

(a) *Commission* means the Postal Rate Commission.

(b) *Individual, record, and system of records* have the meanings specified in 5 U.S.C. 552a(a).

(c) *Day* means a calendar day and does not include Saturdays, Sundays, and legal holidays.

§ 3003.3 Procedures for requesting inspection, copying, or correction.

(a) An individual who—

(1) Wishes to know whether a Commission system of records contains a record about him or her,

(2) Seeks access to a Commission record about him or her that is maintained in a system of records (including the accounting of disclosures), or

(3) Seeks to amend a record about him or her that is maintained in a system of records, may file a written request with the chief administrative officer of the Commission at the Commission's current address (1333 H Street NW., Suite 300, Washington, DC 20268-0001). The request should state on the outside of the envelope and in the request that it is a Privacy Act request.

(b) A request for amendment must describe the information sought to be amended and the specific reasons for the amendment.

(c) A requester—

(1) May request an appointment to inspect records at the Commission's offices between the hours of 8 a.m. and 4:30 p.m. on any day;

(2) Must present suitable identification, such as a driver's license, employee identification card, or Medicare card;

(3) If accompanied by another individual, must sign a statement, if requested by the chief administrative officer, authorizing discussion of his or her record in the presence of that individual;

(4) Who files a request by mail must include his or her date of birth, dates of employment at the Commission (if applicable), and suitable proof of identity, such as a facsimile of a driver's license, employee identification card, or Medicare card; and

(5) Must, if requested by the chief administrative officer, provide additional proof of identification.

§ 3003.4 Response to a request.

(a) In the case of a request for notice of the existence of a record, the chief administrative officer shall respond within 10 days of receipt of a request and shall inform the individual whether a system of records maintained by the Commission contains such a record.

(b) In the case of a request for access to a record or for a copy of a record, the

chief administrative office shall acknowledge the request within 10 days and shall promptly thereafter—

(1) Fulfill the request by mail or arrange for an inspection by the requester in the Commission's offices; or

(2) If the request is denied, notify the requester of the denial, the reasons for the refusal, the procedures for appealing the refusal, and the name and address of the Chairman of the Commission who will consider an appeal.

(c) In the case of a request for amendment, the chief administrative officer shall

(1) Acknowledge the request in writing within 10 days;

(2) Promptly review the record; and

(3)(i) Make any requested amendment of a record found to be not accurate, relevant, timely, or complete; notify the requester of the change and provide a copy of the corrected record; and notify any previous recipient of the record (excluding Commission staff who obtained the record in the performance of their duties and recipients under the Freedom of Information Act) of any change; or

(ii) Inform the requester of a refusal to amend the record, the reasons for the refusal, the procedures for appealing the refusal, and the name and address of the Chairman of the Commission who will consider an appeal.

§ 3003.5 Appeals of denials of access or amendment.

(a) If a request for access to or amendment of a record is denied, the requester may file a written appeal with the Chairman of the Commission. The Chairman will decide each appeal within 30 days of receipt unless the Chairman has, for good cause, extended the period for another 30 days.

(b) If an appeal is denied, the requester will be notified of the decision, the reasons for the denial, the right to file a concise statement of disagreement, the procedures for filing a statement of disagreement, the subsequent uses of a statement of disagreement, and of the right to seek judicial review in accordance with subsection (g) of the Privacy Act.

§ 3003.6 Fees.

The first copy of any record furnished under the Privacy Act of 1974 will be provided without charge. Additional copies will be charged at the cost of reproduction.

§ 3003.7 Exemptions.

The Postal Rate Commission has not established any exempt system of records.

[FR Doc. 99-23431 Filed 9-9-99; 8:45 am]

BILLING CODE 7710-FW-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 435, 436, and 440

[HCFA-2082-P]

RIN 0938-AG72

Medicaid Program; Optional Coverage of Certain Tuberculosis-Related Services to TB-Infected Individuals

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the existing Medicaid regulations to incorporate statutory provisions that allow States to cover a limited Medicaid service package to an eligibility group of low-income individuals infected with tuberculosis (TB). The services provided under this optional coverage are limited to those related to the treatment of TB. This optional coverage will ensure Medicaid services for the treatment of TB-infected individuals who would otherwise be unlikely to receive coverage under Medicaid. This proposed rule would incorporate and interpret provisions of the Omnibus Budget Reconciliation Act of 1993.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 9, 1999.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-2082-P, P.O. Box 9010, Baltimore, MD 21244-9010.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC, or C5-14-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-2082-P.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to: Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: John Burke, HCFA-2082-P; and Lauren Oliven, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 3001, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:
Ingrid Osborne (410) 786-4461, Gerald Zelinger (410) 786-5929.

SUPPLEMENTARY INFORMATION:

I. Background

Because of the emerging recurrence of tuberculosis (TB) in this country, Congress included provisions in its 1993 legislation that allows States, at their option, to extend Medicaid eligibility to low-income individuals infected with TB. The Omnibus Budget Reconciliation Act of 1993 (OBRA '93), Public Law 103-66, amended the Social Security Act (the Act) in several ways to provide for this coverage. Prior to OBRA '93, TB-infected individuals who did not qualify as disabled under the disability definition under the Supplemental Security Income (SSI) program would have been unlikely to receive Medicaid coverage. Even though these individuals might have met the income and resource requirements of the cash assistance programs, they could not meet the categorical requirements necessary to qualify for Medicaid.

Consistent with the addition of the new eligibility group whose eligibility is based on, among other factors, being infected with TB, Congress limited the services available to this new eligibility group. Congress effected this limitation by amending the statutory text following section 1902(a)(10)(F) of the Act to provide for an exception to the comparability rules, which require certain types of eligibility groups to be treated comparably in terms of the services available. The new exception provides that coverage for individuals who are eligible for Medicaid under the optional TB-infected eligibility group is

limited to the TB-related services listed in section 1902(z)(2). Congress amended section 1915(g)(1) to permit States to provide targeted case management services to TB-infected individuals. Section 13603 of OBRA '93 added a new section 1902(z)(2) that specifies the categories of services that eligible TB-infected individuals may receive. The services listed in section 1902(z)(2) include—

- (1) Prescribed drugs;
- (2) Physicians' services and services described in section 1905(a)(2) of the Act (these services include outpatient hospital services, rural health clinic services, and Federally qualified health center services);
- (3) Laboratory and X-ray services (including services to confirm the presence of infection);
- (4) Clinic services and Federally qualified health center services;
- (5) Case management services (as defined in section 1915(g)(2)); and
- (6) Services (other than room and board) designed to encourage completion of regimens of prescribed drugs by outpatients, including services to directly observe the intake of prescribed drugs.

Since the last of these listed services was not previously within the scope of coverable Medicaid services, section 13603 of OBRA '93 amended section 1905(a)(19) of the Act to add to the overall list of coverable Medicaid services the TB-related services described in section 1902(z)(2)(F). Section 1902(z)(2)(F) describes the new services as services (other than room and board) designed to encourage completion of regimens of prescribed drugs by outpatients, including services to directly observe the intake of prescribed drugs.

The amendments made by section 13603 of OBRA '93 apply to medical assistance furnished on or after January 1, 1994, without regard to whether or not final regulations to carry out the amendments had been promulgated by that date.

II. Provisions of the Proposed Regulations

We propose to incorporate the OBRA '93 provisions relating to optional coverage of TB-infected individuals in the Medicaid regulations and provide the following interpretations:

A. Eligibility Requirements

Section 1902(z)(1) of the Act, as added by OBRA '93, describes the low-income individuals infected with TB who may be eligible for Medicaid. We propose to add new §§ 435.219 and 436.219 to incorporate this optional

group and interpret the eligibility requirements.

1. Individuals Who Are Infected with TB

As indicated in the legislative history of section 13603 of OBRA '93, the conference committee intended that eligibility on the basis of the criterion of being infected with TB be interpreted as broadly as possible in order to allow the maximum number of TB-infected persons to receive services. (H. Rept. No. 213, 103rd Cong., 1st Sess. 833 (1993) and H. Rept. No. 111, 103rd Cong., 1st Sess. 219-220 (1993)).

Therefore, we are proposing that, in determining eligibility under this group, States need not rely on "positive" test results for determining who is infected with tuberculosis. The committee recognized that traditional TB tests and diagnostic methods are of questionable value, particularly among persons with low immune function, and may possibly produce both false positive and false negative test results. For purposes of determining eligible individuals infected with TB, we propose to use customary medical criteria that define the symptoms and conditions that differentiate TB from other diseases. We consulted the Centers for Disease Control and Prevention (CDC) regarding the types of medical criteria that physicians use when diagnosing suspected cases of TB. On the basis of the CDC medical advice, we propose to define a TB-infected individual for purposes of the section 1902(z)(1) requirement as any individual who has a positive diagnosis as confirmed by certain tests or a suspicion of TB infection in his or her diagnosis. These individuals could include—

- Any individual with a positive tuberculin skin test using the Mantoux method and who receives treatment for latent TB infection or active tuberculosis;
- Any individual with a negative tuberculin skin test but whose sputum culture or culture from another tissue sample is positive for the tuberculosis organism;
- Any individual who never received a tuberculin skin test but whose sputum culture or culture from another tissue sample is positive for the tuberculin organism;
- Any individual whose TB skin test is negative and whose sputum or other tissue culture for tuberculosis is not or cannot be obtained, but who, in the physician's judgment, requires and is given TB-related drug or surgical therapy or both; and
- Any symptomatic individual with a negative TB skin test who is being

treated with a TB drug regimen while awaiting the TB culture results because the physician suspects the individual may have active TB, and whose cultures turn out to be negative for TB, causing the TB drug regimen to be discontinued.

2. Individuals Who Are Not Eligible as a Mandatory Categorically Needy Group or Special Group

According to the statute, the optional eligibility group of TB-infected individuals does not include any individuals who would be eligible for mandatory coverage because they are (or are deemed to be) cash assistance recipients or are members of special groups described under section 1902(a)(10)(A)(i) of the Act. The statute includes TB-infected persons as an optional categorically needy eligibility group only under the provisions of section 1902(a)(10)(A)(ii).

In terms of the distinction between mandatory and optional categorically needy groups, we believe that the language describing the new eligibility group as "not described as mandatory categorically needy" does not create a problem. This is because if an individual qualifies under a mandatory categorically needy group, the individual would have more services available (including TB-related services that the State elects to provide) than if the individual qualified only under the new TB-infected group. Since the service package available to mandatory categorically needy individuals must include all services otherwise available (under § 1902(a)(10)(b)(i)), these individuals will not lose access to any services.

3. Financial Eligibility Requirements

Sections 1902(z)(1)(B) and (z)(1)(C) of the Act specify the income and resource requirements that individuals must meet in order to be eligible for Medicaid as TB-infected individuals. While the individual need not be "disabled" as described in section 1902(a)(10)(A)(i) in order to be eligible for the optional TB-infected group, section 1902(z)(1)(b) requires that his or her gross income must not exceed the maximum amount a disabled individual may have and remain eligible for Medicaid under the State plan. Disabled individuals are among those eligible for benefits under the SSI program under title XVI of the Act, and among the types of individuals described in section 1902(a)(10)(A)(i) who are eligible for Medicaid because they are individuals to whom SSI benefits are being paid. Reading section 1902(z)(1) in context, we thus concluded that the reference to "disabled individual" in section 1902(z)(1)(B) is properly read to refer to

disabled individuals under the SSI program. To develop a uniform standard for eligibility of TB-infected individuals, we thus looked to financial eligibility for disabled individuals under the SSI program. Many of the SSI income exclusions, however, are linked to circumstances related to particular disabilities. These exclusions would not be appropriate for the TB-infected eligibility group, since that group is generally not disabled, and would thus never qualify for these exclusions.

To give effect to the statutory link between eligibility for TB-infected individuals and the standards of the SSI program applicable to disabled individuals, while recognizing that TB-infected individuals are not disabled, we propose to use a method based on the most generous income exclusions under section 1612(b) of the Act that are not dependent on disabled status. Using this method, we calculate the maximum income level a TB-infected individual may have by determining the maximum income level that an individual hypothetically could have if these income exclusions were applied in full. The resulting amount is a national uniform standard for income eligibility for the TB-infected eligibility group. The income exclusions that we use in the formula to determine the maximum income for TB-infected individuals are the general earned or unearned income exclusions under section 1612(b)(2)(A), the general earned income exclusion under section 1612(b)(4)(B)(i), and the additional earned income exclusion under section 1612(b)(4)(B)(iii). Since these are the most generous income disregards that are not related to disabling conditions and connected expenses, using this methodology will result in the most liberal interpretation possible. The general income exclusion is \$20, the general earned income exclusion is \$65 (for a total of an \$85 general exclusion), and the additional earned income exclusion is 50 percent of additional earned income. The formula that we propose to use to determine the maximum monthly income for eligibility as a TB-infected individual is 2 times the SSI Federal Benefit Rate (FBR) plus \$85 ($2 \times \text{FBR} + \85). (See section 00810.350 of the Program Operations Manual System (POMS SI).) Income above this level would result in countable income in excess of ordinary SSI eligibility standards. We are proposing to require States to apply this SSI break-even point methodology for the income eligibility calculation of TB-infected individuals.

We note that this formula does not represent the actual application of SSI methods and standards to any particular

individual, or even to any particular hypothetical individual, as he or she would apply under the SSI program. For example, under SSI, an individual with earned income sufficient to demonstrate "significant gainful activity" would not be "disabled," and thus the earned income disregard would not ordinarily be applicable to income of a disabled individual above the level to demonstrate significant gainful activity. Since TB-infected individuals are not ordinarily disabled, we did not believe it would be appropriate to limit earned income (and the earned income disregard) to the level showing significant activity in devising an eligibility formula for TB-infected individuals.

We propose to permit States to use the section 1902(r) authority (which permits States to use more liberal income and resource methodologies than those used under the cash assistance programs) to disregard income when making the eligibility determination for the section 1902(z) group. Use of the section 1902(r) authority will permit States to make eligible, under section 1902(z), persons with gross income in excess of the amount derived from the formula set forth above. Because the income eligibility standards are based on standards for disabled SSI recipients, we propose that the income limits set forth at section 1903(f) that limit Federal financial participation for individuals whose eligibility standards are related to the standards for Aid to Families with Dependent Children (in effect as of July 16, 1996) would not apply for TB-infected individuals. Otherwise these limits might render meaningless the financial eligibility standards permitted by section 1902(z)(1)(B).

In cases where both members of a married couple, or more than one member of a family are TB-infected, we have interpreted section 1902(z)(1) to mean that each applicant will be considered as a single *individual* and thus will be subject to income standards independent from his or her spouse or child. Section 1902(z) specifies that each family member should be considered separately by applying the eligibility standard for "a disabled individual."

When only one spouse is eligible or applies for Medicaid, the *other spouse's* income should be deemed to be considered as available income as permitted under the State plan. If the members of a couple were legally separated, or if some of the spouse's income was allocated to other individuals (for example, if the spouse had dependent children for whom the applicant was not legally responsible),

the income would be deemed accordingly.

We propose that the resource eligibility requirements for the optional TB-related group remain consistent with the SSI resource limit of \$2,000 for an individual. However, States would again be permitted under the authority of section 1902(r)(2) to use more liberal resource requirements in making eligibility determinations for TB-infected applicants.

We propose to require section 1902(f) States that use more restrictive requirements than the SSI program uses to disregard SSI payments and optional State supplementation payments when determining financial eligibility of a TB-infected individual under section 1902(z)(1). A section 1902(f) State that includes aged, blind, or disabled individuals as medically needy under its approved plan must allow individuals deemed to be SSI recipients, essential spouses, State supplementation payment recipients, and individuals who are eligible for State supplements but who do not receive them to spend down to the State's more restrictive January 1, 1972 standard or to the SSI income standard. A section 1902(f) State that does not include aged, blind, or disabled individuals as medically needy may allow individuals to spend down only to the income standard that the State would use if there were no optional categorically needy eligibility groups included under its January 1, 1972 approved plan.

We propose to require that territories base their maximum financial eligibility levels for TB-infected individuals on the standards under their State Medicaid plans for disabled individuals, that is, the Aid to the Aged, Blind, or Disabled (AABD) program. The territories must describe in their State plans the financial eligibility standards and methodologies that are applicable to the TB-infected group. Although we recognize that this policy may restrict eligibility for TB-infected individuals in territories that have limited AABD programs, the statutory language specifically ties eligibility for TB-infected individuals to eligibility of disabled individuals under the State plan.

B. Services

1. New Service Category

Section 1905(a)(19) was amended by OBRA '93 to add a new TB-related service category to the overall list of coverable services. The new service category described in section 1902(z)(2)(F) of the Act specifies the

limited services available to eligible individuals who are infected with TB. In order for a State to make this service available to any categorically needy eligible individual, including the new TB-infected group, the State must elect to cover this service under its State plan and make it available to all categorically needy individuals for whom the service is medically necessary. Like most other optional Medicaid services included in section 1905(a), when a State elects to make the service available under its Medicaid plan, the service must be equally available in amount and scope to all individuals in a covered group who need the service. As such, if a State elects this service it must be equally available to TB-infected categorically needy individuals. Similarly, if a State elects this service for its medically needy eligibility group, the service must be equally available to that population as well. However, because this service is described in the statute as a TB-related service it is available only to those individuals who are under a drug treatment regimen for the treatment of TB. We also propose to add a new § 440.164 to incorporate the services provisions. A further discussion of the scope of this benefit is provided below.

2. List of Services and Applicable Limitations

Section 1902(z)(2) lists the following service categories that are available to the group of eligible TB-infected individuals:

- Prescribed drugs;
- Physicians' services, outpatient hospital, rural health clinics, federally qualified health clinic services;
- Laboratory and x-ray services, including services to diagnose and confirm the presence of infection;
- Clinic and federally qualified health center services;
- Targeted case management services; and
- Services, other than room and board, designed to encourage completion of regimens of prescribed drugs by outpatients.

Even though section 1902(z)(2) lists these above services as available to the new eligibility group, the services (except for case management and services designed to encourage the completion of TB-drug regimens) are available only to the extent they are otherwise available to mandatory categorically needy eligibility groups under the State's Medicaid plan. That is, although the statutory material found in the matter following section 1902(a)(10)(F) (which provides exceptions to the Medicaid comparability rules), specifically limits

the services available to the new group to those categories listed above, there is nothing in the exception to the comparability rules that would permit the State to offer the new eligibility groups any more services than are available to all other categorically needy groups.

Some of the services listed in section 1902(z)(2), specifically, physician, outpatient hospital, rural health center, federally qualified health center, laboratory, and x-ray services, are mandated services. This means that States that elect to extend eligibility to the new group of TB-infected individuals must make these categories of services available to the new group to the same extent the services are available under the plan as long as the services are TB-related.

With regard to prescribed drugs and clinic services, the State may only make these service categories available if the service category is already available under the approved State Medicaid plan. That is, a State could not make prescribed drugs available to an individual eligible under the new TB-infected group if the State does not make prescribed drugs available to the categorically needy under its State plan. To do so would violate the Medicaid comparability rules which require that services be available in equal amount, duration, and scope to all categorically needy individuals. Conversely, if a State offers prescribed drugs and clinic services under its plan, the comparability requirements dictate that the State must make these categories available to the new group to the same extent the services are available under the plan as long as the services are TB-related. Any limitations on amount, duration, and scope that otherwise apply under the plan also apply to the new group. For example, if a State limits the number of prescriptions an individual may receive in a month, that same limitation applies to individuals eligible under the new TB-infected group.

With regard to case management services, OBRA '93 also provides that a State may limit case management services to TB-infected individuals. In order to make the services available only to the new eligibility group, the State must identify the new eligibility group as a target group under its State plan. If a State chooses to broaden the target group to encompass all TB-infected individuals, including individuals in other categorically needy groups, it may do so.

As indicated earlier, services designed to encourage completion of drug regimens are not subject to the

comparability rules that require services to be available in the same amount, duration, and scope to all eligibility groups. However, the comparability rules would apply within the covered TB-infected group.

With the exception of services designed to encourage completion of drug regimens, each of the outpatient services must meet the requirements and conditions of the existing regulations and statutory provisions applicable to regular Medicaid. That is—

- Prescribed drugs must meet the definition in § 440.120 and the FFP conditions of sections 1903(i) and 1927 of the Act relating to drug rebates and drug rebate agreements with manufacturers and the FFP limitations of §§ 441.25, 447.331, and 447.332.

- Physicians' services must meet the definition in § 440.50; outpatient hospital services and rural health clinic services must meet the definition in § 440.20; and Federally qualified health center services must meet the definition in section 1905(l)(2) of the Act. We propose to permit States to claim FFP for costs incurred by physicians who diagnose and treat individuals suspected of being infected with TB. Individuals whom a physician suspects are TB-infected are eligible to receive services. If the individual is later determined to not be TB-infected under the specified criteria, eligibility will end on the last day of the month in which the State takes action to terminate eligibility and sends appropriate advance notice.

- Laboratory and X-ray services, including services to confirm the presence of infection, must meet the definition in § 440.30;

- Clinic services must meet the definition in § 440.90, and Federally qualified health center services must meet the definition in section 1905(l)(2) of the Act;

- Case management services must meet the definition in section 1915(g)(2) of the Act.

With respect to the services described in section 1902(z)(2)(F) that are designed to encourage completion of regimens of prescribed drugs by outpatients, including services to directly observe the intake of prescribed drugs, we propose to permit States the option to authorize providers broad latitude in furnishing a limited package of TB-related services to individuals who qualify for Medicaid under the provisions of section 1902(z)(1) of the Act. We believe that services designed to encourage completion of drug regimens will vary among States. Permitting a broad interpretation will

allow States to design the program most appropriate to their needs. Any service related to the completion of a prescribed drug regimen, except for inpatient services and room and board, may be covered. For example, the types of services may include:

(1) Transportation to and from necessary treatment services.

(2) In-home monitoring of the individual's illness and adherence to a prescribed drug regimen.

(3) Patient education and anticipatory guidance. These services are directly related to ensuring the patient's completion of the prescribed drug regimen.

(4) Certain other medical services which are not otherwise included under section 1905(a) that will encourage completion of the drug regimen; for example, coverage of pick up and delivery of prescribed drugs as long as this service is not generally provided for free in the community.

These services may also include other medical services designed to minimize barriers to completion of a prescribed drug regimen. However, nonmedical services would be excluded. For example, nonmedical services would include monetary incentives or gifts used as an incentive to induce recipients to complete drug regimens; these items are not medical nor would they minimize barriers to completion of a drug regimen.

We propose to require a State to specify in its State plan the services that will be made available under the benefit to encourage outpatients to complete regimens of prescribed drugs.

Services available to this new group are available only if they relate to the treatment of TB. We propose to allow the State to make the determination of whether any particular service relates to the treatment of TB on the basis of the individual's circumstances. For example, some prescribed drugs for the treatment of TB can cause side effects that may require additional care by specialists, such as ophthalmologists, and the prescription of additional drugs to treat side effects. Also, inpatient services are not covered, whether for acute care hospitalization or for long-term care (H.R. Rep. No. 111, 103rd Cong., 1st Sess., 219 (1993)).

C. Conforming Changes

We propose to amend §§ 435.201 and 436.201 to specify TB-infected individuals as a separate optional group. In addition, we propose to amend § 440.250 to specify the limitations on services to TB-infected persons.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Regulatory Impact Statement

Section 804(2) of title 5, United States Code (as added by section 251 of Public Law 104-121), specifies that a "major rule" is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign based enterprises in domestic and export markets.

We estimate that the federal share of Medicaid program costs associated with this proposed rule, contingent upon 100 percent participation by States, is approximately \$100 million in FY 1999. Therefore, this rule is a major rule as defined in Title 5, United States Code, section 804(2).

HCFA has examined the impact of this proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities. However, we do consider most Medicaid-participating physicians to be small entities if they have revenues of \$5 million or less annually.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural

hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This proposed rule would incorporate in regulations statutory changes that are already in effect. The statutory provisions are effective on the statutory established date, regardless of whether or not we have issued final regulations. The statutory changes that expand eligibility groups and coverage of

services will increase Medicaid program expenditures independently of the promulgation of this rule. Program costs associated with these proposed regulations, which are reflected in the following chart, are the result of legislation or due to the interpretation of statutory changes already in effect.

[Dollars in millions rounded to the nearest \$5 million]

	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003
Federal	100	105	115	125	135
State	75	85	90	95	105

These cost estimates are based on Center for Disease Control (CDC) data on active, suspected (where a treatment regimen is begun until infection is ruled out), and inactive (discovered during screenings and are put on a prevention regimen) TB cases. The cost estimates are also based on demographic, coverage, and income data in the Current Population Survey and make assumptions regarding case growth and medical inflation. The details of the cost estimate calculations are available upon request. In addition, Federal administrative costs associated with these proposed regulations are estimated at \$5 million annually. State and local administrative costs are also estimated at \$5 million annually.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this proposed rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;

- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section 440.164 of this document contains requirements that a State must specify in its State Medicaid plan what services will be provided as TB-related services and describe any services that the State will cover as services designed to encourage completion of regimens of prescribed drugs by outpatients. We estimate that the public reporting burden for this collection of information is approximately 1 hour.

A notice will be published in the **Federal Register** when approval is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the officials whose names appear in the **ADDRESSES** section of this preamble.

List of Subjects

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 436

Aid to Families with Dependent Children, Grant programs-health, Guam, Medicaid, Puerto Rico, Supplemental Security Income (SSI), Virgin Islands.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Chapter IV, Subchapter C, would be amended as follows:

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

A. Part 435 is amended as follows:
1. The authority citation for part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 435.201, the introductory text of paragraph (a) is republished, paragraphs (a)(7) and (a)(8) are reserved, and a new paragraph (a)(9) is added, to read as follows:

§ 435.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart.

* * * * *
(9) Individuals infected with tuberculosis (as defined in § 435.219).

* * * * *
3. A new § 435.219 is added under the undesignated center heading "Options for Coverage of Families and Children and the Aged, Blind, and Disabled" to read as follows:

§ 435.219 Individuals infected with tuberculosis (TB).

(a) *General rule.* The agency may provide certain tuberculosis (TB) related services (as defined in § 440.164 of this subchapter) as Medicaid to individuals who—

- (1) Are not mandatory categorically needy under subpart B of this part;
- (2) Are infected with tuberculosis, as defined in paragraph (b) of this section; and
- (3) Meet the income and resource requirements specified in paragraph (c) of this section.

(b) *Definition of a TB-infected individual.* An individual is considered

to be TB-infected if any of the following conditions exist:

(1) The individual has a positive tuberculin skin test using the Mantoux method and receives treatment for latent TB infection or active tuberculosis;

(2) The individual has a negative tuberculin skin test but has sputum culture or culture from another tissue sample that is positive for the tuberculosis organism;

(3) The individual has never received a tuberculin skin test but has sputum culture or culture from another tissue sample that is positive for the tuberculin organism;

(4) The individual has a tuberculosis skin test that is negative and whose sputum or other tissue culture for tuberculosis that is not or cannot be obtained, but in the physician's judgment the individual requires and is given TB-related drug or surgical therapy or both; or

(5) The individual has a negative tuberculosis skin test, is being treated with a tuberculosis drug regimen while awaiting the tuberculosis culture results because the physician suspects that the individual may have active tuberculosis, and has cultures that turn out to be negative for tuberculosis, causing the tuberculosis drug regimen to be discontinued.

(c) *Income and resource eligibility criteria.*

(1) Except as provided under paragraph (c)(2) of this section, the individual must have—

(i) Gross monthly income that does not exceed an amount equal to 2 times the SSI Federal Benefit Rate (as specified in 20 CFR §§ 416.105 and 416.410) plus \$85; and

(ii) Resources that do not exceed the SSI resource standard.

(2) The State may use—

(i) More restrictive Medicaid financial eligibility requirements applicable to disabled individuals as specified in §§ 435.121 and 435.230; and

(ii) More liberal income and resource methodologies as specified under § 435.601(d).

B. Part 436 is amended as follows:

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

1. The authority citation for part 436 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 436.201, the introductory text of paragraph (a) is republished, paragraphs (a)(8) and (a)(9) are reserved, and a new paragraph (a)(10) is added, to read as follows:

§ 436.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart:

* * * * *

(10) Individuals infected with tuberculosis (as defined in § 436.219).

* * * * *

3. A new § 436.219 is added to read as follows:

§ 436.219 Individuals infected with tuberculosis (TB).

(a) *General rule.* The agency may provide certain tuberculosis (TB) related services (as defined in § 440.164 of this subchapter) as Medicaid to individuals who—

(1) Are not mandatory categorically needy under subpart B under this part;

(2) Are infected with tuberculosis, as defined in paragraph (b) of this section; and

(3) Meet the income and resource requirements specified in paragraph (c) of this section.

(b) *Definition of a TB-infected individual.* An individual is considered to be TB-infected if any of the following conditions exist:

(1) The individual has a positive tuberculin skin test using the Mantoux method and receives treatment for latent TB infection or active tuberculosis;

(2) The individual has a negative tuberculin skin test but has sputum culture or culture from another tissue sample that is positive for the tuberculosis organism;

(3) The individual has never received a tuberculin skin test but has sputum culture or culture from another tissue sample that is positive for the tuberculin organism;

(4) The individual has a tuberculosis skin test that is negative and whose sputum or other tissue culture for tuberculosis that is not or cannot be obtained, but in the physician's judgment the individual requires and is given TB-related drug or surgical therapy or both; or

(5) The individual has a negative tuberculosis skin test, is being treated with a tuberculosis drug regimen while awaiting the tuberculosis culture results because the physician suspects that the individual may have active tuberculosis, and has cultures that turn out to be negative for tuberculosis, causing the tuberculosis drug regimen to be discontinued.

(c) *Income and resource eligibility criteria.*

(1) Except as provided under paragraph (c)(2) of this section, the individual must have—

(i) Gross monthly income that does not exceed the AABD income standard for disabled individuals, applying the maximum income exclusion or disregards that are not dependent on disabled status.

(ii) Resources that do not exceed the AABD resource standard (as applicable to disabled individuals).

(2) The State may use more liberal income and resource methodologies as specified under § 436.601(d).

C. Part 440 is amended as follows:

PART 440—SERVICES: GENERAL PROVISIONS

1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. A new § 440.164 is added to read as follows:

§ 440.164 Tuberculosis-related services.

Tuberculosis (TB)-related services for individuals described in §§ 435.219 and 436.219 of this subchapter means the following outpatient services—

(a) Prescribed drugs (as defined in § 440.120 and subject to the FFP limitations of §§ 441.25, 447.331 and 447.332 of this subchapter);

(b) Physicians' services (as defined in § 440.50) and services described in section 1905(a)(2) of the Act.

(c) Laboratory and X-ray services including services to confirm the presence of infection (as defined in § 440.30);

(d) Clinic services (as defined in § 440.90) and Federally qualified health center services (as defined in section 1905(l)(2) of the Act).

(e) Case management services (as defined in section 1915(g)(2) of the Act); and

(f) Services (other than room and board) designed to encourage completion of regimens of prescribed drugs by outpatients, including services to observe directly the intake of prescribed drugs.

(1) The agency must specify in its State plan the types of services it will provide under this benefit.

(2) The services may not include nonmedical services, such as monetary incentives or gifts, inpatient services, or room and board.

(3) The services may not include a service that is generally provided free in the community.

3. Section 440.250 is amended by adding a new paragraph (u), to read as follows:

§ 440.250 Limits on comparability of services.

* * * * *

(u) If the agency elects to cover individuals infected with tuberculosis as specified in §§ 435.219 and 436.219 of this subchapter, medical assistance to those individuals is limited to TB-related services described in § 440.164.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778—Medical Assistance Programs)

Dated: September 1, 1998.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

Dated: April 28, 1999.

Donna E. Shalala,
Secretary.

[FR Doc. 99-23515 Filed 9-9-99; 8:45 am]

BILLING CODE 4120-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 15, 22, 24, 25, 26, 27, 90, 95, 100, and 101

[WT Docket No. 99-266, FCC 99-205]

Extending Wireless Telecommunications Services to Tribal Lands

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document seeks comment on potential terrestrial wireless and satellite policy initiatives to address the telecommunications needs of Indians living on tribal lands. The Commission has been instructed to help ensure that all Americans have access to affordable telecommunications services. Consistent with that mandate, the Commission seeks to secure for consumers living on tribal lands the same opportunities to take advantage of telecommunications capabilities that other Americans have. In addition, the Commission seeks comment on whether to extend these initiatives to consumers in other unserved areas.

DATES: Comments are due November 9, 1999, and reply comments are due December 9, 1999.

ADDRESSES: Federal Communications Commission, Secretary, 445 Twelfth Street, SW, Room TW-A325, Washington, DC 20554. Comments filed through the Commission's Electronic Comment Filing System (ECFS) can be sent as an electronic file via the Internet to <http://www.fcc.gov/e-file/ecfs.html>. See the **SUPPLEMENTARY INFORMATION**

section for additional information about paper and electronic filing.

FOR FURTHER INFORMATION CONTACT: Joel Taubenblatt, Wireless Telecommunications Bureau, at (202) 418-1513.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking (NPRM)* in WT Docket No. 96-266, adopted August 5, 1999 and released August 18, 1999. The complete text of this *NPRM* is available for inspection and copying during normal business hours in the Commission's Reference Center, room CY-A257, 445 12th Street SW, Washington, DC. This *NPRM* is also available through the Internet at <http://www.fcc.gov/Bureaus/Wireless/Notices/1999/fcc99205.pdf>. The complete text may be purchased from the Commission's duplicating contractor, International Transcription Service, Inc. (ITS, Inc.) at 1231 20th Street NW, Washington, DC 10036, (202) 857-3800.

I. Introduction

1. The Telecommunications Act of 1996 has instructed the Commission to help ensure that all Americans have access to affordable telecommunications services. Consistent with that mandate, the Commission seeks comment on the potential of terrestrial and satellite wireless technologies to provide basic telephone service on tribal lands and other unserved areas, particularly in remote areas where wireline alternatives would be significantly more expensive. The Commission also seeks comment on possible changes to our rules for terrestrial wireless and satellite services that would provide greater incentives for terrestrial wireless and satellite carriers to extend service to tribal lands and other unserved areas.

2. In conjunction with this *NPRM*, the Commission adopted a companion Further Notice of Proposed Rulemaking in CC Docket No. 96-45, FCC 99-204 (to be published at a later date in the **Federal Register**) in which the Commission proposes initiatives to encourage the extension of wireline service to tribal lands and other unserved areas and to expand subsidies for all telecommunications carriers—whether wireline, terrestrial wireless, or satellite—that serve such areas.

II. Background

3. Commission representatives have met with many tribal leaders and other representatives of Indian communities to obtain their insights into the problem of low telecommunications penetration on tribal lands. Earlier this year, the Commission held two public hearings at

which federal and state officials, tribal officials, consumer advocates, and telecommunications service providers addressed issues such as the costs of delivering services to remote areas having very low population densities, the impact of the size of local calling areas on the affordability of service, the quality of telephone service on tribal lands, the complexities of governmental jurisdiction and sovereignty issues, and the effects of low incomes and high unemployment on tribal lands on telephone service.

4. Because many tribal lands, particularly those in the western United States, are geographically isolated, obtaining the lowest cost for providing basic telephone service to the population on the tribal land may often require use of a terrestrial wireless technology, a satellite technology, or a combination of these technologies. Terrestrial wireless technology includes both mobile services, such as cellular and Personal Communications Service (PCS), and fixed "wireless local loop" services (WLL). A hybrid terrestrial/satellite wireless model would involve a satellite providing the communications link between an isolated community and the nation's public switched telephone network for long distance telephony, with a terrestrial wireless loop used to link the individual residents and businesses in a particular community for local telephony. Alternatively, satellites can be used alone for long distance and local telephony through the use of handheld phones that can communicate directly with the satellites.

III. Discussion

5. Accordingly, this *NPRM* seeks comment on whether certain changes to the Commission's rules for terrestrial wireless and satellite services would provide greater incentives for existing carriers to extend these services to tribal lands and other unserved areas. Possible rule changes include: (a) Relaxing power and antenna height limits for wireless services to reduce the number of transmitting facilities required to provide service to a tribal land/unserved area, and thus reduce the cost of providing service to that tribal land/unserved area, without creating a significant risk of interference among wireless systems; (b) creating incentives in our buildout requirements to encourage buildout on tribal lands and other unserved areas (e.g., for services subject to a specific population/geographic coverage requirement, apply a multiplier to the population or land area of a tribal land/unserved area for purposes of meeting the requirement);