Jefferson Davis Highway, Arlington, VA 22202, (703–557–1800).

**SUPPLEMENTARY INFORMATION:** EPA issued a notice, published in the Federal Register of March 21, 1984 (49 FR 10572), which announced that Union Carbide Agricultural Products Company, Inc., PO Box 12014, T.W. Alexander Dr., Research Triangle Park, NC 27709, had filed pesticide petition 4E3019 with the EPA. The petition proposed amending 40 CFR 180.324 to reflect residues of the herbicide bromoxynil resulting from the application of the phenol, octanoic, or butyric acid esters of bromoxynil in or on the fodder, forage, and grain of corn and sorghum. The existing tolerances permit residues of the butyric and octanoic acid esters of bromoxynil in or on these commodities at 0.1 part per million (ppm). No change was proposed for the established tolerance level.

There were no comments received in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data evaluated for bromoxynil octanoate (technical) include an acute oral study (rat) with a lethal dose ($LD_{50}$) equal to 270 milligrams (mg)/kilograms (kg); an acute oral study (rabbit) with an $LD_{50}$ equal to 335 mg/kg; an acute oral study (dog) with an $LD_{50}$ greater than 50 and less than 150 mg/kg; a 13-week feeding study (dog) with a no-observed-effect level (NOEL) of 5 mg/kg/day (200 ppm); and a 13-week feeding study (rat) with a NOEL of 312 ppm. The studies evaluated for bromoxynil technical include a teratology study (rats) with a teratogenicity NOEL of greater than 15 mg/kg and a fetal toxicity NOEL equal to 5 mg/kg; a microbial mutagenic assay, nonmutagenic to *S. typhimurium* tester strains, and a three-generation reproduction (rat) study with a NOEL of 300 ppm.

Data currently lacking include additional information on previously submitted oncogenicity and chronic feeding studies on rats and mice. The company has been notified of the deficiencies and has agreed to submit the additional information.

The current provisional acceptable daily intake (PADI) is 0.0025 mg/kg/day based on the 13-week dog feeding study noted and using a 2000-fold safety factor. The maximum permitted intake (MPI) for a 60-kg human is calculated to be 0.15 mg/day. The theoretical maximum residue contribution from existing tolerances for a 1.5 kg daily diet is calculated to be 0.0352 mg/day. The current action does not increase the PADI. Published tolerances utilize 23.49 percent of the PADI.

The nature of the residues is adequately understood and an adequate analytical method, gas chromatography with 63 Ni electron detector, is available for enforcement purposes. Since no detectable residues are expected in corn grain, fodder, forage, or sorghum grain, forage or fodder, no detectable residues would be expected in meat, milk, poultry, and eggs. Even if residues do occur in corn, the established meat tolerances will cover any secondary residues resulting from this use. There are presently no actions pending against the continued registration of the pesticide.

The pesticide is considered useful for the purpose for which the tolerances are sought. Based on the information cited above, the Agency has determined that the establishment of the tolerances will protect the public health and are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–534, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

(Sec. 408(d)(2), 68 Stat. 512 (21 U.S.C. 346a(d)(2)))

**List of Subjects in 40 CFR Part 180**

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: October 19, 1984.

**Steven Schatzow,**

*Director, Office of Pesticide Programs.*

## PART 180—[AMENDED]

Therefore, 40 CFR 180.324 is amended by designating the existing paragraph as paragraph (a) and adding paragraph (b) to read as follows:

**§ 180.324 Bromoxynil; tolerances for residues.**

* * * * *

(b) Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) resulting from application of its phenol, octanoic, or bytyric acid esters in or on the following raw agricultural commodities:

| Commodities | Parts per million |
|---|---|
| Corn, fodder | 0.1 |
| Corn, forage | 0.1 |
| Corn, grain | 0.1 |
| Sorghum, fodder | 0.1 |
| Sorghum, forage | 0.1 |
| Sorghum, grain | 0.1 |

[FR Doc. 84–28671 Filed 10–30–84; 8:45 am]

**BILLING CODE 6560–50–M**

## 40 CFR Part 721

**[OPTS–50510A; FRL–2625–1]**

## Significant New Uses of Chemical Substances; Substituted Polyglycidyl Benzeneamine

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is issuing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for a chemical substance which was the subject of premanufacture notice PMN P–83–394 and a TSCA section 5(e) consent order issued by EPA. The agency believes that the uses described in this rule could allow significant exposure to P–83–394.

**DATES:** This rule shall be promulgated for purposes of judicial review at 1:00 p.m. eastern time on November 14, 1984. This rule shall become effective January 14, 1985.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Toll free: (800–424–9065), In Washington, D.C.: (554–

1404), Outside the USA: (Operator–202–554–1404).

**SUPPLEMENTARY INFORMATION:** OMB Control Number 2070–0012.

## I. Authority

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule, after considering all relevant factors, including those listed in section 5(a)(2). Once a use is determined to be a significant new use, persons must, under section 5(a)(1)(B), submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use. Such a notice is subject to the same requirements and procedures as a PMN submitted under section 5(a)(1)(A) of TSCA which are interpreted at 40 CFR Part 720 published in the **Federal Register** of May 13, 1983 (48 FR 21722). In particular, these include the information submission requirements of section 5(b) and (d)(1), certain exemptions authorized by section 5(h), and the regulatory authorities of section 5(e) and (f). If EPA does not take regulatory action under section 5, 6, or 7 to control activities on which it has received a SNUR notice, section 5(g) requires the Agency to explain in the **Federal Register** its reasons for not taking action.

Substances covered by proposed or final SNURs are subject to the export reporting requirements of TSCA section 12(b). EPA regulations interpreting section 12(b) requirements appears at 40 CFR Part 707. Substances subject to final SNURs are subject to TSCA section 13 import certification requirements at 19 CFR 12.118 through 12.127, and 127.28, published in the **Federal Register** of August 1, 1983 (48 FR 34734). The EPA policy in support of these requirements appear at 40 CFR Part 707 published in the **Federal Register** of December 13, 1983 (48 FR 55462).

## II. Applicability of General Provisions

EPA has promulgated general provisions under 40 CFR Part 721, Subpart A which are applicable to SNURs and were published in the **Federal Register** of September 5, 1984 (49 FR 35011). These general provisions will apply to this SNUR without change except as discussed in this preamble and as provided in the rule. Interested persons should refer to the above-cited document for a detailed discussion of the general provisions.

The general provisions governing SNUR reporting were promulgated subsequent to the proposal of this rule in the **Federal Register**. Therefore, this final rule is structurally different from its proposal format because the non-substantive and procedural matters are now contain in Subpart A to Part 721.

## III. Summary of This Rule

The chemical substance subject to this rule is identified generically as substituted polyglycidyl benzeneamine. It was the subject of PMN P–83–394. EPA is designating the following as significant new uses of the substance:

A. Use in spray applications.

B. Manufacture or processing of the substance without establishing and enforcing a program whereby: (1) persons employed by or under the control of the manufacturer or processor who may be exposed to the substance wear (a) gloves which cover the arm up to the elbow and which have been determined to be impervious to the substance under conditions of exposure (gloves may be determined to be impervious to the substance through standard testing methods or by relying on the manufacturer's specifications for the gloves selected), (b) a face shield of at least eight inches in length, and (c) clothing covering any other exposed part of the arms, legs, and torso; (2) all persons required to wear protective equipment are informed of the health concerns which may be presented by the substance; and (3) packages containing the substance or formulations containing the substance are labeled according to the terms specified in the rule.

One comment stated that manufacturers or processors should only be expected to require their own employees or persons whom they control to wear the protective equipment identified in § 721.180. The Agency agrees with this comment and has adjusted the rule language accordingly by adding the phrase "persons employed by or under control of the manufacturer or processor."

## IV. Background

The chemical substance subject to this rule was the subject of a PMN designated P–83–394. The notice submitter claimed the following as confidential business information (CBI): the specific chemical identity, intended use, and proposed production volume. For purposes of clarity, the substance is referred to in this preamble and § 721.180 by its generic chemical name and PMN number.

The Agency proposed a SNUR for this substance which was published in the **Federal Register** of December 29, 1983 (48 FR 57440) as § 721.40 (now § 721.180). The background of the PMN and the reasons for proposing the SNUR are set forth in the preamble to the proposed rule.

EPA has considered and responded to all comments received during the public comment period for this SNUR. After the close of the comment period, EPA received comments from the Chemical Manufacturers' Association (CMA) which addressed this SNUR and several others recently proposed by EPA. These comments raised a number of issues about these SNURs and made general suggestions for changes. For example, CMA proposed that EPA's SNURs (1) address hazard communication issues by referencing regulations which were recently promulgated by the Occupational Safety and Health Administration (OSHA), (2) provide an expedited procedure for the review of alternative types of protective measures rather than the submission of a full SNUR notice with a 90-day review period, and (3) simplify SNUR recordkeeping requirements.

EPA is considering these late comments and may propose amendments to this SNUR in the future to implement some or all of these suggestions. However, because the chemical substance which is identified in this SNUR has been on the Inventory for some time, EPA is concerned that the significant new uses of this substance could be commenced without EPA review. Accordingly, the Agency has decided to proceed with promulgation of this SNUR now. If EPA determines that changes to this rule are necessary in response to CMA's comments, amendments to this rule will be made.

## V. Designation of Significant New Uses

To determine what would constitute a significant new use of this chemical substance, EPA considered relevant information about the toxicity of the substance and likely exposures associated with possible uses (for example those uses not allowed under the section 5(e) order), including the four factors listed in section 5(a)(2) of TSCA. In particular, EPA considered the extent to which potential uses may change or increase the exposure to humans. Based on these considerations, EPA is defining the significant new uses of P–83–394 as they appear in Unit III of this preamble and § 721.180.

Based on data on structurally similar chemicals, and data submitted in the PMN, the Agency believes significant exposure to P–83–394 would present a health risk to workers. EPA is concerned that the substance may cause carcinogenicity, skin and eye irritation, skin sensitization, reproductive effects, and liver and kidney effects.

The Agency believes that the data described in this preamble and in the preamble to the proposed rule are sufficient to substantiate the contention that the significant new uses of P–83–394 present a potentially significant increase in the magnitude and type of exposure. Section 5(a)(2) of TSCA does not require the Agency to make either a "may present" or a "will present" risk finding with regard to satisfying the requirements for a significant new use. The statute imposes the requirement that the Agency provide for a "consideration of all relevant factors." The Agency believes that a reasonable qualitative assessment of these factors was incorporated in the preamble of the proposed rule published in the **Federal Register** of December 29, 1983 (48 FR 57440). EPA received no comments on its assessment of the potential health effects of P–83–394.

A comment suggested that the SNUR be structured to require reporting by manufacturers and processors who fail to require (1) the use of the equipment specified in the proposal or (2) equipment which has been determined to provide the same level of protection. Pending EPA's complete consideration of CMA's comments, the Agency has decided not to allow the potential manufacturer or processor to make a determination of the adequacy of the level of protection provided by an alternative means of controlling exposure. While EPA has determined that the equipment called for the SNUR will reduce the concerns below a level about which EPA would have sufficient concern to justify regulation, the Agency has made no such determination about potential alternative choices of equipment. The Agency believes it is appropriate to make such an evaluation on a case-by-case basis in light of the information which would be contained in a SNUR notice submission.

One comment suggested that OSHA hazard communication regulations at 29 CFR 1910.1200 would include and apply to substances which present the concerns which this substance does, making this rule redundant. EPA's regulations under this SNUR provide a unique requirement for a substance about which it has a particular concern. Pending EPA's complete consideration of CMA's comments, the Agency believes a chemical-specific regulation is appropriate in this situation rather than the broader regulations promulgated by OSHA. Further, the OSHA regulations are not yet in effect. Therefore, EPA has determined that this regulation will complement the OSHA regulations in question.

## VI. Alternatives

In the proposed SNUR, EPA considered other possible approaches. These alternatives included the promulgation of a section 8(a) reporting rule, and/or regulation under section 6. One comment supported the idea of extending the restrictions of the section 5(e) order to other persons who may manufacture or process the substance, but favored the use of sections 6 or 8 of TSCA. While there may be instances where sections 6 or 8 are more appropriate authorities for following up section 5(e) orders, in situations such as this where (1) there are inadequate data to support a section 6 rule, and (2) the Agency wishes to be able to review SNUR notices and perhaps take action under section 5(e) in response to those notices, EPA prefers the alternative of promulgating a SNUR.

## VII. Recordkeeping

To ensure compliance with this rule, and to assist enforcement efforts, EPA is requiring under its authority in sections 5 and 8(a) of TSCA that, in addition to the requirements in § 721.17, the following records be maintained for five years after the date of their creation, by persons who manufacture, import, or process P–83–394:

(1) The names of persons required to wear protective equipment in accordance with paragraph (a) of this rule, the date(s) on which they were informed, and the means by which they were informed.

(2) The name and address of each person to whom the substance is sold or transferred and the date(s) of any such sale or transfer.

(3) The method used for determining that the gloves prescribed by paragraph (a) of this rule are impervious to P–83–394, the date(s) such determination was made, and the results of that determination.

As suggested in one comment, the Agency wishes to make clear that these records will be kept by persons who employ the protective equipment identified in § 721.180(a)(2)(ii). Because those persons will not be commencing that significant new use, a SNUR notice is not required of those persons for that use.

The Agency considered omitting recordkeeping requirements, but believes compliance monitoring for this SNUR would be made more difficult without them. As stated earlier, in response to CMA's late comments, EPA is considering modifying this rule, including its recordkeeping requirements, to make it more closely resemble those contained in OSHA's hazard notification regulations. Should amendments to this rule be necessary, EPA will announce them in the **Federal Register.**

## VIII. Exemptions to Reporting Requirements

The Agency has promulgated exemptions to SNUR reporting requirements under § 721.19. In the case of P–83–394, the terms of § 721.19 apply without change.

EPA issued its final premanufacture notification rules under 40 CFR Part 720 which were published in the **Federal Register** of May 13, 1983 (48 FR 21722) including § 720.36 which contained detailed rules for the section 5(h)(3) exemption for chemical substances manufactured or imported in small quantities solely for research and development. On September 13, 1983 (48 FR 41132), EPA stayed the effectiveness of § 720.36, among other provisions of the PMN rule, pending further rulemaking to revise the provisions. Because § 720.36 was not in effect when EPA codified § 721.19, the Agency relied on the general definition of "small quantities solely for research and development" in § 720.3(cc) and section 5(h)(3) of TSCA to determine whether activities qualify under this exemption. Upon promulgation of a revised § 720.36, EPA intends to amend § 721.19 to adopt the provisions of the revised § 720.36.

Section 721.19(g) of the general SNUR provisions exempts persons from SNUR reporting when they manufacture or process the substance solely for export and label the substance in accordance with section 12(a)(1)(B) of TSCA. While EPA is concerned about worker exposure during manufacture and processing of the substance, EPA lacks the authority under section 12(a) of TSCA to require reporting of such manufacture or processing for a significant new use. EPA does not yet have sufficient information to make the "will present an unreasonable risk" finding necessary to regulate a substance manufactured or processed solely for export. However, persons must notify EPA of such export under section 12(b) of TSCA (see § 721.7 of the general SNUR provisions). Such notifications will allow EPA to monitor manufacture and processing activities which are not subject to significant new use reporting. The term "manufacture solely for export" is defined in the PMN rule (40 CFR 720.3(s)). The term "process solely for export" is defined in § 721.3 of the general SNUR provisions in a similar fashion. Thus persons would be exempt from reporting under this SNUR if they manufacture (the term manufacture

includes import) or process the substance solely for export from the U.S. under the following restrictions: (1) there is no use of the substance in the U.S.; (2) processing is restricted to sites under the control of the manufacturer or processor, respectively; and (3) distribution in commerce is limited to purposes of export. If a person manufactured or processed the substance both for export and for use in the U.S.

### IX. Applicability to Uses Which May Have Occurred Before Promulgation of Final Rule

To establish a significant new use rule, the Agency must, among other things, determine that the use is not ongoing. In this case, the chemical substance in question had just undergone premanufacture review. The Agency received no information that the significant new uses are ongoing. Therefore, at this time, the Agency has concluded that these uses are significant new uses.

As indicated in the proposal, EPA has found that the intent of section 5(a)(1)(B) is best served by determining whether a use is a significant new use as of the proposal date of the SNUR. If uses begun during the proposal period were not considered to be significant new uses, it would be almost impossible for the Agency to establish SNUR notice requirements, since any person could defeat the SNUR by initiating the proposed significant new uses before the rule becomes final. This is contrary to the general intent of section 5(a)(1)(B).

Thus, even if the substance was imported, manufactured, or processed for the significant new use between proposal and promulgation of this rule, such activities may not continue after the effective date of this rule. Any such person must cease such activity until it has complied with all SNUR notice requirements.

### X. Determining When a Substance Is Subject to This Rule

EPA has promulgated procedures at § 721.6 under which any person who intends to manufacture, import, or process a chemical substance within the generic chemical name in paragraph (a)(1) of this rule may ask EPA whether or not their chemical substance is subject to this SNUR.

One comment stated that processors should be excluded from the *bona fide* provisions for inquiring as to whether a substance is subject to a SNUR. Instead, the commenter suggested, manufacturers and importers should be required to explicitly tell their processors of the existence of a SNUR. The Agency has decided to follow the provisions of § 721.6 and § 721.5. These provisions are intended to allow the greatest flexibility while ensuring compliance with SNURs. Section 721.5(a)(2) of the general SNUR provisions should encourage most manufacturers, importers, and processors of a substance (who do not themselves commence a significant new use) to inform their customers who process a substance of the existence of a SNUR rather than submitting a SNUR notice themselves. This should minimize the need for processors to inquire whether a substance is covered by a SNUR. However, since some processors may not obtain chemical substances directly from a manufacturer, importer, or processor, EPA wishes to provide them with a means of conclusively determining whether the substances they may purchase are subject to SNURs.

### XI. Test Data and Other Information

EPA recognizes that under TSCA section 5, a person is not required to develop any particular test data before submitting a notice. Rather, a person is required only to submit test data in that person's possession on control and to describe any other data known to or reasonably ascertainable by that person. However, in view of the potential health risk that may be posed by a significant new use of P–83–394, EPA encourages possible SNUR notice submitters to test the substance's potential for carcinogenic effects, reproductive effects, and kidney and liver effects. These data might be generated by a two-year bioassay, a two-generation reproductive study in the rat, a three-week patch test in guinea pigs, and a subchronic toxicity (90-day feeding) study, respectively. However, these studies may not be the only means of addressing the potential risks. If a SNUR notice is submitted for a use involving significant exposure without adequate test data, EPA is likely to take action under section 5(e). As an alternative to testing the substance, potential notice submitters may want to consider the use of engineering controls and/or personal protective equipment to reduce exposure to the substance.

EPA encourages persons to consult with the Agency before selecting a protocol for testing the substance. As part of this prenotice consultation, EPA will discuss the test data it believes necessary to evaluate significant new uses of the substance. Data should be developed and submitted in accordance with the TSCA good laboratory practices regulations at 40 CFR Part 792 published in the **Federal Register** of November 29, 1983 (48 FR 53922).

EPA urges SNUR notice submitters to provide detailed information on human exposure that will result from the significant new uses. In addition, EPA urges persons to submit information on potential benefits of the substance and information on risks posed by the substance compared to risks posed by potential substitutes.

### XII. Economic Analysis

The Agency have evaluated the potential costs of establishing significant new use reporting requirements for P–83–394. This evaluation is summarized in the proposed rule (48 FR 57440). A more complete economic analysis of this SNUR is included in the rulemaking record and is available for public review.

### XIII. Judicial Review

Judicial review of this final rule may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review two weeks after publication in the **Federal Register**, as reflected in **"DATES"** in this document. The effective date has, in turn, been calculated from the promulgation date.

### XIV. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS–50510A). A public version of this record from which CBI has been deleted is available to the public from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in the OTS Reading Room, Rm. E–107, 401 M St. SW., Washington, D.C.

The record includes basic information considered by the Agency in developing this rule. The record now includes the following:

1. The PMN for the substance.
2. The **Federal Register** notice of receipt of the PMN.
3. The proposed SNUR.
4. A copy of the section 5(e) consent order.
5. The economic analysis of this SNUR.
6. The economic assessment prepared for the section 5(e) consent order.

7. The health hazard assessment prepared for the section 5(e) consent order.

8. The environmental fate and environmental and consumer exposure analysis prepared for the PMN review.

9. Public comments.

### XV. Regulatory Assessment Requirements

*A. Executive Order 12291*

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this rule is not a "Major Rule" because it does not have an effect on the economy of $100 million or more and it will not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the annual cost of this rule, EPA believes that the cost will be low. In addition, because of the nature of the rule and the substance subject to it, EPA believes that there will be few significant new use notices submitted. Further, while the expense of a notice and the suggested testing and the uncertainty of possible EPA regulation may discourage certain innovation, that impact may be limited because such factors are unlikely to discourage an innovation which has high potential value. Finally, this SNUR may encourage innovation in safe chemical substances or highly beneficial uses.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

*B. Regulatory Flexibility Act*

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA certifies that this rule will not have a significant economic impact on a substantial number of small businesses. The Agency cannot determine whether parties affected by this rule are likely to be small businesses. However, EPA believes that the number of small businesses affected by this rule would not be substantial even if all the potential new uses were developed by small companies. EPA expects to receive few SNUR notices for the substance.

*C. Paperwork Reduction Act*

Information collection requirements contained in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act of 1980, U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070-0012.

**List of Subjects in 40 CFR Part 721**

Environmental protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: October 16, 1984.

**Alvin L. Alm,**

*Acting Administrator.*

## PART 721—[AMENDED]

Therefore, part 721 of Chapter I of Title 40 is amended as follows:

1. By adding the following definition to § 721.3 in alphabetical sequence:

**§ 721.3 Definitions.**

* * * * *

"Spray application" means any method of projecting a jet of vapor of finely divided liquid onto a surface to be coated; whether by compressed air, hydraulic pressure, electrostatic forces, or other methods of generating a spray.

* * * * *

2. By adding § 721.180 to Subpart B to read as follows:

**§ 721.180 Substituted Polyglycidyl Benzeneamine.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The following chemical substance, referred to by premanufacture notice number and its generic chemical name, is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section: Substituted polyglycidyl benzeneamine, P-83-394.

(2) The significant new uses are:

(i) Use in spray applications.

(ii) Manufacture or processing without establishing a program whereby:

(A) During all stages of manufacture and processing of the substance, and during response to emergencies and spills involving the substance, any person employed by or under the control of the manufacturer or processor who may potentially be dermally exposed to the substance wears:

(*1*) Gloves which cover the arm up to the elbow and which have been determined to be impervious to the substance under conditions of exposure (gloves may be determined to be impervious by standard testing methods or by reliance on the manufacturer's specifications for those gloves selected);

(*2*) A face shield of at least 8 inches in length; and

(*3*) Clothing which covers any other exposed areas of the arms, legs, and torso.

(B) All workers described in paragraph (a)(ii)(A) of this section are informed in writing, or by presenting the information as part of a training program in a safety meeting where attendance is recorded, of the following: to avoid all contact with this substance; that structurally similar chemicals have been found to cause cancer, reproductive effects, kidney and liver effects in laboratory animals, and allergic reactions in humans; that this substance is a severe skin and eye irritant; and that the use of impervious gloves, face shields and other clothing to cover exposed areas of the arms, the legs, and the torso is required.

(C) A label is affixed to each container of the substance or of a formulation containing the substance which (in a print size no smaller than ten point type) contains, at a minimum, the following information:

WARNING: CONTACT WITH SKIN AND EYES IS HARMFUL

—Severe skin and eye irritant.

—Similar chemicals cause cancer, reproductive effects, and kidney and liver changes in laboratory animals. They have also caused allergic reactions in humans.

—Prevent all contact with skin, eyes, and clothing.

—Wear impervious gloves, face shield, and protective clothing. Promptly remove and wash contaminated non-impervious clothing before re-use.

—Wash thoroughly after handling and before eating, drinking, or smoking.

STORAGE INSTRUCTIONS:

—Keep closure tight and upright to prevent leakage.

—Keep container closed during shipment and when not in use.

—In case of spillage absorb with sand or vermiculite and flush with plenty of water.

FIRST AID:

—In case of eye contact, immediately flush with plenty of water and get immediate medical attention.

—In case of skin contact, immediately wash with soap and water and get immediate medical attention.

(b) *Specific requirements.* The provisions of Subpart A of this Part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* In addition to the requirements of § 721.17, manufacturers, importers, and processors of the chemical substance identified in paragraph (a)(1) of this section must maintain the following records for five years from their creation:

(i) The names of persons informed, the date they are informed, and the means by which they are informed in accordance with paragraph (a)(2)(ii)(B) of this section.

(ii) The names of any transferee and the dates of any transfers of containers which are labeled in accordance with paragraph (a)(2)(ii)(C) of this section.

(iii) The method used to determine that the protective gloves are impervious to the substance and date and the results of that determination.

(2) [Reserved]

(Approved by the Office of Management and Budget under control number 2070-0012)

(Secs. 5, 8, Pub. L. 94-469, 90 Stat. 2012 (15 U.S.C. 2604, 2607))

[FR Doc. 84-28436 Filed 10-30-84; 8:45 am]

BILLING CODE 6560-50-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### 42 CFR Parts 400 and 441

### Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program

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

**ACTION:** Final rule.

**SUMMARY:** This final rule modifies present regulations to conform to legislative changes enacted by section 2181 of Pub. L. 97-35, the Omnibus Budget Reconciliation Act of 1981. That section eliminates the penalty which reduces by one percent Federal funds for a State's Title IV-A program, Aid to Families with Dependent Children (AFDC), for any quarter during which a State fails to: (1) Inform all AFDC families of the availability of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services; (2) provide or arrange for requested screening services; and (3) arrange for corrective treatment of health problems found as a result of screening. In addition, even though the penalty has been eliminated, section 2181 mandates that States incorporate these three requirements into their Medicaid State plan with respect to all EPSDT eligibles.

Further, this rule modifies current regulations to reflect Congressional intent that while States should continue to develop fully effective EPSDT programs, the Federal government should work to reduce current reporting requirements which entail a large volume of paperwork.

**DATE:** These regulations are effective January 29, 1985.

**FOR FURTHER INFORMATION CONTACT:** Thomas Hoyer, (301) 594-9446.

**SUPPLEMENTARY INFORMATION:**

## I. Legislative Background

In 1967, section 1905(a)(4)(B) of Title XIX was added to the Social Security Act (Act) by Pub. L. 90-248, Social Security Amendments of 1967, to provide early and periodic screening, diagnosis and treatment, (EPSDT) for eligibles under 21. The amendment became effective July 1, 1969 and required States to ascertain these children's "physical or mental defects", and to provide "health care, treatment, and other measures to correct or ameliorate any defects and chronic conditions discovered . . .".

In 1972, section 403(g) was added to the Act by Pub. L. 92-603, Social Security Amendments of 1972. This section provided for a penalty that would reduce by one percent Federal funds for a State's Title IV-A program, Aid to Families with Dependent Children (AFDC), for any quarter during which a State failed to—

- Inform all AFDC families of EPSDT availability;
- Provide or arrrange for requested screening services; and
- Arrange for corrective treatment of health problems found.

Section 2181 of Pub. L. 97-35, the Omnibus Budget Reconciliation Act of 1981 (OBRA), eliminated section 403(g) of the Act which contained the EPSDT penalty. This legislation also amended section 1902(a) of the Act by adding a new paragraph (44) (renumbered as paragraph (43) in Pub. L. 98-369) that requires State plans to provide for the following activities—

- Informing all Medicaid recipients under 21, who are eligible for EPSDT under the plan, or EPSDT availability;
- Providing or arranging for requested screening services; and
- Arranging for corrective treatment of health problems found as a result of screening.

In addition, section 131 of Pub. L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), exempts from Medicaid copayment requirements services provided to children under 18 (or up to 21 at State option), except for any enrollment fee, premium, or similar charge that may be imposed on medically needy recipients.

## II. Proposed Rule

On August 22, 1983, we publish in the **Federal Register** a proposed rule (48 FR 38011) on the EPSDT program. The major provisions of that proposal were as follows:

### *A. Informing*

The Medicaid agency would be required to inform effectively, through a combination of written and oral methods, all EPSDT eligibles (including the blind or deaf, or those who cannot read or understand English) of the following: (1) The benefits of preventive health care; (2) that the EPSDT services are available without cost, and where and how to obtain them; and (3) that necessary transportation and scheduling assistance is available upon request. We also proposed that the agency must assure that processes are in place to inform effectively all EPSDT eligibles, generally within 60 days of initial Medicaid eligibility, and in the case of families that have not utilized EPSDT services, annually thereafter.

### *B. Screening*

We proposed to require that States provide, to eligible recipients who request it, a screening package that, at a minimum, includes: (1) A comprehensive health and developmental history; (2) comprehensive unclothed physical examination; (3) appropriate vision, hearing and laboratory tests; and (4) dental screening services furnished by direct referral to a dentist beginning at age 3 (or at an appropriate age which reflects reasonable standards of dental practice determined by the agency after consultation with recognized dental organizations involved in child health care, within an outer limit of age 5).

### *C. Diagnosis and Treatment*

Under the proposal, we would require that States provide vision, hearing, and dental services found necessary by the screening to EPSDT eligible children even if those services are not otherwise included in the State plan. We would also require appropriate immunizations, even if this service were not otherwise included in the plan.

### *D. Timeliness*

Under our proposed rule, States would be required to set standards for the timely provision of EPSDT services which meet reasonable standards of medical and dental practice determined after consultation with recognized medical and dental organizations involved in child health care. The agency also must demonstrate that processes are in place to ensure service delivery, generally within an outer limit of 6 months from the request for services.

### *E. Periodicity Schedule*

A State would be required to implement a periodicity schedule which—

(1) Meets reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care.

(2) Specifies the screening services applicable at each stage of a recipient's life, beginning with a neonatal examination and extending to the age at which an individual is no longer eligible.

(3) At the agency's option, provides for needed screening services in addition to otherwise applicable screening services.

*F. Requests for Screening Services*

We proposed a provision clarifying that an agency must provide screening services upon the recipient's initial request following initial eligibility, but need not provide such services to an EPSDT eligible if written verification exists that the most recent age-appropriate screenings due under the agency's periodicity schedule have already been provided to the recipient.

*G. Accountability*

States would be required to maintain (as currently required under 42 CFR 431.17 and 431.18) records and program manuals, a description of their screening packages, and copies of rules and policies used to assure that the informing requirement is met.

*H. Coordination With Programs and Utilization of Providers*

We proposed a requirement that agencies make available a variety of individual and group providers qualified and willing to provide EPSDT services, and we proposed that agencies coordinate with existing health services and programs where possible to assure an effective child health program. We would also require that an agency provide referral assistance to individuals who need treatment not covered under the State plan.

*I. Continuing Care Providers*

Under the proposed rule there was a provision that would provide States with the enhanced flexibility to achieve their desired child health program goals through the optional use of continuing care providers. We would deem an agency to meet all EPSDT requirements with respect to those recipients furnished care by a continuing care provider if certain requirements are met.

*J. Transportation and Scheduling*

We would require that the agency offer necessary assistance with transportation and scheduling.

*K. Penalty Regulations*

Current regulations §§ 441.70–441.90, regarding the application of the penalty under section 403(g) of the Act, would be deleted except for certain concepts (e.g. informing) that would be retained as State plan requirements.

**III. Public Comments**

We received 60 comments on the proposed rule from State and local agencies, national and State health professional organizations, advocacy groups and others. The main comments and our responses to those comments are as follows:

*A. General*

*Comment*—Several commenters expressed concern that the effectiveness of the program would be minimized because the regulation is often too general, giving excessive latitude to States. They are concerned that the EPSDT program might be weakened by States misusing the flexibility provided by the regulation and suggested that the regulation should be more proscriptive and detailed.

*Response*—While the Medicaid statute as a whole establishes certain Federal requirements, it also provides States with considerable discretion in determining how best to administer their separate State Medicaid programs. Therefore, to be consistent with the statute, our regulations allow for some flexibility so that States can most effectively and efficiently utilize their available resources to meet the needs of their recipients. With respect to the EPSDT program, this latitude provides States the opportunity to be innovative in the techniques and approaches used to administer the program in their respective localities. Additionally, Congress, when repealing the EPSDT penalty provision, expressly stated its intent to "streamline" EPSDT reporting requirements. However, while States are afforded some flexibility and the paperwork burden has been reduced, our regulations clearly set forth the requirements and standards that States must meet to have comprehensive and effective programs and to comply with the intent of the EPSDT legislation that States should continue to develop fully effective EPSDT programs. In this regard, we are charged with the responsibility to ensure that States appropriately use the flexibility permitted while fully meeting the requirements of these regulations.

*Comment*—Two commenters asked what type of quarterly EPSDT reports will be required of the States.

*Response*—We have developed a revised EPSDT report, HCFA–420, to replace the HCFA–156 which was formerly used for EPSDT reporting. The new report requests the following: (1) The number of children eligible for EPSDT in each State; (2) the number of these eligible children enrolled in "continuing care" arrangements, with a breakdown according to whether or not the continuing care provider routinely reports to the Medicaid agency services provided; (3) the number of initial and periodic examinations during the quarter; and (4) the number of examinations that indicated that at least one health problem was discovered as a result of the screen. The information is to be arranged into two groupings according to the ages of the children (0 to 5, and age 6 and over).

The report is to be prepared quarterly by each State agency and submitted to the HCFA Bureau of Data Management and Strategy (BDMS) within 30 days following the end of the quarter covered by the report. Instructions for completing the new format have been included in the State Medicaid Manual, Part 2—State Organization, section 2700.4, Transmittal 18, November 1983. For data elements, 1, 3 and 4, the first reports will be due April 30, 1984. States will be notified of a separate effective date for beginning to include element 2 in the quarterly reports.

For those States which implement the sample data tape option for Medicaid statistical data reporting, HHS will not require submission on the HCFA Form 420 of those data elements that can be reproduced from the data tapes.

*Comment*—One commenter suggested that the regulations "should specify that a certain percentage of previous year's expenditures will be spent nationally in the subsequent year for research and evaluation activities". The commenter believes that these funds should be available on a competitive grant basis.

*Response*—Annually in the **Federal Register**, we announce subject areas for research and demonstration grants for the purpose of resolving major health policy and program issues or developing innovative methods for Medicare and Medicaid administration. The amount of funds to be used for these grants depends on the budget available and is not, therefore, related to expenditures under Title XIX.

*Comment*—One commenter asked if any portion of these regulations is penalty related.

*Response*—As stated earlier, section 2181 of OBRA repealed the specific EPSDT penalty contained in section 403(g) of the Act. Therefore, as a result of the repeal, our regulations no longer set forth specific requirements that must be met to avoid the imposition of the penalty under section 403(g) of the Act. However, OBRA also amended section 1902(a) of the Act by adding a new paragraph (44) (renumbered as

paragraph (43) in Pub. L. 98-369) that requires State plans to provide for certain activities in connection with EPSDT services for those eligible. As with other State plan requirements, States under the EPSDT program will be subject under section 1904 of the Act to the withholding of Federal funds, if it is determined, after reasonable notice and opportunity for hearing, that the program is not being administered in compliance with Federal requirements. Periodic Federal audits and reviews will be used to ensure that State plans are being administered according to Federal requirements.

*Comment*—Several commenters questioned whether the proposed rules provided for a reduction in paperwork.

*Response*–All of § 441.90, Documentation, and the penalty related documentation requirements it contained were deleted in the proposed regulation. This deletion significantly reduces the administrative burden placed on States.

*Comment*—One commenter recommended that the regulation include a specific acknowledgment that those administering the program cannot force its benefits on children over the objections of their parents.

*Response*—We believe the suggested addition is unnecessary because at various points the regulation underscores the fact that participation in EPSDT is voluntary. Screening, other health services, and transportation and scheduling assistance are provided only after the recipient, or recipient's family, requests the services.

*B. Informing*

*Comment*—One commenter believes recipients should be informed that EPSDT treatment will be made available only if it is covered by the State plan. Recipients should have this information because they may not want to be screened for fear of finding problems they cannot afford to treat.

*Response*—We do not agree with this comment for several reasons. First, not receiving a screening for fear of finding a problem a person may not be able to afford to treat may very well result in more serious problems and the need for more expensive treatment. Moreover, under § 441.56(c), a State must provide to EPSDT recipients certain Medicaid services, even if not included in the State plan. In addition, under § 441.57, a State may provide certain other medical or remedial care even if the agency does not provide these services or provides them in a lesser amount, duration, or scope. Further, in the event that services found to be needed as a result of screening and diagnosis cannot be provided as EPSDT services, States, under § 441.61(a), are required to provide referral assistance and to advise recipients of those providers who have indicated a willingness to furnish those services at little or no cost. Therefore, we are making no change to the regulations.

*Comment*—One commenter recommended that the requirement that agencies annually inform, about EPSDT, families who have not used the program, should specify that this requirement is applicable only if the family is still eligible.

*Response*—Section 441.56(a)(1) of the regulation indicates that the requirement to inform individuals about the program only pertains to those individuals (or their families) who are eligible; therefore, no change is necessary.

*Comment*—Nine commenters objected to the proposed reduction of the current informing requirement from 13 to only 4 items of information that must be provided to recipients. One commenter, concerned with the reduction in the number of specific items, asked whether the proposed regulations left the content of the explanation of the information strictly up to the States' discretion.

*Response*—While current regulations list 13 specific items, the proposed regulation includes four general statements describing the information about the EPSDT program that must be provided to individuals. However, it is important to note that the four general statements encompass the same information required under current regulations. Even though the information that must be provided to recipients has been described in more simplified language, we expect States to continue to provide recipients with all the essential information they need in order to utilize fully the services to which they are entitled.

*Comment*—One commenter asked if there was a requirement to inform an eligible recipient after a period of ineligibility.

*Response*—Section 441.56(a)(3) of the proposed regulation (§ 441.56(a)(4) of this final rule) requires agencies to inform eligible individuals about the program after their initial Medicaid eligibility determination and, in the case of families that have not utilized EPSDT services, annually thereafter. We expect States to reinform about the program, those individuals who are determined to be EPSDT eligible after a period of ineligibility, if they have not used the services for at least a year and are due for a screening.

*Comment*—Seven commenters recommended that the regulation should continue to require that EPSDT informing be in clear and nontechnical language.

*Response*—We agree that this is an important element in ensuring effective informing. We have added to § 441.56(a) the requirement that agencies use clear and nontechnical language in providing to recipients the required information under this section.

*Comment*—One commenter believes it would be helpful for HCFA to provide in regulations additional guidance concerning the requirement to "effectively inform". The commenter also thinks the regulation should require agencies to ensure that individuals are informed about the program in their native language or other mode of communication. If the native language or other mode of communication of the individual is not a written language then the agency should be required to utilize other methods such as oral translation.

*Reponse*—In the preamble to the proposed rule we stated that it was our intent to simplify and provide for State flexibility in the informing requirement while still requiring that States effectively inform eligibles about EPSDT. To this end, we believe that any further detail or specificity beyond that contained in the proposed regulation, along with the change described above to § 441.56 in this final rule, is inappropriate.

Effective informing requires States to use methods of communication that recipients can clearly and easily understand to ensure that they have the information they need to utilize fully the services to which they are entitled. The proposed regulations require agencies to provide for a combination of written and oral methods designed to effectively inform all EPSDT eligible individuals (or their families) about the program. As a result of the change to § 441.56 just discussed, States, to effectively inform individuals about EPSDT, must now provide them with certain required information described in § 441.56(a)(2) of the final regulation using clear and nontechnical language. Further, States are also required to effectively inform individuals who are blind or deaf, or who cannot read or understand the English language. To effectively inform these individuals about the program, communication methods that meet their needs must be used.

*Comment*—One commenter recommended that States be required to develop, for public comment, oral informing plans that identify the methods they will use, the content of the message, and the population at which the oral information will be aimed.

*Reponse*—We do not think requiring States to develop oral informing plans for public comment is necessary to ensure that recipients are effectively informed about EPSDT. Also, imposing such an additional administrative burden on the States would not be appropriate since it is the intent of Congress that the volume of paperwork required of the States be reduced.

*Comment*—One commenter recommended that States be required to ensure that eligible adolescents are informed about the program.

*Reponse*—We do not believe that the regulation should require special efforts for encouraging older children to use the program. The OBRA amendments do not mention specific groups of recipients but rather require States to effectively inform all EPSDT eligible about the program. To be consistent with the statute, we do not think the regulation should place special emphasis on informing any particular group of recipients. Further, we think the need for such efforts will vary and should be a matter for State discretion.

*Comment*—One commenter stated that requiring agencies to inform all EPSDT eligibles that the services provided under the EPSDT program are without cost to the individual is not consistent with section 131 of Pub. L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982 that adds a new section to Title XIX of the Social Security Act regarding cost sharing by Medicaid recipients.

*Response*—We agree that the statutory change necessities a revision to the proposed regulation. We are revising the language at § 441.56(a)(1)(iii) (now § 441.56(a)(2)(iii) to indicate that services provided under the EPSDT program to the EPSDT eligible individual are without cost to eligible categorically needy recipients "under 18 years of age, and if the agency chooses, to those 18 older, up to age 21". Additionally, these services are without cost to eligible medically needy recipients under 18, or if the agency chooses, to those 18 up to age 21, (except for any enrollment fee, premium, or similar charge provided for by the State agency.)

*Comment*—One commenter recommended that the regulation specify what percent of the population must consist of individuals who do not understand English before States are required to use translated materials.

*Response*—As stated earlier, it is our intent to simplify and provide for State flexibility in the informing requirement while still requiring that States effectively inform eligibles about EPSDT; therefore, we do not believe it appropriate to include such detail in the regulations. States are in the best position to determine the needs of recipients in their localities. However, States may wish to consider the guideline generally used by the Office for Civil Rights (OCR), DHHS. According to OCR guidelines if there are at least 100 potential users of a DHHS program in a specific geographic area, who do not read or understand English and share the same non-English language, special measures should be taken to inform them about the availability of the program. One method of informing such individuals would be the use of translated materials. Generally, since EPSDT is a state-wide program, States will have to use their discretion in defining what consitutes a specific geographic area.

*Comment*—Fifteen commenters objected to allowing States to use a combination of writtern and oral methods to inform eligible individuals about the program, rather than requiring them to use face-to-face informing for all eligibles.

*Response*—We recognize the value of oral informing and agree that States should not rely completely on written methods to inform recipient about the EPSDT program. However, we believe that written methods can be used to effectively provide information about the program.

Moreover, all recipients do not need oral informing to be effectively informed about the program. Therefore, we continue to require in the final regulation that a State "effectively inform" eligibles using a combination of oral and written methods, without imposing additional requirements as to which situations require the use of which methods. We would, of course, expect States to use oral informing for those individuals whose circumstances indicate that they would most benefit from it. For example, States might consider such methods for first time mothers, those not using the program for over two years, or first time eligibles.

*Comment*—One commenter thinks it would be useful to the States and to advocates to specify, in the regulation, minimum participation rates in the EPSDT program that must be met in order for a State to qualify as having an effective informing system.

*Response*—We do not believe such a requirement is appropriate since use of EPSDT services is entirely voluntary. However, we will address the commenter's concern that effective informing actually take place, through our monitoring and assessement programs. As part of our assessement program for ensuring that State plans are in compliance, we will periodically review the States' conformance with the EPSDT regulation, including the requirement to effectively inform recipients about the program. Additionally we will be monitoring the rate of recipient participation in the EPSDT program through federally required monitoring reports which States must submit quarterly as an indicator of the effective implementation of EPSDT requirements.

*Comment*—One commenter suggested that the 60-day time requirement for informing new participants of EPSDT seems excessively long. However, fourteen others recommended that the current 60 day requirement be retained, but stated that having "processes" to ensure general timeliness, as contemplated under proposed 42 CFR 441.56(a)(3), is not acceptable since there is no explicit requirement that the State implement the process.

*Response*—We do not agree that the language of § 441.56(a)(3), redesignated in this final rule as § 441.56(a)(4), which requires States to have processes in place for effectively informing recipients about EPSDT, should be amended. To comply with this section we expect States to effectively inform recipients about the program. Also, this section will enable us to monitor effectively the States' activities in informing recipients and it will reduce, as mandated by Congress, the amount of paperwork required to ensure that recipients are being effectively informed.

The provisions of the proposed regulations pertaining to informing require States to employ processes which effectively inform recipients about the program generally within 60 days of their Medicaid eligibility determination. It is important to note that, even though the word "generally" has been added to the proposed regulation with regard to the 60-day time frame, this does not relax the requirement for States to promptly inform recipients about the program. The addition of the word "generally" is only for the purpose of accommodating legitimate and unavoidable problems that cause delays in informing recipients about EPSDT; e.g., States may not be promptly notified of SSI eligibility determinations that result in individuals becoming Medicaid eligible. The standard is still for States to inform individuals within 60 days.

*Comment*—One commenter objected to any requirement that recipients be notified of the next scheduled examination due under the periodicity schedule.

*Response*—Periodic screening is required under sections 1902(a)(43) and 1905(a)(4)(B) of the Act and § 441.58 of the proposed regulations requires States to implement periodicity schedules that identify the screening services that are applicable at each stage of a recipient's life up to the age at which he or she is no longer eligible for EPSDT. We expect States to notify recipients of the appropriate time to receive services. For recipients enrolled with a continuing care provider, the provider should furnish this notification.

*C. Screening*

*Comment*—Two commenters suggested that the requirement for States to provide appropriate vision testing and appropriate hearing testing is too vague and might allow doctors to slip into old habits, such as whispering behind children's backs to test their hearing.

*Response*—Section 441.56(b)(2) of the regulation states that screening services must be provided in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care. Therefore, we do not think the word "appropriate", as it is used in § 441.56(b)(1), needs further clarification.

*Comment*—One commenter suggested the preamble should mention that the State agency is charged with the responsibility to determine what periodicity schedules and screening processes will be used.

*Response*—We believe this is implied in the regulation. The regulation requires the agency to implement a periodicity schedule that meets reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations.

*Comment*—One commenter suggested that the regulation and preamble should make specific reference to health education and counseling and that these services should be added to the list of required services.

*Response*—The preamble to the proposed regulation, in discussing screenings or periodic child health assessments, included the following statement: "Assessment visits also generally include . . . nutritional and anticipatory guidance (i.e., help or assistance to families in understanding what to expect in terms of a child's development) and information about health-related topics such as disease and accident prevention. We recognize that health education efforts by parents and a sound practitioner/patient relationship can have significant positive impacts on the child's health status and that these efforts should be begun at an early age." We think this statement from the preamble indicates the importance we place on health education and counseling. The health assessment provides States with the context in which to provide health education and counseling. However, the regulation does not specifically mention these services because we believe they would be delivered as part of the services specified in the regulation.

*Comment*—One commenter asked that the regulation require that developmental evaluations be provided in accordance with reasonable standards of medical practice.

*Response*—The regulation requires that EPSDT screening services be provided in accordance with reasonable standards of medical and dental practice. As indicated in the preamble and § 441.56(b)(1) of the regulation, a developmental assessment is an integral part of the screening service. Therefore, such assessments must also be furnished in accordance with reasonable standards of medical practice.

*Comment*—One commenter recommended that we require, at the very least, that a dietitian or nutritionist be part of the consultation process pertaining to nutritional assessments.

*Response*—We do not think it is appropriate for the regulation to require that certain methods and procedures be followed in providing screening services. Instead, the regulation requires that screening services, which include nutritional assessments, must be provided in accordance with reasonable standards of medical and dental practice determined by the State after consultation with recognized medical and dental organizations involved in child health care. States, after consultation with these organizations, determine what specific protocols or procedures will be followed in providing screening services and we accept those determinations, as long as they meet reasonable medical and dental standards.

*Comment*—One commenter suggested that the regulation or preamble should recommend some of the professional associations from whom consultation should be sought, while another recommended that consultation with representatives of recognized optometric and other health professional groups should be required. Similar recommendations were made by three other commenters with respect to consultation with groups regarding developing the periodicity schedule. One commenter also believed regulations should specify how conflicts should be resolved.

*Response*—We expect States to consult with recognized organizations that are knowledgeable about the general physical and mental health, growth, development and nutritional status of infants, children and youth, including those orgainzations with expertise pertaining to vision, hearing and dental evaluations. These consultations are important in ensuring that each component of the EPSDT screening and the establishment of a periodicity schedule meet reasonable standards of medical and dental practice. However, we believe the decision regarding which particular organizations or sources to consult should be made by the States. Therefore, we have not compiled a list of organizations that States should consult in determing the standards.

With respect to resolving any conflicts within the consultation process, we believe decisions to give more weight to recommendations of one group over another or to otherwise resolve or deal with defferences of professional opinion can best be made by each State.

*Comment*—Five commenters opposed categorizing immunization as a treatment service. Some stated that by categorizing it as a treatment rather than as a screening service we will increase provider paperwork and the cost of the program in those States where immunizations are included as part of the screening package. Also, some believed that since some State medical practice laws prohibit nurses or clinicians from performing diagnoses and treatment, many health department professionals might be banned from providing immunizations at the time of screening, which effectively may interfere with children being immunized. Some commenters objected to the change, believing that needed immunizations could no longer be provided as part of the screening process and that children would have to be referred to a doctor's office for this service.

One commenter also believed that these situations would result in a reduction in the number of screenings because immunizations are an inducement to have children screened.

*Response*—Although immunizations have been recategorized as a treatment service, the regulation emphasizes that States are still required to provide immunizations at the time of screening if it is medically necessary and appropriate to provide them at that time. To emphasize this, reference is made to

immunizations under the sections of the regulations on diagnosis and treatment and on screening. It may be that the language contained in the proposed §441.56(c)(3), which states that only immunizations that are "medically necessary" are to be provided at the time of screening, has been misinterpreted by some commenters to mean that immunizations generally should not be provided as part of a screening. To emphasize and clarify our intent in this regard, we are replacing the words "medically necessary" with the word "needed". As in the past, when a clinic determines at the time of screening that an immunization is needed, rather than refer the child to a doctor's office, it can provide the service as part of the screening package. Clinics are still encouraged to provide necessary and appropriate immunizations during the screening process in order to facilitate the provision of these preventive health care services and to promote cost effectiveness. Also, it is State medical practice laws, and not how immunizations are categorized in the regulations, that will determine the types of health care professionals and technicians that may provide this service. Therefore, we do not believe there is anything in the final regulations to warrant concern that health department professionals might be barred, due to State medical practice laws, from providing immunizations because they have technically been categorized as a treatment service.

Further, States need not refer children to doctors' offices for immunizations and since States are still required to provide immunizations at screening if needed and appropriate, we would expect the inducements to have children screened would still exist.

When immunizations are provided during the screening process, they can be billed as part of the screening package. A spearate billing procedure is not required. Also, States can continue to negotiate flat rates with providers for screening packages that include needed immunizations.

*Comment*—Nine commenters expressed concern because developmental and nutritional assessments are not specifically mentioned as screening services in the proposed regulation. The commenters believe that many children will not receive these assessments, unless the regulation specifically mentions them as screening services.

*Response*—To be consistent with medical terminology, and at the suggestion of the pediatric community, we have not listed developmental and nutritional assessments as separate screening items. However, a comprehensive health and developmental history and a comprehensive physical examination have been listed separately and these items, by definition, include an assessment of a child's development and nutritional status. This would be understood by any qualified provider. To further emphasize this, the regulation defines EPSDT screenings as ". . . (periodic comprehensive child health assessments); that is, regularly scheduled examinations and evaluations of the general health, growth, development, and nutritional status of infants, children, and youth". As indicated by this definition, an EPSDT screening includes an examination and evaluation of the developmental and nutritional status of the recipient. Therefore, we do not believe it is necessary to specify developmental and nutritional assessments as separate elements of the screening. However, we have added the words "physical and mental", which also appear in § 441.50, to more clearly reflect the language of the statute which relates to both the physical and mental health of recipients.

*Comment*—One commenter expressed concern about the quality of care as it pertains to the procedures used in providing screenings and the personnel conducting the screenings. Another commenter believes that it is absolutely essential that a physician do the visual screening of infants and young children. The commenter also stated that referrals for visual treatment of infants and young children, as well as for non-refractive errors in older children, should be to an ophthalmologist.

*Response*—To address properly questions concerning the acceptability of various standards or methods of providing screening services, the proposed rule included a requirement that screening services, be provided in accordance with reasonable standards of medical and dental practice, determined by the agency after consultation with recognized medical and dental organizations involved in child health. We think this adequately addresses the need to ensure that EPSDT screenings will meet professional standards. Generally, the decision concerning who can provide EPSDT services is made by the States according to their medical practice laws. We accept these decisions as adequate as long as they meet specific Medicaid requirements (for example, 42 CFR 440.50(b)) that certain services be provided under the direction of a physician and services be delivered according to reasonable standards of medical and dental practice.

*Comment*—One commenter recommends that the EPSDT regulations preferably use the term dental (or oral) examination, rather than dental screening, and provide some explanation of its content/use.

*Response*—The regulation requires States to provide screening to eligible EPSDT recipients who request it. Screening is defined in the regulation as periodic comprehensive child health assessments; that is, regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. As required by the regulation, these screenings must include dental screening services furnished by direct referral to a dentist. The terminology "dental screening services", as used in the regulation, means a comprehensive and thorough dental examination, provided in accordance with reasonable dental standards, to identify any oral or dental defects. However, to be consistent with the language used in the EPSDT legislation, the required dental examinations are referred to, in the regulation, as screenings.

*Comment*—One commenter suggested that instead of specifying in the regulation the age requirement for dental referrals, we should leave it to the State agencies in consultation with recognized dental organizations. Twenty-seven other commenters objected to the proposed regulation because it allows States to defer initial dental referrals of EPSDT children until the age of 4 or 5 under certain circumstances.

*Response*—Because the lack of proper dental care for children can cause associated health problems and result in the need for more serious and costly dental treatment in adolescence and adulthood, we believe it is appropriate to set some minimal Federal requirements regarding the age at which EPSDT children must be referred to a dentist. With regard to the specific age set, the provision in the proposed regulation was intended to permit States to defer dental referrals in a limited number of situations, in recognition of the fact that there may be legitimate and unavoidable difficulties that require exceptions to the requirement that referrals begin at age 3. For example, some States have reported that they do not have an adequate number of dentists participating as Medicaid providers to meet the age 3 requirement.

Because of the comments we have received and the concerns expressed by

the States we have revised the language contained in the proposed rule. The regulation, as revised, requires that dental screening services be furnished by direct referral to a dentist for children beginning at 3 years of age. However, Medicaid State agencies may request from HCFA an exception from this age requirement (within an outer limit of age 5) for a two year period and may request additional two year exceptions. If an agency requests an exception, it must satisfactorily demonstrate to HCFA that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement. Also, the request must explain the policy and program efforts the State has made to meet the age 3 direct referral requirement using its current dental resources. The State will remain responsible for required treatment for dental problems identified by other EPSDT screening. If a State requests exceptions beyond the initial 2 year period, it must describe the steps it has taken to achieve maximum participation of dentists in the State and improvements that have taken place. In evaluating the State's request for an exception, HCFA also will consider any objective evidence submitted by knowledgeable professionals and members of the public. An exception will be granted only when there is persuasive evidence that a shortage of dentists prevents the agency from providing dental screenings through direct referral to a dentist for eligible children beginning at 3 years of age. We believe that this approach will address the real problems some States face in providing dental services under EPSDT, while ensuring that decisions allowing exceptions to the usual referral age are made appropriately.

*Comment*—One commenter suggested that subparagraph (b) of § 441.56 has a weakness in that recipients have to request EPSDT services. The commenter believes it is contrary to the intent of Congress to require that EPSDT services be requested. Also, one commenter believes that all children determined eligible for EPSDT services should be required to participate in the EPSDT program as a condition of the family's eligibility for Titles XIX and IV-A.

*Response*—The purpose of the EPSDT program is not to compel individuals to participate, but to make available early and periodic screening, diagnostic and treatment services to those determined eligible and to assist eligible individuals in receiving these services (section 1902(a)(43) of the Act). The EPSDT statutory language states that State plans are to provide for "screening services in all cases where they are requested." The proposed regulation is consistent with this language. We think that forcing individuals to participate in the EPSDT program is not feasible and would be contrary to the intent of the statute. However, it is important to note that States are required to effectively inform all EPSDT recipients about the availability of EPSDT services, regardless of whether this information is requested or not.

*D. Diagnosis and Treatment*

*Comment*—Five commenters recommended that in order to avoid unnecessary screenings as a prerequisite to needed diagnostic and treatment care, we should permit the provision of interperiodic diagnostic and treatment care to children who are up-to-date in their screenings.

*Response*—Section 1902(a)(10) of the Act in conjunction with sections 1905(a)(4)(B) to 1902(a)(43) requires States to provide early and periodic screenings of eligible persons and to arrange for corrective treatment if a need is disclosed by such health screening services. The statutory language indicates that the diagnostic and treatment services, authorized by the EPSDT legislation, for the purpose of correcting and ameliorating problems discovered by EPSDT screenings. Thus, it is necessary for diagnoses and treatments to be linked to screening to be considered part of EPSDT. However, § 441.58(c) of the regulations does allow States to provide needed screening services in addition to screenings specified in their periodicity schedules. This provision gives the States additional flexibility to meet the needs of children who may require screening, diagnostic and treatment services in between regularly scheduled screenings.

*Comment*—Two commenters recommended that, in addition to vision, hearing, and dental care, any diagnostic or treatment services should be provided and paid for, if an EPSDT screening indicates these services are needed. One other commenter recommended that States be required to provide for the testing and diagnosis and treatment of speech and language disorders.

*Response*—With respect to providing screening for speech and language disorders, § 441.56(b) in general requires that EPSDT screening services be provided in accordance with reasonable standards of medical and dental practice and include examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children and youth. In developing acceptable standards and protocols for these comprehensive child health assessments, especially as they pertain to required developmental evaluations, we would expect States to include examinations which would enable detection of speech and language disorders.

We have retained existing requirements with respect to the services which are required because they address the principal health problems found as a result of EPSDT screenings and because in repealing the EPSDT penalty and adding new EPSDT process requirements to the State plan, Congress did not indicate any intent to change these requirements.

*E. Timeliness*

*Comment*—One commenter suggested that States, in setting timeliness standards, should be required to consult with parents, consumers and other State health agencies in determining reasonable standards for timeliness and in establishing periodicity schedules as well.

*Response*—We believe that periodicity and timeliness requirements should be set based on professional judgment since that best reflects what is required in order for proper medical treatment to be provided. The regulations reflect that approach.

*Comment*—Three commenters referred to the current requirement that States provide timely delivery of EPSDT services and objected to our substituting the requirement that States demonstrate that processes are in place for such delivery.

*Response*—We have clarified this requirement (§ 441.56(e)), and a similar requirement for monitoring continuing care providers (§ 441.60(c)), to make clear that States must employ methods to ensure timely delivery and assure providers' compliance with their agreements.

*Comment*—Seven commenters objected to allowing an outer limit of generally within 6 months for the provision of EPSDT services, asserting that such a lapse between screening and treatment was unreasonable and without medical or other foundation. Another commenter found the time period to be unduly long, but recognized that it might be necessary in some environments. One commenter suggested a 2 months cycle, and another 4 months.

*Response*—We are amending § 441.56(e) to make clear that the 6 month limit does not begin on the date the screening is provided but rather on the date on which the screening is

requested, and ends with the initiation of necessary treatment. Thus, within 6 months of the request for service, the screeening, problem identification, and initiation of treatment should occur. We have retained the 6 month outer limit that is also in the current regulations to ensure a minimum national standard. Further, we believe that requiring States to establish time standards which meet reasonable standards of medical and dental practice will ensure that States adopt the shortest possible time-span for each step of the EPSDT cycle compatible with efficient administration of the Medicaid program.

*F. Periodicity Schedule*

*Comment*—Two commenters questioned whether input from recognized medical and dental organizations must be incorporated in state programs or is to be viewed as consultative. One other commenter questioned whether States would have to undergo the consultation process once again considering the new requirement that periodicity schedules must now meet "reasonable standards of medical and dental practice . . . ".

*Response*—The additional requirement that periodicity schedules meet reasonable standards of medical and dental practice, determined by the agency after consultation with recognized medical and dental organizations, affirms that: (1) Consultation with the stated organizations is mandatory; (2) the responsibility for determining the standards rests with the State agency; and (3) the standards must reflect reasonable standards of medical and dental practice.

If the standards a State has in place were adopted after such consultation, and reflect reasonable standards of practice, additional consultation is not required. It is expected that States will want to maintain a dialogue with organizations in order to ensure their periodicity schedules reasonably reflect current professional judgment.

*Comment*—Three commenters supported the requirement that schedules specify the services applicable at each stage of a recipient's life. Three other commenters recommended continuing the current requirement that schedules specify months and years between examinations, or that "reasonable" in the phrase "reasonable standards of medical and dental practice" be defined.

*Response*—We have retained the phrase, "reasonable standards of medical and dental practice", because it provides States the flexibility to weigh different factors and yet precludes use of inappropriate standards. Defining such a phrase would be impossible without emphasizing one factor or factors over others which may inhibit best serving the needs of recipients in particular States. Further, we believe that specifying screening services applicable at each stage of a recipient's life is sufficient to ensure that States develop schedules and procedures which delineate when services are due.

*Comment*—One commenter objected to provisions that make optional the coverage of recipients 18 through 20 years of age.

*Response*—The regulation implements statutory changes in section 1905(a)(i) of the Act, enacted by Pub. L. 97–35, the Omnibus Budget Reconciliation Act of 1981; therefore, no changes can be made in that provision.

*G. Requests for Screening Services*

*Comment*—Four commenters supported the requirement that the agency provide screening services upon the recipient's request. One commenter stated that the language was confusing, by referring to both initial request and initial eligibility determintion. One commenter questioned what the State's responsibility was to an individual who declines EPSDT services after initially being determined Medicaid eligible and later requests services when, according to the periodicity schedule, no screening is required.

*Response*—We have amended the language at § 441.59(a) to clarify that agencies must provide EPSDT services upon the eligible recipient's request, even when the recipient had previously declined services. The only time an agency need not provide requested screening services to an EPSDT-eligible individual occurs when written verification exists that the most recent age-appropriate screening services, due according to the agency's periodicity schedule, have been provided to that individual. We agree that unless a child is up to date on screening, screening should be available when requested, and not delayed until the next age level noted in the periodicity schedule.

*Comment*—Two commenters agreed with the provision that States may deny requested screening services when written verification exists that the most recent age-specific screening services have been provided. One of the commenters recommended additional provisions that would permit denial only when optional screening is not provided and schedules meet reasonable standards, and that a child must be covered for diagnosis and treatment services for conditions found by screening during a prior period of eligibility.

*Response*—We do not believe that the recommended additions are necessary because the regulation's provisions for screening services, discretionary services, and options for screening services in addition to regularly scheduled examinations provide a sufficient framework to control potential isolated instances of inappropriate barriers to EPSDT services.

*H. Accountability*

*Comment*—Six commenters objected to the absence of child-specific documentation requirements for services, including transportation and scheduling assistance, provided recipients. One commenter recommended specific documentation requirements for some of these areas. These commenters believed HCFA would be without the means of monitoring performance and enforcing compliance if the documentation required under current regulations were not maintained. One of the commenters also believed the regulation exceeded Congressional directives to streamline paperwork.

*Response*—Program experience indicates that the detailed documentation previously required proved to be counter-productive in that the unintended result was an emphasis on recordkeeping at the expense of providing services. We believe Congressional directives to streamline paperwork while requiring fully effective EPSDT programs have been met by the requirements established in this regulation which are supplemented by general Medicaid program regulations at §§ 431.17 and 431.18 concerning maintenance of agency records and availability of agency program manuals. Together with our program requirements, these provide a framework for States to develop records, manuals, descriptions of the screening package, and methods of assuring informing, that both support effective administration and enable HCFA to monitor the adequacy and functioning of State program management.

*Comment*—Three commenters asked what reporting would be required. One of them asked whether HCFA will develop its own reportable elements.

*Response*—We distinguish between documentation requirements, which enable verification of the receipt of required and optional services, and reporting of program data to HCFA. Under these regulations, to meet documentation requirements, States

establish systems to provide the data and information that is needed to substantiate the provision of EPSDT services. Reporting requirements are described in the Quarterly EPSDT Report, Form HCFA–420, which was discussed earlier in this preamble.

*Comment*—One commenter requested clarification of the records agencies must maintain.

*Response*—In these regulations, we have sought to establish auditable requirements which do not create a heavy paperwork burden. The section on accountability requires agencies to maintain records and manuals as required by § 431.17 and § 431.18 of the Medicaid regulations, which are necessary for the proper and efficient operation of the plan. This would include records needed by the State, to establish that it has fulfilled the requirements specified in the regulation. These represent the minimum amount of recordkeeping that would be required normally by effective management practices. They are not as detailed and burdensome as those documentation requirements that were included in regulations associated with the EPSDT penalty.

*Comment*—One commenter suggested that the final regulation emphasize the mandatory nature of EPSDT and the consequences of being out of compliance and subverting the intent of the program.

*Response*—We believe the mandatory nature of the program is highlighted at the outset of the regulation, where it is noted that the State Plan must meet program requirements, and these are specified in the sections of the regulation that follow. Further, we believe that the new requirements for States to use effective informing methods, develop screening packages, and establish timeliness standards and periodicity schedules which meet accepted reasonable medical and dental practice standards will result in full realization of program intent.

*I. Coordination With Programs and Utilization of Providers*

*Comment*—Three commenters objected to the requirement under § 441.61 that the agency make available a "variety of individual and group providers", stating that the current regulation requires States to make maximum use of existing providers, and that the proposed rule seemed to conflict with "freedom of choice" requirements.

*Response*—Current regulations require States to make maximum use of existing services provided by *public and voluntary agencies*, not of providers per se. The proposed regulation will encourage States to broaden the provider base to include, for example, physicians in individual and group practices and primary health care centers, as well as previously listed "well-baby clinics, neighborhood health centers, rural health clinics". Hence, we believe that the reference to "a variety of individual and group providers" enhances recipients' choice of providers. This is in keeping with section 1902(a)(23) of the Act, which provides that recipients may obtain services from any qualified Medicaid provider and that States may set reasonable standards relating to providers' qualifications.

*Comment*—One commenter suggested that the regulations mention that physicians may need training to adequately fulfill their EPSDT responsibilities.

*Response*—Many States do provide a planned orientation program for newly certified providers. Therefore, we do not believe it is necessary to make this function a specific requirement in regulations, since State certification and program management processes normally address such issues.

*Comment*—One commenter requested further clarification of the phrase "individual and group providers", querying whether other health professionals, such as nurses, dietitians or social workers, were included if they were qualified and willing to provide the services.

*Response*—Qualifications to provide EPSDT services will be judged by the State Medicaid agency recognizing applicable State laws and regulations relating to scope of practice and reasonable standards of medical and dental practice. Thus, States may utilize qualified professionals (for example, in the fields noted by the commenter) who meet the applicable requirements.

*Comment*—Eleven commenters objected to the apparent elimination of manadatory coordination provisions when we combined elements contained in current § 441.59 and § 441.60 into a new section. They cited sections 1902(a)(11) and 1902(a)(22)(C) of the Act, requiring Medicaid agencies to coordinate services with Title V programs, and enter into cooperative arrangements with State agencies responsible for administering health services and vocational rehabilitation services and with Title V grantees (Maternal and Child Health/Crippled Children's Services).

One commenter suggested that the rule provide for coordination with State education agencies responsible for administering Pub. L. 94–142, The Education For All Handicapped Children Act of 1975, another suggested that State agencies be required to refer eligibles to the Special Supplemental Food Program for Women, Infants and Children (WIC), and a third recommended that the regulation describe mechanisms for facilitating coordination.

*Response*—We agree that the coordination provisions should be further clarified, and have amended the regulation: (1) To require program coordination with State health agencies, State vocational rehabilitation agencies, and Title V grantees (Maternal and Child Health/Crippled Children's Services; and (2) to identify other related programs which have come into being subsequent to the Act's provisions, with which program coordination should be made.

However, we have not made specific mention in the coordination section with regard to developing cooperative relationships and implementing interagency agreements since we believe § 431.615 provides an ample description of mechanisms to facilitate such coordination.

*Comment*—Two commenters supported retaining the current rule requiring States to refer children needing services not covered in the plan to providers willing to provide them at little or no cost. However, one commenter believed that the requirement to provide names, addresses and telephone numbers of such providers was not realistic.

*Response*—States are required to advise recipients of providers who have indicated a willingness to furnish needed but uncovered services at little or no expense to the recipient. We believe it is realistic to expect the States to have knowledge of providers willing to provide such services. Referral sources might include crippled children's services, voluntary and public agency programs offering services free or on a sliding fee scale. Cooperative interagency working relationships and networks are a useful source of information on the availability of such resources.

*J. Continuing Care Providers*

*Comment*—Eight commenters specifically endorsed the continuing care concept. Benefits cited included: (1) It brings the regulation up to date with current health delivery initiatives; (2) preventive, acute and episodic care from the same provider will bring profound long term benefit to the health of children from low income families; and (3) the need for recipients to go from provider to provider is eliminated, and

the State's administrative role is lessened.

*Response*—We agree that the continuing care option provides States enhanced flexibility to achieve child health goals while easing administrative burdens.

*Comment*—Four commenters queried whether continuing care arrangements were mandatory. Two stated that the concept should not be emphasized to the exclusion of other means of providing EPSDT services. One commenter believed that the concept could dilute service agency programs and increase costs.

*Response*—We believe that the regulation makes clear that continuing care is an optional method in administering the EPSDT program. State plans may provide for agreements with continuing care providers; and if States elect to pursue that option, they must employ methods for monitoring providers' compliance with their agreements.

We understand that not all States will wish to implement the continuing care option at this time, or be able to implement it universally within a particular State. However, we do encourage continuing care where feasible as an effective way to build ongoing provider, child and family relationships that provide for a regular source of health care. Rather than diluting the program and increasing costs, this option should result in a more consistent and coordinated delivery of services and lessening of total health care costs for EPSDT eligibles.

*Comment*—One provider contended that the continuing care option negated "freedom of choice".

*Response*—We disagree. The recipient or family chooses to enroll with a continuing care provider. Indeed, we believe that the option expands the range of choice open to recipients in those States electing to develop continuing care arrangements. Also, the regulation does not prohibit recipients from terminating their enrollment and changing providers.

*Comment*—Four commenters expressed concern with the term "formally enrolled" with a continuing care provider. Three believed the term was limited to prepaid health plans. One commenter believed the term applied to recipients enrolled in specific health programs, such as family planning or well child clinics.

*Response*—By formal enrollment, we mean that a recipient, or recipient's family, has agreed to use one continuing care provider to be the regular source of the described set of EPSDT services for a stated period of time, and that the recipient and the provider have both signed statements which specify their obligations under the continuing care arrangements. We have added clarifying language to the regulation at § 441.60(d) which describes enrollment requirements.

While it is true that the term enrollment is commonly used regarding prepaid health plans and family health centers, it is also often used in relation to individual and group practices. However, mere enrollment under capitation arrangements or prepaid health plans does not constitute a continuing care arrangement nor does enrollment in specific categorical health clinics. The State agency must determine that a provider is capable and qualified to provide the complete set of described continuing care services, have an agreement with that provider, and employ monitoring methods to assure compliance with that agreement.

*Comment*—Four commenters were unclear about who might qualify to be continuing care providers, and their need to provide all the stated EPSDT services. Some believed that the option was limited to health maintenance organizations. Others recommended that agencies providing only screening services should be included.

*Response*—Individual, group and institutional providers are potential continuing care providers, provided they are found capable and qualified, and have an agreement with the State agency to provide reports as required under § 441.60(b) and at least the set of described continuing care services under § 441.60(a). The continuing care provider could, of course, make referrals for specialty services which go beyond the practice of, for example, a pediatrician or family practitioner. Providers who furnish only screening services however, would not qualify as continuing care providers.

The set of services lists only two services to be provided at the provider's option: Dental services and transportation and scheduling assistance. The agreement must specify to what degree the provider will furnish those two. If the provider elects not to provide them, then the provider must so state in the agreement and refer recipients to the State agency to obtain those essential services.

*Comment*—Four commenters noted that the term "physicians' services" was to abstract, and suggested that the regulation make clear that a continuing care provider is responsible for provision of necessary care for acute, episodic, and chronic illnesses and conditions.

*Response*—We agree with the commenters and have amended the regulation at 42 CFR 441.60 to clarify that continuing care providers are responsible for providing physicians' services as needed by the recipient for acute, episodic and/or chronic illnesses or conditions. However, we recognize that continuing care providers may, in some instances, have to arrange for certain specialty services that are beyond the scope of their practice; e.g., ophthalmological or cardiology services.

*Comment*—Three commenters questioned how States would monitor continuing care providers. One suggested that States be required to establish periodic review plans for reviewing case files and measuring compliance with each of the terms of the continuing care agreements.

*Response*—To clarify our expectation that States will not only have, but will use, monitoring methods to assure providers' compliance with their continuing care agreements, we have amended the regulation to require that States "employ methods to assure the providers' compliance with their agreements". We do not wish to specify detailed monitoring protocols or methods, since their design, use, evaluation and redesign are essential elements of State program management. However, we have revised the language at §441.60(c) to require States to described in their State plans the methods they will use to assure that providers comply with their agreements.

*Comment*—One commenter suggested that the regulation require the continuing care provider agreements to make reference to one other specific health discipline, as it does regarding the provision of dental services; i.e., the service may be furnished by the continuing care provider or by direct referral.

*Response*—We do not believe the suggested addition would be helpful. The two options for the continuing care provider were derived from the total operational context of the EPSDT program and the usual capabilities of health service providers. How to use other specific health disciplines is a matter for State discretion and reasonable standards of medical and dental practice needed to achieve an effective and efficient child health program.

*Comment*—Two commenters were unclear how costs of continuing care providers' services would be reimbursed.

*Response*—The costs for the required set of continuing care services are legitimate Medicaid costs. The specific

reimbursement approach used is a matter determined by the State, within applicable Federal requirements. For example, the State agency may negotiate reimbursement rates for those services described in its agreement with a continuing care provider on a fee-for-service, fee-for-time, or capitation basis.

*Comment*—One commenter expressed concern that adequate tracking may not occur if case management responsibility is shifted to continuing care providers.

*Response*—Tracking is inherent in the described set of services which continuing care providers are required to provide. Moreover, as part of their program management, State agencies are required to monitor providers' compliance with their responsibilities. It is expected that case management will, in fact, improve under continuing care arrangements because the regular relationship between provider and recipient will facilitate appropriate delivery of needed health care.

*Comment*—One commenter expressed doubt that many pediatricians would become continuing care providers if reports are required.

*Response*—As required by sections 1902(a)(4) and 1902(a)(27) of the Act and § 431.17 of the regulations, all Medicaid providers are required to keep records and provide information pertaining to services furnished recipients. Moveover, specific reports may be needed by the States to monitor or evaluate continuing care arrangements, therefore, we are making no change.

*Comment*—One commenter was unclear how to divide administrative responsibility for continuing care when two State agencies jointly administer the EPSDT program.

*Response*—The Medicaid agency, as the single State agency, has final administrative responsibility; however, coordinated interagency agreements for EPSDT services are common among State health and social service agencies; and exercising the continuing care option should be viewed in that context. Interagency agreements should specify the expectations for the services each agency will provide.

*K. Transportation and Scheduling*

*Comment*—One commenter endorsed the transportation and scheduling provisions. Five commenters were unclear about the proposed use of the term "neceessary" which was not included in the current EPSDT transportation requirement.

*Response*—Even though the term "necessary" was not included, it was the intent of the current regulations to require States to provide only that transportation and scheduling assistance that is necessary for ensuring that recipients obtain needed Medicaid services. While the word "necessary" was not included in the current EPSDT regulation, it is included in the new regulation for purposes of emphasis and clarity.

The general requirement for "necessary transportation for recipients" is currently a basic State plan requirement. (See 42 CFR 431.53.) The determination of whether transportation or scheduling assistance is necessary must be decided on a case-by-case basis. This determination will depend on each individual's particular circumstances, including for example, whether the individual's family can furnish transportation, public transportation factors, the individual's physical abilities, geographic location, type of service required and available sources of medical care.

## IV. Changes to the Regulations

Based on the comments received and other considerations, we are making the following changes to the proposed rule.

*A. Informing*

We are amending regulations located at § 441.56 to:

—Require that agencies, in the informing activity, use clear and nontechnical language in providing the specified information to recipients; and

—Conform to the TEFRA provision that those 18 or older, up to age 21, are exempt from copayment requirements only at State option and that medically needy recipients may be subject to premium, enrollment or similar charges.

*B. Screening*

We are amending regulations located at § 441.56(b) to:

—More clearly reflect the language of the statute which relates to both the physical and mental health of recipients; and

—Require that dental screening services be furnished by direct referral to a dentist for children beginning at 3 years of age with exceptions permitted (within an outer limit of age 5) only if the agency can demonstrate to HCFA's satisfaction that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement. Agencies may request from HCFA exceptions for a two year period and may request additional two year exceptions.

*C. Diagnosis and Treatment*

We are amending regulations located at § 441.56(c) to:

—Emphasize that immunizations, if needed and appropriate to provide at the time of screening, can and must be provided at that time.

*D. Timeliness*

We are amending regulations located at § 441.56(e) to:

—Clarify that agencies are required to *employ* processes to ensure screening and initiation of treatment rather than simply demonstrate that processes are in place to do so; and

—Clarify that the 6 months limit begins with a request for screening and ends with initiation of treatment.

*E. Requests for Screening Services*

We are amending regulations located at § 441.59 to:

—Clarify the requirement that agencies must provide needed EPSDT services upon an eligible recipient's request, even when services were previously declined. (The only exception to this, unchanged from our proposed rule, would be when written verification exists that the most recent age-appropriate screening services due under the periodicity schedule have been provided to the individual.)

*F. Coordination With Programs and Utilization of Providers*

We are amending regulations located at § 441.61(b) to:

—Require program coordination with State health agencies, State vocational rehabilitation agencies and Title V grantees; and

—Identify other related programs with which coordination should continue to be a focus for interagency child health initiatives.

*G. Continuing Care*

We are amending regulations located at § 441.60 to:

—Clarify the meaning of formal enrollment with the continuing care provider;

—Clarify that continuing care providers are responsible for providing or arranging for, as needed by the recipient, necessary physicians' services for acute, episodic or chronic illnesses or conditions; and

—Clarify and emphasize that, in the State monitoring requirement, States must employ, rather than simply "have", methods to assure continuing care provider compliance with State agreements. States must also describe in their State plans the methods they will use to assure that providers comply with their agreements.

*H. Amending Regulations*

We are amending regulations located at § 441.50 to reflect a change made by Pub. L. 98–369. Section 1902(a)(44) of the Act was renumbered as 1902(a)(43).

In addition to changes made to the proposed rule, we are also making a minor technical change to regulations regarding sterilizations. These regulations are located at 42 CFR Part 441, Subpart F. Part 441 includes an Appendix which contains the consent forms used in connection with Medicaid-funded sterilizations. When the regulations on sterilizations were issued in 1978 (43 FR 52171) the Appendix immediately followed Subpart F. However, when Subpart G, Home and Community Based Services: Weaver Requirements, was issued in 1981 (46 FR 48541), it was inserted between Subpart F and the Appendix. Because this interrupts the continuity of the material on sterilizations, we are redesignating the Appendix to Part 441 as an Appendix immediately following Part 441, Subpart F. The title of the Appendix is also being revised to read "Appendix to Subpart F—Required Consent Form".

**V. Impact Analyses**

*A. Executive Order 12291*

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual effect on the economy of $100 million or more, cause a major increase in costs or prices, or meet other threshold criteria that are specified in that order. In addition, the Regulatory Flexibility Act (Pub. L. 96–354) requires us to prepare and publish a regulatory flexibility analysis for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities. Under both the Executive Order and the Regulatory Flexibility Act (RFA), such analysis must, when prepared, show that the agency issuing the regulations has examined alternatives that might minimize unnecessary burden or otherwise ensure the regulations to be cost-effective.

As discussed earlier, the NPRM and these final rules reflect section 2181 of Pub. L. 97–35 which eliminated the prior statutory penalty imposed under section 403(g) of the Act. That penalty reduced by one percent Federal funds for a State's Title IV–A program, AFDC, for any quarter in which a State failed to meet certain requirements. In addition, section 2181 mandated that States incorporate those requirements into their State Medicaid plan with respect to all EPSDT eligibles. Further, these final rules reduce previous reporting requirements (which entailed a large volume of paperwork) while continuing to develop a fully effective EPSDT program.

Changes From NPRM

As noted elsewhere in the preamble, we have made several changes to provisions of the NPRM. These changes are minor, mostly clarifying the language of specific provisions that restates our position as first noted in the NPRM. Therefore, these clarifications in the final rule do not change our assessment of the economic impact of this rule as first presented in the NPRM. To reiterate the major points of that discussion, we note that: (1) There is the potential for a significant economic impact on States that may have incurred a penalty under this section if it were not eliminated, however, any impact would be the result of the statute; (2) we anticipate that some reduction in State administrative costs will result because of reduced documentation burden (although no national figures exist for costs associated with documentation, we have no reason to believe that reductions will approach the criteria for a major rule); and, (3) other provisions of our regulations basically retain requirements contained in current regulations, but allow States more flexibility in designing their EPSDT programs within certain minimum limits.

Therefore, we have determined that this final rule will not result in an annual economic impact that will meet the threshold criteria of section 1(b) of the Executive Order.

*B. Regulatory Flexibility Analysis*

We note that these regulations primarily affect State Medicaid agencies by reflecting Congressional elimination of the penalty under section 403(g) of the Social Security Act, by reducing State administrative documentation burden, and increasing State flexibility in the i mplementation of their EPSDT programs. However, State Medicaid agencies do not represent small governmental jurisdictions as defined under section 601 of the Regulatory Flexibility Act. (Section 601(b) defines "small entities" as small businesses, not-for-profit enterprises independently owned and operated and not dominant in their fields, and government jurisdcitions serving less than 50,000 persons.) However, small entities that provide EPSDT services to Medicaid recipients may be affected to some degree, depending upon a State's choice to expand or limit their EPSDT programs under these regulations. We do not expect any effect to represent a significant impact on a substantial number of small entities. Therefore, the Secretary certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), that this final rule will not result in a significant impact on a substantial number of small entities.

**VI. Paperwork Reduction Act of 1980**

Sections 441.56(a) (1) and (2) (i) through (iv), 441.56(d), 441.58(b), 441.60(a) (4) and (5), 441.60(c), and 441.61(a), of this rule contain information collection. As required by section 3504h of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504), we submitted a copy of this document to the Executive Office of Management and Budget (EOMB) for its review of these information collection requirements.

Those requirements were approved on July 20, 1984 by EOMB. The EOMB approval number is 0938–0354, and the expiration date is July 31, 1987. In accordance with EOMB's regulations for controlling paperwork burdens on the public, 5 CFR Part 1320, we are revising § 400.310 by adding these sections and control number to the list of currently valid control numbers contained in that section.

**VII. List of Subjects**

*42 CFR Part 400*

Definitions, OMB Control Numbers, Reporting and recordkeeping requirements.

*42 CFR Part 441*

Abortions, Aged, Early Periodic Screening Diagnosis and Treatment (EPSDT), Family Planning, Grant-in-Aid program—Health, Health facilities, Infants and children, Institutions for mental diseases (IMD), Kidney diseases, Maternal and child health, Medicaid, Mental health centers, Ophthalmic goods and services, Penalties, Psychiatric facilities, Sterilizations.

42 CFR Chapter IV is amended as set forth below.

**PART 400—INTRODUCTION: DEFINITIONS**

The authority citation for Part 400 reads as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

**§ 400.310 [Amended]**

I. Section 400.310 is amended by inserting, in the appropriate columns, immediately preceeding the line "441.302—0938–0268", text to read as follows:

441.56(a)(1), 441.56(a)(2)(i)–441.56(a)(2)(iv), 441.56(d), 441.58(b), 441.60(a)(4)–441.60(a)(5), 441.60(c), 441.61(a)—0938–0354

## PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

II. 42 CFR Part 441 is amended as set forth below:

1. The authority citation for Part 441 is revised to read as follows:

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

2. The authority citation for Subpart B is removed.

3. The Table of Contents is amended by revising Subpart B to read as follows:

**Subpart B—Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21**

Sec.
441.50 Basis and purpose.
441.55 State plan requirements.
441.56 Required activities.
441.57 Discretionary services.
441.58 Periodicity schedule.
441.59 Treatment of requests for EPSDT screening services.
441.60 Continuing care.
441.61 Utilization of providers and coordination with related programs.
441.62 Transportation and scheduling assistance.

4. Subpart B is revised to read as follows:

### Subpart B—Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21

#### § 441.50 Basis and purpose.

This subpart implements sections 1902(a)(43) and 1905(a)(4)(B) of the Social Security Act, by prescribing State plan requirements for providing early and periodic screening and diagnosis of eligible Medicaid recipients under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found.

#### § 441.55 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of §§ 441.56–441.62, with respect to EPSDT services, as defined in § 440.40(b) of this subchapter.

#### § 441.56 Required activities.

(a) *Informing.* The agency must—

(1) Provide for a combination of written and oral methods designed to inform effectively all EPSDT eligible individuals (or their families) about the EPSDT program.

(2) Using clear and nontechnical language, provide information about the following—

(i) The benefits of preventive health care;

(ii) The services available under the EPSDT program and where and how to obtain those services;

(iii) That the services provided under the EPSDT program are without cost to eligible individuals under 18 years of age, and if the agency chooses, to those 18 or older, up to age 21, except for any enrollment fee, premium, or similar charge that may be imposed on medically needy recipients; and

(iv) That necessary transportation and scheduling assistance described in § 441.62 of this subpart is available to the EPSDT eligible individual upon request.

(3) Effectively inform those individuals who are blind or deaf, or who cannot read or understand the English language.

(4) Provide assurance to HCFA that processes are in place to effectively inform individuals as required under this paragraph, generally, within 60 days of the individual's initial Medicaid eligibility determination and in the case of families which have not utilized EPSDT services, annually thereafter.

(b) *Screening.* (1) The agency must provide to eligible EPSDT recipients who request it, screening (periodic comprehensive child health assessments); that is, regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. (See paragraph (c)(3) of this section for requirements relative to provision of immunization at the time of screening.) As a minimum, these screenings must include, but are not limited to:

(i) Comprehensive health and developmental history.

(ii) Comprehensive unclothed physical examination.

(iii) Appropriate vision testing.

(iv) Appropriate hearing testing.

(v) Appropriate laboratory tests.

(vi) Dental screening services furnished by direct referral to a dentist for children beginning at 3 years of age. An agency may request from HCFA an exception from this age requirement (within an outer limit of age 5) for a two year period and may request additional two year exceptions. If an agency requests an exception, it must demonstrate to HCFA's satisfaction that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement.

(2) Screening services in paragraph (b)(1) of this section must be provided in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care.

(c) *Diagnosis and treatment.* In addition to any diagnostic and treatment services included in the plan, the agency must provide to eligible EPSDT recipients, the following services, the need for which is indicated by screening, even if the services are not included in the plan—

(1) Diagnosis of and treatment for defects in vision and hearing, including eyeglasses and hearing aids;

(2) Dental care, at as early an age as necessary, needed for relief of pain and infections, restoration of teeth and maintenance of dental health; and

(3) Appropriate immunizations. (If it is determined at the time of screening that immunization is needed and appropriate to provide at the time of screening, then immunization treatment must be provided at that time.)

(d) *Accountability.* The agency must maintain as required by §§ 431.17 and 431.18—

(1) Records and program manuals;

(2) A description of its screening package under paragraph (b) of this section; and

(3) Copies of rules and policies describing the methods used to assure that the informing requirement of paragraph (a)(1) of this section is met.

(e) *Timeliness.* With the exception of the informing requirements specified in paragraph (a) of this section, the agency must set standards for the timely provision of EPSDT services which meet reasonable standards of medical and dental practice, as determined by the agency after consultation with recognized medical and dental organizations involved in child health care, and must employ processes to ensure timely initiation of treatment, if required, generally within an outer limit of 6 months after the request for screening services.

#### § 441.57 Discretionary services.

Under the EPSDT program, the agency may provide for any other medical or remedial care specified in Part 440 of this subchapter, even if the agency does not otherwise provide for these services to other recipients or provides for them in a lesser amount, duration, or scope.

#### § 441.58 Periodicity schedule.

The agency must implement a periodicity schedule for screening services that—

(a) Meets reasonable standards of medical and dental practice determined by the agency after consultation with

recognized medical and dental organizations involved in child health care;

(b) Specifies screening services applicable at each stage of the recipient's life, beginning with a neonatal examination, up to the age at which an individual is no longer eligible for EPSDT services; and

(c) At the agency's option, provides for needed screening services as determined by the agency, in addition to the otherwise applicable screening services specified under paragraph (b) of this section.

**§ 441.59 Treatment of requests for EPSDT screening services.**

(a) The agency must provide the screening services described in § 441.56(b) upon the request of an eligible recipient.

(b) To avoid duplicate screening services, the agency need not provide requested screening services to an EPSDT eligible if written verification exists that the most recent age-appropriate screening services, due under the agency's periodicity schedule, have already been provided to the eligible.

**§ 441.60 Continuing care.**

(a) *Continuing care provider.* For purposes of this subpart, a continuing care provider means a provider who has an agreement with the Medicaid agency to provide reports as required under paragraph (b) of this section and to provide at least the following services to eligible EPSDT recipients formally enrolled with the provider:

(1) With the exception of dental services required under § 441.56, screening, diagnosis, treatment, and referral for follow-up services as required under this subpart.

(2) Maintenance of the recipient's consolidated health history, including information received from other providers.

(3) Physicians' services as needed by the recipient for acute, episodic or chronic illnesses or conditions.

(4) At the provider's option, provision of dental services required under § 441.56 or direct referral to a dentist to provide dental services required under § 441.56(b)(1)(vi). The provider must specify in the agreement whether dental services or referral for dental services are provided. If the provider does not choose to provide either service, then the provider must refer recipients to the agency to obtain those dental services required under § 441.56.

(5) At the provider's option, provision of all or part of the transportation and scheduling assistance as required under § 441.62. The provider must specify in the agreement the transportation and scheduling assistance to be furnished. If the provider does not choose to provide some or all of the assistance, then the provider must refer recipients to the agency to obtain the transportation and scheduling assistance required under § 441.62.

(b) *Reports.* A continuing care provider must provide to the agency any reports that the agency may reasonably require.

(c) *State monitoring.* If the State plan provides for agreements with continuing care providers, the agency must employ methods described in the State plan to assure the providers' compliance with their agreements.

(d) *Effect of agreement with continuing care providers.* Subject to the requirements of paragraphs (a), (b), and (c) of this section, HCFA will deem the agency to meet the requirements of this subpart with respect to all EPSDT eligible recipients formally enrolled with the continuing care provider. To be formally enrolled, a recipient or recipient's family agrees to use one continuing care provider to be a regular source of the described set of services for a stated period of time. Both the recipient and the provider must sign statements that reflect their obligations under the continuing care arrangement.

(e) If the agreement in paragraph (a) of this section does not provide for all or part of the transportation and scheduling assistance required under § 441.62, or for dental service under § 441.56, the agency must provide for those services to the extent they are not provided for in the agreement.

**§ 441.61 Utilization of providers and coordination with related programs.**

(a) The agency must provide referral assistance for treatment not covered by the plan, but found to be needed as a result of conditions disclosed during screening and diagnosis. This referral assistance must include giving the family or recipient the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.

(b) The agency must make available a variety of individual and group providers qualified and willing to provide EPSDT services.

(c) The agency must make appropriate use of State health agencies, State vocational rehabilitation agencies, and Title V grantees (Maternal and Child Health/Crippled Children's Services). Further, the agency should make use of other public health, mental health, and education programs and related programs, such as Head Start, Title XX (Social Services) programs; and the Special Supplemental Food Program for Women, Infants and Children (WIC), to ensure an effective child health program.

**§ 441.62 Transportation and scheduling assistance.**

The agency must offer to the family or recipient, and provide if the recipient requests—

(a) Necessary assistance with transportation as required under § 431.53 of this chapter; and

(b) Necessary assistance with scheduling appointments for services.

5. The Appendix to Part 441 is redesignated as an Appendix immediately following Part 441 Subpart F. The title of the Appendix is revised to read as follows:

**Appendix to Subpart F—Required Consent Form**

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program)

Dated: March 15, 1984.

**Carolyne K. Davis,**

*Administrator, Health Care Financing Administration.*

Approved: June 29, 1984.

**Margaret M. Heckler,**

*Secretary.*

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## FEDERAL COMMUNICATIONS COMMISSION

**47 CFR Ch. I**

**[CC Docket No. 81-893; FCC 84-483]**

## Procedures for Implementing Detariffing of Customer Premises Equipment and Enhanced Services (Second Computer Inquiry)

**AGENCY:** Federal Communications Commission.

**ACTION:** Order establishing requirements (Third Report and Order).

**SUMMARY:** This Order establishes rules and requirements regarding the removal from regulated service of embedded customer premises equipment (CPE) owned by Independent telephone companies and tariffed at the state level. The Order is necessary because it constitutes a further step taken by the Commission in removing carrier-supplied CPE from tariff regulation, consistent with the policies established by the Commission in other proceedings. The intended effect of this Order is to: