Sec. 17-134d-81. Policy and procedures governing the billing and payment for prescription drugs on behalf of title XIX medicaid recipients

(a) **Scope**

This regulation governs the billing and payment for prescription drugs and Pharmaceutical Services provided to persons determined eligible for such goods and services under provisions of Connecticut's Medical Assistance Program in accordance with Section 17-134d of the General Statutes of Connecticut.

(b) **Definitions**

For the purpose of Regulation Section 17-134d-81, the following definitions apply:

(1) "Average Wholesale Price" (A.W.P.) means the published wholesale price as determined by the Department from the price listed by one or more national publications recognized by the Department.

(2) "Brand Name/Trade Name" means the name assigned to a drug by the pharmaceutical innovator, i.e., manufacturer and/or distributor for the purpose of distribution to wholesalers or retailer, whether or not this name is registered in the United States Patent Office.

(3) A "Compounded Prescription" means two or more drugs mixed together and at least one ingredient must be a legend drug. A compounded prescription must include name, strength, and amount of each prescribed ingredient.

(4) "Connecticut Over-the-Counter Formulary" means the formulary of O.T.C. (nonlegend) drugs which are reimbursable by the Department.

(5) "Department" means the Connecticut Department of Income Maintenance.

(6) "Dispensing Fee" means an amount of money paid to a pharmacist for rendering a professional service involving the preparation and dispensing of a prescribed drug order by a licensed authorized practitioner.

(7) "Documented in Writing" means that the prescription has been handwritten, typed or computer printed. Computerized systems must meet all of the requirements of the Commission of Pharmacy Regulations Chapter 382 Sections 20-164b-1 through 20-164b-11 for non-controlled drugs and Sections 21a-244-1 through 21a-244-6 for controlled drugs and as they may be amended from time to time. (Note: Record retention for all Medicaid claims extends to a five (5) year period per (g)(2) of this regulation.)

(8) "Drug Efficacy Study Implementation (DESI) Program" means the program through which the Food and Drug Administration has identified certain products which lack sufficient evidence of their effectiveness for the approved indication(s).

(9) "Estimated Acquisition Cost" (E.A.C.) means the Department's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers.

(10) "Federal Acquisition Cost/Federal Upper Limit" (F.A.C.) means the upper limit allowable cost established and published by HCFA for those multiple source drugs which appear on HCFA's list of multiple source drugs for which upper limits have been established and as revised from time to time.

(11) "HCFA" means the Health Care Financing Administration of the United States Department of Health and Human Services.

(12) "Legend Drugs" means any article, substance, preparation or device which bears the legend: "Caution Federal Law prohibits dispensing without a prescription."

(13) "Licensed Authorized Practitioner" means any physician or other licensed practitioner who is authorized to prescribe drugs within the scope of his or her professional practice as defined and limited by Federal and State law.

(14) "Multiple-source Drug" means a drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names, or both under a proprietary name and without such a name.

(15) "Nutritional Supplements" means commercially prepared products, the primary purpose of which is to treat a diagnosed deficiency or potential deficiency in the patient's diet or nutrition.

(16) "Over-the-Counter/Nonlegend Drugs" (O.T.C.) means drugs which do not require a prescription by Federal or State law (O.T.C. items are available for purchase by the general public with or without a prescription) and generally are used for persons residing in the community and is usually administered or used by the patient on the basis of self-diagnosis.

(17) "Pharmacy" means a facility licensed by the Commission of Pharmacy in the Department of Consumer Protection under Section 20-168 of the Connecticut General Statutes, or by the appropriate regulatory body of the state in which it is located.

(18) "Prescribed Drug" means a single drug or compound or mixtures or substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that is:

(A) Prescribed by a licensed authorized practitioner within the scope of his or her professional practice as defined and limited by Federal and State law; and

(B) Dispensed by the licensed pharmacist on a written or oral prescription issued in accordance with the State Medical Practice Act and that is recorded and maintained in the pharmacist's records.

(19) "Prescription" means an order issued by a licensed authorized practitioner and documented in writing by either the practitioner or the pharmacist. In nursing homes the signed order of a licensed authorized practitioner will be accepted in lieu of a written or oral prescription. The written prescription includes:

(A) the name and address of the patient; and

(B) whether the patient is an adult or a child, or the patient's specific age; and

(C) the compound or preparation ordered; and

(D) its strength when applicable and the specific amount thereof, to be dispensed at one time; and

(E) directions for the use of the medication and any cautionary statements required; and

(F) the number of times that the prescription may be refilled, if applicable; and

(G) date of issuance; and

(H) name and address of the prescribing practitioner and his/her Drug Enforcement Act number when appropriate.

(20) "Prior Authorization" (P.A.) means approval for a service from the Department before the provider actually provides the services. In order to receive approval from the Department a provider must comply with all prior authorization requirements found in regulation. P.A. does not, however, guarantee payment unless all other eligibility requirements are met.

(21) "Usual and Customary Charge to the General Public" means a charge which will be made for the particular prescription by the provider to the patient group accounting for the largest number of non-Medicaid prescriptions. In determining such charge, all charges made to third party payors and special discounts offered to an individual such as a senior citizen will be excluded.

(c) **Provider Participation**

In order to participate in the Medicaid program and receive payment directly from the Department all pharmaceutical providers must:

(1) be licensed by the appropriate regulatory body of the state in which it is located to operate a pharmacy and provide the Department with a copy of the license; and

(2) meet and maintain all applicable license requirements of Federal and State statutes and regulations; and

(3) meet and maintain all applicable Departmental enrollment requirements; and

(4) have a valid provider agreement on file which is signed by the provider and the Department upon application for enrollment into the Medicaid program and periodically thereafter as required by the Department and which is in effect for the period as stated in the agreement. The provider agreement specifies conditions and terms (Federal and State statutes, regulations and standards) which govern the program and to which the provider is mandated to adhere to in order to participate in the program.

(d) **Eligibility**

Payment for Pharmaceutical Services is available for all Medicaid eligible recipients subject to the conditions and limitation which apply to these services.

(e) **Services Covered and Limitations**

(1) Services Covered

Except for the limitations and exclusions listed below, the Department will pay for drugs which are prescribed by a licensed authorized practitioner as a result of accepted methods of diagnosis and treatment.

(2) Service Limitations

(A) Maximum Allowable Supply

The Department will not reimburse for an original prescription or refill that exceeds the supply requirement for a period of thirty (30) days not to exceed two hundred and forty (240) units except in the following instances:

(i) Prescriptions for chronic conditions or maintenance drugs shall be for at least a thirty (30) day supply not to exceed two hundred and forty (240) units unless a lesser amount is prescribed.

(ii) For prescriptions for oral contraceptives, a supply sufficient for a maximum period of three (3) months may be dispensed at any time.

(B) Refills

Payment will be made for a refill of a prescription as authorized by the licensed authorized practitioner for an acute, or chronic illness, or condition as follows:

(i) Payment will be made for the original prescription and as many refills as ordered by the licensed authorized practitioner covering a maximum period of six (6) months. This does not apply to those items which fall within the "Controlled Substance Act," that being five (5) refills or six (6) months whichever comes first as is governed by 21 U.S.C. Section

829 (b) and Section 21a-249 (h) of the Connecticut General Statutes and as they may be amended from time to time.

(ii) Payment shall be made for a refill of a prescription for oral contraceptives which may cover a maximum period of twelve (12) months, including the original filling.

(C) The Department will not pay for any nonlegend drugs for nursing home patients when these items are used in usual and customary amount of routine care and treatment; the cost of such items is included in the nursing home's daily rate as set by the Department.

(D) The Department will not pay for any nutritional supplements for nursing home patients; the cost of such items is included in the nursing home's daily rate as set by the Department.

(E) A licensed authorized practitioner may telephone prescription orders to a pharmacist. These orders must be documented in writing and countersigned or initialed by the pharmacist and must include the date of the telephone call.

(3) Services Not Covered

The Department will not pay for:

(A) Any vaccines and/or biologicals which can be obtained free of charge from the Connecticut State Department of Health Services. The Department will notify pharmacists of such vaccines and biologicals.

(B) Any drugs used in the treatment of obesity.

(C) Drugs included in the DESI program. The Department will notify providers of such drugs.

(D) Controlled Substance dispensed to Medicaid recipients which are in excess of the product manufacturer's recommendation for safe and effective use for which there is no documentation of medical justification in the pharmacy's file.

(E) Drugs for a Lock-In recipient who is not locked into the billing pharmacy.

(F) Alcoholic liquors.

(G) O.T.C.s except those on the State of Connecticut's "O.T.C. Formulary" or as otherwise provided in these regulations.

(H) Anything of an unproven, experimental or research nature.

(I) Items used for personal care and hygiene or for cosmetic purposes.

(J) Drugs not directly related to the patient's diagnosis, when diagnosis is required by the Department to be written on the prescription.

(K) Drugs solely used to promote fertility.

(L) Drugs used to promote smoking cessation.

(f) **Need for Service and Authorization Process**

(1) Need for Service

A patient's need for pharmaceutical service is indicated when a licensed authorized practitioner prescribes a legend or nonlegend drug for treatment of or prevention of an illness or condition as documented in the patient's medical record.

(2) Prior Authorization

(A) The Department will not require P.A. for certain prescribed drugs which otherwise would require P.A. when prescribed by a licensed authorized practitioner for certain specified diagnoses The diagnoses must be written on the prescription either by the authorized practitioner, or the pharmacist, after verification with the prescriber. The

Department will notify providers of such medications with the corresponding diagnosis and diagnosis indicator.

The following drugs require prior authorization for all patients:

(B) Any prescribed nonlegend (O.T.C.) medication or its equivalent used in the treatment of specific condition and which does not appear on the Connecticut's "O.T.C. Formulary," or on the NDC/Diagnosis cross reference list with an appropriate diagnosis indicator (see (f) (2) (A)).

(C) All Vitamins, except pediatric vitamins for children prior to the child's seventh birthday, vitamins with fluoride and Legend Hematinic alone or in combination with vitamins, or any product so specified by the manufacturer as a hematinic.

(D) Nutritional supplements (not covered under (f) (2) (A)).

(E) Amphetamines, amphetamine-like drugs (not covered under (f) (2) (A)).

(3) Authorization Procedures

(A) Prior authorization for prescribed drugs is obtained by submitting the Department's P.A. form, "Authorization Request and Bill for Prescription Drugs" to:

Department of Income Maintenance
110 Bartholomew Avenue
Hartford, Connecticut 06106
Attention: Medical Unit

(B) Prior authorization will be approved covering a maximum of a three (3) month period. The effective starting date will be the date service is initially rendered and approved. If the need for service exceeds the authorization period, a request for an extension must be submitted on a form provided by the Department and approved prior to the onset of the period of extension. The request is sent to the Department with documentation by the physician that the medication continues to be medically necessary.

(C) A pharmacist receiving a prescription for medication requiring prior authorization must complete the pharmacy section of the P.A. form. The licensed authorized practitioner (prescriber) must complete all relevant portions of the P.A. form. The pharmacist will then submit the request to the Department for consideration.

(D) In emergency situations, the pharmacist may telephone the Department to obtain verbal authorization. The written request for authorization must be submitted to the Department within fifteen (15) working days following verbal authorization.

(E) In emergency situations, which occur after normal working hours, the pharmacist must call the Department for verbal approval on the following work day. The written request for authorization must be submitted to the Department within fifteen (15) working days following the date the medication was dispensed.

(g) **Other**

(1) Information Required on Prescriptions

All prescriptions must be processed in accordance with the regulations of the Commission of Pharmacy.

(2) Retention of Prescriptions

All claims for covered drugs must be substantiated by a prescription from a licensed authorized practitioner on file in the pharmacy supplying the service, in accordance with Section 20-184c of the Connecticut General Statutes. In addition, documentation of

prescriptions and/or medication orders must be retained by the pharmacy for a period of five (5) years or if any dispute arises concerning a prescription, until such dispute has been finally resolved.

(3) Patient Profile

A patient profile record listing prescriptions must be maintained by the pharmacy for Title XIX patients.

(4) Oral Prescriptions

An oral prescription which is telephoned by a licensed authorized practitioner to a pharmacist must be documented in writing by the pharmacist for his records. These orders must be countersigned or initialed by the pharmacist and must meet the requirements as contained in Section 20-184b of the General Statutes and as it may be amended from time to time.

(h) **Billing**

Bills for covered drugs from pharmacy providers, are submitted on the Pharmacy Claim form or electronically transmitted to the Department's billing fiscal agent and must include all information required by the Department to process the claim for payment.

(i) **Payment**

(1) Payment for Legend Drugs

Except for vaccine(s) utilized in mass inoculation, payment for legend drugs shall be based on the quantities set forth in A.W.P. for one hundred units, a pint if liquid or pound if powder, or as determined by the Department. Reimbursement will be made under E.A.C. or F.A.C., whichever is applicable to the particular drug dispensed plus the dispensing fee, or the usual and customary charge to the general public, whichever is lower.

The Department will pay for mass inoculation of Influenza, Pneumovax or Hepatitis-B vaccine(s) provided they are prescribed by a licensed authorized practitioner and documented in the patient's medical record. The reimbursable amount and reimbursement procedures will be determined by the Department and supplied to providers via a fee schedule.

(A) Estimated Acquisition Cost

The Department of Income Maintenance must determine an E.A.C. for all legend drugs not covered by the F.A.C.

(i) The Department's E.A.C. will be the Department's best estimate of the price generally and currently paid by providers for a drug marketed and sold by a particular manufacturer or labeler in the package size of drugs most frequently purchased by providers. E.A.C. will be set at a percentage of A.W.P. The Department will notify providers in the event that the Department's best estimate of the appropriate percentage changes.

(ii) The Department shall reimburse providers at the lower of the following:

a. The Department's E.A.C. plus the applicable dispensing fee; or

b. The provider's usual and customary charge to the general public; or

c. The amount billed by the provider.

(B) Multiple-source Drugs

For each multiple-source drug for which HCFA has identified and designated a F.A.C., reimbursement shall be the lower of the following:

(i) The F.A.C. as established by HCFA plus the applicable dispensing fee; or

(ii) The provider's usual and customary charge to the general public; or

(iii) The amount billed by the provider.

(C) Certification of Brand Name Drugs

Reimbursement for multiple-source drugs for which HCFA has designated a F.A.C. is not limited to the F.A.C. if a licensed authorized practitioner determines that a specific brand is medically necessary for a particular patient, provided the following requirements are met:

(i) A licensed authorized practitioner may certify in writing that there shall be no substitution for a specified brand name drug product prescribed for a particular patient, by writing the phrase "Brand Medically Necessary," on the prescription form. The phrase shall be in the practitioner's handwriting and shall not be preprinted, stamped, initialed, or checked off in a box on such form.

(ii) If the licensed authorized practitioner specifies by telephone that there shall be no substitution, handwritten certification bearing the phrase "Brand Medically Necessary," must be mailed to the pharmacy within ten days. The written certification must be kept by the pharmacist as part of his or her permanent records.

(D) Compounded Prescriptions

The Department will pay for compounded prescriptions at the lower of:

(i) The E.A.C. or F.A.C., whichever is applicable to the given drug, for each ingredient plus an applicable dispensing fee; or

(ii) The provider's usual and customary charge to the general public; or

(iii) The amount billed by the provider.

(E) Unit Dose Packaging

The Department will not pay providers for unit dose packaging or any other specially packaged drugs when standard packages are available and/or where the special packaging is strictly for convenience and does not contribute to the therapeutic benefit of the drug.

(2) Payment for Nonlegend Drugs

(A) The Department of Income Maintenance will pay for all O.T.C. drugs listed on the Connecticut O.T.C. Formulary, provided they are prescribed for a specific illness and/or condition by a licensed authorized practitioner.

(i) The reimbursable amount shall be established by the Commissioner. The Department will publish the reimbursable amounts via a fee schedule.

(ii) The Commissioner shall appoint a committee to periodically review the drugs listed on the Connecticut O.T.C. Formulary. Periodically a report of the committee's recommendations will be submitted to the Commissioner for consideration. The committee may include one or more of the following; a physician, a pharmacist and a nurse consultant.

(iii) For any non-legend drug prescribed in less than the standard packaged amount, the Department will pay for the contents of the full package size which is closest to the amount ordered and still be sufficient to supply the amount prescribed.

(3) Dispensing Fees

Dispensing fees will be established by the Department after periodic review of pharmacy operational cost. Pharmacy providers will be advised of such fees and any changes.

(4) Substitution of generically Equivalent Drugs

(A) The Department will pay a pharmacist a professional dispensing fee of fifty cents ($.50) per prescription in accordance with Section 17-134q of the Connecticut General

Statutes in addition to any other dispensing fee, for substituting a generically equivalent drug product, in accordance with Section 20-185b of the Connecticut General Statutes, for the drug prescribed by the licensed authorized practitioner for a Medicaid recipient, except in the following instances:

(i) When a drug product is dispensed for which HCFA has designated a F.A.C.; or
(ii) When a compounded prescription is dispensed; or
(iii) When a nonlegend drug is dispensed; or
(iv) When the substitution is required by Federal law or regulation.

(Effective July 29, 1992)