Preface……i
Public Health Nursing Protocol Ageement……..……....ii
Table of Contents……iii

SECTION I: EMERGENCY MANAGEMENT

ACUTE ASTHMA ATTACK 1.010
ACUTE POISONING 1.020
ANAPHYLAXIS 1.030
Emergency Drug Chart
ANIMAL BITES 1.040
BURN - FIRST DEGREE 1.050
CARDIAC EMERGENCIES..... 1.060
EMERGENCY CHILDBIRTH 1.070
Apgar Scoring System
HEMORRHAGE/HEMORRHAGIC SHOCK..... 1.080
INSECT (NON SPIDER) BITES 1.090
LACERATION..... 1.100
PUNCTURE WOUND 1.110
RESPIRATORY EMERGENCY 1.120
SEIZURES..... 1.130
SHOCK..... 1.140
SYNCOPE/VASOVAGAL REACTION/COMMON FAINT..... 1.150
TICK BITE……..……1.160
VACCINATION CLINIC, COMMUNITY LOCATED……..1.170

SECTION II: FAMILY PLANNING

ALL METHODS, QUICK START 2.010
BASIC INFERTILITY SERVICES……..2.011
CERVICAL CANCER SCREENING..... 2.020
COMBINED HORMONAL CONTRACEPTION..... 2.030
CONDOMS, SPONGE, AND SPERMICIDAL AGENTS..... 2.040
Contraceptive Patch….*RESCINDED APRIL 2015, Combined with 2.030* 2.050
DIAPHRAGM 2.060
DYSMENORRHEA 2.070
EMERGENCY CONTRACEPTIVE PILLS (ECPS)..... 2.080
FERTILITY AWARENESS-BASED METHODS (FAM)..... 2.090
INTRAUTERINE CONTRACEPTIVE (IUC)..... 2.100
PRECONCEPTION HEALTH SERVICES……..2.105
PREGNANCY TEST 2.110
PROGESTIN-ONLY IMPLANT(S) 2.120
PROGESTIN-ONLY INJECTABLE CONTRACEPTION..... 2.130
PROGESTIN-ONLY PILLS (MINIPILL) 2.140
STERILIZATION..... 2.150
Vaginal Contraceptive Ring….*RESCINDED APRIL 2015, Combined with 2.030*..... 2.160

FAMILY PLANNING REFERENCE SECTION……..…….…….....2.170
Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

SECTION III: GENERAL

ACNE..... 3.010
ACUTE UPPER RESIRATORY INFECTION (COMMON COLD)..... 3.020
ANEMIA, IRON DEFICIENCY…… 3.025
ASCARIASIS (ROUNDWORMS) 3.030
BLOOD PRESSURE, ELEVATED, ADULT..... 3.040
BLOOD PRESSURE, ELEVATED, CHILD..... 3.050
CERUMEN, IMPACTED (EAR WAX) 3.060
CHIGGERS, (DEMATOPHILIS PENTRANS)..... 3.070
Childhood Anemia *RESCINDED FEB 2013* *3.080*
CHOLESTEROL RISK ASSESSMENT 3.090
CONSTIPATION, ACUTE, CHILD..... 3.100
CONSTIPATION, ADULT..... 3.110
DIAPER DERMATITIS (DIAPER RASH) 3.120
DIARRHEA..... 3.130
DILATION FOR RETINAL IMAGING……..3.135
ENTEROBIUS VERMICULARIS (PINWORMS) 3.140
Fever, Vaccine Associated *RESCINDED MAY 2014* *3.150*
Refer to Appendices for Fever guidance
FLUORIDE DEFICIENCY 3.160
FLUORIDE VARNISH..... 3.170
FOLIC ACID PROPHYLACTIC THERAPY FOR WOMEN AGED 10-44..... 3.180
FOODBORNE OUTBREAK INVESTIGATION 3.190
HAEMOPHILUS INFLUENZA, INVASIVE TYPE B, CONTACT 3.200
HEPATITIS A, CASE OR PRESUMPTIVE 3.210
HEPATITIS A, POST EXPOSURE..... 3.220
HERPES SIMPLEX TYPE I (FEVER BLISTER)..... 3.230
HERPETIC STOMATITIS (GINGIVOSTOMATITIS) 3.240
HORDEOLUM (STY)..... 3.250
IMPETIGO/BULLOUS IMPETIGO..... 3.260
Iron Deficiency Anemia age 18 and over *RESCINDED FEB 2013* *3.270*
LEAD TOXICITY SCREENING..... 3.280
MENINGOCOCCAL DISEASE, CASE..... 3.290
MENINGOCOCCAL INVASIVE DISEASE, CONTACT 3.300
MILIARIA (PRICKLY HEAT, HEAT RASH) 3.310
OBSTRUCTED NASOLACRIMAL DUCT..... 3.320
ORAL CANDIDIASIS/MONILIASIS (THRUSH) 3.330
PEDICULOSIS CAPITIS (HEAD LICE) 3.340
PERIODICITY SCHEDULE - INFANCY-ADOLESCENCE 3.350
Periodicity Schedule - 22 years & over *RESCINDED NOV 2014*..... *3.360*
PITYRIASIS ROSEA..... 3.370
POISON IVY DERMATITIS..... 3.380

PREVENTION OF VITAMIN DEFICIENCY - PRENATAL 3.390
SARCOPTES SCABIEI (SCABIES) 3.400
SEBORRHEIC DERMATITIS (CRADLE CAP) 3.410
SMOKING CESSATION 3.420
Smoking Cessation Counseling & Treatment
Patient Willing to Make Quit Attempt
Patient Not Willing to Make Quit Attempt
Pharmacotherapies for Smoking Cessation
Patient Tobacco Survey
Tobacco Cessation Clinical Form -Initial Clinical Visit
Tobacco Cessation Clinical Form - Resupply Visit
TINEA CORPORIS (RINGWORM) 3.430
TINEA CRURIS (JOCK ITCH, GYM ITCH) 3.440
TINEA VERSICOLOR 3.450
TESTING FOR TB INFECTION (TST OR IGRA) 3.460
TUBERCULIN SKIN TESTING, TWO STEP PROCEDURE 3.470
TUBERCULOSIS, CASE OR SUSPECT (INITIAL VISIT) 3.480
TUBERCULOSIS, LATENT TUBERCULOSIS INFECTION (LTBI) 3.490
Urine Abnormal, Adult *RESCINDED NOV 2012* *3.500*
Urine Abnormal, Child *RESCINDED NOV 2012* *3.510*
URTICARIA (HIVES) 3.520
VARICELLA (CHICKENPOX) 3.530

SECTION IV: IMMUNIZATIONS

COMVAX (Combined HIB/Hep B) 4.010
DIPHTHERIA, TETANUS TOXOID & ACELLULAR PERTUSSIS (DTaP) 4.020
DIPHTHERIA and TETANUS TOXOID, PEDIATRIC (DT Pediatric) 4.030
DIPHTHERIA, TETANUS TOXOID, ACELLULAR PERTUSSIS,
INACTIVATED POLIO VACCINE (DTaP-IPV) (Kinrix) ……4.040
DIPHTHERIA, TETANUS TOXOID and ACELLULAR PERTUSSIS,
INACTIVATED POLIO, HAEMOPHILUS INFLUENZAE TYPE B
COMBINATION VACCINE (DTaP-IPV-Hib)(Pentacel)……..….4.050
GENERIC INJECTIONS 4.060
HAEMOPHILUS b CONJUGATE VACCINE (Hib) 4.070
HEPATITIS A VACCINE 4.080
HEPATITIS A INACTIVATED, HEPATITIS B RECOMBINANT VACCINE
ADULT (age 18 years and up)(Twinrix)……...…… 4.090
HEPATITIS B RECOMBINANT VACCINE, Pre-Exposure (Birth - 18 years) 4.100
HEPATITIS B RECOMBINANT VACCINE, Pre-Exposure Adult (19 years & Up) 4.110
HERPES ZOSTER (SHINGLES) VACCINE - LIVE VACCINE.…….....4.115
HUMAN PAPILLOMAVIRUS VACCINE (HPV) 4.120
H1N1 Influenza *RESCINDED MAY 2014*……*4.125*
H1N1 (LAIV) *RESCINDED MAY 2014*……*4.126*
INFLUENZA VACCINE, LIVE ATTENUATED (LAIV) 4.130
INFLUENZA VACCINE, TRIVALENT INACTIVATED (TIV) 4.140

MEASLES, MUMPS, RUBELLA VACCINE (MMR) 4.150
MENINGOCOCCAL VACCINE (MENACTRA)..... 4.160
MENINGOCOCCAL VACCINE (MENOMUNE) 4.170
PEDIARIX (DTaP/HEP B/IPV) 4.180
PNEUMOCOCCALVACCINE FOR CHILDREN AGES 6 WEEKS
THROUGH 18 YEARS……....4.190
PNEUMOCOCCAL VACCINE FOR ADULTS WITH HIGH RISK CONDITIONS
AGES 19 THROUGH 64 YEARS……....4.191
PNEUMOCOCCAL VACCINE FOR ADULTS ≥65 YEARS 4.200
POLIO VACCINE, INACTIVATED 4.210
RABIES VACCINE, POST-EXPOSURE..... 4.220
RABIES VACCINE, PRE-EXPOSURE 4.230
ROTAVIRUS VACCINE..... 4.240
TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS VACCINE (TDAP)
(7 through 18 years, Adacel or Boostrix)..... 4.250
TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS VACCINE (TDAP) .....
(19 years and up, Adacel or Boostrix)…..……..……4.260
TETANUS AND DIPHTHERIA TOXOID, ADULT TYPE (Td)..... 4.270
TETANUS PROPHYLAXIS IN WOUND MANAGEMENT 4.280
VARICELLA VACCINE 4.290

SECTION V: SEXUALLY TRANSMITTED DISEASES

CHLAMYDIA AND GONORRHEA, CASE OR CONTACT..... 5.010
CHLAMYDIA TRACHOMATIS, PARTNER DELIVERED THERAPY…… 5.030
Gonorrhea, Case or Contact, *COMBINED WITH CHLAMYDIA 5.010* 5.040
HEPATITIS B, CASE OR PRESUMPTIVE..... 5.060
HEPATITIS B, INFANT CONTACTS 5.070
HEPATITIS B, ALL OTHER CONTACTS 5.080
HEPATITIS C, (NON - A, NON - B), CASE 5.090
HERPES SIMPLEX (GENITAL HERPES)..... 5.100
HIV TESTING AND COUNSELING..... 5.110
PEDICULOSIS PUBIS (PUBIC LICE) 5.130
SYPHILIS, CASE OR CONTACT 5.140
TRICHOMONIASIS, CASE OR CONTACT..... 5.160

SECTION VI: DISASTER PREPAREDNESS AND BIOTERRORISM

ANTHRAX VACCINE 6.010
POTASSIUM IODIDE ADMINISTRATION 6.020
SMALLPOX VACCINE 6.030

APPENDICES

A. ADDITIONAL IMMUNIZATION INFORMATION 7.010

5 Rights of medication administriation
Vaccines & Routes of Administration
How to Administer Intramuscular (im) Injections
How to Administer Subcutaneous (sc) Injections
Emergency Supplies and Equipment
Pharmacy Policy 3.03B, Labeling of Medications

TIPS ON SAFEGUARDING YOUR VACCINE SUPPLY
(Refer to Vaccine Storage and Handling Toolkit)

B. **LIST OF STANDARD ABBREVIATIONS** 7.020

INDEX……7.040

MENINGOCOCCAL, INVASIVE DISEASE, Contact

BACKGROUND

Invasive infections with *Neisseria meningitidis* may present as meningococcemia (an infection of the bloodstream), meningococcal meningitis (inflammation of the protective membranes that cover the brain and spinal cord), or both. Invasive meningococcal disease is rare (about 1,000 cases occur in the United States each year) and serious. About 10% of cases die. Among survivors, 11-20% suffer neurologic damage or loss of limbs. Invasive meningococcal disease is spread person to person through exchange of respiratory and throat secretions such as coughing, kissing or sharing eating utensils. The incubation period of meningococcal disease is 1-10 days, usually less than 4 days. Meningococcal vaccines cannot prevent all cases of meningococcal disease and is not a factor in decisions concerning chemoprophylaxis of contacts.

SUBJECTIVE

Referred to Health Department with history of exposure to confirmed case of invasive meningococcal disease within 7 days of onset of disease in the index case and less than 2 weeks after exposure and other resources not available for patient to purchase medication.

OBJECTIVE

Chemoprophylaxis recommended (high risk)

Chemoprophylaxis is indicated for the following close contacts, ideally within 24 hours of diagnosis of *Neisseria meningitidis* invasive disease in the index case, but *not* more than 2 weeks after exposure.

- Household members, roommates, intimate contacts in the 7 days prior to disease onset
- Child care or preschool contacts any time during 7 days before onset of illness
- Direct exposure to index patient's oral secretions through kissing or through sharing toothbrushes, cigarettes, drinks or eating utensils, markers of close social contact, at any time during 7 days before onset of illness.
- Mouth-to-mouth resuscitation, *unprotected* endotracheal intubation or endotracheal tube management during 7 days before onset of illness
- People who frequently slept in the same dwelling as index patient during 7 days before onset of illness
- Passengers seated directly next to the index patient during airline flights lasting more than 8 hours

Consult with Regional Health Officer as needed for further identification/clarification of contacts needing chemoprophylaxis

Observe for symptoms of fever, malaise, nausea, vomiting, severe headache, increase sensitivity to light, altered mental status or confusion

IF SYMPTOMATIC, DO NOT PROVIDE PROPHYLAXIS, REFER IMMEDIATELY FOR DEFINITIVE DIAGNOSIS AND TREATMENT

ASSESSMENT
Provide chemoprophylaxis as indicated

PLAN
Obtain order from health care provider to issue Rifampin (no known allergy to Rifampin)

Obtain Rifampin from regional pharmacy; ask regional pharmacist to repackage tablets for adults and mix suspension for children

Rifampin: **Adults:** 600 mg every 12 hours x 2 days
Children: (**1 month-12 years**) 10 mg/kg/dose every 12 hours x 2 days not to exceed 600 mg/dose
Infants: (**less than 1 month**) 5 mg/kg/dose every 12 hours x 2 days

Ciprofloxacin: 500 mg STAT dose may be issued or prescribed as an alternate treatment for persons **over age 18** years

Health Teaching
Counsel patient that chemoprophylaxis is not 100% protective, review the signs and symptoms of meningococcal disease (sudden onset of fever, chills, malaise, muscle pain or a rash), advise to seek immediate medical attention should these signs develop.
Instruct patient regarding side effects and contraindications of chemoprophylaxis
Advise barrier method (foam, film or condoms) for oral contraceptive clients
Advise that tears will be orange and stain contacts lenses; urine may be orange
Notify regional health officer, communicable disease director and nursing supervisor
Should check to see that index case received Rifampin post treatment to eradicate upper respiratory tract colonization of organism

Referral Indicators:
Symptomatic for meningitis
Unable to tolerate Rifampin

REFERENCES

American Academy of Pediatrics. Meningococcal infections. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. *Red Book: 2012 Report of the Committee on Infectious Diseases.* Elk Grove Village, IL: American Academy of Pediatrics; 2012:500-509.

CDC. Meningococcal Disease
www.cdc.gov/meningococcal/about/symptoms.html

Epidemiology and Prevention of Vaccine-Preventable Diseases, Department of Health and Human Services, Centers for Disease Control and Prevention, 12th Edition, May 2011

Immunization Action Coalition, Meningococcal: Questions and Answers Information about the disease and vaccines, March 2012
http://www.immunize.org/catg.d/p4210.pdf

Kaplan SL, & Pentima CD. Meningitis in Children Beyond the Basics, In: UpToDate, Torchia, MM (Ed), Waltham, MA, 2013
Red Book, Report of the Committee on Infectious Diseases, 29th Edition, 2012

GENERIC INJECTIONS

GENERAL INFORMATION

Patient presents to health department with a written order from their Primary Care Physician or other private physician requesting administration of a specific injection.
Patient may have received one injection, without side effects, from the private provider
The order must be current (within 6 months) and include the dosage, route (IM, SC), frequency and duration. The order must also be approved by the health officer.

PLAN

Health Officer will review and approve all private physicians' orders requesting injections for appropriateness

Approval will be granted for a maximum 6 months (time frame dependent on specific injection and/or individual circumstances)

Patient to provide own medication

Read medical insert regarding administration and side effects of the medication

Administer medication as ordered by physician

Counsel on side effects

Give return appointment

Rotate injection sites on return appointments

Renew physician orders as indicated

GENERAL MEDICAL 3.0

Pharmaceutical Maintenance and Issuance – 3.03

Department of Health Pharmaceutical Management – 3.03.b

Date Issued: August 18, 2015

Date Last Revised:

Signature:

By:

Leslie Humphreys, MPA
Assistant Commissioner
Division of Community Health Services

POLICY
The Department of Health Regional Pharmacy Directors are licensed with the Tennessee Board of Pharmacy. The Regional Pharmacy Director shall be responsible for maintaining, securing, and accounting for medications in the Regional Pharmacy. The Regional Pharmacy Director will direct the management of inventories in the local health department clinics and supervise the implementation of the policy. Health Department Regional pharmacies and clinics will adhere to internal control standards.

APPLICABILITY
This policy applies to all Health Department Regional Pharmacies and clinics.

PURPOSE
To provide internal control standards for all Regional Health Department Pharmacies and Health Department clinics.

PROCEDURE
CONTROL ENVIRONMENT

1. The Regional Pharmacy Director will maintain records in the Regional Pharmacy that will show the following: products ordered and received by Regional Pharmacy, stock levels of products in the Pharmacy using a perpetual inventory system, and medications supplied to clinic sites. These records shall be retained for a period of three (3) years.

2. The Regional Pharmacy will periodically review the current stock and usage of each clinic, and re-supply appropriate quantities of products to the clinics based on usage and clinic requests. Any medications shipped to clinics from the Regional Pharmacy will be entered into the system by the Regional Pharmacy as they are shipped. Any products ordered by Pharmacy and shipped directly from a vendor to the clinics will be entered into the system appropriately at the Regional Pharmacy as soon as the reconciled packing slip/invoice is scanned by the clinic site and received by Regional Pharmacy.

   If it is anticipated that a pharmaceutical stocked in a clinic will not be used/issued prior to the expiration date, the Nursing Supervisor will contact the Regional Pharmacy Director to determine if the product may be relocated for use prior to the expiration date. Arrangements for transferring pharmaceuticals may be made between clinic sites by local clinical staff. The Regional Pharmacy Director will be included in such communications at all times. The inventory in the system will be adjusted after product is transferred and transfer documents are scanned and received by the Regional Pharmacy. Clinics are responsible for retaining pharmaceutical transfer records for a period of one (1) year.

3. All pharmaceuticals will be stored by lot number and expiration date so that the stock with the shortest expiration date may be distributed, administered, or issued first. All products shall be stored according to manufacturer recommendations. If the Regional Pharmacy receives any pharmaceuticals with an unreasonably short expiration date, or a date shorter than acceptable according to statewide contract with the source, appropriate action will be taken to return the products for credit or for replacement with more reasonable expiration dates.

   Any outdated pharmaceuticals in the Regional Pharmacy shall be segregated from other pharmaceuticals in a container marked “DO NOT USE”. Outdated products will be appropriately processed for shipment to the currently contracted reverse distributor through the appropriate wholesaler accounts.

4. When there is a medication recall, the Regional Pharmacy Director will check the Regional Pharmacy records confirming receipt of the affected medication. If confirmed, the Nursing Supervisor in each potentially affected clinic within the Region will be contacted immediately to check current stock for any of the affected medication. If the clinic has any affected stock, the Nursing Supervisor will immediately remove it from the stock, and return it to the Regional Pharmacy for appropriate processing.

5. Physicians, Nurse Practitioners, Public Health Nurses, and Licensed Practical Nurses are the only staff authorized to label and issue medications and related pharmaceutical supplies. The provider must be knowledgeable of the adverse effects and possible complications associated with each medication issued, and share this information with the patient or caregiver as appropriate.

   All medications and State-purchased vaccines will be ordered by the corresponding Regional Pharmacy. Over-the-counter products (OTCs), oral contraceptives (OCs),

and administered injectable medications will be ordered and shipped directly to the clinic from the State-contracted source. Labels for issuing the OCs to the patients will be adhered to the medication packaging in a location that allows the original lot number and expiration to be read.

All medications issued to patients will be labeled with the patient name, provider name, issue date, medication name, dose, quantity, and instructions for administration prior to issuing. Only child-proof capped, amber containers shall be used for medications that are repackaged. The one exception is nitroglycerin sublingual, which will not have a child-proof cap. All medications issued will be recorded in the computer system in order to maintain an accurate perpetual inventory.

Control Activities

1. The Nursing Supervisor is responsible for inventorying, requesting, storing, handling, and issuing of all medications in the clinic. He/she may designate appropriate staff to assist in this responsibility. Packing slips/invoices received with medications will be reconciled with the shipment, and any discrepancies noted on the packing slip/invoice. The Regional Pharmacy will be notified immediately of any discrepancy in the order. All packing slips/invoices will be signed, dated, and scanned to the Regional Pharmacy as soon after shipment arrival as possible. The original document will be maintained at the clinic site for a period of one (1) year.

2. The Regional Pharmacy will be locked at all times in the absence of the Pharmacist or Pharmacy Technician. Access to the Pharmacy will be secured by use of locks and alarm systems and/or security guards according to State rules and regulations.

   All pharmaceuticals in the clinic sites will be stored in a designated locked cabinet or medication room with access limited to specifically authorized personnel. The Nursing Supervisor is responsible for the security and control of all medications and related pharmaceutical supplies at the clinic. In the event of loss of key/ access card to a medication room, the person responsible will immediately notify their supervisor and a new lock will be installed or access entry changed as appropriate on the medication room door to avoid unauthorized access. If there is a code entry to the medication room, the code will be changed periodically to avoid potential unauthorized entry. A refrigerator and freezer will be available for storage of pharmaceuticals requiring refrigeration and freezing. The refrigerator and freezer will be secured at all times.

Monitoring

1. Each clinic Nursing Supervisor is responsible for assuring the monitoring of expiration dates of all pharmaceuticals within the clinic. This includes inspecting the expiration dates of all medications and vaccines stored in the clinic on at least a monthly basis.

2. Any unopened expired medications or vaccines will be removed from stock and placed in a container marked “OUT OF DATE – DO NOT USE” in the medication storage room. Expired unopened medications and State-purchased vaccines will

be returned to the Regional Pharmacy as soon as possible. Once the medications are received, Regional Pharmacy will adjust the clinic inventory in the system to reflect the returned quantities. Expired unopened Federal vaccines will be managed according to current guidance from the State Immunization Program. In Regions without an on-site Regional Pharmacy Director, there will be a system implemented by the Regional Medical Director to assure that unopened expired pharmaceuticals are properly separated from unexpired stock and returned to a secured Regional location for appropriate processing. Pharmaceuticals will not be administered or issued after the expiration date on the label. The expiration date of a product that is issued to a patient must not be reached prior to the completion of the patient regimen for the quantity used.

3. If a refrigerator or freezer in a clinic has a temperature excursion, all pharmaceuticals will be transferred to a refrigerator or freezer designated as a back-up for such a situation and placed in a container marked "DO NOT USE". The clinic will notify the Regional Pharmacy Director of the product(s), lot number(s), expiration date(s), and quantity(ies) affected; the temperature extreme experienced; and the timespan of the excursion. If vaccine products are affected, the clinic will follow the Tennessee Immunization Program (TIP) notification procedures for advice on viability of vaccine products. The Regional Pharmacy Director will be included in the communications with the TIP.

   The Regional Pharmacy Director will contact the manufacturer(s) of non-vaccine affected product(s) to assess potency and receive guidance of any adjustment in expiration date. The Pharmacy Director will then provide this guidance to the Nursing Supervisor or designee.

   The TIP representative will contact the manufacturer(s) of vaccine products and provide guidance on need for disposal of product, assess potency and receive guidance of any adjustment in expiration date. The Regional Pharmacy Director will be included in the communications with the TIP.

   If a product is given a shorter expiration date, the Pharmacy Director/TIP representative will provide the guidance in an email to the clinic Nursing Supervisor or designee. With this information, a single thin line will be drawn through the original date on the label/packaging. "New" and the new expiration date will be clearly written on the label/packaging and initialed by the nurse making the change. The email guidance will be printed and filed in the clinic medication room. If the manufacturer recommends not using a product, any opened containers will be appropriately discarded at the clinic site. The TIP representative will provide guidance for any Federal Vaccine. Any unopened containers of State-purchased vaccine or non-vaccine product will be promptly returned to the Regional Pharmacy for appropriate processing.

   The Regional Pharmacy Director will be apprised of actions taken with all inventory.

4. In the event that a pharmaceutical expiration date is extended by the Food and Drug Administration (FDA) by issue of an Abbreviated New Drug Application

(ANDA), use of medication beyond the initial expiration date requires that a copy of the appropriate ANDA be maintained in the clinic medication room with the product for the extended time period. A copy of the appropriate ANDA will also be filed in the Regional Pharmacy.

5. Health Department clinics will conduct a physical inventory of all medications at least quarterly. All discrepancies between the perpetual and physical inventory will be analyzed jointly by clinic staff and the Regional Pharmacy Director to determine if corrective action is indicated. The discrepancies and corrective action will be forwarded to the Nursing Supervisor, County Director, Regional Nursing Director, Regional Pharmacy Director, Regional Medical Director, and Regional Director of the affected clinic.

6. An annual inventory of products in the Regional Pharmacy will be performed with an internal auditor on a date specified by Central Office personnel in Nashville.

REFERENCE DOCUMENTS

1. Tennessee Code Annotated - Title 63: Professions of the Healing Arts; Chapter 10: Pharmacy; Part 2: Pharmacy Practice: 63-10-205.

2. Rules of the Tennessee Board of Pharmacy, Chapter 1140-9: Manufacturers and Wholesalers; Part .05: Minimum Requirements for Operation, 1140-9-.05.

3. 21 Code of Federal Regulations 1304.04 - Maintenance of Records and Inventories.

4. Tennessee Code Annotated - TITLE 9: Public Finances; Chapter 18: Financial Integrity Act of 1983; 102: Internal Controls - Management Assessment of Risk, 9-18-102.

5. Tennessee Code Annotated - TITLE 9: Public Finances; Chapter 18: Financial Integrity Act of 1983; 104: Report by Head of Executive Agency, 9-18-104.

OFFICE OF PRIMARY RESPONSIBILITY

Office of the Medical Director, Division of Community Health Services, 615-253-3407