

ANTIEPILEPTIC DRUG PROGRAM

PURPOSE

This technical assistance guideline establishes the procedure for county health departments (CHD) or designated agent to implement the Antiepileptic Drug Program (ADP).

PROGRAM BENEFIT

Persons participating in the ADP receive epilepsy medications that are available from the Department of Health Central Pharmacy at no cost or a reduced cost based on a sliding fee scale.

DEFINITIONS

- (1) "Bona fide resident" means a person living in Florida with the intent to remain.
- (2) "Current prescription" means a prescription written within 3 months of application for the ADP and effective for no more than 6 months after it is written. The prescription must be written by a licensed health care practitioner authorized by law to prescribe medicine and include the following information:
 - (a) Person's name (printed or typed)
 - (b) Person's date of birth
 - (c) Physician's state license number
 - (d) Physician's name, typed or printed
 - (e) Physician's phone number
 - (f) Date of prescription
 - (g) Type of medication to be issued
 - (h) Amount of medication to be issued at each visit - up to a three months supply
 - (i) Whether and how many refills are allowed
- (3) "Designated agent" means any pharmacy that has entered into a written agreement with a county health department to provide epilepsy medication to approved ADP participants in accordance with this guideline.
- (4) "Family" means one or more persons living in one dwelling place who are related by blood, marriage, law or conception. A single adult, over 18, living with relatives is considered to be a separate family.
- (5) "Gross family income" means the sum of income available to a family at the time of application. Gross family income is based on all income to be earned or received or anticipated to be earned or received in the current month. Gross family income does not include Supplemental Security Income (SSI) or any income received by the SSI eligible individual(s) and any income received by the minor sibling(s) of the eligible individual(s). Gross family income includes the following:
 - (a) Wages and salary
 - (b) Child support
 - (c) Alimony
 - (d) Unemployment compensation
 - (e) Worker's compensation for lost income
 - (f) Veteran's pension
 - (g) Social Security
 - (h) Pensions or annuities

- (i) Dividends, interest on savings, stocks, or bonds
 - (j) Income from estates or trusts
 - (k) Net rental income or royalties
 - (l) Net income from self-employment
 - (m) Contributions
 - (n) Public assistance or welfare payments
 - (o) Cash amounts received or withdrawn from any source including savings, investments, trust accounts and other resources which are readily available to the family
 - (p) Other cash income
- (6) "Net family income" means gross family income minus the standard work-related, child care, and child support expenses or deductions as used in determining presumptive eligibility for Medicaid.
- (7) "Poverty guidelines" means the non-farm family poverty income scale adopted by the United States Department of Health and Human Services (HHS), as published annually by HHS in the Federal Register.
- (8) "Self-declaration" means a written statement made by a person applying for epilepsy medication regarding Florida residency, family size, insurance coverage, and assets. Self-declaration does not include any documentation. Self-declaration includes the statement and signature of the person making the statement, and a signed acknowledgement by the applicant that the statement is true at the time it is made and that the applicant understands that the CHD has the option of verifying the statement.
- (9) "Verification" means to confirm the accuracy of information through sources other than the self-declaratory statement of the individual that originally supplied the information.

ELIGIBILITY DETERMINATION AND DOCUMENTATION

A person applying to participate in the ADP must complete the Epilepsy Medication Request form, DH 2007, and provide a current prescription for epilepsy medications. The prescription may either be written on the Epilepsy Medication Request Form or provided separately and attached to the form completed by the applicant.

Upon receipt of a completed application, the CHD or designated agent will determine the applicant's eligibility based on the criteria below:

- Is a bona-fide resident of Florida.
An illegal alien that lives in Florida with the intent to remain meets the residency requirement for the ADP. The program does not include a requirement to establish citizenship or alien status.
- Has a diagnosis of epilepsy
- Is uninsured or is lacking insurance that covers epilepsy medications.
- Has a gross family income at or below 100% of the poverty guidelines.
If the applicant's dwelling place includes more than one family or more than one unrelated individual, the poverty guidelines shall be applied separately to each family or unrelated individual and not the dwelling place as a whole.
- Has no more than \$2,500 in private funds, bank accounts, or assets other than a homestead.

Florida residency, insurance status, and assets are self-declared by the applicant and documented on the Epilepsy Medication Request Form. A diagnosis of epilepsy is documented with a written statement by a health care professional. Income is verified as follows:

- (1) Applicants shall be required to sign a self-declaration statement of income, specifying all gross income available to the applicant and the number of people dependent upon that income.
- (2) The self-declaration statement shall include a signed acknowledgement that the statement is true at the time it is made and that the person making the statement understands that the CHD will attempt to verify the statement.
- (3) Verification may be by telephone, in written form, or by face-to-face contact. Verification does not require written documentation to confirm an applicant's statement. Examples of verification include:
 - (a) A statement from a state or federal agency which attests to the applicant's financial status.
 - (b) A statement from the applicant's or family member's employer.
 - (c) Pay stubs for four consecutive weeks.
 - (d) A statement from a source providing unearned income to the applicant or family unit.
- (4) If the CHD is unable to verify wages paid or an employer will not verify wages paid, the self-declaratory statement provided by the applicant may be accepted as accurate.
- (5) If the applicant declares zero income, the CHD may require the applicant to describe in detail their living circumstances and how they obtain basic necessities such as food, shelter, clothing, medical care, and transportation.

The CHD has the authority to make the final determinations of eligibility for the ADP.

Indicate on the application whether the applicant is eligible or not eligible for the program and sign and enter the date of eligibility determination on the application.

If the applicant is determined eligible for the program, enter the date of eligibility expiration on the application (one year from the eligibility determination date).

Clients of Children's Medical Services (CMS) diagnosed with epilepsy are covered for antiepileptic medications through CMS directly, or through the Florida Medicaid Program if they are Medicaid recipients. Effective March 1, 2006, clients served by CMS are no longer eligible for the ADP.

Applicants eligible as a Qualified Medicaid Beneficiary (QMB) but not eligible to receive medications through Medicaid, are eligible to receive medications from the ADP. Maintain documentation verifying that the medications cannot be obtained through Medicaid, the justification and length of time, if appropriate. A waiver may be requested from Medicaid so that Medicaid will cover the epilepsy medication. The waiver demonstrates a bona fide diagnosis of epilepsy and that the medication requested for waiver is prescribed to treat seizures, not another disorder or medical condition. Follow-up by the CHD is required to assure a determination by Medicaid and remove the client from the ADP once Medicaid approves coverage of the medication.

Applicants who do not have a diagnosis of epilepsy must be referred to the program appropriate for their particular diagnosis to obtain medication assistance.

ELIGIBILITY REVIEW AND RE-DETERMINATION

Each time a client picks up medication, CHD staff will review client eligibility and ask the client if there have been any changes in the eligibility information. CHD staff will advise clients that any time they experience a change in status, which could affect their eligibility; they must report this change to the CHD within 30 days of the change.

CHD staff will re-determine client eligibility every 12 months or when a client reports a change in status. Follow the process in the "Eligibility Determination" section of this guideline to re-determine eligibility.

Current clients whose annual net family income has increased to 101% to 200% of the Federal poverty guidelines and who meet all of the other eligibility criteria may be continued in the ADP until another source for the epilepsy medication can be found. These clients shall be charged a fee for the epilepsy medications based on a sliding fee scale as set forth in Chapter 64F-16, F.A.C.

SERVICE AREA

Each CHD is responsible for the residents of their county that apply for and participate in the Insulin Distribution Program. Each CHD will determine if applications for the program will be accepted from individuals living in another county. Consideration should be given to "customer" convenience and volume. An agreement between the CHDs involved may be advisable.

EMERGENCY ISSUANCE

If an applicant is not eligible for the ADP but has declared that he/she does not have the resources to purchase epilepsy medications and no other source can be found for his/her medications, the applicant is eligible to receive a one-month emergency supply of medication at no cost, one time within a 12-month period.

CODING EPILEPSY MEDICATION DISTRIBUTION

Each time epilepsy medication is distributed, CHD staff will record the service in the Health Management Component Reporting System. For details, see Personal Health Coding Pamphlet, DHP 50-20.

CONTINUITY OF OPERATION PLAN (COOP)

CHD staff will develop a written plan for continued operation of this program during emergency situations and share the plan with program clients.

CLIENT RECORD REVIEW

CHD staff will conduct an annual review of ADP client records to assure that the program requirements are being followed and that eligibility is being determined and documented according to this guideline. If a designated agent is implementing the program, the CHD will conduct an annual review of the client records maintained by the designated agent.

CHD staff will use the client record review form, included as an attachment to this guideline, to complete the record review and will select a random sample of client records for this review. CHD staff will determine the sample size based on the total number of client records and utilize the review findings to identify and take corrective action regarding areas in need of improvement.

Send a copy of the completed record review form to the Epilepsy Program at the address below or fax to (850) 245-4391.

4052 Bald Cypress Way

TA CHRONIC 12

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HSFCD Bin A-18
Tallahassee, FL 32399-1744

REFERRAL TO EPILEPSY SERVICES PROGRAM

Refer each ADP client and applicant to the Epilepsy Services Program (ESP) in your county, particularly if the client/applicant is determined ineligible for the ADP. The referral may be in writing or by phone.

OTHER SOURCES OF EPILEPSY MEDICATIONS

Utilize the following list to try to locate another source of epilepsy medication for individuals that are not eligible for the ADP:

Free Medicine Program http://www.freemedicineprogram.com/available_medicine/

Partnership for Prescription Assistance <https://www.pparx.org/Intro.php>

RxHope http://www.rxhope.com/pap_info.asp

The only patient assistance Internet initiative financially supported by the Pharmaceutical and Research Manufacturers of America. (PhRMA)

RxAssist created by Volunteers in Health Care <http://www.rxassist.org/>

Needy Meds <http://www.needymeds.com>

Patient Assistance Programs for Seizure Medications

ATIVAN - Wyeth Pharmaceutical Assistance Foundation — 1-800-568-9938

CARBATROL - Roberts Pharmaceuticals (Shire US Patient Assistance Program) 908-203-0657

DEPAKOTE - Abbott Laboratories — 1-800-222-6885

DIAMOX - Wyeth Pharmaceutical Assistance Foundation — 1-800-568-9938

DIASTAT - Xcel Patient Assistant Program — 1-908-850-9902 or Elan Pharma 800-528-4362

DILANTIN - Pfizer, Inc. — 1-800-707-8990

FELBATOL - Medpointe Pharmaceuticals — 1-800-678-4657

GABITRAL - Gabitril Assistance Program — 1-800-511-2120

KEPPRA - UCB Pharmaceuticals, Inc. — 1-800-477-7877 x 7

KLONOPIN - Roche Labs — 1-800-285-4484

LAMICTAL - GlaxoSmithKline Bridges To Access — 1-866-728-4368

*Advocate must call to pre-enroll each patient.

MYSOLINE - Xcel Patient Assistant Program — 1-908-850-9902 or Elan Pharma 800-528-4362

NEURONTIN - Pfizer, Inc. (Connection To Care) — 1-800-707-8990

PHENYTEK - Bertek Pharmaceuticals, Inc. — 1-888-823-7835

TEGRETOL, TEGRETOL XR - Novartis Patient Assistance Program — 1-800-277-2254

TOPAMAX - Ortho McNeil Pharmaceutical — 1-800-577-3788

TRILEPTAL - Novartis Patient Assistance Program — 1-800-277-2254

ZARONTIN - Pfizer, Inc. (Connection To Care) — 1-800-707-8990

ZONEGRAN - Elan Medical Needs Program — 1-866-347-3185

ADDITIONAL INFORMATION

For additional information, contact the Epilepsy Program at (850) 245-4330 or SunCom 205-4330.

ATTACHMENTS

Client Record Review Form
Epilepsy Medication Request Form



Epilepsy Medication Request

SECTION I. TO BE COMPLETED BY PHYSICIAN: (Procedures for use on back of form)

Name: _____ Date: _____
 (Please Print) Last First Middle
 Address: _____ DOB: _____
 City: _____ State: _____ Zip Code: _____ SS#: _____

I hereby certify that this client has a diagnosis of epilepsy and should be on prophylactic medications against recurrence of epileptic seizures.

Prescription:

Number of Refills:

6 mo. _____
 9 mo. _____
 12 mo. _____

*Physician Signature: _____

*Physician Name (typed or printed): _____

*License Number: _____

*Address: _____

DEA Number: _____

*Physician Phone Number: _____

***(Items that must be completed)**

SECTION 2. TO BE COMPLETED BY CLIENT/APPLICANT:

_____ I am a Florida resident _____ I receive Medicaid, my number is _____

_____ I have no insurance for medication _____ My child is a client of Children's Medical Services

_____ My assets, other than my homestead, are below \$2,500.

My annual net family income is \$_____ and there are _____ people in my family.

I am requesting medication for the treatment of epilepsy or a seizure disorder. I agree that all the information provided about income, assets, and insurance is true and correct. I will notify the county health department within 30 days should my income, assets or any of the above information change.

Signature of client/applicant: _____ Date: _____

SECTION 3. TO BE COMPLETED BY COUNTY HEALTH DEPARTMENT (CHD) REPRESENTATIVE:

I certify that the above client is eligible for assistance according to Internal Operating Policy: Chronic-3. Copies of this form are maintained in our files for post-audit purposes by the Department of Health or other authorized government agencies.

_____/_____
 County Health Department (CHD) Signature of CHD Director or Title Date
 or Clinic Authorized Representative

Epilepsy Medication Request

The County Health Department (CHD) Guidebook Technical Assistance Guidelines: Chronic 12 provides guidelines for implementation of the Antiepileptic Drug Program.

PURPOSES OF THIS FORM:

1. To provide a prescription sheet for each medication being ordered.
2. To document determination of eligibility.

PROCEDURES FOR USE OF FORM:

The CHD will make this form available to physicians and the Epilepsy Services Program provider in the county.

1. The physician or nurse practitioner will complete Section 1 of the form to prescribe epilepsy medications.
2. A prescription may be attached to this form in lieu of a completed Section 1 only if all the following are included on the prescription:
 - Physician's or Nurse Practitioner's license number
 - Physician's or Nurse Practitioner's DEA number, if required
 - Physician's or Nurse Practitioner's name, typed or printed
 - Number of refills indicated
 - Phone number of physician or nurse practitioner
3. The client will complete Section 2 and return the form to the CHD.
4. The CHD will determine the client's eligibility on a recurring basis throughout the year in accordance with Internal Operating Policy: Chronic-3 and Technical Assistance Chronic -12 using the most recent "HHS Income Guidelines for Use with Sliding Fee Scales." Gross annual income is defined in Chapter 64F-16, Florida Administrative Code. The CHD will verify the client's financial eligibility has been determined within 12 months by completing Section 3 each time an Epilepsy Medication Request form is submitted.
5. If the CHD has a pharmacy, the prescription will be filled on site. The original Epilepsy Medication Request form will be retained by the pharmacy. A copy of the form will be included in the client's file.
6. If the CHD has no pharmacy on-site, the CHD Director or authorized CHD representative will send the original form and prescription to:

Central Pharmacy
2818-B Mahan Drive
Tallahassee, Florida 32308
(850) 922-9036
7. A copy of the Epilepsy Medication Request form will be retained in the client's file at the CHD.
8. The Central Pharmacy will ship the medication to the CHD for distribution. Allow at least 10 working days for Central Pharmacy to fill the prescription.
9. The CHD must manage their slot allocation for Expansion Pilot Program medications. Once the allocation is reached, the CHD must refer the client to

the local Epilepsy Service Provider for help in locating another source of prescription assistance.

PROCEDURES FOR REFILLS:

Six weeks before the client's medication supply runs out, the CHD should:

- a. Notify the client of CHD's intent to reorder.
- b. Contact client's physician to verify prescription.
- c. The CHD will verify client's eligibility each time a prescription is filled.
- d. If no changes are indicated, send a copy of the prescription to Central Pharmacy for refill. (Not applicable for CHDs with on-site pharmacies)
- e. Medications can be refilled as ordered for a maximum of one year (**6 months for controlled substances**) before a new prescription is required. This is contingent upon maintenance of a current financial eligibility status.
- f. If there is a change of address, the file copy can be altered and a photocopy sent for refilling.
- g. A change in physician or prescription requires completion of a new Epilepsy Medication Request form.
- h. Allow 10 working days for refill after receipt of prescription by Central Pharmacy. (Not applicable for CHDs with on-site pharmacies)

AVAILABLE MEDICATIONS:

Important! Please use the following units of issue:

- Acetazolamide 250mg tablet, 100/btl. (Diamox)**
- Carbamazepine 100mg chewable and 200mg tablet, 100/btl.**
- *Clonazepam 0.5mg, 2mg tablet, 100/btl. (Klonopin)**
- Divalproex Sodium 125mg, 250mg, 500mg tablet, 100/btl. (Depakote)**
- Ethosuximide 250mg capsule, 100/btl. (Zarontin)**
- Ethosuximide syrup, 250 mg/5ml, 16 oz. btl. (Zarontin)**
- Felbamate 400mg tablet, 100/btl. (Felbatol)**
- Felbamate Susp. 600mg/5ml, 8 oz. btl. (Felbatol)**
- Gabapentin 100mg capsule, 100/btl. (Neurontin)**
- Gabapentin 300mg capsule, 100/btl. (Neurontin)**
- Lamotrigine 25mg, 100mg tablet, 100/btl. (Lamictal)**
- *Mephobarbital 32mg tablet, 100/btl. (Mebaral)**
- *Mephobarbital 50mg tablet, 100/btl. (Mebaral)**
- Methsuximide 300mg capsule, 100/btl. (Celontin)**
- *Phenobarbital 15mg (1/4 gr.) tablet, 100/btl.**
- *Phenobarbital 30mg (1/2 gr.) tablet, 100/btl.**
- *Phenobarbital 100mg (1 1/2gr.) tablet, 100/btl.**
- *Phenobarbital Elixir 20mg/5ml, 16 oz. btl.**
- Phenytoin Sodium 30mg capsule, 100/btl.**
- Phenytoin 50mg chewable tablet, 100/btl.**
- Phenytoin Sodium 100mg capsule, 100/btl.**
- Phenytoin oral suspension 125mg/5ml, 8 oz. btl.**
- Primidone 50mg, 250mg tablet, 100/btl. (Mysoline)**
- Primidone oral suspension 250mg/5ml, 8 oz. btl. (Mysoline)**
- Valproic Acid Syrup 250mg/5ml 16 oz.btl (Depakene)**
- * DEA number required**
- Gabrilil 4mg, 12mg, 16 mg tablet, 100/btl.**
- Tegretol XR 100mg, 200mg, 400mg tablet, 100/btl.**

Epilepsy Medication Request

Topamax 25mg, 100mg, 200mg tablet, 60/btl.

**ANTIPILEPTIC DRUG PROGRAM
CLIENT RECORD REVIEW**

Completed by: _____

Date: _____

Enter a client identification number in each space below

AUTHORITY Internal Operating Policy CHRONIC 3					
The following is included or documented in the client record:	Enter "Y" for yes or "N" for no in the box below.				
Epilepsy Medication Request Form is completed correctly.					
Eligibility is determined within the past 12 months.					
Eligibility is determined and documented according to criteria.					
Sliding fee assessed if income is between 101 and 200 percent of poverty.					
Diagnosis of epilepsy					

Send a copy of the completed record review form to the Epilepsy Program via fax at (850) 245-4391.