualified hearing aid dealer means any person, partnership, association or corporation engaged in the selecting, fitting and dispensing of hearing aids and currently registered in the State by the Department of State pursuant to Article 37, Section 781(a) of the General Business Law.

(b) Standards. All audiology services and hearing aid services and products must meet the requirements set forth in this Part and must be provided in accordance with the New York State Department of Health's regulations governing the provision of audiology services, audiometric

screening and hearing aid services.

(c) Recommendation requirements.

(1) All recommendations for hearing aids must be in writing and comply with Article 37 of the General Business Law.

(2) The written recommendation must indicate the need for a hearing aid and include the results of pure tone speech audiometry or equivalent testing conducted in a sound treated room or test suite meeting the American National Standard Institute's specifications.

(3) A prescription for a specific hearing aid requires a pure tone and sound field speech audiometry. The tests must be conducted by or under the direction and personal supervision of an otolaryngologist or qualified audiologist. When a specific device is prescribed, the hearing aid dealer must dispense as written.

(4) When a general recommendation is made, the hearing aid dealer must perform tests and procedures necessary to determine the specific hearing aid which will be of maximum benefit to aid or improve the impaired hearing.

(5) Hearing aids must be dispensed within six months of the date of the recommendation.

(d) Source of recommendation.

(1) All written recommendations for hearing aids for children under 21 years of age must be from speech and hearing centers approved to provide services under the Physically Handicapped Children's Program. The written recommendation must be signed by a qualified otolaryngologist or qualified audiologist. For persons under 21 residing in New York State Developmental Centers, the recommendation for a hearing aid may be from the developmental center.

(2) Written recommendations for hearing aids for persons 21 years of age and older must be from a qualified otolaryngologist, a speech and hearing center approved to provide services under the Physically Handicapped Children's Program, a qualified audiologist, or a facility approved pursuant to Article 28 of the Public Health Law and certified to render speech and hearing or audiology services.

(e) Prior approval requirements.

(1) Prior approval of the local Physically Handicapped Children's Program medical director is required for all hearing aid services furnished to persons under 21 years of age.

(2) Prior approval from the New York State Department of Health is required for hearing aids, dispensing and administrative fees as defined by regulations of the New York State Department of Health, and special fittings when the source of the recommendation is not a speech and hearing center approved to provide services under the Physically Handicapped Children's Program. Batteries not listed in the department's provider manual and repairs costing $70 or more require prior approval from the New York State Department of Health regardless of the source of the order.

(f) Written statements required.

(1) Audiology services, except for conformity evaluations (hearing aid checks), must be supported by a written referral by a licensed physician. The written referral must be maintained with the recipient record.

(2) A statement of recipient rights and obligations must be provided to the recipient by the hearing aid dealer at the

time the hearing aid is dispensed. The hearing aid dealer must also place a copy of the statement in the recipient's record. The statement must explain the 30 day trial period and the recipient's right to return to the dealer for all necessary adjustments and calibrations of the hearing aid during the 30 day trial period and to return an unsatisfactory hearing aid.

(g) Review of claims.

(1) The identity of the physician, audiologist, speech and hearing center approved to provide services under the Physically Handicapped Children's Program, or the facility approved pursuant to Article 28 of the Public Health Law and certified to render speech and hearing or audiology ervices which ordered the hearing aid service or product must be recorded by the hearing aid dealer on the claim for payment by entering in the license or MMIS provider ID number of the orderer where indicated.

(2) The identity of the referring physician must be recorded on the claim for payment for audiology services by entering the license or MMIS provider ID number of the physician where indicated.

(3) Written statements referring persons for audiology services and recommendations or prescriptions for hearing aid services and products must be maintained by the provider submitting the claim for audit by the department or other authorized agency for six years from the date of payment.

(4) Hearing aid dealers must also maintain at each of their business locations the records specified in 19 NYCRR 191.13.

(5) The financial liability of the referring or ordering provider for any audiology services or hearing aid services or products determined on audit not to be medically necessary is set forth in Part 518 of this Title.

(h) Payment.

(1) Hearing aid services and products payment.

(i) Payment for hearing aid services and products is limited to providers enrolled in the medical assistance program as hearing aid dealers, speech and hearing centers approved by the Physically Handicapped Children's Program to provide speech and hearing services, or facilities approved pursuant to Article 28 of the Public Health Law and certified to render speech and hearing or audiology services.

(ii) Hearing aids must be provided for a trial period of at least 30 days.

(iii) The dispensing and administrative fees, as defined by regulations of the New York State Department of Health, are reimbursable to for-profit hearing aid dealers only.

(iv) Reimbursement for hearing aids is made at acquisition cost, net of any discounts or rebates, supported by a copy of the invoice. The invoice must include the brand, model, and serial number of the dispensed hearing aid.

(v) Reimbursement for dispensing and administrative fees, as defined by regulations of the New York State Department of Health, batteries, earmolds, and replacement parts is based on the fee schedule for hearing aid/audiology supplies and services. The fee schedule for hearing aid/audiology supplies and services available from the department and is also contained in the Medicaid Management Information System (MMIS) Provider Manual (Hearing Aid/Audiology Services). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, New York 12204.

Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manual is provided free of charge to every provider of hearing aid services and products at the time of enrollment in the MA program.

(2) Audiology payment.

(i) Payment for audiology services is limited to providers enrolled in the medical assistance program as audiologists, speech and hearing centers approved by the Physically Handicapped Children's Program to provide speech and hearing services, or facilities approved under Article 28 of the Public Health Law and certified to render speech and hearing or audiology services.

(ii) Reimbursement to qualified audiologists or hearing aid dealers that employ qualified audiologists for audiology services is based on the fee schedule for hearing aid/audiology supplies and services. The fee schedule for hearing aid/audiology supplies and services is available from the department and is also contained in the MMIS Provider Manual (Hearing Aid /Audiology Services). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, New York 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, New York 12243. The manual is provided free of charge to every provider of audiology services at the time of enrollment in the MA program.

(iii) Reimbursement to facilities approved under Article 28 of the Public Health Law and certified to render speech and hearing or audiology services is limited to the rates set by the New York State Department of Health for speech and hearing or audiology services.