12VAC30-50-160. Home health services.

A. Service must be ordered or prescribed and directed or performed within the scope of a license of a practitioner of the healing arts. Home health services shall be provided in accordance with guidelines found in the Virginia Medicaid Home Health Manual.

B. Nursing services provided by a home health agency.

1. Intermittent or part-time nursing service provided by a home health agency or by a registered nurse when no home health agency exists in the area.

2. Patients may receive up to 32 visits by a licensed nurse annually. Limits are per recipient, regardless of the number of providers rendering services. Annually shall be defined as July 1 through June 30 for each recipient. If services beyond these limitations are determined by the physician to be required, then the provider shall request prior authorization from DMAS for additional services. Payment shall not be made for additional service unless authorized by DMAS.

C. Home health aide services provided by a home health agency.

1. Home health aides must function under the supervision of a registered nurse.

2. Home health aides must meet the certification requirements specified in 42 CFR 484.36.

3. For home health aide services, patients may receive up to 32 visits annually. Limits shall be per recipient, regardless of the number of providers rendering services. Annually shall be defined as July 1 through June 30 for each recipient.

D. Durable medical equipment (DME) and supplies suitable for use in the home.

1. General requirements and conditions.

a. All medically necessary supplies and equipment shall be covered. Unusual amounts, types, and duration of usage must be authorized by DMAS in accordance with published policies and procedures. When determined to be cost effective by DMAS, payment may be made for rental of the equipment in lieu of purchase.

b. DME providers shall adhere to all applicable DMAS policies, laws, and regulations for durable medical equipment and supplies. DME providers shall also comply with all other applicable Virginia laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations shall result in denial of coverage for durable medical equipment or supplies which are regulated by such licensing agency or agencies.

c. DME and supplies must be furnished pursuant to a Certificate of Medical Necessity (CMN) (DMAS-352).

d. A CMN shall contain a physician's diagnosis of a recipient's medical condition and an order for the durable medical equipment and supplies that are medically necessary to treat the diagnosed condition and the recipient's functional limitation. The order for DME or supplies must be justified in the written documentation either on the CMN or attached thereto. The CMN shall be valid for a maximum period of six months for Medicaid recipients 21 years of age

and younger. The maximum valid time period for Medicaid recipients older than 21 years of age is 12 months. The validity of the CMN shall terminate when the recipient's medical need for the prescribed DME or supplies ends.

e. DME must be furnished exactly as ordered by the attending physician on the CMN. The CMN and any supporting verifiable documentation must be complete (signed and dated by the physician) and in the provider's possession within 60 days from the time the ordered DME and supplies are initially furnished by the DME provider. Each component of the DME must be specifically ordered on the CMN by the physician.

f. The CMN shall not be changed, altered, or amended after the attending physician has signed it. If changes are necessary, as indicated by the recipient's condition, in the ordered DME or supplies, the DME provider must obtain a new CMN. New CMNs must be signed and dated by the attending physician within 60 days from the time the ordered supplies are furnished by the DME provider.

g. DMAS shall have the authority to determine a different (from those specified above) length of time a CMN may be valid based on medical documentation submitted on the CMN. The CMN may be completed by the DME provider or other health care professionals, but it must be signed and dated by the attending physician. Supporting documentation may be attached to the CMN but the attending physician's entire order must be on the CMN.

h. The DME provider shall retain a copy of the CMN and all supporting verifiable documentation on file for DMAS' post payment audit review purposes. DME providers shall not create nor revise CMNs or supporting documentation for this service after the initiation of the post payment review audit process. Attending physicians shall not complete, nor sign and date, CMNs once the post payment audit review has begun.

2. Preauthorization is required for incontinence supplies provided in quantities greater than two cases per month.

3. Supplies, equipment, or appliances that are not covered include, but are not limited to, the following:

a. Space conditioning equipment, such as room humidifiers, air cleaners, and air conditioners;

b. Durable medical equipment and supplies for any hospital or nursing facility resident, except ventilators and associated supplies or specialty beds for the treatment of wounds consistent with DME criteria for nursing facility residents that have been approved by DMAS central office;

c. Furniture or appliances not defined as medical equipment (such as blenders, bedside tables, mattresses other than for a hospital bed, pillows, blankets or other bedding, special reading lamps, chairs with special lift seats, hand-held shower devices, exercise bicycles, and bathroom scales);

d. Items that are only for the recipient's comfort and convenience or for the convenience of those caring for the recipient (e.g., a hospital bed or mattress because the recipient does not have a decent bed; wheelchair trays used as a desk surface); mobility items used in addition to primary assistive mobility aide for caregiver's or recipient's convenience (i.e., electric wheelchair plus a manual chair); cleansing wipes;

e. Prosthesis, except for artificial arms, legs, and their supportive devices which must be preauthorized by the DMAS central office (effective July 1, 1989);

f. Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (for example, dentifrices; toilet articles; shampoos which do not

require a physician's prescription; dental adhesives; electric toothbrushes; cosmetic items, soaps, and lotions which do not require a physician's prescription; sugar and salt substitutes; and support stockings);

g. Orthotics, including braces, splints, and supports;

h. Home or vehicle modifications;

i. Items not suitable for or not used primarily in the home setting (i.e., car seats, equipment to be used while at school, etc.); and

j. Equipment that the primary function is vocationally or educationally related (i.e., computers, environmental control devices, speech devices, etc.).

4. For coverage of blood glucose meters for pregnant women, refer to 12VAC30-50-510.

5. ~~Reserved~~. Coverage of ~~home~~ intravenous infusion therapy. ~~Home~~ intravenous infusion therapy shall be defined as the intravenous administration of fluids, drugs, chemical agents, or nutritional substances to recipients in the home setting. DMAS shall reimburse for these services, supplies, and drugs ~~on a service day rate~~ using a per diem methodology as established in Attachment 4.19-B (~~12 VAC 30-80-30~~ 12 VAC 30-80-40). The therapies to be covered under this policy shall be: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). All the therapies which meet criteria set out below in paragraph B 1-4 will be covered for three months. If any therapy service is required for longer than the original three months, prior authorization shall be required [for the DME component] for its continuation. The established ~~service day rate~~ per diem rate shall ~~reimburse~~ be used for reimbursement purposes for all services delivered in a single day. There shall be no additional reimbursement for special or extraordinary services. In the event of incompatible drug administration, a separate HCPCS code shall be used to allow for rental of a second infusion pump and purchase of an extra administration tubing. When applicable, this code may be billed in addition to the other ~~service day rate~~ per diem codes. There must be documentation to support the use of this code on the I.V. Implementation Form. This documentation shall include the need for pump administration of the medications ordered, frequency of administration to support that they are ordered simultaneously, and indication of incompatibility of the medications. The ~~service day rate~~ per diem payment methodology shall be mandatory for reimbursement of all IV therapy services except for the

recipient who is enrolled in the Technology Assisted waiver program. The following limitations shall apply to this service:

a. This service must be medically necessary to treat a recipient's medical condition. The service must be ordered and provided in accordance with accepted medical practice. The service must not be desired solely for the convenience of the recipient or the recipient's caregiver.

b. In order for Medicaid to reimburse for this service, the recipient must:

(1) Reside in either a private home or a domiciliary care facility, such as an adult care residence. Because the reimbursement for DME is already provided under institutional reimbursement, recipients in hospitals, nursing facilities, rehabilitation centers, and other institutional settings shall not be covered for this service.

(2) Be under the care of a physician who prescribes the home infusion therapy and monitors the progress of the therapy.

(3) Have body sites available for peripheral intravenous catheter or needle placement or have a central venous access; AND

(4) Be capable of either self-administering such therapy or have a caregiver who can be adequately trained, is capable of administering the therapy, and is willing to safely and efficiently administer and monitor the home infusion therapy. The caregiver must be willing to and be capable of following appropriate teaching and adequate monitoring. In those cases where the recipient is incapable of administering or monitoring the prescribed therapy and there is no adequate or trained caregiver, it may be appropriate for a home health agency to administer the therapy.

6. The medical equipment and supply vendor must provide the equipment and supplies as prescribed by the physician on the certificate of medical necessity. Orders shall not be changed unless the vendor obtains a new certificate of medical necessity prior to ordering or providing the equipment or supplies to the patient.

7. Medicaid shall not provide reimbursement to the medical equipment and supply vendor for services provided prior to the date prescribed by the physician or prior to the date of the delivery or when services are not provided in accordance with published policies and procedures. If reimbursement is denied for one of these reasons, the medical equipment and supply vendor may not bill the Medicaid recipient for the service that was provided.

8. The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to the department. Medically necessary DME and supplies shall be:

a. Ordered by the physician on the CMN;

b. A reasonable and necessary part of the recipient's treatment plan;

c. Consistent with the recipient's diagnosis and medical condition particularly the functional limitations and symptoms exhibited by the recipient;

d. Not furnished solely for the convenience, safety, or restraint of the recipient, the family, attending physician, or other practitioner or supplier;

e. Consistent with generally accepted professional medical standards (i.e., not experimental or investigational); and

f. Furnished at a safe, effective, and cost-effective level suitable for use in the recipient's home environment.

9. Coverage of enteral nutrition (EN) which does not include a legend drug shall be limited to when the nutritional supplement is the sole source form of nutrition, is administered orally or through a nasogastric or gastrostomy tube, and is necessary to treat a medical condition. Coverage of EN shall not include the provision of routine infant formulae. A nutritional assessment shall be required for all recipients receiving nutritional supplements.

E. Physical therapy, occupational therapy, or speech/language pathology services and audiology services provided by a home health agency or medical rehabilitation facility.

1. Service covered only as part of a physician's plan of care.

2. Patients may receive up to 24 visits for each rehabilitative therapy service ordered annually without authorization. Limits shall apply per recipient regardless of the number of providers rendering services. Annually shall be defined as July 1 through June 30 for each recipient. If services beyond these limitations are determined by the physician to be required, then the provider shall request prior authorization from DMAS for additional services.

F. The following services are not covered under the home health services program:

1. Medical social services;

2. Services or items which would not be paid for if provided to an inpatient of a hospital, such as private-duty nursing services, or items of comfort which have no medical necessity, such as television;

3. Community food service delivery arrangements;

4. Domestic or housekeeping services which are unrelated to patient care and which materially increase the time spent on a visit;

5. Custodial care which is patient care that primarily requires protective services rather than definitive medical and skilled nursing care; and

6. Services related to cosmetic surgery.

12VAC30-50-210. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

A. Prescribed drugs.

1. Drugs for which Federal Financial Participation is not available, pursuant to the requirements of §1927 of the Social Security Act (OBRA "90 §4401), shall not be covered.

2. Nonlegend drugs shall be covered by Medicaid in the following situations:

a. Insulin, syringes, and needles for diabetic patients;

b. Diabetic test strips for Medicaid recipients under 21 years of age;

c. Family planning supplies;

d. Designated categories of nonlegend drugs for Medicaid recipients in nursing homes; and

e. Designated drugs prescribed by a licensed prescriber to be used as less expensive therapeutic alternatives to covered legend drugs.

3. Legend drugs are covered with the exception of the drugs or classes of drugs identified in 12VAC30-50-520. FDA-approved drug therapies and agents for weight loss, when preauthorized, will be covered for recipients who meet the strict disability standards for obesity established by the Social Security Administration in effect on April 7, 1999, and whose condition is certified as life threatening, consistent with Department of Medical Assistance Services' medical necessity requirements, by the treating physician.

4. Notwithstanding the provisions of §32.1-87 of the Code of Virginia, and in compliance with the provision of §4401 of the Omnibus Reconciliation Act of 1990, §1927(e) of the Social Security Act as amended by OBRA 90, and pursuant to the authority provided for under §32.1-325 A of the Code of Virginia, prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332 shall be filled with generic drug products unless the physician or other practitioners so licensed and certified to prescribe drugs certifies in his own handwriting "brand necessary" for the prescription to be dispensed as written.

5. New drugs shall be covered in accordance with the Social Security Act §1927(d) (OBRA 90 §4401).

6. The number of refills shall be limited pursuant to §54.1-3411 of the Drug Control Act.

7. Drug prior authorization.

a. Definitions. The following words and terms used in these regulations shall have the following meaning, unless the context clearly indicates otherwise:

"Board" means the Board for Medical Assistance Services.

"Committee" means the Medicaid Prior Authorization Advisory Committee.

"Department" means the Department of Medical Assistance Services.

"Director" means the Director of Medical Assistance Services.

"Drug" shall have the same meaning, unless the context otherwise dictates or the board otherwise provides by regulation, as provided in the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia).

b. Medicaid Prior Authorization Advisory Committee; membership. The Medicaid Prior Authorization Committee shall consist of 11 members to be appointed by the board. Five members shall be physicians, at least three of whom shall care for a significant number of Medicaid patients; four shall be pharmacists, two of whom shall be community pharmacists; one member shall be a consumer of mental health services; and one shall be a Medicaid recipient.

(1) A quorum for action of the committee shall consist of six members.

(2) The members shall serve at the pleasure of the board; vacancies shall be filled in the same manner as the original appointment.

(3) The board shall consider nominations made by the Medical Society of Virginia, the Old Dominion Medical Society, the Psychiatric Society of Virginia, the Virginia Pharmaceutical Association, the Virginia Alliance for the Mentally Ill, and the Virginia Mental Health Consumers Association when making appointments to the committee.

(4) The committee shall elect its own officers, establish its own procedural rules, and meet as needed or as called by the board, the director, or any two members of the committee. The department shall provide appropriate staffing to the committee.

c. Duties of the committee.

(1) The committee shall make recommendations to the board regarding drugs or categories of drugs to be subject to prior authorization, prior authorization requirements for prescription drug coverage and any subsequent amendments to or revisions of the prior authorization requirements. The board may accept or reject the recommendations in whole or in part, and may amend or add to the recommendations, except that the board may not add to the recommendation of drugs and categories of drugs to be subject to prior authorization.

(2) In formulating its recommendations to the board, the committee shall not be deemed to be formulating regulations for the purposes of the Administrative Process Act (§9-6.14:1 et seq.).

The committee shall, however, conduct public hearings prior to making recommendations to the board. The committee shall give 30 days written notice by mail of the time and place of its hearings and meetings to any manufacturer whose product is being reviewed by the committee and to those manufacturers who request of the committee in writing that they be informed of such hearings and meetings. These persons shall be afforded a reasonable opportunity to be heard and present information. The committee shall give 30 days notice of such public hearings to the public by publishing its intention to conduct hearings and meetings in the Calendar of Events of The Virginia Register of Regulations and a newspaper of general circulation located in Richmond.

(3) In acting on the recommendations of the committee, the board shall conduct further proceedings under the Administrative Process Act.

d. Prior authorization of prescription drug products; coverage.

(1) The committee shall review prescription drug products to recommend prior authorization under the state plan. This review may be initiated by the director, the committee itself, or by written request of the board. The committee shall complete its recommendations to the board within no more than six months from receipt of any such request.

(2) Coverage for any drug requiring prior authorization shall not be approved unless a prescribing physician obtains prior approval of the use in accordance with regulations promulgated by the board and procedures established by the department.

(3) In formulating its recommendations to the board, the committee shall consider the potential impact on patient care and the potential fiscal impact of prior authorization on pharmacy, physician, hospitalization and outpatient costs. Any proposed regulation making a drug or category of drugs subject to prior authorization shall be accompanied by a statement of the estimated impact of this action on pharmacy, physician, hospitalization and outpatient costs.

(4) The committee shall not review any drug for which it has recommended or the board has required prior authorization within the previous 12 months, unless new or previously unavailable relevant and objective information is presented.

(5) Confidential proprietary information identified as such by a manufacturer or supplier in writing in advance and furnished to the committee or the board according to this subsection shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§2.1-340 et seq. of the Code of Virginia). The board shall establish by regulation the means by which such confidential proprietary information shall be protected.

e. Immunity. The members of the committee and the board and the staff of the department shall be immune, individually and jointly, from civil liability for any act, decision, or omission done or made in performance of their duties pursuant to this subsection while serving as a member of such board, committee, or staff provided that such act, decision, or omission is not done or made in bad faith or with malicious intent.

f. Annual report to joint commission. The committee shall report annually to the Joint Commission on Health Care regarding its recommendations for prior authorization of drug products.

8. Coverage of ~~home~~ intravenous infusion therapy. This service shall be covered consistent with the limits and requirements ~~set out within home health services (12 VAC 30-50-160).~~ of the fee-for-service programs specified in 12 VAC 30-80-40 provided by Medicaid. Multiple applications of the same therapy (e.g., two antibiotics on the same day) shall be covered under one ~~service day rate~~ per diem rate of reimbursement. Multiple applications of different therapies (e.g., chemotherapy, hydration, and pain management on the same day) shall be covered under a full ~~service day rate~~ per diem methodology as provided in pharmacy services reimbursement.

B. Dentures. Dentures are provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.

C. Prosthetic devices.

1. Prosthetic services shall mean the replacement of missing arms, legs, and breasts and the provision of any internal (implant) body part. Nothing in this regulation shall be construed to refer to orthotic services or devices or organ transplantation services.

2. Prosthetic devices (artificial arms and legs, and their necessary supportive attachments, implants and breasts) are provided when prescribed by a physician or other licensed practitioner of the healing arts within the scope of their professional licenses as defined by state law. This service, when provided by an authorized vendor, must be medically necessary and preauthorized for the minimum applicable component necessary for the activities of daily living.

D. Eyeglasses. Eyeglasses shall be reimbursed for all recipients younger than 21 years of age according to medical necessity when provided by practitioners as licensed under the Code of Virginia.

12VAC30-80-40. Fee-for-service providers: Pharmacy.

Payment for pharmacy services shall be the lowest of items 1 through 5 (except that items 1 and 2 will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.331 (c) if the brand cost is greater than the HCFA upper limit of VMAC cost) subject to the conditions, where applicable, set forth in items 6 and 7 below:

1. The upper limit established by the Health Care Financing Administration (HCFA) for multiple source drugs pursuant to 42 CFR 447.331 and 447.332, as determined by the HCFA Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the HCFA Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.

2. The Virginia Maximum Allowable Cost (VMAC) established by the agency plus a dispensing fee for multiple source drugs listed on the VVF.

3. The Estimated Acquisition Cost (EAC) which shall be based on the published Average Wholesale Price (AWP) minus a percentage discount established by the methodology set out in a through c below.

a. Percentage discount shall be determined by a statewide survey of providers' acquisition cost.

b. The survey shall reflect statistical analysis of actual provider purchase invoices.

c. The agency will conduct surveys at intervals deemed necessary by DMAS.

4. (Reserved).

5. The provider's usual and customary charge to the public, as identified by the claim charge.

6. Payment for pharmacy services will be as described above; however, payment for drugs will include the allowed cost of the drug plus only one dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements.

7. The Program pays additional reimbursement for the 24-hour unit dose delivery system of dispensing drugs. This service is paid only for patients residing in nursing facilities. Reimbursements are based on the allowed payments described above plus the unit dose add-on fee and an allowance for the cost of unit dose packaging established by the state agency. The maximum allowed drug cost for specific multiple source drugs will be the lesser of: either the VMAC based on the 60th percentile cost level identified by the state agency or HCFA's upper limits. All other drugs will be reimbursed at drug costs not to exceed the estimated acquisition cost determined by the state agency.

8. Determination of EAC was the result of an analysis of FY'89 paid claims data of ingredient cost used to develop a matrix of cost using 0 to 10% reductions from AWP as well as discussions with pharmacy

providers. As a result of this analysis, AWP minus 9.0% was determined to represent prices currently paid by providers effective October 1, 1990.

The same methodology used to determine AWP minus 9.0% was utilized to determine a dispensing fee of $4.40 per prescription as of October 1, 1990. A periodic review of dispensing fee using Employment Cost Index - wages and salaries, professional and technical workers will be done with changes made in dispensing fee when appropriate. As of July 1, 1995, the Estimated Acquisition Cost will be AWP minus 9.0% and dispensing fee will be $4.25.

9. ~~Home~~ Intravenous Infusion Therapy.

a. For fee-for-service patients, ~~The~~ the following therapy categories shall have a pharmacy per diem payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, total parenteral nutrition (TPN). The service day rate payment for the pharmacy component shall apply to the basic components and services intrinsic to the therapy category. Submission of claims for the per diem rate shall be accomplished by use of the HCFA 1500 claim form.

b. The cost of the active ingredient or ingredients for hydration, chemotherapy, pain management, and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient

CERTIFIED:

____Oct. 19, 1999_____ __/s/ Dennis G. Smith_____
Date Dennis G. Smith, Director
Dept. of Medical Assistance Services