DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF SOCIAL SERVICES

Statutory Authority: 31 Delaware Code,
Section 512 (31 **Del.C.** §512)

PUBLIC NOTICE

Pharmaceutical Services Program

Nature Of The Proceedings

Delaware Health and Social Services ("Department") / Division of Social Services initiated proceedings to amend the Title XIX Medicaid State Plan with respect to the Pharmaceutical Services Program: 1) to implement a prior authorization process with a preferred drug list (PDL); 2) to revise the prescription quantity and duration provisions; and, 3) to seek supplemental drug rebates from pharmaceutical manufacturers. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The agency published this state plan amendment as a notification in the April register. As a result of the changes recommended by the CMS, the originally published plan has changed significantly. The agency is publishing the revised state plan as emergency order APA 05-35, effective 4/1/05 and also as proposed regulation, APA 05-35a, in order to solicit public comment prior to establishing a final order.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Sharon L. Summers, Policy & Program Development Unit, Division of Social Services, P.O. Box 906, New Castle, Delaware 19720-0906 by July 31, 2005.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

Summary Of Changes

Purpose

The purpose of this action is to implement a preferred drug list and prior authorization for pharmacy services. The agency submitted an amendment to the Title XIX Medicaid State Plan to the Centers for Medicare and Medicaid Services (CMS) to implement:

- a prior authorization process with a preferred drug list (PDL) for certain designated drugs in selected therapeutic classes covered under the prescription drug program;
- revisions to prescription quantity and duration provisions; and,
- supplemental drug rebates.

Statutory Basis

- Social Security Act, Title 19, Section§1927
- 42 United States Code s1396r-8

Amending the Following State Plan Page

Attachment 3.1-A, Page 5 Addendum, Limitations

Summary of Provisions

To ensure that the state delivers a medical assistance prescription drug program, which is both cost effective and prudently administered, the following describes the coverage changes for prescribed drugs and/or supplies, effective April 1, 2005 for Prior Authorization with Preferred Drug List and Supplemental Rebates:

1) Prior Authorization with a Preferred Drug List

a) A process is established which utilizes a preferred drug list (PDL) for selected therapeutic classes. Drugs included on the preferred drug list (PDL) are automatically prior authorized. Drugs in those classes that are not included on the PDL shall require prescribers to obtain prior authorization. The Pharmaceutical & Therapeutics (P&T) Committee, comprised of physicians, pharmacists and community members appointed by the Secretary, Delaware Health & Social Services, selects drugs for the PDL.

b) Providers are notified of the drugs selected for placement on the PDL by selected therapeutic classes prior to implementation of the prior authorization process and as additional drugs are subsequently added to the list. This information is posted on the DMAP website.

c) The prior authorization process provides for a turn-around response within 24 hours of receipt of a completed prior authorization request from a prescribing provider by telephone, mail or electronic communication. In emergency situations, providers may dispense at least a 72-hour supply of medication as mandated and pursuant to 42 United States Code s1396r-8.

d) The Drug Utilization Review (DUR) Board will make recommendations to the Department regarding drugs to be considered for prior authorization.

2) Prescription Quantity and Duration

a. Dosage limits: Medications are limited to a maximum dose recommended by the FDA, peer review journals that indicate that doses that exceed FDA guidelines are both safe and effective or doses that are specified in regional or national guidelines.

b. Quantity limits are placed on therapeutic categories that will allow for coordinated care and improve outcomes. Limits exist for:

1) Sedative hypnotics-15 doses per 30 days
2) Triptans, acute treatment of migraines, 9 doses per 45 days
3) Opioid analgesics-200 doses per 30 days
4) Skeletal muscle relaxants-120 tablets/capsules per 30 days
5) Benzodiazepines-120 tablets per 30 days
6) Tramadol-240 tablets per 30 days
7) Narcotic cough medications-480ml per 30 days
8) Adjunctive anticonvulsants-240 tablets/capsules per 30 days
9) Nebulizer solutions-3 acute exacerbations per 30 days
10) Clients utilizing greater than 15 unique medications per 30 days
11) Medications that are dosed once a day are limited to one dose per day unless that total dosage required is within the limits stated above and require more than one tablet/capsule to obtain the required therapeutic amount.

c. Duration of therapy

1) Nicotine cessation products are limited to the duration that has been approved by the FDA.
2) Palivizumab-6 months during the high viral period of the year.

d. Prescriptions are limited to a quantity not to exceed the greater of 100 dosing units or a 34-day supply except for drugs selected and received through the mail order process.

3) Supplemental Drug Rebates

a. CMS has authorized the state of Delaware to enter into The State of Delaware Department of Health and Social Services supplemental drug rebate agreement. This supplemental drug rebate agreement was submitted to CMS on April 7, 2005 and has been authorized by CMS.

b. The Division of Social Services (DSS) has contracted with an independent organization to negotiate supplemental rebate agreements with manufacturers.

By implementing these processes, the Department ensures that all eligible Medicaid beneficiaries have the same comprehensive pharmacy coverage available to them, while reducing the cost of pharmaceutical products to the state. Physicians and patients continue to have access to the same FDA-approved drugs as they have had in the past.

Findings Of Fact

The Department finds that the proposed changes as set forth in the April 2005 Register of Regulations should be adopted with changes recommended by CMS.

THEREFORE, IT IS ORDERED, that the proposed regulation to establish the provisions related to prior authorization, preferred drug list and supplemental drug rebates is adopted as an emergency order with an effective date of 4/1/05.

Vincent P. Meconi, Secretary, DHSS , 6/16/2005

DSS PROPOSED REGULATION #05-35

REVISIONS:

LIMITATIONS

~~**Prescribed Drugs:**~~

~~The following drugs are not covered by Delaware Medicaid or are covered with limitations:~~

- ***DESI Drugs*** - products and known related drug products that lack substantial evidence of effectiveness. The State of Delaware does not cover DESI drugs for reimbursement purposes.
- ***Drugs Used for Cosmetic Purposes*** - products, such as Minoxidil Lotion and Retin A are not covered for adults, except for certain medical conditions.
- ***Fertility Drugs*** - are not covered when prescribed to stimulate fertility (example: Clomid).
- ***Anorectic Drugs*** - for the purpose of weight control are not covered. They may be reimbursed when prescribed to remedy hyperactivity in children and for certain sleep disorders.

~~Delaware Medicaid does not limit the quantity, days supply, or the number and/or frequency of refills for any prescription.~~

~~Participating manufacturers' new drugs are covered (except excluded/restricted drugs specific in section 1927(d)(1)-(2) of the Social Security Act) for six months after FDA approval and upon notification by the manufacturer of a new drug.~~

~~**Prosthetic Devices:**~~

~~Prosthetic and orthotic devices, as well as other durable medical equipment and assistive technology services, are covered when documented as medically necessary.~~

~~**Diagnostic Services:**~~

~~Medicaid will pay for the rental of an apnea monitor to monitor the breathing of an infant for whom a diagnosis of apneic episodes (near-miss Sudden Infant Death Syndrome) has been made.~~

12.a. Prescribed Drugs:

Drug Coverage

1. Drug products are covered when prescribed or ordered by a physician, or other licensed practitioner within the scope of their practice and when obtained from a licensed pharmacy. Covered drugs, as defined in Section 1927(k)(2) of the Act, are those which are prescribed for a medically accepted indication, medically necessary, and produced by any pharmaceutical manufacturer, which has entered into and complies with a drug rebate agreement under Section 1927(a) of the Act.

2. Drugs excluded from coverage as provided by Section 1927(d)(2) of the Act, include:

a. Drugs designated less than effective by the FDA (DESI drugs) or which are identical, similar, or related to such drugs;

b. Drugs when used for cosmetic purposes or hair growth (products, such as Minoxidil Lotion and Retin A are not covered for adults, except for certain medical conditions);

c. Drugs when used to promote fertility;

d. Drugs that have an investigational or experimental or unproven efficacy or safety status;

e. Drugs when used for anorexia, weight loss, or weight gain. Drugs for the purpose of weight control may be reimbursed when prior authorized following established criteria as reviewed and approved by the DUR Board and deemed medically necessary.

3. Non-covered services also include: drugs used to correct sexual dysfunction and compound drugs (compound prescriptions must include at least one medication that on its own would be a covered entity).

4. Participating manufacturers' new drugs are covered (except excluded/restricted drugs specified in Section 1927[d][1]-[2] of the Social Security Act) for six months after FDA approval and upon notification by the manufacturer of a new drug.

Quantity and Duration

1. Dosage limits: Medications are limited to a maximum dose recommended by the FDA, peer review journals that indicate that doses that exceed FDA guidelines are both safe and effective or doses that are specified in regional

or national guidelines published by established expert groups such as the American Academy of Pediatrics, or guidelines recommended by the Delaware Medicaid Drug Utilization Review (DUR)Board and accepted by the DHSS Secretary.

2. Quantity limits are placed on therapeutic categories that will allow for coordinated care and improve outcomes. Limits exist for:

a. Sedative hypnotics-15 doses per 30 days
b. Triptans, acute treatment of migraines, 9 doses per 45 days
c. Opioid analgesics-200 doses per 30 days
d. Skeletal muscle relaxants-120 tablets/capsules per 30 days
e. Benzodiazepines-120 tablets per 30 days
f. Tramadol-240 tablets per 30 days
g. Narcotic cough medications-480ml per 30 days
h. Adjunctive anticonvulsants-240 tablets/capsules per 30 days
i. Nebulizer solutions-3 acute exacerbations per 30 days
j. Clients utilizing greater than 15 unique medications per 30 days
k. Medications that are dosed once a day are limited to one dose per day unless that total dosage required is within the limits stated above and require more than one tablet/capsule to obtain the required therapeutic amount.

3. Duration of therapy

a. Nicotine cessation products are limited to the duration that has been approved by the FDA. Palivizumab-6 months during the high viral period of the year.

b. Prescriptions are limited to a quantity not to exceed the greater of 100 dosing units or a 34-day supply except for drugs selected and received through mail order.

Prior Authorization

1. Prior authorization requirements may be established for certain drug classes or particular drugs, or a medically accepted indication for uses and doses.

2. The DUR Board determines which prescription drugs may require prior authorization. The Board assesses data on drug use in accordance with predetermined standards. The standards shall be:

- monitoring for therapeutic appropriateness
- over-utilization and underutilization
- appropriate use of generic products
- therapeutic duplication
- drug-disease contraindications
- drug-drug interactions
- incorrect drug dosage or duration of drug treatment
- clinical efficacy
- safety
- medical necessity
- potential for abuse, misuse and diversion
- experimental use opportunity
- cost effectiveness relative to similar therapies

The recommendations of the DUR Board constitute interpretive guidelines to be used in determining whether to grant or deny prior authorization of a prescription drug. The make up and membership authority for the DUR Board complies with 42U.S.C. S1396r-8.

3. A request for prior authorization for covered outpatient drugs is processed within 24 hours of receipt of a completed prior authorization request from a prescribing provider by telephone, mail or electronic communication. A 72-hour supply of medically necessary covered drugs is provided in an emergency situation as mandated and pursuant to 42 United States Code s1396r-8.

Preferred Drug Lists with Prior Authorization

A process is established which utilized a preferred drug list (PDL) for selected therapeutic classes. Drugs included on the PDL are automatically prior authorized. Drugs in those classes that are not included on the PDL shall require prior authorization. A Pharmaceutical & Therapeutic (P&T) Committee, comprised of pharmacists, physicians, and community members, appointed by the Secretary, Delaware Health & Social Services, selects drugs

for the PDL.

Drug Rebate Agreements

CMS has authorized the state of Delaware to enter into The State of Delaware Department of Health and Social Services supplemental drug rebate agreement. This supplemental drug rebate agreement was submitted to CMS on April 7, 2005 and has been authorized by CMS.

- Pharmaceutical manufacturers are allowed to audit utilization rates;
- Compliance with the reporting requirements for state utilization information and restrictions to coverage;
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification; and,
- Rebate agreements between the state and a pharmaceutical manufacturer that are separate from the drug rebate agreements of Section 1927 are approved by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary of Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected.

Diagnostic Services:

Medicaid will pay for the rental of an apnea monitor to monitor the breathing of an infant for whom a diagnosis of apneic episodes (near-miss Sudden Infant Death Syndrome) has been made.

9 DE Reg. 73 (7/1/05) (Prop.)