

TABLE OF CONTENTS

19.1	Pharmacy Services	3
19.1.1	Description	3
19.1.2	Amount, Duration and Scope	3
19.1.3	Drug Formulary	3
19.1.3.1	General	3
19.1.3.2	Drugs	3
19.1.3.3	The Drug Use Review (DUR) Board	4
19.1.4	Exclusions	4
19.1.5	Limitations	6
19.1.5.1	General	6
19.1.5.2	Medicare Issues	7
19.1.5.3	Long Term Care Issues	8
19.1.5.4	Medical Supplies	9
19.1.5.5	Clinical Screening, Counseling and Patient Profiles	9
19.1.5.6	Emergency Dispensing of Drugs Not in the Formulary or Require Prior Authorization	9
19.1.5.7	Drug Abuse/Over-Utilization	9
19.1.5.8	Drug Services – covered with limitations	9
19.1.6	Authorization Requirements	10
19.1.6.1	General Prior Authorization Information	10
19.1.6.2	Emergency Dispensing of Drugs Which Require Prior Authorization	12
19.1.6.3	Processing of Claims for Non-Rebate Drugs	13
19.1.6.4	Specific Brand Product	13
19.1.6.5	Other Prior Authorization Issues	13
19.1.7	Billing	15
19.1.7.1	General Pharmacy Billing Policies	15
19.1.7.2	Clarification of Decimal Units Billing	15
19.1.7.3	Claims for Injectables – Billing Units	16
19.1.7.4	Dispense as Written (DAW)	16
19.1.7.5	Billing Procedures for Partial Filling of Prescriptions	18
19.1.7.6	Early Refills	19
19.1.7.7	Vacation Supply	19
19.1.7.8	Other Billing Information	20
19.1.7.9	Adjustments Requests	21
19.1.7.10	Qualified Medicare Beneficiaries (QMB) versus Dual Eligibles	21
19.1.7.11	Claims Submittal	21
19.1.7.12	Point of Sale (POS) System	22
19.1.7.13	Records	22
19.1.8	Reimbursement of Pharmacy Claims:	23
19.1.8.1	General	23
19.1.8.2	Dispensing Fee	24
19.1.8.3	Clarification of One Dispensing Fee Allowable Per 30 Days	25
19.1.8.4	Compounding Fees	26
19.1.9	Long Term Care Issues	26

19.1.9.1	Emergency Calls _____	26
19.2	Hospital Outpatient Pharmacy _____	27
19.2.1	Description _____	27
19.2.2	Amount, Duration and Scope _____	27
19.2.3	Drug formulary, Exclusions, Limitations, Authorization Requirements, Reimbursement of Pharmacy Claims and Long term Care _____	27
19.2.4	Billing _____	27
19.3	Home Pharmacy Services and Supplies _____	29
19.3.1	Description _____	29
19.3.2	Amount, Duration and Scope _____	30
19.3.3	Limitations _____	30
19.3.4	Authorization _____	31
19.3.4.1	General _____	31
19.3.4.2	Authorization Criteria (Excluding Catheter Care, Enteral and Parenteral Nutrition) _____	32
19.3.4.3	Approval Criteria for External Infusion Pumps _____	32
19.3.4.4	Authorization Criteria for IV Catheter Care _____	32
19.3.4.5	Authorization Criteria for Enteral Nutrition _____	32
19.3.4.6	Authorization Criteria for Parenteral Nutrition _____	33
19.3.4.7	Reimbursement _____	33
19.3.4.8	Components _____	36

19.1 Pharmacy Services

For the most current updates and information, refer to the Pharmacy Fiscal Agent's website listed in Appendix 1.

19.1.1 Description

The Medicaid program pays for medically necessary and non-experimental drugs and pharmacy services with certain limitations.

19.1.2 Amount, Duration and Scope

Licensed pharmacies may dispense formulary medications to recipients. Pharmacy technicians may help prepare the prescriptions if supervised by a licensed pharmacist but the pharmacist must review all work and is responsible for the actions of the pharmacy technician. Licensed physicians or prescribers may administer or dispense formulary medications to their patients. Nursing staff under the prescriber's supervision may administer formulary medications.

19.1.3 Drug Formulary

19.1.3.1 General

- a) The Medicaid Drug Formulary is basically an open formulary with specific exclusions and limitations.
- b) Choices of drug products are based upon therapeutic efficacy, safety and economy from manufacturers participating in the federally required rebate program as described in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90).
- c) Nothing in the formulary or general rules gives permission or is intended to encourage violation of state or federal laws or regulations.

19.1.3.2 Drugs

- a) Payments shall be made for drugs when dispensed to eligible recipients within the following guidelines:
 - When prescribed by a practitioner licensed by the state;
 - For prescriptions prescribed by an out-of-state practitioner, state regulations regarding the filling of out-of-state prescriptions would apply including the requirement that the prescriber must be licensed in his/her own state;

- When the drug has been approved by the U.S. Food and Drug Administration for the purpose for which it is prescribed for human use;
 - When the drug can be expected to be of therapeutic value for the disease or condition under treatment; and
 - When the medication is covered by the program or prior authorization has been obtained from the Fiscal Agent.
- b) On rare occasions, a non-rebate manufacturer's product may be the only appropriate medication for the recipient's condition. In this case, the MQD Administrator must approve the prior authorization because no federal funding will be provided.
- c) Medications for inpatients of acute care facilities and patients undergoing renal dialysis are exempt from formulary restrictions. Drug claims for recipients receiving renal dialysis must still be billed to other primary insurance such as Medicare, if applicable.
- d) When a Specific Brand is Required:
- The statement "Brand Medically Necessary" or "Do Not Substitute" must be written on the face of the prescription by the prescribing physician. Preprinted or prestamped notations are not acceptable.
 - The pharmacist receiving telephone requests must write on the face of the prescription, "Brand Specified by Dr. _____" and sign their full name. The prescribing physician is to document the brand specifically designated and the reason for the medication in the patient's chart.

19.1.3.3 The Drug Use Review (DUR) Board

The DUR Board consists of appointed actively practicing physicians and pharmacists from various settings and one drug manufacturer representative. The Board meets quarterly to discuss retrospective drug utilization issues; prior authorization criteria, ongoing education and other drug related issues. The DUR Board is part of the Drug Use Review program required by Section 1927 of the Social Security Act. For more details, see Appendix 6, Drug Use Review Program.

19.1.4 Exclusions

- a) Certain combinations of drugs for which the pharmacological action of the components is subject to question or because of excessive costs are excluded.
- b) Drugs for the treatment of pulmonary tuberculosis or for Purified Protein Derivative (P.P.D.) conversion are excluded. Exceptions for chemoprophylaxis of tuberculosis with isoniazid for children is permitted based on the criteria listed in Appendix 6, Drug Coverage Criteria.

Patients with pulmonary tuberculosis must be referred to Lanakila Health Center or Leahi Hospital on Oahu, or local health department tuberculosis clinics on neighbor islands.

- c) Drugs for the treatment of Hansen's disease are excluded and recipients should be referred to the Department of Health's Hansen's Disease Program for medications provided free of charge.
- d) Drugs not approved by the FDA for the purpose for which it is being prescribed, as well as drugs deemed "less than effective" are not covered. Refer to periodic lists of "less than effective" (LTE) drugs which are commonly referred to as Drug Efficacy Study Implementation (DESI) 5 or 6 drugs. (See the Pharmacy Fiscal Agent's website for the current list of LTE drugs)
- e) Foods and food supplements are not considered drugs and are, therefore, excluded from the formulary. These require prior authorization and are billed using HCPCS codes.
- f) Natural, organic and herbal preparations are excluded.
- g) Products for cosmetic purposes, such as tretinoin (Retin-A) for skin improvement or Minoxidil (Rogaine) for hair growth, are not covered. However, their uses for pathological conditions, e.g., Minoxidil as an antihypertensive medication, are covered.
- h) Hypopigmentation agents such as Lustra, Solaquin, Esoterica and Nuquin HP
- i) Fertility agents or those inducing ovulation are excluded.
- j) Vaccines for travel and vaccines provided by the Vaccines for Children Program (VFC) are excluded. Refer to the Immunization section, Chapter 6.
- k) Experimental drugs are excluded
- l) Treatments for erectile dysfunction in males such as, penile prostheses, etc. are excluded.
- m) Drug products supplied by manufacturers that do not participate with the CMS (formerly HCFA) drug rebate program are not covered. Contact the Pharmacy Fiscal Agent by phone or through the website for the listing of drug manufacturers who participate with the CMS Drug Rebate Program.
- n) Androgens and estrogens for establishment or maintenance of gender reassignment (transsexual) are excluded unless the individual's sex was changed by court order. A diagnosis is required for all prescriptions and claims for estrogens and androgens when prescribed for patients under 40 years of age.

19.1.5 Limitations

19.1.5.1 General

- a) Anabolic steroids require approval on a Request for Medical Authorization Form 1144b prior to dispensing. Refer to Appendix 4 for a sample of the form.
- b) Appetite suppressants (anorexics) require prior authorization. Information on the Request for Medical Authorization form (Form 1144b) must include the patient's weight and program for weight loss. (Refer to Appendix 4 for information about completing Form 1144b.) Other types of weight loss products such as Meridia may have more specific prior authorization criteria. Please refer to the list of medications requiring prior authorization in Appendix 6 Drug Coverage Criteria or to the Pharmacy Fiscal Agent's website (listed in Appendix 1).
- c) Methylphenidate and amphetamines are payable without prior authorization only for treatment of hyperkinesis, attention deficit disorders or narcolepsy. The diagnosis must appear on the prescription and the claim.
- d) If prior authorization is required but has not been obtained, the claim will be denied.
- e) The prior authorization requirement for designated medications is waived in certain instances for specified practitioner specialties. Psychiatrists may prescribe most typical antipsychotics without prior authorization approval. Non-psychiatrists must obtain prior authorization for clozapine, olanzapine, risperidone, quetiapine and ziprasidone. Refer to the Drug Coverage Criteria in the Pharmacy Fiscal Agent's website for additional information.
- f) Vitamins and minerals are excluded from the program except:
 - Multiple vitamins taken during pregnancy or lactation. The acceptable diagnosis of "pregnancy" or "lactation" must appear on the prescription and the claim.
 - Pediatric multiple vitamins, including those with fluoride, for children who are 12 years and younger.
 - Vitamins for specific deficiencies, e.g., pernicious anemia, sprue, scurvy, beriberi, etc., for outpatients with prior authorization. Physical, laboratory or other findings establishing the diagnosis must be available in the prescribing physician's medical records.
 - One multivitamin orally without prior authorization, for patients in nursing facilities. Claims must indicate the facility where the patient is confined.

- g) Coverage of non-prescription drugs is limited. See the Pharmacy Fiscal Agents website listed in Appendix 1 for the Over the Counter (OTC) Formulary.
- h) For diabetic supply limitations, please refer to Chapter 10, DMEPOS.
- i) The maximum quantity of medication, which may be dispensed at one time for outpatients, is a 30-day (one month) supply or 100 eaches, or 50 gms or 50 mls, whichever is greater.

If the estimated days supply exceeds thirty (30) days:

- 1) And the drug prescribed is dispensed in the original, unbreakable, sole or smallest unit, the days supply may be entered as thirty (30) days; or
- 2) The prescriber orders a quantity that exceeds thirty (30) days but the smallest package would result in less than a thirty (30) day supply, the provider should dispense the smallest quantity that would exceed the thirty (30) days supply and enter thirty (30) days supply.
- j) Lower cost therapeutically equivalent drug products must be dispensed if available in the marketplace and substitution is not prohibited by Part VI, Drug Product Selection of Chapter 328, HRS. The recipient may refuse the lower cost drug products but must pay the entire cost of the higher cost equivalent.

19.1.5.2 Medicare Issues

Medications that are covered by Medicare must be billed to Medicare first. Medicaid is always the payer of last resort.

a) Insulin Used in Insulin Infusion Pumps

- 1) As of April 1, 2000, Medicare reimburses the following:
 - The external ambulatory infusion pump for insulin,
 - Injection, insulin
 - Supplies for the insulin pump
- 2) Claims for the above items for recipients with Medicare and Medicaid coverage who meet the Medicare criteria such as Type 1 diabetes and require multiple daily injections and glucose injections, must be billed to the Medicare Part B Durable Medical Equipment Carrier Regional Carrier (DMERC) first. If postpayment reviews by the Med-QUEST

Division (MQD) show claims are being inappropriately billed to and paid by Medicaid, recovery of all allowances involved will be made.

b) Self-Administered Anti-emetic Drugs

- 1) Effective for dates of service on or after January 24, 1996, Medicare pays for the oral or rectal versions of self-administered anti-emetic drugs when they are necessary for the administration and absorption of primary Medicare covered oral anti-cancer chemotherapeutic agents when a high likelihood of vomiting exists. Coverage is presently limited to those agents given within 2 hours of the administration of the oral anti-cancer drug. The Medicare Part B DMERC should be billed for these claims.
- 2) Physicians and other prescribers should note the oral anti-cancer agent being used, the frequency of administration (if not included on the same prescription as the anti-emetic) and the diagnosis code for cancer on the prescription to assist the pharmacy providers with billing Medicare.

c) Coverage of Immunosuppressant Drugs Following Covered Organ Transplants

- 1) Effective December 21, 2000, eligible Medicare beneficiaries who receive drugs used for immunosuppressive therapy to prevent transplant rejections will continue to be eligible for this benefit from Medicare without limitations.
- 2) Medicare will also cover currently Medicare eligible beneficiaries who had their drug coverage terminated prior to December 21, 2000 due to previously imposed time limitations.

d) Coverage of Annual Influenza and Pneumococcal Vaccines

Medicare Part B covers 100 percent of the reasonable cost of both of these vaccines provided to nursing home residents who are Medicare beneficiaries. Refer to the Immunization section, Chapter 6.

e) Other Criteria and Restrictions

See Appendix 6, Drug Coverage Criteria, or the Pharmacy Fiscal Agent's website (listed in Appendix 1) for additional information regarding Medicare coverage and Medicaid restrictions for such drugs as oral anti-cancer agents and immunosuppressive agents, etc.

19.1.5.3 Long Term Care Issues

- a) Emergency Calls, see 19.1.9.2.

19.1.5.4 Medical Supplies

- a) Medical supplies, such as insulin needles and syringes or sick room supplies, are not included in the formulary because they are not drugs; however, they are included in the program and may be obtained by prescription.
- b) Information about medical supplies can be reviewed in Chapter 10, DMEPOS.

19.1.5.5 Clinical Screening, Counseling and Patient Profiles

Pharmacy providers must perform prospective drug use review, which includes the following elements:

- Perform clinical screening on all fee-for-service Medicaid prescriptions.
- Offer counseling on all prescriptions – new and refills.
- Maintain appropriate documentation.
- Maintain patient profiles.

See Appendix 6, Prospective DUR, for more detailed criteria and requirements.

19.1.5.6 Emergency Dispensing of Drugs Not in the Formulary or Require Prior Authorization

Drug products that are not covered by the program or that require prior authorization may be provided in an “emergency situation”. The supply is not to exceed 72 hours. See section 19.1.6.2.

19.1.5.7 Drug Abuse/Over-Utilization

- a) All providers are urgently requested to assist the Medicaid program in identifying cases of drug abuse or over-utilization. Information should be transmitted to DHS/MQD/MSB. Refer to Appendix 1 for the address and telephone number.
- b) The program may restrict recipients who are overutilizing controlled substances or who are receiving unusually extensive medical services from multiple providers to one primary care provider and pharmacy.

19.1.5.8 Drug Services – covered with limitations

- a) Drugs must be prescribed by a licensed prescriber and be medically necessary for the treatment of the condition for which it was prescribed.

- b) The maximum quantity of medication which may be dispensed at one time is as follows:
- Patients discharged from hospitals or acute care facilities may receive up to a 7-day supply of take home medications. This must be billed as part of the inpatient care. Refer to Outpatient Hospital Pharmacy, Section 19.2.
 - Outpatients may receive the larger of a one-month supply 50 gms, 50 mls or 100 eaches. All formulary guidelines and restrictions apply.
- c) Quantities exceeding these limits must be approved by the Pharmacy Fiscal Agent on the Request for Medical Authorization form - Form 1144b.
- d) Drugs approved by prior authorizations on Form 1144b must also be dispensed within guidelines a) and b) above unless specifically approved for amounts exceeding the maximum limits.
- e) For drugs used during treatment in the emergency room, take home drugs for outpatients treated in the emergency room, and drugs provided to waitlisted long-term care patients; see section 19.2, Hospital Outpatient Pharmacy.
- f) Additional limitations are described in Section 19.1.3, Drug Formulary.

19.1.6 Authorization Requirements

19.1.6.1 General Prior Authorization Information

- a) Approval is required before a non-formulary drug; an excluded drug or most restricted drugs under limitations are reimbursed.
- b) A request for prior authorization must be submitted by the prescriber or the pharmacy provider on the Medical Authorization form (Medicaid Form 1144b). The use of any unauthorized form is not acceptable.
- c) The Form 1144b must include but is not limited to the following: the drug name, strength and NDC number; daily dose, units (milligrams, milliliters, etc.) and quantity; diagnosis, expected effect and reasons for not using a drug product covered by the program. See the Pharmacy's Fiscal Agent's website listed in Appendix 1.
- d) Refer to Appendix 6, Drug Coverage Criteria for additional information regarding medications that require prior authorization.

- e) A cover sheet must accompany each 1144b form with the name, telephone number, and facsimile number of the pharmacy and the name of the contact person at the pharmacy. These must be sent by facsimile or mailed to the Pharmacy Fiscal Agent, ACS/Consultec. The fax number and mailing address are in Appendix 1.
- f) The Fiscal Agent will respond to requests for prior authorization of drugs submitted on the "Request for Medical Authorization" form (Medicaid Form 1144b) within twenty-four (24) hours of receipt. A fax cover page with the reviewer's first name, the approval period, the PA number or the reason for denial/deferral with a copy of the 1144b will be faxed back to the supplier and/or prescriber.

The Fiscal Agent will respond with its decision:

- an approval (A); if duplicate or overlapping authorizations are for a drug which is medically necessary and covered by Medicaid, the first complete authorization received by the Fiscal Agent will be approved and an authorization number will be provided by telephone to the pharmacy if applicable. Approvals on the Form 1144b may be for up to 1 year from the date of approval.
 - a denial (N); if duplicate or overlapping authorizations are for a drug which is medically necessary and covered by Medicaid, the second or later complete authorization received by the Fiscal Agent will be denied.
 - or a deferral (R) when the justification submitted is insufficient for either an approval or denial or if the form is incomplete (i.e., the physician's signature, his/her Medicaid Provider number and date of signature; the supplier's name, signature, Medicaid Provider number and date of signature.)
- g) The original 1144b should not be mailed to the Fiscal Agent. The pharmacy should retain the original 1144b form signed by the physician for its records. If the prescriber retains the original 1144b, the pharmacy should have a copy on file.
- h) Requests for vendor/supplier changes shall only be honored under the following circumstances:
- The original approval has expired.
 - If the original approval has not expired, the Fiscal Agent receives a written release from the original vendor/supplier on his/her letterhead. The effective date of the release, the recipient's name and the supplier's Medicaid provider number must be included. The new vendor must send a new 1144b to the Fiscal Agent for approval.

19.1.6.2 Emergency Dispensing of Drugs Which Require Prior Authorization

a) In an emergency situation, pharmacies can dispense a seventy-two (72) hour supply of an outpatient prescription drug which requires prior authorization under the conditions listed below:

- The situation must be a true emergency such that the consequence of delaying the dispensing of the drug by 24 to 72 hours results in a high probability of serious adverse effects on the person's health. Serious adverse effects are hospitalization, medically necessary emergency room care, and loss of bodily function or life.
- The dispensing of the 72 hour emergency supply of drugs applies ONLY TO OUTPATIENT PRESCRIPTION DRUGS from manufacturers that participate in the Drug Rebate Program and for drugs that are NOT determined to be less than effective (LTE) (DESI 5 and 6). See the Pharmacy Fiscal Agent's website for LTE drugs and for information on the Drug Rebate Program. The website address is listed in Appendix 1.
- A prescription is presented to a pharmacist for filling at a time when the prescribing physician cannot be reached to authorize medication changes and delayed receipt of the medication will be extremely detrimental to the patient's health.
- A similar medication covered by the program is not available to the community and to delay would seriously endanger the patient's life.
- There is no similar medication available without prior authorization or the patient has a documented intolerance for the similar agent. (Example: Patient has an intolerance for cimetidine and must take ranitidine.)
- An emergency supply of a specific brand name drug may be dispensed if the patient's physician has previously documented that the patient is unable to use a generic form of a drug (which does not require prior authorization) because of an allergy or history of a serious adverse reaction to the generic drug.

b) The following procedures should be used for emergency dispensing of drugs:

- An 1144b form must be completed and submitted to the Fiscal Agent following the steps outlined above and in Section 19.1.6.1.

In addition, the phrase "emergency dispensing," the date, time, and justification for dispensing of the drug must be entered under the name of the drug.

- Claims for payment of medications dispensed in an “emergency situation” must be so labeled **boldly** across the face of the claim. Complete a Form 1144b stating the time, dates and circumstances of the emergency and attach the claim to the back of the form. For service dates prior to August 1, 2001, mail these claims to the Medicaid Fiscal Agent, ACS. For service dates after July 31, 2001, mail these claims to the Pharmacy Fiscal Agent – ACS Pharmacy Benefit Management (PBM). Refer to Appendix 1 for the mailing addresses.
- When approved, the claim will be processed and a cover page with the reviewer’s first name and a copy of the Form 1144b will be faxed/sent to the provider.

19.1.6.3 Processing of Claims for Non-Rebate Drugs

- a) Non-rebate drugs are occasionally covered if there are no rebate drugs which would adequately replace the therapeutic effect of the non-rebate drug and if it is medically necessary for the recipient to receive this the non-rebate drug.
- b) Authorization for non-rebate drugs is given on the Request for Medical Authorization Form 1144b by the MQD Administrator. Claims for non-rebate drugs cannot be processed electronically or by POS; they must be billed by hard copy.
- c) A copy of the 1144b form authorizing the non-rebate drug must be stapled to the top of the 204 claim form and addressed to the Pharmacy Fiscal Agent as indicated in Appendix 1.

19.1.6.4 Specific Brand Product

Prior Authorization is generally required for payment for a specific brand product for a multiple source drug when the allowance is limited by the most current FUL (federal upper limit) price. See CMS’s website (listed in Appendix 1) for drugs on the FUL price list. Providers should indicate that at least two generic drugs have been tried and were not effective or have caused adverse effects. Providers may contact the MQD Pharmacy Fiscal Agent for a listing of the FUL prices if the internet is not accessible.

19.1.6.5 Other Prior Authorization Issues

- a) Unless specifically stated, prior authorization requirements of a class of drugs (example: non-sedating antihistamines, atypical antipsychotics) apply to all NEW drugs added to the class and not specifically referred to in a Medicaid memorandum.
- b) Prior authorization requirements have been waived when certain classes of drugs are prescribed by physicians with specific specialties. The waiver given to these specific specialties applies to new drugs added to the same class and may not be specifically referenced in a Medicaid memorandum. See the Pharmacy Fiscal Agent’s website listed in Appendix 1 for the most current information. See “Drug Coverage Criteria” in Appendix 6 or

in the Fiscal Agent's website for a listing of practitioner specialties and other criteria. Additional information such as diagnosis codes may also be required.

- c) Non-psychiatrists must complete and submit a Request for Medical Authorization (1144b), a Use of Clozapine, Olanzapine, Quetapine and Ziprasidone (1162) form and a Brief Psychiatric Rating Scale (BPRS) for atypical antipsychotics. See Appendix 4 for the 1162 Form and instructions.
- d) Medications dispensed in excess of 100 eaches (tablets or capsules) or a 30 day (one month) supply whichever is greater require prior authorization except for the following:
- Liquids or sprays or inhalers which may be dispensed up to 50 mls, 50 gms or a 30 day (one month) supply whichever is greater, or
 - Birth control pills which may be dispensed for up to three cycles of 28 days.
- e) When a drug billed on a hard copy claim requires prior authorization, these claims must be submitted timely and need to be checked prior to dispensing for the following:
- PA approved if applicable;
 - Participating rebate manufacturer; and
 - Non-DESI product
- Refer to the Pharmacy Fiscal Agent's website under the Drug Coverage heading and PA criteria; under the Communications heading for the Drug Rebate report and the DESI listing. Providers without Internet access may contact the Pharmacy Fiscal Agent's Help Desk for a printed copy. The website and phone number are listed in Appendix 1.
- f) Prior authorization for medical supplies, durable medical equipment (DME), orthotic devices and prosthetic devices should not be submitted on the same 1144b form as the outpatient prescription drugs. See Chapter 10, DMEPOS.
- g) The 24-hour return time does not apply to authorizations for enteral and parenteral nutrition as these therapies are generally considered to be medical supplies/durable medical equipment (DME), are coded primarily with CMS alphanumeric codes and are subject to the DME authorization guidelines.

*19.1.7 Billing**19.1.7.1 General Pharmacy Billing Policies*

The National Council for Prescription Drug Programs (NCPDP) standard billing units are required for all drug claims. Metric decimal quantities are to be submitted on all claims for medications.

- a) There are three types of billing units: eaches, milliliters and grams. There are very few exceptions to the use of these three units including, but not limited to, Herceptin, which is billed by the number of milligrams and human antihemophilic factor, which is billed by the number of units.
- b) The proper billing units for a drug can be obtained from the following sources: First Data Bank software, the Red Book and the drug manufacturer.
- c) The NCPDP units assigned to an NDC number may not be the same as the units assigned to the drug's Health Care Financing Administration (HCFA) Common Procedural Coding System (HCPCS) alpha numeric code. The units assigned to a HCPCS code should not be used for an NDC number without verifying that the units are correct.

19.1.7.2 Clarification of Decimal Units Billing

- a) The proper billing of units for Medicaid drug claims are decimal quantities.
- b) For software systems that bill by decimal or whole number quantities, the provider's software manual and/or vendor should be consulted to determine the decimal capacity of the provider's computer's billing system for Point-of-Sale (POS) electronic transmissions.
- c) If the provider's system does not accept decimal quantities (because it is a whole number system), then claims for these units need to be billed manually for the decimal quantity.
- d) It is not an option to round up the decimal to a whole number. It is not an option to bill it incorrectly via electronic transmission by POS. The drug claim must be billed manually to correctly indicate the decimal quantity. The billed price must be accurate on a decimal quantity basis regardless of the quantity specified in the non-decimal units field, when entering it into your whole number system.
- e) Once a drug claim is submitted with incorrect information and the provider has knowingly submitted the claim with incorrect information, MQD shall consider this fraudulent billing

Examples follow:

Product			Quality Dispensed	Proper Billing of Units	
Name	NDC No.	Size		Decimal System	Whole Number System
Beclovent Inhalation Aerosol	00173-0312-88	16.8 gm	1 inhaler	16.8 gm	*
			2 inhalers	33.6 gm	*
Genoptic Ophthalmic Ointment	00023-0320-04	3.5 gm	1 tube	3.5 gm	*
			2 tubes	7 gm	7 gm
Lovenox prefilled syringe	00075-0624-03	0.3 ml	3 syringes	0.9 ml	*
			4 syringes	1.2 ml	*
			5 syringes	1.5 ml	*
			10 syringes	3 ml	3 ml
Metaproterenol Inhalation Solution		2.5 ml	25 vials	62.5 ml	*
Xalatan	00013-8303-04	2.5 ml	1 bottle	2.5 ml	*

*The drug claim must be billed manually to correctly indicate decimal quantity.

19.1.7.3 Claims for Injectables – Billing Units

When billing for injectable medications such as Herceptin, Rituxan, Cyclophosphamide, etc., the actual amount provided to the recipient must be billed. If a partial container is provided, the quantity billed should reflect this regardless of the size of the package. If the patient only uses a partial container, the entire package can only be billed when no other patient uses any portion of the container and the remainder has to be discarded. Documentation of the wastage must be included in patient records.

19.1.7.4 Dispense as Written (DAW)

- a) DAW 1 represents when a physician has written “Brand Medically Necessary” or “Do Not Substitute”. Claims for brands without FUL (Federal Upper Limit) or SMAC or for specific generic labeling may be processed using DAW 1.

b) DAW 5 represents brand dispensed, priced as generic.

- **Federal Upper Limit (FUL).** If a provider wishes to dispense a brand name product and be reimbursed at the FUL price since the generic is not available at a particular time or the “brand” is considered the provider’s generic, Medicaid will reimburse these claims without prior authorizations unless Brand Medically Necessary is noted.
- **State Maximum Allowable Cost (SMAC).** If the provider is willing to accept the SMAC reimbursement for a brand product (including branded generics), the provider may submit the claim with DAW 5. Products with FULs or SMACs are NOT considered part of the Generic Mandatory Program described below.
- **Generic Mandatory Program – No FUL or SMAC.** A generic is mandatory for a brand if 2 or more therapeutically equivalent generic products are available. The provider may submit a claim without a prior authorization for drugs that meet all of the following criteria:
 1. A brand product or expensive generic (branded generic);
 2. No Federal Upper Limit (FUL) or SMAC for the product;
 3. Part of the mandatory generic program;
 4. Submitted with a DAW 5 code; and
 5. A total submitted charge less than or equal to \$15.00 (includes dispensing fee).

Some possible options for submitting a claim for a brand or a branded generic that has been denied after submitting with a DAW 5 and receiving an alert of “PA required” are as follows:

1. The claim can be submitted via Point-of-Sale (POS) if the provider bills and accepts the total payment of \$15.00 or less.
2. A claim can be submitted after prior authorization (Form 1144b) for the prescriber justifying the need for the specific branded generic is authorized. The DAW 5 code and the PA number for the branded generic must be submitted.
3. An “expedited” prior authorization (Form 1144b) may be submitted to the Pharmacy Fiscal Agent without a prescriber signature ONLY when there is a product shortage for less expensive generics. The Pharmacy Fiscal Agent will authorize the drug if both of the following conditions are met:
 - a) A completed prior authorization (Form 1144b) without the prescriber signature; and

- b) The justification field of the 1144b is completed with the specific language that states: “Branded generic: Less expensive generic not available from wholesaler.”

For auditing purposes, it is recommended that documentation be noted on the written prescription.

4. If a less expensive generic is not available at the pharmacy, the recipient can be referred to another pharmacy that does stock a less expensive generic.
5. The actual brand product may be used if indicated by the prescriber as Brand Medically Necessary or Do No Substitute. The claim can be submitted with DAW 1.

Claims for brands (including branded generics) with a total charge greater than \$15.00 require prior authorization if the prescriber has not indicated “Brand Medically Necessary” or Do Not Substitute”.

If a generic product has not yet been approved for automatic substitution by the Department of Health due to the monthly meeting of the Hawaii State Drug Product Selection Board, the provider may submit the claim for the brand product on paper. The paper claim submitted for brand pricing must have boldly stated across the claim “Generic Not Yet Approved.”

- c) DAW 7 represents substitution not allowed - brand drug mandated by law. If a provider dispenses seizure medications used for the treatment of epilepsy, Medicaid will reimburse these claims as brand as mandated by law.

Claims for Coumadin and brand oral contraceptives with a Federal Upper Limit (FUL) price should be billed using DAW 7 unless the prescriber has noted brand medically necessary on the prescription. In this case, DAW 1 should be used.

19.1.75 Billing Procedures for Partial Filling of Prescriptions

- a) When a pharmacy provider cannot dispense the entire quantity required by a prescription due to an insufficient supply, the recipient may be given a partial quantity and asked to return for the remainder at a later date. In this situation, there are 2 different ways to proceed which would be acceptable to Med-QUEST Division (MQD):
- Bill the initial quantity plus the dispensing fee and when the remainder is picked up, the initial claim is canceled and a new claim for the entire amount is submitted; or

- Wait until the entire quantity is dispensed before submitting a claim for payment.

b) Under no circumstances is the MQD to be billed more than one dispensing fee.

19.1.7.6 Early Refills

No payment will be made for medication refills obtained more than one week before the anticipated end of the previous supply based on a 30-day supply. The POS system will reject all early refills. The Pharmacy Fiscal Agent will accept calls to the Help Desk concerning early refill authorizations for the scenarios listed below. If a prior authorization number is obtained, pharmacists may enter the number in the prior authorization field of their claims screen, and claims for early refills will adjudicate point-of-sale, without requiring a paper claim to be submitted to the Pharmacy Fiscal Agent. Manual claims must be submitted stating the reason for the early refill, such as:

1. Change in dose.
2. Additional therapy authorized.
3. Member was readmitted to a long term care facility.
4. Lost or stolen medication (see additional information below).

For members who have lost their medication or had their medication stolen, a maximum of one (1) early refill per month will be allowed for controlled substances and a maximum of two (2) early refills per month will be allowed for non-controlled substances by the Pharmacy Fiscal Agent. If claims are submitted manually, "Early Refill," "Lost Meds" or "Stolen Meds" must be written across the top of the claim form.

19.1.7.7 Vacation Supply

If a recipient is temporarily going out of state and needs a supply of medications to cover this period, a prior authorization request must be submitted for approval. If a recipient asks for refills of medication to be mailed to an out-of-state address, the recipient's assigned worker must be notified.

Requests for early refills due to vacation/funeral leave etc. will be accepted by the Pharmacy Fiscal Agent prior authorization department through a faxed 1144b form. The following information must be included on the physician-signed 1144b form when submitting a request for a vacation supply:

1. Medication to be filled early.
2. Quantity to be filled early.
3. Vacation destination (Neighbor Island will NOT be approved).
4. Length of trip

The authorization may not be greater than thirty (30) days in duration. The prior authorization number generated by the PA department will allow the early refill claim to adjudicate point-of-sale or submit the paper claim with a copy of the approved 1144b form. The paper claim must have noted boldly across the top the reason: "Vacation Refill."

19.1.7.8 Other Billing Information

- a) Claims for medications are not to be submitted on the UB-92 form unless provided as part of an emergency room visit.
- b) All charges for drugs used in a practitioner's office for testing are included in the fee for the specific procedure; no additional allowance for the drugs will be made.
- c) Only drugs are submitted in National Drug Code (NDC) format. Durable medical equipment (DME), medical supplies, and orthotic and prosthetic devices are not drugs even if they have valid NDC numbers. Therefore, for claims submittal and requests for authorization, DME, medical supplies, orthotic and prosthetic devices must be coded using applicable and appropriate alpha numeric Health Care Financing Administration (HCFA) Common Procedural Coding System (HCPCS) codes.
- d) All claims for drugs submitted by outpatient pharmacies, long term care pharmacies and prescribers must be coded with the NDC numbers assigned to the individual drugs. The only exception relates to compounded drugs.
- e) All drugs in the compounded product which have NDC numbers should be coded with NDC numbers and correct units. However, if any of the drugs to be compounded do not have an NDC number, the name of the drug and quantity must be provided.
- f) Claims for compounded drugs must be submitted hardcopy. Claims submitted electronically or via POS are not permitted.
- g) HCPCS codes are used for billing the intramuscular/subcutaneous administration of drugs. All drugs are billed using appropriate NDC numbers.
- h) Claims for patients with drug coverage through other primary health care insurance(s) commonly called third party liability (TPL) must **not** be submitted electronically or via Point-Of-Sale (POS). The pharmacy must bill the TPL first and then submit a claim for any co-payment via a HARDCOPY Pharmacy 204 Form with the Explanation of Benefits (EOB) or other accepted documentation attached. Drugs not covered by Medicare may be billed electronically or via POS. Medicaid is always the payer of last resort. Billing instructions are provided with the Pharmacy 204 form in Appendix 3.
- i) For claims from Hospital Outpatient Pharmacy, see section 19.2.4, Billing.

- j) The pharmacy provider is not obligated to refund recipients who have paid for prescriptions and then receive their Medicaid cards which include coverage for that time period. The MQD does not refund the recipient for any of their incurred expenses.
- k) The ACS Help Desk is available twenty-four (24) hours a day, seven (7) days a week. The Prior Authorization (PA) Desk is available 7 days a week. The toll-free number is located in Appendix 1.

19.1.7.9 Adjustments Requests

- a) To expedite the processing of adjustment requests:
 - Attach a copy of the remittance advice to the request with the claim number highlighted as this document contains all the necessary information to identify the claim; and
 - Indicate the specific reason for the adjustment (provider number should be ____, quantity should be ____, etc.). Noting “overpayment” or “underpayment” is not sufficient.
- b) Claims that a provider may feel are underpaid should be submitted with additional documentation to justify the services. Claims submitted with no additional documentation with not be considered for additional payment.

19.1.7.10 Qualified Medicare Beneficiaries (QMB) versus Dual Eligibles

- a) Under the Qualified Medicare Beneficiaries (QMB) plan, Medicaid only pays the Medicare premiums, deductibles and co-payments for the recipient. As such, QMB recipients are only entitled to Medicare benefits. Medicare should be billed for Medicare covered medications and the recipients should be charged for the drugs not covered by Medicare. A provider must be a registered with MQD as a QMB provider to be reimbursed for the deductibles on Medicare crossover claims.
- b) For recipients with dual coverage, QMB and Medicaid, Medicare should be billed for the Medicare covered drugs and Medicaid for the rest. For dual eligibles, the provider does not have to be a registered QMB provider.
- c) See Chapter 3, Provider, for additional information.

19.1.7.11 Claims Submittal

Claims can be submitted as electronic medical claims (EMC), by hard copy CMS (formerly HCFA) 1500 or Form 204 – the prescription drug claim form, or through the point of sale (POS) program.

19.1.7.12 Point of Sale (POS) System

- a) The POS system will be restricted to Medicaid pharmacy providers who have National Association of Boards of Pharmacy (NABP) numbers.
- b) Claims for the following are excluded from the POS system:
- Patients with Third Party Liability (TPL): The pharmacy must bill the TPL first and then submit any co-payment on a hard copy Pharmacy 204 or CMS (formerly HCFA) 1500. The Medicaid Program will recover any overpayments made for claims with TPL.
 - Medical supplies or Durable Medical Equipment (DME) will not be processed by the POS system;
 - Home infusion therapy drugs – if a provider “prepares” a medication for parenteral administration such as Rocephin mixed into a 100cc partial fill bag for in the home setting; See section 19.3, Home Pharmacy Services and Supplies;
 - Multiple submissions of the same claim via different submission methods – paper, EMC, POS;
 - Drugs compounded by the pharmacy;
 - Drugs prescribed for recipients with Medicaid coupons;
 - Drugs prescribed for recipients with “spend-down” (cost-share) requirements, if service date is prior to August 1, 2001;
 - Non-rebate drugs; or
 - Drugs prescribed for prisoners

19.1.7.13 Records

a) Records Maintenance

Providers under the Medicaid Program shall maintain and keep all records necessary to fully disclose the extent of services rendered to recipients. Records are to be retained for a period of at least 7 calendar years and must comply with Federal retention rules. These records include the following:

- Signature logs noting counseling and medication being dispensed to specific recipient; and

- Records of prescriptions, medications, assistive devices or appliances prescribed, ordered or furnished.

b) Examination of Records, see Chapter 2.

19.1.8 Reimbursement of Pharmacy Claims:

19.1.8.1 General

a) The maximum allowance for medications is the lowest of the following:

- Single source drugs:
 - 1) Estimated Acquisition Cost (EAC) plus a dispensing fee;
 - 2) The billed charge; or
 - 3) Provider's usual and customary charge.
- Multiple Source Drugs:
 - 1) The billed charge;
 - 2) The provider's usual and customary charge to the general public;
 - 3) The Federal Upper Limit (FUL) price plus dispensing fee; See Appendix 1 for CMS website for the FUL price list.
 - 4) The State Maximum Allowance Cost (SMAC) plus dispensing fee; or
 - 5) The Estimated Acquisition Cost (EAC) plus dispensing fee.
- Over-The Counter (OTC) Drugs:
 - 1) The billed charge;
 - 2) The provider's usual and customary charge to the general public including any sale item which may be available on the day of service;
 - 3) The State Maximum Allowable Cost (SMAC) plus a dispensing fee;

- 4) The Federal Upper Limit (FUL) price plus a dispensing fee; See Appendix 1 for CMS website for the FUL price list or
 - 5) The Estimated Acquisition Cost (EAC) plus a dispensing fee.
- b) The EAC is defined as the Average Wholesale Price (AWP) minus 10.5%.
 - c) The program shall not pay more than the general public for the same medication.
 - d) If at least two therapeutically equivalent generic drugs are available in the marketplace, Point-of-Sale (POS) claims will reject a submitted brand to bill for a generic product.
 - e) Payment will not be made for brand medications subject to the FUL when a less expensive therapeutically equivalent generic product is available and the prescriber has not noted "Brand Medically Necessary" on the prescription. If the recipient insists on the brand product, the recipient shall pay for the entire cost of the prescription.
 - f) Prescriptions must be written generically to allow dispensing of the most economically priced drug products available to the pharmacist or other dispenser, pursuant to the State generic product substitution act.
 - g) If the practitioner does not recall the generic name, "Substitution O.K.", "Generic Equivalent" or other similar notation may be written on the face of the prescription.
 - h) Certain products are exempt from the FUL price such as oral contraceptives, warfarin and antiepileptic medications when actually used for epilepsy as stated in Part VI, Drug Product Selection of Chapter 328, HRS. When anti-seizure medications are used for other indications, therapeutically equivalent generics are to be provided unless "Brand Medically Necessary" or "Do Not Substitute" is noted on the prescription. If the provider is not sure of the diagnosis, the provider must contact the prescriber for this information. (See section 19.1.7.4, Dispense as Written).
 - i) Claims for medications not dispensed or administered within applicable State and Federal laws will not be paid.

19.1.8.2 *Dispensing Fee*

- a) The State agency sets the dispensing fee based on results of surveys on the cost of pharmacy operations. This dispensing fee is added to ingredient cost when calculating payment for prescriptions.
- b) The dispensing fee for any maintenance or chronic medication shall be extended only once per 30 days without medical authorization from the program. Other appropriate limits

regarding the number of dispensing fees paid per interval of time shall be determined as necessary by the program. Note the following:

- Previously permitted quantities for more than 30 days such as birth control pills are not affected;
 - Previous allowance period for refills is not affected so a prescription may still be refilled up to 7 days early;
 - Maintenance/chronic medications dispensed on a trial basis (such as a 15 day supply) refilled for no more than 2 months are not included;
 - New prescriptions for maintenance/chronic medications due to a direction change are not included.
- c) The current dispensing fee for pharmacy providers is paid per claim. Other practitioners who dispense medications from their offices shall receive a different dispensing fee per claim. If a pharmacy is not located within 5 miles of the practitioner's office, special consideration for payment at the pharmacy rate may be made upon written request to the MQD Administrator for approval.

19.1.8.3 Clarification of One Dispensing Fee Allowable Per 30 Days

a) Specific Quantity Determined by Prescriber

- As stated in the Hawaii Administrative Rules (HAR), the MQD will only extend one dispensing fee per 30 days for any maintenance or chronic medication. However, a specific quantity determined by the prescriber if it lasts less than 30 days will be honored. When a specific quantity (examples: 20 tablets; 1 inhaler; 100 inhalations; 15gm) is stated on the prescription, the pharmacy provider may bill a dispensing fee for each refill regardless of the time period. However, to encourage patient compliance, the prescriber should be contacted for appropriate corrections if the quantity is not adequate. Example: An ointment is to be applied to most of an adult body twice times daily and a 15 gm tube is prescribed.
- For topical products, the number entered in the "Days Supply" field on the claim should be an appropriate estimate.

b) Quantity Determined by the Pharmacy Provider

- When the quantity is not determined by the prescriber but is left to the discretion of the pharmacy provider dispensing the medication (examples: PRN; 1 tube – if various sizes

are available), Medicaid will only extend one dispensing fee per 30 days regardless of how many times the prescription is refilled during that period.

- Examples:

- 1) Albuterol Inhaler – 2 puffs QID prn (no quantity stipulated)

If pharmacy provider determines how many inhalers and the size of the inhaler, the MQD would only extend 1 dispensing fee per 30 days because the prescriber did not specify the size.

- 2) Hydrocortisone Cream – apply BID prn

Dispense: 1 tube

If pharmacy provider determines the tube size dispensed, the MQD would only extend one dispensing fee per the 30 days because the prescriber did not specify the size.

19.1.8.4 Compounding Fees

Compounded drug allowances are determined as follows:

- a) Solutions and/or suspensions compounded from 2 liquids are reimbursed based on the cost of each solution or suspension plus the dispensing fee and a compounding fee.
- b) Ointments or creams compounded from two or more ointments or creams are reimbursed based on the cost of each ointment or cream plus the dispensing fee and a compounding fee.
- c) Ointments or creams compounded from substances levigated into ointment or cream base are reimbursed based on the cost of each ointment or cream plus the dispensing fee and a compounding fee.

19.1.9 Long Term Care Issues

19.1.9.1 Emergency Calls

- a) An emergency call shall be one that cannot be delayed, i.e. non-routine call to the patient of a facility by the pharmacist in a life-threatening situation. All other services shall be handled during the pharmacist's routine visits whenever possible.
- b) Pharmacists may be required to make emergency calls to the long-term care facility. A maximum of 4 visits per month may be paid at a rate per call for each 100 beds in the facility at the time the services are rendered. Any fraction of one hundred beds shall be prorated

accordingly. For facilities with less than 25 beds at the time services are rendered, pharmacists may charge up to one full emergency call per month.

19.2 Hospital Outpatient Pharmacy

19.2.1 Description

Pharmacy services may be provided through hospital outpatient pharmacies.

19.2.2 Amount, Duration and Scope

a) The drug is medically necessary to treat a recipient's medical condition as in the following:

- Outpatient drugs used during treatment in emergency rooms;
- Take home medications for outpatient treatment in emergency rooms;
- Take home medications for inpatients being discharged from a medical facility;
- Drugs used in the renal dialysis unit;
- Drugs used in the cancer chemotherapy unit;
- Drugs used in the hospital outpatient treatment room; or
- Waitlisted skilled nursing facility (SNF) or intermediate care facility (ICF) recipients who are located in the acute care area waiting for a space in the SNF or ICF area to become available.

c) Criteria in section 19.1.2, Pharmacy Services, also pertain to this section, Hospital Outpatient Pharmacy.

19.2.3 Drug formulary, Exclusions, Limitations, Authorization Requirements, Reimbursement of Pharmacy Claims and Long term Care

See Sections 19.1.3, 19.1.4, 19.1.5, 19.1.6, 19.1.8, and 19.1.9, respectfully in Pharmacy Services.

19.2.4 Billing

a) Emergency Room

- Outpatient drugs used during treatment in the emergency room are to be billed on the hospital claim form (UB-92) under the revenue codes specific for drugs 250.

- Take home medications for outpatients treated in the emergency room are to be billed on the Prescription Drug Claim 204 billing form, Electronic Media Claim (EMC) or using the Point-of-Sale (POS) system.

b) Inpatient Discharge

- Take home medications for inpatients being discharged from a medical facility must be billed as part of the hospital stay on the UB-92 claim form. A maximum of seven (7) days supply of medications may be dispensed at the time of discharge.

c) Hospital Outpatient (other than emergency room), Waitlisted SNF or ICF, and SNF or ICF

- Hospital outpatient would include such settings as a renal dialysis unit or cancer chemotherapy unit as well as hospital outpatient treatment rooms. Waitlisted SNF or ICF refers to recipients who are located in the acute care area waiting for a space in the skilled nursing or intermediate care facility area to become available. SNF or ICF refers to recipients who are located in the long-term care units of acute care hospitals. Medications provided in these settings must be billed on the Prescription Drug Claim 204 billing form, Electronic Media Claim (EMC) or using the Point-of-Sale (POS) system.
- Although the prescription number is a required field on the 204 form, the field does not require validation or a set format. Therefore, since the drugs provided in the outpatient hospital, acute waitlisted SNF and ICF settings are ordered by the physicians in the patient's medical chart and no formal prescriptions are filled, a written hospital order signed by the physician is an acceptable substitute for a prescription. The facility is not required to convert a written hospital order to a hard copy prescription. Because the accuracy of claims processing is not affected and documentation of all pharmacy orders is available, the facility may assign designated prescriptions numbers. Claims may have the same number (9999) or different numbers (100, 200, 300).
- Since waitlisted SNF and ICF and hospital outpatient orders do not indicate "refills", chronic medications should be billed once a month. Each month's billing will be considered a "new" order and must meet the requirements of a new prescription. Recertification of waitlisted SNF or ICF status must be performed each month. Thus, hospital orders for waitlisted SNF and ICF patients must be reviewed monthly.
- Billings for chronic medication should be for the medications supplied in one month and only for medications that have been administered to the patient. Billings for antibiotics or other drugs that are indicated for specific short-term therapy (7 days, 2 weeks) should be submitted once after the therapy has been completed or discontinued. For injectable medications that are prepared for the patient (e.g. Rocephin and 5% Dextrose), the

quantity of each ingredient should be billed separately by NDC number with one dispensing fee per line item.

- Outpatient drugs are usually administered following protocols that may be adjusted depending on the patient's response. Therefore, if the drugs and dosages of the drugs do not change during the month, they should be considered chronic medications and billed once a month. However, for drugs such as antibiotics and chemotherapy agents, if there is an adjustment to the drugs or dosages to the extent that a product with a different NDC number is used, the drugs with different NDC numbers used in a session do not have to be billed once during that month. If the same NDC number(s) are used, the dosages should be totaled and billed once a month.
- Medications such as Calcijex and Infed used in conjunction with routine clinical procedures such as hemodialysis are considered chronic medications. Although the quantity may vary during the month, the total amount given per month should be calculated and billed monthly. If fractional quantities cannot be processed by the provider's computer software billing program, the provider must bill the fractional quantities according to the procedures that apply to compounded drugs. The Fiscal Agent's pharmacy consultant will review these manual claims and extend payment for the correct quantity.
- If outpatient pharmacy software is used to submit long term care (LTC) claims, unique prescription numbers may be needed. If so, the patient's medications must be renewed at the time of the physician's required evaluation such as monthly or quarterly. The renewals may be used as prescriptions and a copy of the renewals must be present in the pharmacy. Any changes to the renewals must be posted in the patients' prescription profiles. If there are no changes on the physician renewals, the order will be valid for a one month supply with refills that do not exceed State regulations. Orders for controlled substances must indicate the quantity and refill status and be in accordance with State and Federal controlled substance requirements.

19.3 Home Pharmacy Services and Supplies

19.3.1 Description

- a) Home Pharmacy Services and Supplies, also called Home Infusion Services and Supplies, are those services and supplies related to the administration of fluids, drugs and chemical agents intravenously in the home setting.
- b) In addition, drugs and chemical agents provided by other parenteral means (Example: Subcutaneously, epidurally) which require the use of an infusion pump and the provision of nutritional substances parenterally or enterally to Medicaid recipients in the home setting are considered home pharmacy services and supplies.

19.3.2 Amount, Duration and Scope

- a) The service/supply is medically necessary to treat a recipient's medical condition.
- b) The therapy and therapeutic agents are non-experimental and can be safely provided in the home setting.
- c) It is medically justified to provide the service/supply in the home setting.
- d) The service/supply must be authorized on the Form 1144b.

19.3.3 Limitations

- a) The recipient
 - Must reside in a home (residence) to be eligible for this service. Services and supplies rendered during a stay in a hospital, nursing facility or other institutional setting are not reimbursable as home pharmacy services and supplies.
 - Must have a physician who prescribes the services/supplies and monitors the recipient's response to the therapy.
 - Must not require acute inpatient hospitalization.
 - Must be willing and capable of safely self-administering or have a caregiver who is available, capable and willing to administer and monitor the services/supplies. The recipient/caregiver must have received training to administer and monitor the therapy and must have demonstrated the ability to follow instructions, which were taught.
- b) The provider
 - Must have a valid Medicaid provider number.
 - Must either be accredited by the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) as a free standing home pharmacy or an acute care hospital.
 - Must bill in accordance with Medicaid billing requirements.
 - Must accept Medicaid reimbursement as payment in full and cannot balance bill the recipient.

19.3.4 Authorization

19.3.4.1 General

a) The following information should be documented on the Request for Medical Authorization (Form 1144b):

- Applicable diagnosis(es).
- The specific home pharmacy service(s) being requested—Example: IV anti-infective.
- The drug(s)/agent(s) being administered, the quantity and frequency—Example: ganciclovir, 300 mgms. daily.
- The reasons the service, drug, and method of delivery are medically necessary.
- The projected length of therapy.

b) The following therapies are covered under Medicaid's Home Pharmacy benefit:

- Unless clearly specified, the route of administration of the covered home pharmacy therapies must be intravenous. Generally, subcutaneous/intramuscular injections, such as insulin, growth hormone, epogen, etc., are not included in the covered home pharmacy therapies. However, subcutaneous injections may be covered when it is medically necessary for the drug to be given with a pump (example: subcutaneous narcotics with Patient Controlled Analgesia (PCA) device).
 - 1) IV hydration therapy.
 - 2) IV antibiotic, antiviral and antifungal therapy.
 - 3) IV, subcutaneous with PCA device and epidural chronic pain management.
 - 4) Intrathecal pain management (Implantable infusion pump).
 - 5) IV chemotherapy
 - 6) IV/Subcutaneous chelation therapy; specific IV therapy - immune gammaglobulin, inotropic agents, albumin; other IV therapy—agent must be specified.
 - 7) IV catheter care for a catheter which is not in active use.
 - 8) Enteral nutrition.

9) Parenteral nutrition.

19.3.4.2 *Authorization Criteria (Excluding Catheter Care, Enteral and Parenteral Nutrition)*

- a) The mode of therapy (intravenous, subcutaneous, epidural, intrathecal) is appropriate for the drug.
- b) The patient's condition cannot be treated with oral or intramuscular agents.
- c) The drug, quantity, frequency of administration and duration of therapy are medically appropriate.

19.3.4.3 *Approval Criteria for External Infusion Pumps*

- a) Infusion pumps must not be disposable and must meet at least one of the following criteria:
 - There is medical need for the infusion of the drug at a controlled rate.
 - There is medical need for the drug to be infused over an extended period of time (more than 2 hours) and not by bolus or for a shortened period of time (less than 2 hours).
 - Intermittent infusion by the patient is medically justified (example: PCA devices for intractable pain).
- b) If a stationary infusion pump is medically necessary, an IV pole or supply stand used with infusion pumps will be approved.

19.3.4.4 *Authorization Criteria for IV Catheter Care*

- a) The catheter is not in use.
- b) There is medical justification for not removing the catheter and likelihood that it will be accessed in the near future.

19.3.4.5 *Authorization Criteria for Enteral Nutrition*

- The prepared formula (example: Ensure, Jevity) must be administered through a nasogastric, gastric or other enteral tube.
- Prepared formula can only be authorized for oral intake if it is medically necessary in the treatment of an inborn metabolic abnormality or an abnormality of digestion or absorption.

- Low molecular weight prepared formula (Vivonex, Advera) can be authorized for oral use for patients who meet all of the conditions listed below:
 - a) Extreme weight loss of 20 pounds or 10% of normal body weight over a short period of time.
 - b) Serious diarrhea/malabsorption problems.
 - c) Otherwise would require total parenteral nutrition.
 - d) One of the following diagnoses:
 - AIDS/ARC Syndrome.
 - Chronic Pancreatitis.
 - Inflammatory Bowel Disease.
 - Regional Enteritis (Crohn's Disease).
 - Short Bowel Syndrome.
- 1) Enteral Pumps are authorized when gravity or syringe feedings are not suitable due to reflux, dumping syndromes and other conditions associated with bolus feedings which are ameliorated with the use of an enteral pump.
- 2) Enteral tubes
 - All enteral tubes need to be authorized.
 - A request for authorization of more than 3 nasogastric tubes (examples: B4081-B4083) or one gastrostomy/jejunostomy tube (examples: B4084, B4085) per 3 months must be medically justified.

19.3.4.6 Authorization Criteria for Parenteral Nutrition

The patient must have a condition, which involves the gastrointestinal system and significantly impairs its ability from absorbing the nutrients needed to maintain weight and optimize bodily functions.

19.3.4.7 Reimbursement

- a) Drug:

- Drug(s) are reimbursed at the estimated acquisition cost (EAC) or federal upper limit (FUL) with a dispensing fee. A dispensing fee is paid for each individual drug.
- An individual drug should be billed no more frequently than once per week.
- Drugs must be National Drug Code (NDC) coded. Unit values (milliliters, milligrams, etc.,) used must be those established by the National Council For Prescription Drug Programs (NCPDP)/First Data Bank (FDB) for the specific drug.
- Drugs must be submitted on the CMS (formerly HCFA) 1500 claim form or electronically in that format.
- Until specifically notified by the Med-QUEST Division, home pharmacies CANNOT USE THE POINT OF SALE (POS) program in billing for drugs.

b) Global Rate

The payment methodology for all services and supplies excluding drugs, infusion pumps or IV poles is a fixed global amount for all the services/supplies rendered per day or per dose. Global rates include but are not limited to the following: Mixing and compounding, tubing, adapters, caps, needles, filters, cannulas, cassettes, elastomeric devices, empty bags/minibags, extension sets, alcohol and povidone swabs/swabsticks, IV start kits, central venous catheter dressing kits, syringes, gloves and masks.

c) Global Rate for Multiple Therapies

- When more than one antibiotic, antiviral and/or antifungal is authorized and it is clear that these must be infused separately because of incompatibility, a global rate will be paid for the first drug and a “multiple anti-infective” global rate will be paid for each subsequent anti-infective drug. If multiple drugs of different classes are authorized (Example: hydration and antibiotic), a global rate is allowed for the most costly service and 50% of the global rate for each additional service. Enteral and parenteral nutrition are paid according to Medicare criteria and are not subject to the global multiple therapy rule.
- Global rates are assigned specific local payer HCFA Common Procedure Coding System (HCPCS) codes. The description of the code indicates whether it should be billed per day or per dose and gives limits. For multiple therapies of different classes, the local payer HCPCS code for the most costly therapy should be used, all other therapies should be coded with the local payer code assigned to the therapy followed by the modifier –51.

d) External Non-Disposable Infusion Pumps

The pumps covered are stationary or ambulatory non-disposable infusion pumps, pumps for parenteral nutrition and pumps for enteral nutrition. Although payments for enteral pumps differ from payments extended for external infusion pumps and parenteral nutrition pumps, the payment rules for all non-disposable pumps are similar.

- The external non-disposable infusion pump may be initially purchased or rented.
- When rented, the payment for the pump is based on a monthly rate if the pump is in the home for at least 15 days in the month. One half of the monthly rental will be reimbursed if the pump is in the home for less than 15 days per month—this may be applicable for the first or last month of treatment. Hawaii Medicaid’s policy on extended rentals is a modification of Medicare’s policy regarding capped rental items and is as follows:
 - 1) The monthly rental of the pump cannot exceed a total of 15 months.
 - 2) After 15 monthly rentals have been paid, the supplier must continue to provide the item without charge until the medical necessity for the pump ends or Medicaid coverage ceases.
 - 3) Maintenance and servicing will be paid no more frequently than once every six months after the 15 month rental period has ended and only when the pump is actually serviced, repaired or replaced. An 1144b for maintenance/servicing must be approved.
 - 4) The provision of a usable pump is included in the reimbursement for the maintenance, serving or repair of the pump.
 - 5) The pump is returned to the supplier when it is no longer medically necessary.
- For initially purchased pumps, a maintenance and servicing fee is payable every six months after the manufacturer’s warranty has expired and only when the pump is actually maintained, serviced or repaired. The provision of a usable pump is included in the reimbursement for maintenance, servicing and repair. An 1144b for maintenance/servicing/repair must be approved.
- Disposable infusion pumps (elastomeric devices) are included in the global rates and not separately reimbursable.
- The use of more than one external pump must be medically justified.

e) IV Pole or Equipment Stand

- The payment for the rental of a pole or a stand for use with a stationary nutrition pump is based on a monthly rate. The rental is counted toward the purchase. After six (6) months of rental, the pole/stand is paid in full. The pole is returned to the supplier when it is no longer medically necessary.
- If a stationary pump is initially purchased, the pole or equipment stand can also be purchased.

f) Reimbursement for Enteral and Parenteral Nutrition Therapy

Reimbursement for enteral and parenteral nutrition therapy is based on the methodology and coding system established and used by Medicare Part B, which will be detailed in a subsequent section. If enteral and/or parenteral nutrition therapy is provided with other home pharmacy services, parenteral and enteral therapy services are paid at 100% of allowable and are not subject to the multiple therapy payment rule.

19.3.4.8 Components

The following sections describe the components of the nine (9) covered home pharmacy therapies and external non-disposable pumps and IV pole/equipment stands:

- IV hydration therapy.
- IV antibiotic, antiviral and antifungal therapy.
- IV/Subcutaneous with PCA device and epidural chronic pain management.
- Intrathecal pain management (implantable infusion pump).
- IV chemotherapy.
- Miscellaneous IV/Subcutaneous therapy—chelation, gammaglobulin, inotropic agents, albumin, other agents.
- IV catheter care.
- Enteral nutrition.
- Parenteral nutrition.
- Non-disposable pumps & IV poles/equipment stands.

a) IV hydration therapy

Drugs:

Include, but are not limited to hydration solution, electrolytes, minibags, other additives (Example: multivitamins), flushes—heparin, saline, sterile water, topical analgesics. Drugs can be billed no more frequently than once per week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Global Hydration Supply and Service Per Day:

Includes, but not limited to empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, alcohol/povidone iodine swabs, swabsticks, cotton tip applicators, sharps containers.

b) IV Antibiotic, Antiviral and Antifungal Therapy

Drugs:

Includes all drugs used in the antibiotic, antiviral, antifungal therapy, including the specific anti-infective agent, heparin, saline, sterile water, topical analgesics, epinephrine or anaphylactic kits, minibags, etc. Drugs can be billed no more frequently than once per week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Global Anti-Infective Supply and Service Per Dose:

This includes empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs, swabsticks, cotton tip applicators, sharps containers, etc.

Global Multiple Anti-Infective Supply and Service Per Dose:

If more than one agent can be given together, no additional anti-infective supply fee will be extended. If there is a medical need for more than one agent to be delivered separately (examples: agents not compatible when given together, agents given on separate schedules, etc.) then a multiple anti-infective agent supply per dose can be approved. The global anti-infective supply and service per dose code should be used in billing for

the more frequently administered anti-infective agent and the global code with a modifier –51 should be used for all other anti-infective agents.

c) IV Pain Management Therapy

Drugs:

Include all drugs used in the IV pain management therapy, including the specific pain agent, heparin, saline, sterile water, topical analgesics, minibags, etc. Pain medication administered subcutaneously when a PCA device is medically indicated is included. As with hydration and anti-infective therapy, drugs can be billed no more frequently than once per week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Global IV Pain Management Supply and Service Per Day:

This includes empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs, swabsticks, cotton tip applicators, sharps containers, etc.

d) Intrathecal Pain Management Therapy (only when an implanted infusion pump is used)

Drugs:

Include all drugs used in the intrathecal administration, including the specific pain agent, heparin, saline and sterile water. As with all previous therapies listed above, drugs can be billed no more frequently than once a week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Global Intrathecal Pain Management Supply and Service Per Pump Fill:

This is the charge per pump fill—includes dressing kit, supplies, mixing and compounding, cassettes, etc.

Reprogramming:

This includes reprogramming of the pump upon physician order.

e) IV Chemotherapy

Drugs:

Include all drugs used in IV chemotherapy, including the specific agent(s), oral and or parenterally administered antiemetics, antinausea agents. Drugs can be billed no more frequently than once per week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Global IV Chemotherapy Supply and Service Per Day:

Includes empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs/swabsticks, cotton tip applicators, sharps containers, chemotherapy gloves, spill kits, and disposal kits, etc.

Global Multiple IV Chemotherapy Supply And Service Per Day:

If more than one agent can be given together, no additional daily chemotherapy supply fee will be extended. If there is a medical need for more than one agent to be delivered separately (Examples: Agents not compatible when given together, agents given on separate schedules and the tubing, etc., cannot be reused, etc.), the daily chemotherapy supply and service code should be assigned to one (1) chemotherapy agent and the modifier -51 should be appended to all other chemotherapy agents.

f) Miscellaneous IV/Subcutaneous Therapies

These include but are not limited to:

- Inotropic therapy.
- Immune globulin therapy.
- Albumin therapy.
- Chelation therapy administered intravenously or subcutaneously.
- Other agents (names must be specified).

Drugs:

Include all drugs used in the miscellaneous IV therapy, including the specific agent, heparin, saline, sterile water, topical analgesics, epinephrine or anaphylactic kits, minibags, etc. Drugs can be billed no more frequently than once a week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Global Miscellaneous IV/Subcutaneous Therapy Supplies and Services Per Day:

These include empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs, swabsticks, cotton tip applicators, sharps containers, etc.

Global Multiple Miscellaneous IV/Subcutaneous Therapy Supplies and Services Per Day:

If there is medical need for more than one agent to be delivered separately (Examples: Agents not compatible when given together, agents given on separate schedules and the tubing, etc., cannot be reused, etc.), the global miscellaneous IV therapy supply and service code should be assigned to one (1) therapy and the modifier –51 should be appended to all other therapies.

g) Catheter Care

Drugs:

Include heparin, saline and sterile water flushes, urokinase, etc. and are billable using the NDC number of the specific agents. Drugs are billable no more frequently than once per week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Global Catheter Care Supplies and Service Per Day:

- Include all supplies used to maintain the patency of the catheter including but not limited to syringes, cannulas, needles and dressings.
- Reimbursement for catheter care supplies and services are applicable only when the catheter is not in use.
- Maximum allowable daily catheter care supplies are as follows:
 - 1) Implanted vascular access devices (Example: Port-a-Cath)—maximum of two (2) per week.

- 2) Tunneled external vascular access devices (Examples: Hickman, Groshong, and Broviac). Protocol specific to the type of access device must be submitted at the time of request for authorization as maintenance varies significantly—Maximum of thirty (30) per month.
 - 3) Peripherally inserted central catheter (PICC) and Midline Catheter—Thirty (30) per month.
 - Supplies in excess of the quantities cited above must be specifically authorized.
- h) Additional supplies and services which can be separately authorized and billed:
- Midline and PICC Insertion Supplies include the Midline or PICC catheter and all the supplies used in the insertion of the catheter.
 - “Full Service” Midline and PICC Insertion—this includes the Midline or PICC catheter, all supplies used in the insertion of the catheter, and the skilled insertion service provided by the home infusion therapy provider.
- 1) Enteral Nutrition Therapy
 - Medicare coding and coding rules must be used.
 - Prepared formula:

All formulas should be authorized and billed based on 100 calorie units dispensed per month (28 to 31 days), using the appropriate HCPCS codes.
 - 2) Daily supplies:

Include but are not limited to all the supplies (tape, gauze, etc.) and based on three (3) separate and distinct delivery systems:

 - Syringe Fed
 - Gravity (Bag) Fed
 - Pump Fed
 - 3) Only ONE of the three daily supply methods will be authorized. The authorized supply method is billable per day (maximum of 28 to 31 per month).

Separate supplies:

The following supplies, if medically justified and authorized, are separately billable:

- Nasogastric, gastrostomy, jejunostomy tubes.
- Button G tube Replacement Kits.
- Bolus Extension Sets for button type tubes.
- Continuous extension sets for button type tubes.
- Parenteral Nutrition Therapy

Generally, Medicare coding and coding rules must be used. Because there is no HCPCS code for parenteral nutrition solutions with less than 10 grams of protein, if a solution contains less than 10 grams of protein is being requested, the reason must be provided (Example: Premature infant with short gut) and if medically justified, the appropriate HCPCS code should be used. Also, lipids and other additives not specified as included in the code range B4189 to B4199 and B5000 to B5200 should be coded with NDC numbers and NOT HCPCS codes.

Parenteral Nutrition Solutions:

- These are authorized and billable based on grams of protein using HCPCS codes.
- Parenteral Nutrition Solutions include CARBOHYDRATES, ELECTROLYTES, TRACE ELEMENTS, AMINO ACIDS and VITAMINS. Therefore, no separate billing for these are allowed.

Drugs:

Additives to parenteral nutrition solutions, include but not limited to lipids and H2 blockers such as cimetidine, must be separately authorized and billed using appropriate NDC numbers. CARBOHYDRATES, ELECTROLYTES, TRACE ELEMENTS, AMINO ACIDS AND VITAMINS are considered part of the parenteral nutrition solution and are NOT separately billable. As with all previous drugs, drugs are billable no more frequently than once a week. Reimbursement is based on the EAC or FUL of the drug and a dispensing fee per drug.

Daily Administration Kit:

This is authorized and billable upon approval of the Parenteral Nutrition Solution.

Daily Supply Kit:

This is authorized and billable upon approval of the Parenteral Nutrition Solution.

- External Non-Disposable Pumps and IV Poles/Equipment Stands
 - a) The pumps covered are stationary or ambulatory
 - b) Non-disposable infusion pumps, pumps for parenteral nutrition, and pumps of enteral nutrition. If authorized, the pump will be reimbursed based on its specific code and following the reimbursement policy cited under REIMBURSEMENT.

Specific Coding Used for Authorization and Reimbursement of Home Pharmacy Services and Supplies

- A table that is located in Appendix 6 provides the specific coding, descriptions, and Medicaid's reimbursement rates for the global therapy service and supply codes. To expedite authorization and claims payment, the provider should use these codes.