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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

September 30, 1999

Honorable Feather O. Houstoun, Secretary
Department of Public Welfare
333 Health and Welfare Building
Harrisburg, PA 17105

Hand Delivery

Re: IRRC Regulation #14-459 (#2063)
Omnibus Revisions to Pharmaceutical Services and
Restrictions to Fertility Services

Dear Secretary Houstoun:

We met with your staff on Wednesday, September 29, 1999, to review this regulation. We identified several items that could be corrected or clarified by tolling. We recommend that you consider the following revisions:

1. Subsection 1121.54(2) would prohibit payment to a pharmacy for "drugs whose prescribed use is not for a medically accepted indication." This language is confusing and does not clearly reflect the Department's intent as explained in the meeting.
2. There is a typographical error in Section 1121.22(3). It states "...is prescribed for any of the following exists:...." Subsequent language in this Section may also need to be changed depending on how the language is corrected.
3. The first sentence of Section 1129.56 has a typographical error. It states "...in noncompensible...." rather than "...is noncompensible...."
4. It is not clear whether the phrase "in available dosage forms" is needed in Section 1121.52(d)(1)(iv).
5. The phrase "medically accepted indication" is not used consistently throughout the regulation.

If the Department chooses to toll the review period, it must deliver written notice to both the Standing Committees and the Commission on the same day. The written notice must be delivered prior to any Standing Committee action on the regulation, or before the end of the Standing Committee's review period on October 4, whichever occurs first.

Honorable Feather O. Houstoun
Page 2
September 30, 1999

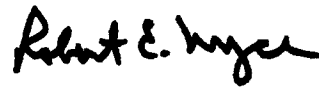
As required by Section 307.5 of our regulations, written notice must include:

1. A citation to the section(s) the Department is considering revising,
2. A description of the revisions being contemplated, and
3. An explanation of how the revisions will satisfy our concerns.

If the Commission objects to tolling the review period, we will notify you and the Standing Committees within two business days after receipt of your tolling notice. In the event the Commission objects to your tolling notice, the review period will not be tolled and your regulation will be considered by the Commission at our public meeting on October 7, 1999. If the Commission does not object, the review period is tolled for up to 30 days beginning with receipt of your letter and ending on the day you resubmit the regulation.

If you have any questions, please call me at 783-5506.

Sincerely,



Robert E. Nyce
Executive Director

REN:wbg
Enclosure

cc: Honorable Harold F. Mowery, (hand delivery)
Honorable Vincent J. Hughes, (hand delivery)
Honorable Dennis M. O'Brien, (hand delivery)
Honorable Frank L. Oliver, (hand delivery)
Thomas A. Hutton, Esq., (hand delivery)
David J. DeVries, Esq.
Joseph E. Concino



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
P.O. BOX 2675
HARRISBURG, PENNSYLVANIA 17105-2675

OFFICE OF MEDICAL
ASSISTANCE PROGRAMS

OCT - 4 1999

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

ORIGINAL: 2063
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INDEPENDENT REGULATORY
REVIEW COMMISSION

Dear Mr. Nyce:

I have been asked to respond to your letter of September 30, 1999 to Secretary Feather O. Houstoun regarding Independent Regulatory Review Commission (IRRC) Regulation #14-459 (#2063), Omnibus Revisions to Pharmaceutical Services and Restrictions to Fertility Services.

The IRRC has suggested corrections to several sections of the final form regulation #14-459 that were submitted for your review. At the Commission's request, the Department is requesting that the time for review of the final form regulations be tolled to make the following revisions that will satisfy the Commission's concerns:

1. Subsection 1121.54(2) would be revised to clarify the Department's intent to preclude payment for a drug product that would have no medically accepted indication. It was not the Department's intent to hold pharmacists accountable to determine if the indication for the medication is one that is medically accepted. The revised text should read "...drugs for which there is no medically acceptable indication" which would mean that the Department would prohibit payment of a drug product that has no medical use.
2. Section 1121.22(3) contains a typographical error. To correct this, we are removing the word "exists" from the text. As a result of this revision, subsection 1121.22(3)(A) will have to be changed to read "a recipient under age 21." and subsection 1121.22(3)(B) will have to be changed to read "a recipient residing in a skilled..."
3. Section 1129.56 contains a typographical error. To correct this, we are changing the wording "...in noncompensable..." to read "...is noncompensable..."

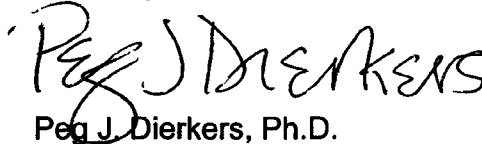
OCT - 4 1999

4. Section 1121.56(d)(1)(iv) will not be changed. The phrase "in available dosage forms" is needed to maintain consistency with the other subsections.
5. Subsections 1121.54(3)(i)(A) and (B) and subsections 1121.54(3)(v)(A) and (B) contain the phrase "medically acceptable indications." This is not consistent with the wording throughout the regulations and will be changed to read "medically accepted indications" to maintain consistency.

Attached are the corrected pages to the final-form regulations reflecting these changes. No changes to the preamble are required as a result of changes to Annex A.

Thank you for your attention in this matter.

Sincerely,

A handwritten signature in black ink that reads "Peg J. Dierkers". The signature is written in a cursive, slightly slanted style.

Peg J. Dierkers, Ph.D.

Deputy Secretary for Medical Assistance Programs

Attachments

cc: The Honorable Harold F. Mowery, Jr.
The Honorable Vincent J. Hughes
The Honorable Dennis M. O'Brien
The Honorable Frank L. Oliver
Howard Burde, Deputy General Counsel

ANNEX A

PART III. MEDICAL ASSISTANCE MANUAL

TITLE 55. PUBLIC WELFARE

CHAPTER 1121

PHARMACEUTICAL SERVICES

* * * * *

§ 1121.22. Scope of benefits for the medically needy.

Medically Needy Only recipients are not eligible for pharmaceutical services covered by the MA Program unless one of the following occurs:

* * * * *

(3) ~~If a compensable vaccine is prescribed through the Early and Periodic Screening, Diagnosis and Treatment Program as described in § 1101.32(a)(1)~~

IF A COMPENSABLE DRUG PRODUCT IS PRESCRIBED FOR ANY OF THE FOLLOWING:

- (i) A RECIPIENT UNDER AGE 21.

- (ii) A RECIPIENT RESIDING IN A SKILLED NURSING FACILITY, AN INTERMEDIATE CARE FACILITY, OR AN INTERMEDIATE CARE FACILITY FOR THE MENTALLY RETARDED. THIS POLICY DOES NOT APPLY TO GENERAL ASSISTANCE RECIPIENTS RESIDING IN A

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§ 1121.54. Noncovered services and items.

Payment will not be made to a pharmacy for the following services and items:

- (1) ~~Methadone~~ LEGEND AND NONLEGEND PHARMACEUTICAL PRODUCTS DISTRIBUTED BY A COMPANY THAT HAS NOT ENTERED INTO A NATIONAL REBATE AGREEMENT WITH THE FEDERAL GOVERNMENT AS PROVIDED UNDER SECTION 4401 OF OBRA '90, EXCEPT FOR THOSE SPECIFIC DRUG PRODUCTS AUTHORIZED BY THE FEDERAL GOVERNMENT AS ESSENTIAL TO THE HEALTH OF A MEDICAL ASSISTANCE RECIPIENT. THE DEPARTMENT WILL ISSUE A SPECIAL LIST COMPRISED OF THOSE COMPANIES THAT SIGNED REBATE AGREEMENTS WITH THE FEDERAL GOVERNMENT AND THOSE PRODUCTS AUTHORIZED AS ESSENTIAL TO THE HEALTH OF A MEDICAL ASSISTANCE RECIPIENT. PHARMACIES ARE RESPONSIBLE FOR CHECKING THE LIST BEFORE FILLING THE PRESCRIPTION.
- (2) ~~Drugs prescribed for treatment of pulmonary tuberculosis. Those tuberculosis drugs which are prescribed for the prevention of meningococcal meningitis are compensable if the diagnosis appears on the prescription~~ LEGEND AND NONLEGEND DRUGS FOR WHICH THERE IS NO MEDICALLY ACCEPTED INDICATION.
- (3) ~~Drugs and other items prescribed for obesity, appetite control, cessation of smoking or other similar or related habit altering tendencies. Drugs which have~~

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OCT 4 1999

~~been cleared for use in the treatment of hyperkinesia in children and primary and secondary narcolepsy due to structural damage of the brain are compensable if the physician indicates the diagnosis on the original prescription~~

LEGEND AND NONLEGEND DRUGS WHEN USED, PRESCRIBED, OR INDICATED FOR ANY OF THE FOLLOWING:

(i) OBESITY, ANOREXIA, WEIGHT LOSS, OR APPETITE CONTROL EXCEPT WHEN BOTH OF THE FOLLOWING EXISTS:

(A) THE DRUG OR ITEM HAS AN APPROVED MEDICAL INDICATION OTHER THAN OBESITY, ANOREXIA, WEIGHT LOSS, OR APPETITE CONTROL OR IS PRESCRIBED FOR ANY MEDICALLY ACCEPTED INDICATION OTHER THAN OBESITY, ANOREXIA, WEIGHT LOSS, OR APPETITE CONTROL.

(B) THE APPROPRIATE MEDICALLY ACCEPTED INDICATION, USE, OR DIAGNOSIS APPEARS ON THE ORIGINAL PRESCRIPTION IN THE PRESCRIBER'S HANDWRITING.

(ii) SMOKING CESSATION.

(iii) HAIR GROWTH OR OTHER COSMETIC PURPOSES.

(iv) SYMPTOMATIC RELIEF OF COUGH OR COLDS, EXCEPT WHEN PRESCRIBED FOR MA RECIPIENTS UNDER 21 YEARS OF AGE OR

#14-459
OCT 4 1999

FOR NURSING HOME RESIDENTS.

(v) TO PROMOTE FERTILITY EXCEPT WHEN BOTH OF THE FOLLOWING EXISTS:

(A) THE FERTILITY DRUG IS PRESCRIBED FOR ANY MEDICALLY ACCEPTED INDICATION OTHER THAN TREATING INFERTILITY.

(B) THE APPROPRIATE MEDICALLY ACCEPTED INDICATION, USE, OR DIAGNOSIS APPEARS ON THE ORIGINAL PRESCRIPTION IN THE PRESCRIBER'S HANDWRITING.

(4) Nonlegend drugs in the form of troches, lozenges, throat tablets, cough drops, chewing gum, mouthwashes and similar or related items.

(5) Pharmaceutical services provided to a hospitalized person.

(6) Single entity and multiple vitamins except for the following:

(i) Single entity and multiple vitamin preparations with or without fluorides for children under 3 years of age.

(ii) A prescription drug product which contains a single entity vitamin combined with a legend drug.

#14-459
OCT 4 1999

CHAPTER 1129

RURAL HEALTH CLINIC SERVICES

* * * * *

PAYMENT FOR RURAL HEALTH CLINIC SERVICES

* * * * *

§ 1129.56. Noncompensable services and items.

Any service not included in the all-inclusive visit fee as set by the Medicare carrier in accordance with 42 CFR §§ 405.2401 - 405-2430 is noncompensable as rural health service but may be compensable under other Medical Assistance regulations. MEDICAL ASSISTANCE WILL NOT REIMBURSE FOR ANY MEDICAL SERVICES, PROCEDURES, OR PHARMACEUTICALS RELATED TO TREATED INFERTILITY, INCLUDING SURROGACY SERVICES.

* * * * *

#14-459
OCT 4 1999

JOHN R. MCGINLEY, JR., ESQ., CHAIRMAN
ALVIN C. BUSH, VICE CHAIRMAN
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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

October 5, 1999

Honorable Feather O. Houstoun, Secretary
Department of Public Welfare
333 Health and Welfare Building
Harrisburg, PA 17105

Re: IRRC Regulation #14-459 (#2063)
Department of Public Welfare
Omnibus Revisions to Pharmaceutical Services and
Revisions to Fertility Services

Dear Secretary Houstoun:

The Commission does not object to tolling the review of the subject regulation.

Therefore, the tolling period began with the receipt of your letter on October 4, 1999. By November 3, 1999, the Department must hand-deliver to the Commission and the Committees either the revised regulation or written notification that the regulation will not be revised. The revised regulation or notification must be accompanied by a transmittal sheet (copy enclosed) confirming deliver to the Committees and the Commission on the same date. The regulation will be deemed withdrawn, if the Department does not return the regulation or provide the required notification by November 3, 1999.

If you have any questions, please call me at 783-5506.

Sincerely,

Robert E. Nyce
Executive Director

REN:kcg
Enclosure

cc: Honorable Harold F. Mowery
Honorable Vincent J. Hughes
Honorable Dennis M. O'Brien
Honorable Frank L. Oliver
Thomas A. Hutton, Esq.
David J. DeVries, Esq.
Joseph E. Concino



COMMONWEALTH OF PENNSYLVANIA
 DEPARTMENT OF PUBLIC WELFARE
 P.O. BOX 2675
 HARRISBURG, PENNSYLVANIA 17105-2675

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INDEPENDENT REGULATORY
 REVIEW COMMISSION

OFFICE OF MEDICAL
 ASSISTANCE PROGRAMS

DEC 12 1991

Mr. Robert J. Taylor
 Associate Regional Administrator
 Division of Medicaid
 HCFA/Department of Health and Human Services
 P.O. Box 7760
 Philadelphia, Pennsylvania 19101

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Dear Mr. Taylor:

As you requested in your letter of September 26, 1991, to Acting Secretary of Public Welfare Karen F. Snider, we are providing you with the additional information and the revised pages you require to approve Pennsylvania's State Plan Amendment (SPA) Number 91-25. An outline addressing the modifications we made to the previously submitted SPA 91-25 are listed below in the same sequence as they appeared in your letter.

A. Page 79-d

Now includes a statement of confidentiality for the unit rebate amounts.

B. Attachment 3.1-A

1. We listed the specific nonlegend drugs or categories of nonlegend drugs which the Department will cover as compensable items through the Medical Assistance Program. These compensable nonlegend drugs are listed on pages 5a, 5aa, and 5b.
2. We removed the restrictions for the payment of the drug Methadone.
3. We removed or revised the language under the previous page 5b, items 2, 11, 12, 22, and 23. Because the references to these items were removed, we renumbered the list and the pages. All noncompensable items are now listed on pages 5c, 5cc, 5d, and 5e.
4. We retained the item that limits vitamin coverage to children under 3 years of age (previously item 6 (i), now item 4 (i) on page 5c) based on the medically supported documentation we submitted to HCFA on February 20, 1985. A letter, supplied by the Pennsylvania Chapter of the American Academy of Pediatrics, was included with SPA Number 84-1 as supportive documentation for the vitamin limitation. SPA 84-1 was ultimately approved by HCFA based on this documentation. We amended the language in item 4 (i) to indicate that the limitation is medically supported. We also included a copy of the letter sent to HCFA on February 20, 1985, along with the medical documentation.

5. We removed all references which precluded coverage of drugs for uses other than FDA approved indications. This will now assure that we will provide payment for all medically accepted indications as well as FDA approved indications.

6. We revised the language in item 12 on page 5c (previously item 14 on page 5c) to clarify when a compounded prescription is noncompensable. We also revised the language to item 14 (iii) on page 5d (previously item 17 (iii) on page 5d) to clarify that certain nonlegend drugs are already included in the Department's nursing home per diem rate and are, therefore, not reimbursed to pharmacies.

7. We removed the item which restricts payment for drugs prescribed for any noncovered procedure (previously item 16 on page 5c).

8. (See #6)

9. We revised the third sentence on page 5e, item 17 (previously item 20) to reflect that Commonwealth will "grant" and not "extend" a 30-day grace period after the Notice of Opportunity for Hearing for DESI drugs.

C. Attachment 3.1-B

The Department has established limits for prosthetic devices and eyeglasses for all recipients. However, if an individual under 21 years of age has a medical need for a prosthetic device or eyeglasses that exceeds these established limits, the individual can receive the prosthetic device or eyeglasses with prior authorization. The prior authorization will determine the medical necessity. We revised the language on page 5a, item 12 to reconcile these limitations with the requirements of OBRA '89.

D. Attachment 4.19-B

Item a(2) on page 1 will remain unchanged as per the Department's telephone conversation with the Regional Office. The Department defines the State MAC for HCFA multisource drugs as the federal upper limits for those drugs in a later item number. In addition, the amount of the dispensing fee is included as item b on page 1.

In addition to the changes you requested in your letter of September 26, 1991, we also included statements to Attachment 3.1-A, page 5a, and to Attachment 3.1-B, page 5a, to comply with OBRA '90 requirements to cover new drugs marketed by drug companies participating in the Medicaid Drug Rebate Program without any restrictions for a period of 6 months after FDA approval and upon notification by the drug company that markets that new drug.

Finally, we are submitting our assurances that the Department provides a public notice whenever there is a significant proposed change in its methods and standards for setting payment rates for services, as required by 42 CFR 447.205.

Mr. Robert J. Taylor

-3-

REC 1

If you have any questions regarding the above, please contact the Office of Medical Assistance Programs, Bureau of Hospital and Outpatient Programs at (717) 782-6142.

Sincerely,

David S. Feinberg
Acting Deputy Secretary

Enclosures

JEC/kt

cc: Ms. Snider
Ms. Knowlton
Office of Administration
Mr. Kane
Mr. Lauro
Ms. Stouffer
Mr. Feinberg
RMD/DY/SL
Mr. Concino/SPA91-25.LTR
Control

Revision: HCFA-
JUNE 1991

(BERC)

79-d

OMB No. 1-100

State/Territory: COMMONWEALTH OF PENNSYLVANIA

Citation

4.36 Information Requirements Under the
Omnibus Budget Reconciliation Act of
1990.. (OBRA '90)

1927(b)(2) of
the Act,
P.L. 101-508
(Sec. 4401)

- (a) The Medicaid agency will meet all reporting and provision of information requirements as specified in section 1927(b)(2) of the Act concerning Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) enacted November 5, 1990.
- (b) The Medicaid agency will maintain the confidentiality of the unit rebate amounts and will not disclose for any purposes other than rebate invoicing and verification as specified in Section 1927(b)(2) of the Act concerning Section 4401 of OBRA '90 enacted November 5, 1990.

TN # 91-25 (NEW)

Supersedes

TN # _____ Approval Date _____ Effectived Date _____

SERVICE	LIMITATIONS
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12. Prescribed Drugs, Dentures,
and Prosthetic Devices,
and Eyeglasses

12.a. Prescribed drugs

New drug products marketed by drug companies participating in the Medicaid Drug Rebate Program are covered without any restrictions for a period of 6 months after FDA approval and upon notification by the drug company that markets that new drug, with the exception of those products, specified in Section 1927(d)(1)-(2) of the Social Security Act and which are excluded by the state agency.

Limitations on payment - The following limits apply to payment for compensable services:

- (a) Payment is limited to a 34-day supply or 100 units, whichever is greater.
- (b) Payment for prescribed nonlegend drugs is limited to the following:
 - (1) Those drug products marketed by drug companies which have entered into rebate agreements with the federal government as provided under section 4401 of the Omnibus Budget Reconciliation Act of 1990.
 - (2) Nonlegend drug products listed in the following categories:
 - (i) Analgesics, excluding long acting products: acetaminophen and combinations, aspirin and combinations, salicylates, and ibuprofen.
 - (ii) Antacids.
 - (iii) Antidiarrheals: kaolin-pectin combinations and loperamide.
 - (iv) Antiflatuants: simethicone and simethicone combined with an antacid.

TN# 91-25
Supersedes
TN# 87-02

Approval Date _____

Effective Date _____

SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed drugs (continued)	<ul style="list-style-type: none">(v) Antinauseants: concentrated balanced solutions of sugar and orthophosphoric acid, cyclizine lactate, dimenhydrinate, and meclizine hydrochloride.(vi) Bronchodilators.(vii) Cough and cold preparations, excluding mouthwashes, lozenges, throches, throat sprays, and rubs.(viii) Contraceptives.(ix) Hematinics, excluding long acting products: ferrous fumarate, ferrous gluconate, and ferrous sulfate.(x) Insulin.(xi) Laxatives and stool softeners.(xii) Nasal preparations: oxymetazoline, phenylephrine, xylometazoline, and naphazoline.(xiii) Ophthalmic preparations: ocular lubricants containing polyvinyl alcohol or cellulose derivatives, phenylephrine, and sodium chloride in strengths of 2.0 percent or greater.(xiv) Topical products containing one or more of the following ingredients:<ul style="list-style-type: none">(A) Anesthetics: benzocaine, cyclomethycaine, dibucaine, lidocaine, pramoxine, and tetracaine.(B) Antibacterials: bacitracin, neomycin, polymixin, povidone-iodine, and tetracycline.

TN# 91-25
Supersedes
TN# 87-02

Approval Date _____

Effective Date _____

SERVICE	LIMITATIONS
---------	-------------

12. Prescribed Drugs, Dentures,
and Prosthetic Devices, and
Eyeglasses

12.a. Prescribed drugs
(continued)

(c) Payment to a pharmacy for all prescriptions dispensed to a recipient in either a skilled nursing facility, an intermediate care facility, or an intermediate care facility for the mentally retarded shall be limited to one dispensing fee for each drug dispensed within a 30 day period. A 5-day grace period will be allowed to accommodate prescriptions filled and delivered prior to the normal 30-day cycle. This limitation does not apply to:

1. Antibiotics.
2. Anti-Infectives.
3. Schedule III analgesics.
4. Topical and injectible preparations dispensed in the manufacturer's original package size unless evidence indicates that the quantity issued at each dispensing incident does not relate to the recipient's known monthly requirements for that specific medication.
5. Ophthalmic and otic preparations dispensed in the manufacturer's original package size.
6. Compensable compounded prescription.
7. Insulin.
8. Schedule II drugs.
9. Oral liquid anticonvulsants and oral liquid potassium supplements.
10. Legend cough and cold oral liquid preparation.

TN# 91-25
Supersedes
TN# 87-02

Approval Date _____

Effective Date _____

SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed drugs (continued)	<p>(d) Payment will not be made to any pharmacy for the following services and items:</p> <ol style="list-style-type: none">1. Drugs and other items prescribed for the following:<ol style="list-style-type: none">(i) Obesity or appetite control unless the drug or item is also approved for the treatment of hyperkinesia in children or primary and secondary narcolepsy due to structural damage of the brain.(ii) Cessation of smoking.(iii) Hair growth or other cosmetic purposes.2. Any nonlegend drugs in the form of troches, lozenges, throat tablets, cough drops, chewing gum, mouth washes and similar items.3. Pharmaceutical services provided by any entity to a hospitalized person.4. All single entity and multiple vitamins except for the following:<ol style="list-style-type: none">(i) Single entity and multiple vitamin preparations with or without fluorides for children under three (3) years of age, based on medically supported documentation.(ii) A prescription drug product which contains a single entity vitamin combined with a legend drug.(iii) Vitamin D and its analogs.(iv) Nicotinic acid and its amides.

TN# 91-25
Supersedes
TN# 87-02

Approval Date _____

Effective Date _____

SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed drugs (continued)	(v) Vitamin K and its analogs.
	(vi) Folic acid.
	(vii) Single entity and multiple vitamin preparations when prescribed for prenatal use.
	5. Drugs and devices classified as experimental by the FDA or whose use is classified as experimental by the FDA.
	6. Drugs and devices not approved by the FDA.
	7. Placebos.
	8. Nonlegend soaps, cleansing agents, dentifrices, mouth washes, douche solutions, diluents, ear wax removal agents, deodorants, liniments, antiseptics, irrigants, emollients, and other personal care and medicine chest items.
	9. Nonlegend aqueous saline solutions.
	10. Nonlegend water preparations.
	11. Nonlegend food supplements and substitutes.
	12. Compounded prescriptions when:
	(i) The active ingredients are used in quantities insufficient to produce a therapeutic effect or response, or
	(ii) Noncompensable items are compounded.
	13. Nonlegend drugs not specified in this section.
	14. The following items when prescribed for recipients receiving skilled nursing and intermediate care facility services:

TN# 91-25
Supersedes
TN# 87-02

Approval Date _____

Effective Date _____

SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed drugs (continued)	<ul style="list-style-type: none">(i) Intravenous solutions. The payment for intravenous solutions is included in the nursing home per diem rate.(ii) Those noncompensable drugs and items as specified in this section.(iii) The following classes of nonlegend drugs:<ul style="list-style-type: none">(A) Analgesics.(B) Antacids.(C) Antacids with simethicone.(D) Cough-cold preparations.(E) Contraceptives.(F) Laxative and stool softeners.(G) Ophthalmic preparations.(H) Diagnostic agents.Payment for these nonlegend products is included in the nursing home per diem rate.(iv) Legend laxatives. Payment for all laxatives is included in the nursing home per diem rate.
	15. Items prescribed or ordered by a practitioner who has been barred or suspended during an administrative action from participation in the Medical Assistance Program.

TN# 91-25
Supersedes
TN# 87-09

Approval Date _____

Effective Date _____

SERVICE	LIMITATIONS
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12. Prescribed Drugs, Dentures,
and Prosthetic Devices, and
Eyeglasses

12.a. Prescribed drugs
(continued)

16. Prescriptions or orders filled by a pharmacy other than the one to which a recipient has been restricted because of misutilization or abuse.

17. DESI drugs and any identical, similar or related products or combinations of these products. DESI drugs are defined as those drugs for which Federal Financial Participation (FFP) is not available pursuant to the Federal regulations at 42 CFR § 441.25 (pertaining to less than effective drugs). The State will grant a 30-day grace period from the date of publication of the Notice of Opportunity for Hearing (NOOH) in the Federal Register in order to provide ample time to notify all providers that coverage for DESI drugs shall cease. In addition, the State will use this 30-day grace period to identify all products which are identical, similar or related to the DESI drugs described in the Federal Register and to make any necessary changes to the claims processing system. The State shall not claim FFP for any period beyond the 30-day period after publication of the NOOH in the Federal Register.

18. Nonlegend impregnated gauze and any identical, similar, or related nonlegend products.

19. Any pharmaceutical product marketed by a drug company which has not entered into a rebate agreement with the federal government as provided under Section 4401 of the Omnibus Budget Reconciliation Act of 1990.

TN# 91-25

Supersedes

TN# 91-11

Approval Date _____

Effective Date _____

State/Territory: PENNSYLVANIA

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED
MEDICALLY NEEDY GROUP(S): ALL

-
8. Private duty nursing services.
 Provided No limitations With limitations*
9. Clinic services.
 Provided No limitations With limitations*
10. Dental services.
 Provided No limitations With limitations*
11. Physical therapy.
a. Physical therapy.
 Provided No limitations With limitations*
- b. Occupational therapy.
 Provided No limitations With limitations*
- c. Services for individuals with speech, hearing, and language disorders provided by or under supervision of a speech pathologist or audiologist.
 Provided No limitations With limitations*
12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.
a. Prescribed drugs.
 Provided No limitations With limitations*
- b. Dentures.
 Provided No limitations With limitations*

* Description provided on attachment.

TN # 91-25
Supersedes
TN # 86-11

Approval Date _____ Effective Date _____

HCFA ID: 0140P/0102A

SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u> (Continued)	
12.a. Prescribed drugs	New drug products marketed by drug companies participating in the Medicaid Drug Rebate Program are covered without any restrictions for a period of 6 months after FDA approval and upon notification by the drug company that markets that new drug, with the exception of those products, specified in section 1927(D)(1)-(2) of the Social Security Act, and which are excluded by the state agency. <u>Limitations on payment</u> - Coverage for compensable services is limited to individuals under age 21 under the EPSDT program.
12.c. Prosthetic devices	<u>Limitations on payment</u> - Coverage for prosthetics is limited to individuals under age 21 under the EPSDT program.
12.d. Eyeglasses	<u>Limitations on payment</u> - Coverage for eyeglasses is limited to individuals under age 21 under the EPSDT program.
13. Other diagnostic, screening prevention and rehabilitative services, i.e., than those in this plan.	
(d) Rehabilitative services	
(i) Family-Based Mental Health Rehabilitative Services	
This is a comprehensive mental health service provided primarily in the home of a child or adolescent with a mental illness or a serious behavior disorder which is intended to forestall child and adolescent psychiatric hospitalization and other out of the home placements.	(a) Providers must be licensed as Family-Based Mental Health Rehabilitation Service Providers. (b) Services are available through the early and periodic screening, diagnosis, and treatment (EPSDT) program to identified patients under 21.

SERVICE	LIMITATIONS
1. Individual Practitioners, i.e., Physicians, Dentists, Chiropractors, Optome- trists, Podiatrists	State Agency Fee Schedule Based on Established Criteria*
2. Prescribed Drugs	Usual and customary charge to the general public. - Within the pharmacy program we recognize that the general public includes two groups: the self-paying public and the third party payors. We intend to compensate pharmacies for the additional cost associated with third party reimbursement because pharmacies, unlike other providers, are a high volume, low-profit business with tight controls on reimbursement for the product. However, we intend to limit our reimbursement for the difference between the self-paying program and the third party program to \$.25 per prescription. Payment for legend and nonlegend drugs is restricted to those products marketed by drug companies that have a signed national rebate agreement or an approved existing rebate agreement. Method of payment (a) The Department will determine the payment level to a pharmacy for compensable legend and nonlegend drugs as follows: (1) The payment for single source drugs and those multisource brand name drugs certified as medically necessary will be the lower of the EAC for the drug plus a dispensing fee or the pharmacy's usual and customary charge to third party payors. (2) The payment for HCFA multisource drugs will be the lower of the State MAC for the drug plus a dispensing fee or the pharmacy's usual and customary charge to third party payors. (3) The payment for multisource drugs, not classified as HCFA multisource drugs, will be the lower of the EAC or the State MAC, whichever is applicable, for the drug plus a dispensing fee or the pharmacy's usual and customary charge to third party payors. (b) The Department's current prescription dispensing fee is \$2.75.

TN# 91-25
Supersedes
TN# 91-12

Approval Date _____

Effective Date _____

Concino file



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
HARRISBURG, PENNSYLVANIA 17120

OFFICE OF
MEDICAL ASSISTANCE

~~OFFICE OF~~
POLICY
AND PLANNING

FEB 20 1985

Mr. Peter Goodman
Medical Operations Specialist
Health Care Financing Administration
P.O. Box 7760
3535 Market Street
Philadelphia, Pennsylvania 19101

Dear Mr. Goodman:

On January 18, 1985, we sent to Mr. Everett F. Bryant additional information regarding our Title XIX State Plan Amendment Number 84-1, as he had requested on October 3, 1984. You had indicated that we would need further documentation of medical necessity to support our policy which restricts coverage for all single entity and multiple vitamin preparations with or without fluoride to children under 3 years of age.

We discussed this matter with the Pennsylvania Chapter of the American Academy of Pediatrics. As a follow up, they sent us a letter which I am submitting for your review.

Thank you for your attention in this matter and I hope the attached letter provides you with sufficient information to approve State Plan Amendment 84-1. If you have any further questions, please feel free to contact me.

Sincerely,

David S. Feinberg
Director
Bureau of Policy and Program Development

Attachment

JEC/rlk
cc: Mr. Radke *RD*
NW Mr. Concino/File *File!*
Control

Pennsylvania Chapter American Academy of Pediatrics

"ADVOCATES FOR CHILDREN"



121 Coulter Avenue • Ardmore, Pennsylvania 19003 • 215-649-9117 • Toll Free in PA 1-800-CAR-BELT

Bureau of Policy & Planning
Office of Medical Assistance
RECEIVED
FEB 14 1985

Chairman/President
Susan Aronson, M.D.
605 Moreno Road
Narberth, PA 19072
215-664-3923

Alternate Chairman
Alan Kohrt, M.D.
415 Park Street
Honesdale, PA 18431
717-253-5838

Secretary-Treasurer
Marjeanne Collins, M.D.
330 N. Bowman Avenue
Merion Sta., PA 19066
215-662-2869

Executive Committee

Ian Holzman, M.D.
Pittsburgh, PA

Patricia Rossi, M.D.
Wilkes-Barre, PA

Milton Graub, M.D.
Philadelphia, PA

Past Chairman
Thomas Gessner, M.D.
Latrobe, PA

Executive Secretary
Scott Moyer, A.C.S.W.

January 25, 1985

Mr. David Feinberg
Director of Policy and Program Development
Department of Public Welfare
Commonwealth of Pennsylvania
Harrisburg, PA 19120

Dear Mr. Feinberg:

We write as representatives of the Pennsylvania Chapter of the American Academy of Pediatrics to provide both recommendations and a medical rationale for the provision of vitamin and mineral supplements under the Pennsylvania Medical Assistance Program.

At the present time, Pennsylvania Medical Assistance reimburses the cost of multivitamin supplements (with or without flouride and/or iron) for all eligible children under three years of age. As the program does not provide plain flouride supplements, these preparations have been used to supply flouride in communities with deficient water supplies as well as to hedge against potential micronutrient deficiencies among infants and toddlers likely to consume a marginal diet. Your agency has now been declared 'out of compliance' with Federal regulations because of your 'arbitrary' designation that only children under three years of age may receive micronutrient supplementation. You are directed that unless medical criteria are found for providing supplements to one particular age group (as opposed to all children) 'in need' of supplements, your program must end its practice of reimbursement for routine supplementation.

The Committee on Nutrition of the American Academy of Pediatrics has noted that a child fed a standard prepared formulae for the first six months to twelve months of life and an adequate varied diet thereafter will receive

REFER TO 2/14/85



all of the nutrients he or she will need; the only requirement for supplementation may be for fluoride(1). They note, however that poverty level diets frequently do not meet minimum requirements, nor do the diets of many infants taken off manufactured infant formulae and placed on cow milk with an inappropriate mixture of non-milk foods. One former standard diet, the U.S.D.A. Thrifty Food Plan, has been shown inadequate with respect to micronutrients(2).

The Preschool Nutrition Survey of 1968-1970 documents differences in nutritional status based on socioeconomic status among those children at the ages in question(3). Specifically, it was shown that nutritional status correlates directly with both income level and educational achievement of the parents with education being the stronger determinant. Studies of hemoglobin levels - an indicator of iron nutriture - were included in this study. These findings were consistent with those of other national surveys focusing on dietary intake data(4,5). These show an increased risk for micronutrient deficiency among young children when poverty and lack of education characterize the family. Similarly, local studies of groups of children from high risk populations within the United States demonstrate that (to quote the Committee on Nutrition), "Groups at particular nutritional risk include...children and adolescents from deprived families...."(1,6-8).

The now classic studies by Prasad, et al, of oral contraceptive users in Detroit document a decrease in both vitamin and mineral nutriture among young adult (post teen-age) women from poorer communities(9,10). Thus it is clear that all poor children in this country who are at or just past an age of rapid growth are 'at risk' for micronutrient deficiencies. They have the "...biologic or environmental precursors to malnutrition"(11). These children require routine supplementation.

By contrast, older males and all school age children are at lesser risk. At early school age it is likely that malnourished children are found, for the most part, within families with multiple problems which include inappropriate parenting, lack of skills needed to prepare food, and an inability to utilize educational and medical resources available to them(12,13).

The reason for a lesser risk past age 2 years of age is that caloric requirements are high relative to micronutrient requirements. Thus, by consuming larger amounts of less nutritious foods, older children are able to satisfy their micronutrient requirements. (The term "less nutritious" is defined by a reduction in nutrient density)(14). The following information is calculated from Recommended Daily Dietary Allowances(15):

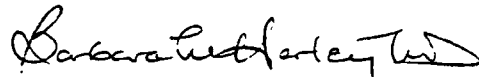
A one year old requires 15 mg of iron in 1000 calories for an Fe/energy ratio of 1.5 mg per 100 calories; at age 2 years this same 15 mg of iron will be consumed in 1300 calories for an Fe/energy ratio of 1.2 mg per 100 calories; by early school age the iron requirement of 10 mg of iron can be provided in 1700 calories for an Fe/energy ratio of 0.60 mg per 100 calories; the required ratio continues to decrease for males, while for females, at menarche, the increase in iron requirements causes the required Fe/energy ratio of the diet to increase, again (see attached table).


For any given family, diet (and thus the iron to energy ratio) is likely to be constant(16). Thus for a family which consumes a well balanced diet with iron containing meat as a staple, the iron to energy ratio will be adequate (>0.6 mg Fe/100 calories). Only infants and teenage girls will be 'at risk'. For families with marginal incomes, marginal food habits and marginal parenting patterns, all children will be 'at risk'; however, for children at early school age this is a problem specific to certain families rather than a condition held in common by all children in all families(8).

A short comment on the interaction between food and micronutrient supplementation: A historic observation has been that "...as income falls, food characteristic of higher earnings disappear until the poor have to support life on foods providing the most calories with the least money"(17). This suggests that when reduction in income is too great, the narrowed selection leads to elimination of one or more essential nutrients from the diet; with prolonged reduction in income the incidence of malnutrition will increase(18). Micronutrient supplementation is one way to counteract this effect.

The maldistribution of income and resources such that those in greatest need have least public services available to them increases the vulnerability of poor people to malnutrition and other consequences of poverty(19,20). Thus, we support your efforts to maintain a needed service.

Sincerely,


Barbara M. Harley, M.D., F.A.A.P.
Medical Assistance Coordinator


Robert J. Karp, M.D., F.A.A.P.
Nutrition Coordinator

cc: Alfred Mauer, M.D., F.A.A.P.
Chairman, Committee on Nutrition
American Academy of Pediatrics

FROM:

RECOMMENDED DAILY DIETARY ALLOWANCES, 1979

CATEGORY AGE Fe (mg) Energy (cal) Hypothetical Fe/Energy
ratio recommended for
daily diet (mg/100 kcal)

Infant	6 mo.	15	700	2.1
Infant	1 yr.	15	1,000	1.5
Child	2 yrs.	15	1,300	1.2
Child	6 yrs.	10	1,700	0.60
Female	15 yrs.	18	2,100	0.81
Male	15 yr.	18	2,800	0.64

References -- letter to Mr. Feinberg

1. Committee on Nutrition - American Academy of Pediatrics, Vitamin and mineral supplement needs in normal children in the United States. *Pediatrics* 66:1015, 1980
2. Lane, S., Vermeersch, J.: Evaluation of the thrifty food plan: menus based on the thrifty food plan cannot assume dietary adequacy. *J Nutr Ed* 11:96, 1973.
3. Owen G., Kram, M., Garry, J.E., et al: A study of nutritional status of preschool children in the United States, 1968-1970. *Pediatrics* 53(supp):597, 1974.
4. Dietary Intake Findings, 1971-1974, National Health Survey. DHEW Pub (HRA) 77-1647, Hyattsville, MD, National Center for Health statistics Series 11, No. 202, 1977.
5. Ten State Nutrition survey, 1968-1970, Highlights, DHEW Pub (HSM) 72-8134, Atlanta, GA, Center for Disease Control, 1970.
6. Ruffin, M., Calloway, D.H., Margen, S.: Nutritional status of preschool children of Marin County welfare recipients. *Am J Clin Nutr* 25:74, 1972.
7. Chase, H.P., Kumar, V., Dodds, J.M., et al: Nutritional status of preschool Mexican-American Migrant farm children. *Amer J Dis Child* 122:316, 1971.
8. Karp, R.J., Haaz W.S., Starko, K., Gorman, J.M.: Iron deficiency in families of iron deficient inner-city school children. *Am J Dis Child* 128:18, 1974.
9. Prasad, A.S., Oberleas, D., Lei, K.Y., et al: Effect of oral contraceptive agents on nutrients I. Minerals. *Am J Clin Nutrition* 28:377, 1975.
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11. Jelliffe, D.B., Jelliffe, E.F.P.: The at risk concept as applied to young child nutrition programs. *Clin Pediatrics* 12:65, 1973.
12. Karp, R.J., Snyder, E., Fairorth J.W., et al: Parental behavior and the availability of foods among undernourished inner-city school children. *J Fam Practice* 18, 731, 1984.
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14. Guthrie, H.: Concept of nutritious food. *J Am Diet Assoc* 71, 14, 1973.
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16. Wretline, A.: Food iron supply. (in) Hallberg, L., Harwerth G.H., Vanotti, (eds) Iron Deficiency, New York, Academic Press, 1970.
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20. Nersesian, W.S., Petit, M.R., Shaper, R.: Childhood death and poverty: A study of all childhood deaths in Maine, 1976 to 1980. *Pediatrics* 75:41, 1985.



125253

Refer to: R3-1-DMD (7)

SEP 26 1991

*Dunkin
R/F 559
Due 10-17-91*

Region III
P.O. Box 7760, 3525 Market St
Philadelphia PA 19101

RECEIVED
Dept of Public Welfare
Office of the Secretary

Mrs. Karen F. Snider
Acting Secretary
Department of Public Welfare
Commonwealth of Pennsylvania
Health & Welfare Building
Post Office Box 2675
Harrisburg, Pennsylvania 17105

SEP 27 1991

Referred To Feinberg

*APPROV OFFICE
w/ Snider
KNOWITON
Saw 11*

Dear Mrs. Snider:

I am writing in response to your submittal of Pennsylvania State Plan Amendment Number 91-25 (SPA 91-25) which was submitted to bring the state plan into compliance with the OBRA '89 provision related to the coverage of services for children under 21 years of age and the OBRA '90 provisions related to the payment and coverage limitations for drug services.

*Kaw
Sile
Laur
Stout*

We have reviewed SPA 91-25 and find that before we can approve the amendment you will need to provide us with some additional information.

Page 79-d

HCFA policy requires that states include a statement that the unit rebate amount is confidential and will not be disclosed for purposes other than rebate invoicing and verification. Please include such a statement on page 79-d.

Attachment 3.1A

1. Pages 5a and 5c, Item 15.

To conform with the requirements of section 1927(d) (2) of the Social Security Act (the Act), you must delete that portion of the third paragraph on page 5a and revise item 15 on page 5c which states that payment for prescribed non-legend drugs is limited to those contained in the Department's established list. These drugs must be specified and already appear to be addressed in item 12.a. (continued), beginning on page 5b, describing when the Commonwealth will not make payment for non-legend drugs.

*OCT 2 11 54 AM '91
SECRETARY
WILL CHECK*

Bureau of Hospital & Outpatient Programs
Office of Medical Assistance Programs

RECEIVED

OCT 03 1991

Refer To: *[Signature]*

2. Page 5b, Item 1.

This item restricts the payment to pharmacies for the drug Methadone. This drug product may not be restricted from coverage because it is not included among those drug products which may be excluded or otherwise restricted at section 1927(d) (2) of the Act.

3. Page 5b, Items 2, 11, 12, 22 and 23.

Unless you can provide other authority, these items must also be removed or revised to conform with the Omnibus Reconciliation Act of 1990. Beginning January 1, 1991, section 1902(a)(54) of the Act prohibits any formularies or similar restrictions except prior authorization programs and those drugs in accordance with section 1927(d) of the Act. A State must permit coverage of covered outpatient drugs of any manufacturer that has entered into and complies with an agreement under section 1927(a), and which are prescribed for a medically accepted indication.

4. In item 6(i).

This item restricts prescription vitamin coverage to children under 3 years of age. That violates the comparability provisions of section 1902(a)(10)(B) of the Act, which provides that medical assistance made available to any categorically needy individual ". . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." The restriction, therefore, must be removed.

5. Page 5c, Item 8.

This item indicates that you will not permit coverage of drugs whose use is not approved by the Food and Drug Administration (FDA). Section 1927(k)(6) of the Act states the requirements for coverage of a covered outpatient drug to be that which are prescribed for a medically accepted indication. Thus, if the drug is approved by the FDA it is covered for the labelled (FDA approved) indications and off-label, medically acceptable indication. Please revise the definition to reflect the requirements at 1927(k)(c).

6. Page 5c, Item 14 and Page 5d, Item 17(iii).

Please clarify what is meant by the terms "compensable" and in item 14, "therapeutic quantities."

7. Page 5c, Item 16.

This item limits the coverage of drugs prescribed in conjunction with sex reassignment or other noncompensable procedure. While the State may exclude certain procedures from its Medicaid coverage, as previously discussed, section 1927(d)(1)(B) does not permit exclusion or restriction of covered outpatient drugs due to medical procedures.

8. Page 5d, Item 17(iii).

It is unclear whether these items are excluded for nursing home residents or included. Please clarify this subsection.

9. Page 5e, Item 20.

Please revise the third sentence to reflect that the Commonwealth will "grant" and not "extend" a 30-day grace period. Pennsylvania has a 30-day grace period after publication of the Notice of Opportunity for Hearing.

Attachment 3.1-B

Page 5a, Item 12.

Item 12 indicates that the Commonwealth intends to impose limitations on coverage of prosthetic devices and eyeglasses for Early and Periodic Screening, and Diagnosis Treatment (EPSDT) recipients. Item 12.c limits prosthetic devices to hearing aids for individuals under age 21. Item 12.d limits payment to one pair of eyeglasses per year.

The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) added section 1905(r) to the Act. Section 1905(r)(5) requires States to provide other necessary health care, diagnostic services, treatment and any other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan. Therefore, if a prosthetic device other than a hearing aid or a second pair of eyeglasses were determined to be medically necessary, these items would be required to be provided to the EPSDT recipient. Please reconcile these limitations with the requirements of OBRA 89.

Attachment 4.19-B

1. Page 1, Item 2.

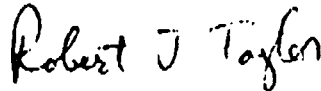
Under Method of Payment, you indicate, "The payment for Health Care Financing Administration multisource drugs will be the lower of the State MAC . . .". Please revise this item in accordance with section 1927(e) of the Act to ensure that the State pays no more than the Federal Upper Limits. Also, HCFA policy requires that states specify the amount of the dispensing fee. Please revise item(a) to include the amount of the dispensing fee wherever the text makes reference to the fee.

Assurances

Federal regulations at 42 CFR 447.205 require that a State submit an assurance that it has provided public notice whenever there is a significant proposed change in its methods and standards for setting payment rates for services. Please provide us with that assurance.

Under Section 1915(f) of the Social Security Act, a state plan amendment must be approved, denied, or have additional information requested about it within 90 days of receipt, or the amendment will be deemed granted. The 90-day period for State Plan Amendment Number 91-25 ends September 26, 1991. This letter constitutes a formal request for additional information, and a new 90-day period will begin upon receipt of your written request.

Sincerely,



Robert J. Taylor
Associate Regional Administrator
Division of Medicaid



JOHN P. WHITE, JR.
SECRETARY

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
P. O. Box 2675
HARRISBURG, PENNSYLVANIA 17105

(717) 787-2600 • 3600

JUN 24 1991

Mr. Maurice Hartman
Regional Administrator
Program Operations
BCFA/Department of Health and Human Services
P.O. Box 7760
3535 Market Street
Philadelphia, Pennsylvania 19101

Re: State Plan Amendment 91-25

Dear Mr. Hartman:

We are submitting our Transmittal No. 91-25 to update Pennsylvania's preprinted State Plan for medical assistance to describe the expanded coverage of services available to Medically Needy recipients under the age of 21 to include pharmaceuticals, medical supplies, durable medical equipment, prosthetics, and orthotics according to the recent clarification of the Omnibus Reconciliation Act of 1989 (OBRA '89). All Medical Assistance Fee Schedule and drug file limitations which govern services for the Categorically Needy will apply to the Medically Needy.

Transmittal No. 91-25 will also update our State Plan to assure our intention to comply with all of the provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). We have removed from our State Plan all references which appear to restrict payment for any participating drug company's drug products and which appear to be inconsistent with the provisions of OBRA '90.

We are submitting with this transmittal a new section 4.36, page 79-D that includes a statement that our State will meet all reporting and provision of information requirements as specified in Section 1927(b)(2). We are also submitting with this transmittal corrected pages 5a, 5b, 5c, 5d, and 5e of Attachment 3.1-A of our preprinted State Plan to insure that any limitations which we placed on the coverage of drugs are allowed by Section 1927(d) of the Act; corrected page 1 of Attachment 4.19-B of our preprinted State Plan to add a statement restricting payment only to those drug companies that have signed national agreements or have an approved existing agreement as described in Section 1927(a) of the Act.

In addition, we are submitting with this transmittal corrected pages 4 and 5a of Attachment 3.1-B of our preprinted State Plan to expand coverage for pharmaceuticals, medical supplies, durable medical equipment, prosthetics, and orthotics to the Medically Needy under age 21 according to the recent clarification of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89).

JUN 24 1991

If you have any further questions concerning the above, please contact the Office of Medical Assistance Programs, Bureau of Hospital and Outpatient Programs at (717)782-6142.

Best wishes.

Sincerely,

John F. White, Jr.

Enclosures

Prepared by: Joseph E. Concino, P.D. (782-6142) (6/10/91)

JEC:djg

cc: Mr. White
Ms. Knowlton
Mr. Radke
Mr. Radke (Control)
Mr. Kane
DSF/RMD/SL
Mr. Concino (STPL91-25.LTR
Mr. Concino/Pending
Control

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	TRANSMITTAL NUMBER 91-25	STATE PENNSYLVANIA
	PROGRAM IDENTIFICATION TITLE XIX	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	PROPOSED EFFECTIVE DATE January 1, 1991	

TYPE OF PLAN MATERIAL (Check One)

NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

COMPLETE NEXT 4 BLOCKS IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)

FEDERAL REGULATION CITATION 42 CFR 435.301; Section 4401 of the Omnibus Budget Reconciliation Act of 1990, P.L. 101-508; The Omnibus Budget Reconciliation Act of 1989.

NUMBER OF THE PLAN SECTION OR ATTACHMENT Section 4.36, Page 79-d Attachment 3.1-A, Pgs 5a, 5b, 5c, 5d & 5e Attachment 3.1-B, Pgs 4 & 5a Attachment 4.19-B - Page 1	NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT Pages 5a, 5b, 5c, 5d & 5e of Attachment 3.1-A Pages 4 & 5a of Attachment 3.1-B Page 1 of Attachment 4.19-B
--	---

SUBJECT OF AMENDMENT

1. Expand coverage available to medically needy recipients under age 21 to include pharmaceuticals, medical supplies, durable medical equipment, prosthetics, and orthotics.

2. Assume compliance with all provisions of the Omnibus Budget Reconciliation Act of 1990. Remove all references which appear to restrict payment for any particular drug company's drug products and appear to be inconsistent with OBRA '90.

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED: Review and approval authority is delegated to the Secretary of Public Welfare

COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

SIGNATURE OF STATE AGENCY OFFICIAL <i>[Signature]</i>	FOR REGIONAL OFFICE USE ONLY	
	DATE RECEIVED	DATE APPROVED
TYPED NAME: John F. White, Jr.	PLAN APPROVED - ONE COPY ATTACHED	
TITLE: Secretary of Public Welfare	EFFECTIVE DATE OF APPROVED MATERIAL	
DATE:	SIGNATURE OF REGIONAL OFFICIAL	
RETURN TO: Commonwealth of Pennsylvania Department of Public Welfare P.O. Box 2675 Harrisburg, Pennsylvania 17105	TYPED NAME:	
	TITLE:	
	REMARKS:	

Revision: HCFA-
JUNE 1991

(BERC)

79-d

OMB No.

State/Territory: COMMONWEALTH OF PENNSYLVANIA

Citation

4.36 Information Requirements Under the
Omnibus Budget Reconciliation Act of
1990.. (OBRA '90)

1927(b)(2) of
the Act,
P.L. 101-508
(Se.c. 4401)

The Medicaid agency will meet all reporting and provision of information requirements as specified in section 1927(b)(2) of the Act concerning Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) enacted November 5, 1990.

TN # 91-25 (NEW)

Supersedes

TN # _____

Approval Date _____

Effectived Date _____

SERVICE LIMITATIONS

12. Prescribed Drugs, Dentures,
and Prosthetic Devices, and
Eyeglasses

12.a. Prescribed drugs

Limitations on payment - The following limits apply to payment for compensable services:

Payment is limited to a 34-day supply or 100 units, whichever is greater.

Payment for prescribed nonlegend drugs is limited to those contained in the Department's established list of compensable nonlegend drugs and to those products marketed by drug companies which have entered into rebate agreements with the federal government as provided under Section 4401 of the Omnibus Budget Reconciliation Act of 1990.

Payment to a pharmacy for all prescriptions dispensed to a recipient in either a skilled nursing facility, an intermediate care facility, or an intermediate care facility for the mentally retarded shall be limited to one dispensing fee for each drug dispensed within a 30 day period. A 5-day grace period will be allowed to accommodate prescriptions filled and delivered prior to the normal 30-day cycle. This limitation does not apply to:

1. Antibiotics.
2. Anti-Infectives.
3. Schedule III analgesics.
4. Topical and injectible preparations dispensed in the manufacturer's original package size unless evidence indicates that the quantity issued at each dispensing incident does not relate to the recipient's known monthly requirements for that specific medication.
5. Ophthalmic and otic preparations dispensed in the manufacturer's original package size.
6. Compensable compounded prescription.
7. Insulin.
8. Schedule II drugs.
9. Oral liquid anticonvulsants and oral liquid potassium supplements dispensed in the manufacturer's original package size.
10. Legend cough and cold oral liquid preparation.

TN# 91-25

Supersedes

TN# 87-02

Approval Date _____

Effective Date _____

SERVICE	LIMITATIONS
<p>12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u></p>	
<p>12.a. Prescribed drugs (continued)</p>	<p>Payment will not be made to any pharmacy for the following services and items:</p> <ol style="list-style-type: none"> 1. Methadone for any use. The Medical Assistance Program provides methadone only through drug and alcohol clinics. 2. Drugs indicated for the treatment of pulmonary tuberculosis except if the tuberculosis drug has an approved indication other than the treatment of tuberculosis. The Department of Health is responsible for providing all drugs indicated for the treatment of tuberculosis to needy citizens through its Tuberculosis Control Program. 3. Drugs and other items prescribed for the following: <ol style="list-style-type: none"> (i) Obesity or appetite control unless the drug or item is also approved for the treatment of hyperkinesia in children or primary and secondary narcolepsy due to structural damage of the brain. (ii) Cessation of smoking. (iii) Hair growth or other cosmetic purposes. 4. Any nonlegend drugs in the form of troches, lozenges, throat tablets, cough drops, chewing gum, mouth washes and similar items. 5. Pharmaceutical services provided by any entity to a hospitalized person. 6. All single entity and multiple vitamins except for the following: <ol style="list-style-type: none"> (i) Single entity and multiple vitamin preparations with or without flourides for children under three (3) years of age. (ii) A prescription drug product which contains a single entity vitamin combined with a legend drug. (iii) Vitamin D and its analogs. (iv) Nicotinic acid and its amides. (v) Vitamin K and its analogs. (vi) Folic acid.

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SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed drugs (Continued)	(vii) Single entity and multiple vitamin preparations when prescribed for prenatal use.
	7. Drugs and devices classified as experimental by the FDA or whose use is classified as experimental by the FDA.
	8. Drugs and devices not approved by the FDA or whose use is not approved by the FDA.
	9. Placebos.
	10. Nonlegend soaps, cleansing agents, dentifrices, mouth washes, douche solutions, diluents, ear wax removal agents, deodorants, liniments, antiseptics, irrigants, emollients, and other personal care and medicine chest items.
	11. Legend and nonlegend aqueous saline solutions for any use other than for intravenous administration.
	12. Legend and nonlegend water preparations such as distilled water, water for injection, and any identical, similar or related products.
	13. Nonlegend food supplements and substitutes.
	14. Compounded prescriptions when: (i) Compensable items are used in less than therapeutic quantities, or (ii) Noncompensable items are compounded.
	15. Nonlegend drugs not listed in the Department's established list of compensable nonlegend drugs.
	16. Drugs prescribed in conjunction with sex reassignment procedures or other noncompensable procedures.
	17. The following items when prescribed for recipients receiving skilled nursing and intermediate care facility services:
	(i) Intravenous solutions. The payment for intravenous solutions is included in the nursing home per diem rate.

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SERVICE	LIMITATIONS
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12. Prescribed Drugs, Dentures,
 and Prosthetic Devices, and
 Eyeglasses

12.a. Prescribed drugs
 (Continued)

- (ii) Those noncompensable drugs and items as specified in this section.
- (iii) The following classes of nonlegend drugs identified in the Department's established list of compensable nonlegend drugs:
 - (A) Analgesics.
 - (B) Antacids.
 - (C) Antacids with simethicone.
 - (D) Cough-cold preparations.
 - (E) Contraceptives.
 - (F) Laxative and stool softeners.
 - (G) Ophthalmic preparations.
 - (H) Diagnostic agents.
- (iv) Legend laxatives. Payment for all laxatives is included in the nursing home per diem rate.

18. Items prescribed or ordered by a practitioner who has been barred or suspended during an administrative action from participation in the Medical Assistance Program.

19. Prescriptions or orders filled by a pharmacy other than the one to which a recipient has been restricted because of misutilization or abuse.

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SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses</u>	
12.a. Prescribed drugs (continued)	20. DESI drugs and any identical, similar or related products or combinations of these products. DESI drugs are defined as those drugs for which Federal Financial Participation (FFP) is not available pursuant to the Federal regulations at 42 CFR § 441.25 (pertaining to less than effective drugs). The State will extend a 30-day grace period from the date of publication of the Notice of Opportunity for Hearing (NOOH) in the <u>Federal Register</u> in order to provide ample time to notify all providers that coverage for DESI drugs shall cease. In addition, the State will use this 30-day grace period to identify all products which are identical, similar or related to the DESI drugs described in the <u>Federal Register</u> and to make any necessary changes to the claims processing system. The State shall not claim FFP for any period beyond the 30-day period after publication of the NOOH in the <u>Federal Register</u> .
	21. Nonlegend impregnated gauze and any identical, similar or related nonlegend products.
	22. Any pharmaceutical services for which payment is available from another public agency or another insurance or health program except for those drugs prescribed through the County Mental Health/Mental Retardation Program.
	23. FDA approved pharmaceutical products whose indicated use is not intended to treat or manage a medical condition, illness or disorder.
	24. Any pharmaceutical product marketed by a drug company which has not entered into a rebate agreement with the federal government as provided under Section 4401 of the Omnibus Budget Reconciliation Act of 1990.

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State/Territory: PENNSYLVANIA

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED
MEDICALLY NEEDY GROUP(S): ALL

8. Private duty nursing services.
 Provided No limitations With limitations*
9. Clinic services.
 Provided No limitations With limitations*
10. Dental services.
 Provided No limitations With limitations*
11. Physical therapy.
a. Physical therapy.
 Provided No limitations With limitations*
- b. Occupational therapy.
 Provided No limitations With limitations*
- c. Services for individuals with speech, hearing, and language disorders provided by or under supervision of a speech pathologist or audiologist.
 Provided No limitations With limitations*
12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.
a. Prescribed drugs.
 Provided No limitations With limitations*
- b. Dentures.
 Provided No limitations With limitations*

* Description provided on attachment.

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Supersedes
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BCFA ID: 0140P/0102A

SERVICE	LIMITATIONS
12. <u>Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses (Continued)</u>	
12.a. Prescribed drugs	<u>Limitations on payment</u> - Coverage for compensable services is limited to individuals under age 21.
12.c. Prosthetic devices	<u>Limitations on payment</u> - Coverage for prosthetics is limited to hearing aids for individuals under age 21 under EPSDT regulations.
12.d. Eyeglasses	<u>Limitations on payment</u> - The following limits apply to payment for compensable services:
	1. Payment is made for eyeglasses for persons eligible under the EPSDT program.
	2. Payment for eyeglasses is limited to one full pair or two lenses and one frame per year.
13. Other diagnostic, screening prevention and rehabilitative services, i.e., than those in this plan.	
(d) Rehabilitative services	
(i) Family-Based Mental Health Rehabilitative Services	
This is a comprehensive mental health service provided primarily in the home of a child or adolescent with a mental illness or a serious behavior disorder which is intended to forestall child and adolescent psychiatric hospitalization and other out of the home placements.	(a) Providers must be licensed as Family-Based Mental Health Rehabilitation Service Providers. (b) Services are available through the early and periodic screening, diagnosis, and treatment (EPSDT) program to identified patients under 21.

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 TN# 90-10

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METHODS AND STANDARDS FOR ESTABLISHING PAYMENTS RATES-OTHER TYPES OF CARE

SERVICE	LIMITATIONS
1. Individual Practitioners, i.e., Physicians, Dentists, Chiropractors, Optometrists, Podiatrists	State Agency Fee Schedule Based on Established Criteria*
2. Prescribed Drugs	Usual and customary charge to the general public. - Within the pharmacy program we recognize that the general public includes two groups: the self-paying public and the third party payors. We intend to compensate pharmacies for the additional cost associated with third party reimbursement because pharmacies, unlike other providers, are a high volume, low-profit business with tight controls on reimbursement for the product. However, we intend to limit our reimbursement for the difference between the self-paying program and the third party program to \$.25 per prescription. Payment for legend and nonlegend drugs is restricted to those products marketed by drug companies that have a signed national rebate agreement or an approved existing rebate agreement. Method of payment (a) The Department will determine the payment level to a pharmacy for compensable legend and nonlegend drugs as follows: (1) The payment for single source drugs and those multisource brand name drugs certified as medically necessary will be the lower of the EAC for the drug plus a dispensing fee or the pharmacy's usual and customary charge to third party payors. (2) The payment for HCFA multisource drugs will be the lower of the State MAC for the drug plus a dispensing fee or the pharmacy's usual and customary charge to third party payors. (3) The payment for multisource drugs, not classified as HCFA multisource drugs, will be the lower of the EAC or the State MAC, whichever is applicable, for the drug plus a dispensing fee or the pharmacy's usual and customary charge to third party payors.

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
P.O. BOX 2675
HARRISBURG, PENNSYLVANIA 17105-2675

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TELEPHONE 717/787-1870
FACSIMILE 717/787-4839

Peg J. Dierkers, Ph.D.
DEPUTY SECRETARY FOR MEDICAL ASSISTANCE PROGRAMS

NOV 03 1999

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

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Dear Mr. Nyce:

I am writing to you regarding Independent Regulatory Review Commission (IRRC) Regulation #14-459 (#2063), Omnibus Revisions to Pharmaceutical Services and Restrictions to Fertility Services.

The Department received several comments and questions regarding regulation #14-459 that was submitted for your review. The Department is withdrawing the regulations to review the comments and concerns and to address the issues raised.

Thank you for your attention in this matter.

Sincerely,

Peg J. Dierkers
Peg J. Dierkers

- cc: The Honorable Harold F. Mowery, Jr.
- The Honorable Vincent J. Hughes
- The Honorable Dennis M. O'Brien
- The Honorable Frank L. Oliver
- Davis DeVries, Chief Deputy Attorney General
- Howard Burde, Deputy General Counsel
- Thomas A. Hutton, Deputy General Counsel
- LeAnn Labecki, Governor's Policy Office
- James M. Smith, IRRC

FAX TRANSMISSION COVER SHEET



ATTORNEY: _____
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
OFFICE OF LEGAL COUNSEL

RM 305, HEALTH & WELFARE BLDG.
HARRISBURG, PA 17120
OFFICE (717) 783-2800
FAX (717) 772-0717

We are FAXing to you 3 pages including cover.

DELIVER TO: Richard Sandusky
FAX #: 3-2664
OFFICE: _____
SENT BY: Ruth O'Brien
DATE: 11-3-99 TIME: 12 NOON

COMMENT/MESSAGE

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