

(a)(3), (a)(6), (b), and (c) to read as follows:

**§ 334.610 Key West Harbor, at U.S. Naval Base, Key West, Fla.; naval restricted areas and danger zone.**

**(a) The areas. \* \* \***

(3) All waters within 100 yards of the U.S. Coast Guard Station and the westerly end of Trumbo Point Annex beginning at the shore at Latitude 24°33'47.6" N., Longitude 81°47'55.6" W.; thence westerly to Latitude 24°33'48" N., Longitude 81°48'00.9" W.; thence due south to Latitude 24°33'45.8" N., Longitude 81°48'00.9" W.; thence westerly to Latitude 24°33'47" N., Longitude 81°48'12" W.; thence northerly to Latitude 24°34'06.2" N., Longitude 81°48'10" W.; thence easterly to a point joining the restricted area around Fleming Key at Latitude 24°34'03.3" N., Longitude 81°47'55" W. (Area #3).

**(6) Danger zone.** All waters within an area along the northeast side of the Naval Air Station on Boca Chica Key defined by a line beginning at Latitude 24°35'27.2" N., Longitude 81°41'48.6" W.; thence proceed in a northerly direction to a point at Latitude 24°35'48" N., Longitude 81°41'49" W.; thence proceed westerly to a point on the shore at Latitude 24°35'49.1" N., Longitude 81°42'03" W. (Area #6).

**(b) The Regulations:** (1) Entering or crossing Restricted Areas #1 and #4 and the Danger Zone (Area #6) described in Paragraph (a) of this section is prohibited.

(2) Privately owned vessels, properly registered and bearing identification in accordance with Federal and/or State laws and regulations may transit the following portions of restricted areas #2, #3 and #5. NOTE: All vessels entering the areas at night must display lights as required by Federal laws and Coast Guard regulations or, if no constant lights are required, then the vessel must display a bright white light showing all around the horizon.

(i) The channel, approximately 75 yards in width, extending from the northwest corner of Pier D-3 of Trumbo Point Annex, eastward beneath the Fleming Key bridge and along the north shore of Trumbo Point Annex (area #3).

(ii) A channel of 150 feet in width which extends easterly from the main ship channel into Key West Bight, the northerly edge of which channel passes 25 feet south of the Trumbo Point Annex piers on the north side of the Bight. While the legitimate access of privately owned vessels to facilities of Key West Bight is unimpeded, it is prohibited to moor, anchor, or fish

within 50 feet of any U.S. Government-owned pier or craft (area #3).

(iii) The dredged portion of Boca Chica channel from its seaward end to a point due south of the east end of the Boca Chica Bridge (area #5).

(iv) All of the portion of Restricted Area No. 2 that lies between the Truman Annex Mole and the Key West Harbor Range Channel. The transit zone extends to the northeasterly corner of the Truman Annex Mole, thence to the northwesterly end of the breakwater at Latitude 24°33'21.3" N, Longitude 81°48'32.7" W.

(3) Stopping or landing by other than Government-owned vessels and specifically authorized private craft in any of the restricted areas or danger zone described in Paragraph (a) of this section is prohibited.

(4) Vessels using the restricted channel areas described in paragraph (b)(2) (i), (ii), (iii), and (iv) of this section shall proceed at speeds commensurate with minimum wake.

(c) The regulations in this section shall be enforced by the Commanding Officer, Naval Air Station, Key West, Florida, and such agencies as he/she may designate.

Dated: September 6, 1994.

Stanley G. Genega,  
Major General, U.S. Army, Director of Civil Works.

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BILLING CODE 3710-82-M

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 70

[WY-001a; FRL-5076-2]

### Clean Air Act Interim Approval of Operating Permit Program; State of Wyoming

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

**ACTION:** Direct final rule.

**SUMMARY:** The EPA is promulgating interim approval of the Operating Permit Program submitted by the State of Wyoming. Wyoming's Operating Permit Program was submitted for the purpose of complying with Federal requirements which mandate that states develop, and submit to EPA, programs for issuing operating permits to all major stationary sources, and to certain other sources.

**DATES:** This direct final rule is effective on November 22, 1994 unless adverse or critical comments are received by October 24, 1994. If the effective date is

delayed, timely notice will be published in the **Federal Register**.

**ADDRESSES:** Comments should be addressed to Laura Farris, 8ART-AP, at the EPA Regional 8 Office listed.

Copies of the State's submittal and other supporting information used in developing this final rule are available for public inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 8, 999 18th Street, suite 500, Denver, Colorado 80202.

### FOR FURTHER INFORMATION CONTACT:

Laura Farris, 8ART-AP, U.S. Environmental Protection Agency, Region 8, 999 18th Street, suite 500, Denver, Colorado 80202, (303) 294-7539.

### SUPPLEMENTARY INFORMATION:

#### I. Background

As required under title V of the Clean Air Act ("the Act") as amended (1990), EPA has promulgated rules which define the minimum elements of an approvable state operating permit program and the corresponding standards and procedures by which the EPA will approve, oversee, and withdraw approval of state operating permit programs (see 57 FR 32250 (July 21, 1992)). These rules are codified at 40 Code of Federal Regulations (CFR) part 70 (part 70), title V requires states to develop, and submit to EPA, programs for issuing these operating permits to all major stationary sources and to certain other sources.

The Act requires that states develop and submit these programs to EPA by November 15, 1993, and that EPA act to approve or disapprove each program within 1 year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the part 70 regulations, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of part 70, EPA may grant the program interim approval for a period of up to 2 years. If EPA has not fully approved a program by 2 years after the November 15, 1993 date, or by the end of an interim program, it must establish and implement a Federal program.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial action and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing interim approval of the Operating Permit Program submitted by the State of Wyoming should adverse or critical

comments be filed. Under the procedures established in the May 10, 1994 *Federal Register*, this action will be effective on November 22, 1994 unless, by October 24, 1994, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on November 22, 1994.

## II. Final Action and Implications

### A. Analysis of State Submission

#### 1. Support Materials

The Governor of Wyoming submitted an administratively complete title V Operating Permit Program (PROGRAM) for the State of Wyoming on November 19, 1993. EPA deemed the PROGRAM administratively complete in a letter to the Governor dated January 4, 1994. The PROGRAM submittal includes a legal opinion from the Attorney General of Wyoming stating that the laws of the State provide adequate legal authority to carry out all aspects of the PROGRAM, and a description of how the State intends to implement the PROGRAM. The submittal additionally contains evidence of proper adoption of the PROGRAM regulations, application and permit forms, and a permit fee demonstration.

#### 2. Regulations and Program Implementation

The Wyoming PROGRAM, including the operating permit regulation (Section 30 of the Wyoming Air Quality Standards and Regulations), substantially meets the requirements of 40 CFR 70.2 and 70.3 with respect to applicability; 40 CFR 70.4, 70.5, and 70.6 with respect to permit content including operational flexibility; 40 CFR 70.5 with respect to complete application forms and criteria which define insignificant activities (emission thresholds are identified in section 30 as one ton per year for regulated pollutants, excluding hazardous air pollutant [HAP] sources, and 1000 pounds per year for HAPs); 40 CFR 70.7 with respect to public participation and minor permit modifications; and 40 CFR 70.11 with respect to requirements for enforcement authority.

Wyoming has the authority to issue a variance from requirements imposed by State law (36-11-601 W.S.A.). The EPA regards this provision as wholly external to the PROGRAM submitted for approval under part 70, and consequently is proposing to take no action on this provision of State law. The EPA has no authority to approve provisions of State law, such as the variance provision referred to, which are inconsistent with the Act. The EPA does not recognize the ability of a permitting authority to grant relief from the duty to comply with a federally enforceable part 70 permit, except where such relief is granted through procedures allowed by part 70. The EPA reserves the right to enforce the terms of the part 70 permit where the permitting authority purports to grant relief from the duty to comply with a part 70 permit in a manner inconsistent with part 70 procedures.

Part 70 of the operating permit regulations requires prompt reporting of deviations from the permit requirements. Section 70.6(a)(3)(iii)(B) requires the permitting authority to define prompt in relation to the degree and type of deviation likely to occur and the applicable requirements. Although the permit program regulations should define prompt for purposes of administrative efficiency and clarity, an acceptable alternative is to define prompt in each individual permit. The EPA believes that prompt should generally be defined as requiring reporting within two to ten days of the deviation. Two to ten days is sufficient time in most cases to protect public health and safety as well as to provide a forewarning of potential problems. For sources with a low level of excess emissions, a longer time period may be acceptable. However, prompt reporting must be more frequent than the semiannual reporting requirement, given this is a distinct reporting obligation under § 70.6(a)(3)(iii)(A). Where "prompt" is defined in the individual permit but not in the program regulations, EPA may veto permits that do not contain sufficiently prompt reporting of deviations. The Wyoming PROGRAM has not defined prompt reporting of deviations.

A letter sent to the State dated May 10, 1994, identified areas in which the Wyoming PROGRAM was deficient and the corrective actions that were to be completed either prior to interim PROGRAM approval or prior to full PROGRAM approval. In a letter dated June 7, 1994, which included an Attorney General's opinion dated June 6, 1994, the State addressed all EPA issues that would have prevented EPA

from issuing interim approval of the Wyoming PROGRAM.

The State has not addressed those issues that require corrective action prior to full PROGRAM approval. Areas in which the Wyoming PROGRAM is deficient and require corrective action prior to full PROGRAM approval are as follows: (1) Section 30 states that research and development (R&D) operations will be considered as separate and discrete stationary sources when determining whether such operations are subject to the PROGRAM. If an R&D facility is a support facility (co-located with a separate source, under common ownership or control and 50% of the output of the support unit is used by the main activity), the emissions from this R&D facility must be included, along with all other emissions at the source, to determine applicability to section 30. Section 30 must be revised to assure R&D support facilities are included in major source determinations. (2) Language in the Wyoming Environmental Quality Act (WEQA) appears to reduce the penalty for civil violations committed by surface coal mine operations from a maximum of ten thousand dollars per day to five thousand dollars per day. This language needs to be changed in the WEQA or clarified in an Attorney General's opinion to indicate that the five thousand dollar penalty relates only to activities subject to the Surface Mining Control and Reclamation Act. (3) The WEQA bases individual and corporate liability on knowing and willful violations of the WEQA. This statute needs to be revised to include language that provides strict liability for corporate officers, directors or agents in civil actions. (4) The WEQA does not provide for a per day, per violation penalty for false statements or tampering with monitoring devices, only a fine of ten thousand dollars or imprisonment for one year in county jail, or both. The statute needs to be changed to include a per day, per violation penalty. (5) Section 30 requires insignificant activities to be listed in permit applications, but does not require that applicable requirements that might apply to such activities be identified. The general provision of 40 CFR 70.5(c) ensures that information concerning applicable requirements will be included in the application. Section 30 must be revised to include language similar to the general provision in 40 CFR 70.5(c), or an AG's opinion must clarify that the State will ensure that all applicable requirements are identified for any insignificant activities. (6) The provision in section 30 regarding

general permits is inconsistent with § 70.6(d) because they do not require notice and an opportunity for public participation consistent with § 70.7(h). This provision must be revised or clarified in an Attorney General's Opinion. (7) It is unclear if section 30 provides the State with authority to implement emissions trading under a permit cap, which is required by § 70.4(b)(12)(iii). The State must clarify its authority on this issue, or revise section 30 to provide such authority. (8) The Governor's letter submitting the Wyoming PROGRAM states that the PROGRAM will apply to all applicable operating stationary sources of air pollutants within the State of Wyoming "with the exception of those sources located on Indian lands." However, the PROGRAM does not define "Indian lands." The State must provide such a definition prior to full PROGRAM approval.

Refer to the technical support document accompanying this rulemaking for a detailed explanation of each PROGRAM deficiency and the State's corrective actions, where provided.

### 3. Permit Fee Demonstration

The State of Wyoming established an initial fee for regulated air pollutants below the presumptive minimum set in title V, section 502 and part 70, and was required to submit a detailed permit fee demonstration as part of its PROGRAM submittal. The basis of this fee demonstration included a workload analysis, which estimated the annual cost of running the PROGRAM to be \$1.43 million. This amount, divided by the total actual emissions from part 70 sources, resulted in a \$10 per ton fee for actual emissions of regulated air pollutants for fiscal year 1993 (fees will not be charged on emissions exceeding 4,000 tons per year per pollutant at a source). This fee structure is subject to a biennial review by the Wyoming Joint Minerals, Business and Economic Development Committee. After careful review, the State of Wyoming determined that these fees would support the PROGRAM costs as required by 40 CFR 70.9(a). Upon review of this demonstration, the EPA noted the following concern: The WEQA gives the State the authority to assess and collect annual permit fees in an amount sufficient to cover all reasonable direct and indirect costs of the PROGRAM for a two year period of time. The Wyoming Legislature must authorize an increase in such fees. If such an increase is not granted, and the State is not able to fund all the costs of the PROGRAM, the EPA would be required to disapprove or

withdraw the part 70 program, impose sanctions, and implement a Federal permitting program.

### 4. Provisions Implementing the Requirements of Other Titles of the Act

*a. Authority and/or Commitments for section 112 Implementation.* Wyoming has demonstrated in its PROGRAM submittal adequate legal authority to implement and enforce all section 112 requirements through the title V permit. This legal authority is contained in Wyoming's WEQA and in regulatory provisions defining "applicable requirements" by stating that the permit must incorporate all applicable requirements. EPA has determined that this legal authority is sufficient to allow Wyoming to issue permits that assure compliance with all section 112 requirements.

For further rationale on this interpretation, please refer to the Technical Support Document accompanying this rulemaking and the April 13, 1993 guidance memorandum titled "Title V Program Approval Criteria for Section 112 Activities," signed by John Seitz.

*b. Implementation of 112(g) Upon Program Approval.* As a condition of approval of the part 70 PROGRAM, Wyoming is required to implement section 112(g) of the Act from the effective date of the part 70 PROGRAM. Imposition of case-by-case determinations of a maximum achievable control technology (MACT) under section 112(g) will require the use of a mechanism for establishing federally enforceable restrictions on a source-specific basis. The EPA is proposing to approve Wyoming's preconstruction permitting program found in section 24, under the authority of title V and part 70 solely for the purpose of implementing section 112(g) during the transition period between title V approval and adoption of a State rule implementing EPA's section 112(g) regulations. EPA believes this approval is necessary so that Wyoming has a mechanism in place to establish federally enforceable restrictions for section 112(g) purposes from the date of part 70 approval. Section 112(l) provides statutory authority for approval for the use of State air programs to implement section 112(g), and title V and section 112(g) provide authority for this limited approval because of the direct linkage between implementation of section 112(g) and title V. The scope of this approval is narrowly limited to section 112(g), and does not confer or imply approval for purposes of any other provision under the Act. If Wyoming does not wish to

implement section 112(g) through its preconstruction permit program and can demonstrate that an alternative means of implementing section 112(g) exists, the EPA may, in the final action approving Wyoming's PROGRAM, approve the alternative instead. To the extent the State does not have the authority to regulate HAPs through existing State law, the State may disallow modifications during the transition period.

This approval is for an interim period only, until such time as the State is able to adopt regulations consistent with any regulations promulgated by EPA to implement section 112(g). Accordingly, EPA is proposing to limit the duration of this approval to a reasonable time following promulgation of section 112(g) regulations so that Wyoming, acting expeditiously, will be able to adopt regulations consistent with the section 112(g) regulations. The EPA is proposing here to limit the duration of this approval to 18 months following promulgation by EPA of section 112(g) regulations. Comment is solicited on whether 18 months is an appropriate period considering Wyoming's procedures for adoption of Federal regulations.

*c. Program for Straight Delegation of section 112 Standards.* Requirements for approval, specified in 40 CFR 70.4(b), encompass section 112(l)(5) requirements for approval of a program for delegation of section 112 general provisions subpart A and standards as promulgated by EPA as they apply to part 70 sources. Section 112(l)(5) requires that the State's program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule, which are also requirements under part 70. The State of Wyoming acknowledges that its request for approval of a part 70 program is also a request for approval of a program for delegation of unchanged existing and future section 112 requirements under the authority of section 112(l) as they apply to part 70 sources. This shall include the most recent versions of any existing standards and all future requirements promulgated under section 112, including the general provisions for part 63 and all other infrastructure rules. The State can now receive delegation of any new authority required by section 112 of the Act through the delegation process.

The radionuclide national emission standard for HAPs (NESHAP) is a section 112 regulation and therefore, also an applicable requirement under the State PROGRAM. Sources which are currently defined as part 70 sources and emit radionuclides are subject to

Federal radionuclide standards. Currently the State of Wyoming has no such sources. However, sources which are not currently part 70 sources may be defined as major sources under forthcoming Federal radionuclide regulations. The EPA will work with the State in the development of its radionuclide program to ensure that permits are issued in a timely manner.

The State also has the option at any time to request, under section 112(l) of the Act, delegation of section 112 requirements in the form of State regulations which the State demonstrates are equivalent to the corresponding section 112 provisions promulgated by EPA. At this time, the State plans to use the mechanism of case-by-case rulemaking to adopt unchanged Federal section 112 requirements into its regulations.

Therefore, the EPA is also proposing to grant approval under section 112(l)(5) and 40 CFR 63.91 of the State's program for receiving delegation of section 112 standards that are unchanged from the Federal standards as promulgated.

*d. Program for Implementing Title IV of the Act.* Wyoming's PROGRAM contains adequate authority to issue permits which reflect the requirements of title IV of the Act, and commits to adopt the rules and requirements promulgated by EPA to implement an acid rain program through the title V permit.

#### *B. Options for Approval/Disapproval and Implications*

The EPA is promulgating interim approval to the operating permit program submitted by the State of Wyoming on November 19, 1993. The State must make the changes discussed above to receive full approval. Evidence of these statutory and regulatory revisions must be submitted to EPA within 18 months of EPA's interim approval of the Wyoming PROGRAM.

At the time of this document, the State had not made an affirmative showing of legal authority to regulate sources within the exterior boundaries of Indian Reservations in Wyoming under the Act. Therefore, interim approval of the Wyoming PROGRAM will not extend to lands within the exterior boundaries of Indian Reservations. Until the State makes such a showing, part 70 sources within the exterior boundaries of Indian Reservations in Wyoming will be subject to the Federal operating permit program to be promulgated in 40 CFR part 71, or subject to the program of any Tribe delegated such authority under section 301(d) of the Act. The EPA anticipates promulgating an Indian Air

Regulation, at which time how the State defines Indian lands could become an approval issue.

This interim approval, which may not be renewed, extends for a period of up to two years. During the interim approval period, the State is protected from sanctions for failure to have a program, and EPA is not obligated to promulgate a Federal permit program in the State. Permits issued under a program with interim approval have full standing with respect to part 70, and the one year time period for submittal of permit applications by subject sources begins upon interim approval, as does the three year time period for processing the initial permit applications.

Requirements for approval, specified in 40 CFR 70.4(b), encompass section 112(l)(5) requirements for approval of a program for delegation of section 112 standards as promulgated by EPA as they apply to part 70 sources. Section 112(l)(5) requires that the State's program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule, which are also requirements under part 70. Therefore, the EPA is also proposing to grant approval under section 112(l)(5) and 40 CFR 63.91 of the State's program for receiving delegation of section 112 standards that are unchanged from Federal standards as promulgated. This program for delegations only applies to sources covered by the part 70 program.

### **III. Administrative Requirements**

#### *A. Request for Public Comments*

The EPA is requesting comments on all aspects of this direct final rule. Copies of the State's submittal and other information relied upon for the development of this rule are contained in a docket maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the review of the PROGRAM and development of this rule. The principal purposes of the docket are:

- (1) To allow interested parties a means to identify and locate documents so that they can effectively participate in the rulemaking process; and
- (2) To serve as the record in case of judicial review. The EPA will consider any comments received by October 24, 1994.

#### *B. Executive Order 12866*

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

#### *C. Regulatory Flexibility Act*

The EPA's actions under section 502 of the Act do not create any new requirements, but simply address operating permit programs submitted to satisfy the requirements of 40 CFR part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

#### **List of Subjects in 40 CFR Part 70**

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401-7671q.

Dated: September 14, 1994.

Kerrigan Clough,

Acting Regional Administrator.

[FR Doc. 94-23599 Filed 9-22-94; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Care Financing Administration**

#### **42 CFR Parts 435 and 436**

[MB-52-IFC]

RIN 0938-AF69

#### **Medicaid Program: Outstation Intake Locations for Certain Low-Income Pregnant Women, Infants, and Children Under Age 19**

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

ACTION: Interim final rule with comment period.

**SUMMARY:** This interim final rule interprets the statutory requirement that State Medicaid agencies must provide for receiving and initially processing Medicaid applications by certain low-income pregnant women, infants, and children under age 19 at locations other than those used for the receipt and processing of applications for Aid to Families with Dependent Children (AFDC). The statutory requirement also provides that the application form for these individuals must be different from the application form used for AFDC.

The basis for the rule is section 1902(a)(55) of the Social Security Act, as added by section 4602(a)(3) of the Omnibus Budget Reconciliation Act of 1990.

**DATES: Effective Date.** This interim final rule is effective on October 24, 1994.

**Comment Date.** Comments will be considered if received at the appropriate

address, as provided in the "ADDRESSES" section below, no later than 5:00 p.m. on November 22, 1994. ADDRESSES: Mail comments (original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: MB-52-IFC, P.O. Box 7518, Baltimore, Md. 21207-0518.

Please address a copy of comments on information collection requirements to: Office of Information and Regulatory Affairs, Attention: Laura Oliven, Office of Management and Budget, Room 3002, New Executive Office Building, Washington, DC 20503.

If you prefer, you may deliver your comments (original and three copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Because of staffing and resource limitations, we cannot accept comments of facsimile (FAX) transmission.

In commenting, please refer to file code MB-52-IFC. Timely comments will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (telephone: (202) 690-7890). FOR FURTHER INFORMATION CONTACT: Robert Tomlinson, (410) 966-4463.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Generally, sections 1902(a)(10)(A) and (C) of the Social Security Act (the Act) specify the groups of individuals who may be eligible for Medicaid. Among these groups are low-income pregnant women, infants, and children under age 19 who have incomes that are a specified percentage of the Federal poverty level. Because Medicaid eligibility for many of the eligibility groups specified under section 1902(a)(10)(A) is associated with eligibility for or receipt of Aid to Families With Dependent Children (AFDC), many State Medicaid agencies provide for the receipt and processing of Medicaid applications at welfare offices, either concurrent with or separate from application for AFDC or other cash assistance. In most cases in which an individual is determined to be eligible for AFDC on the basis of an AFDC application, Medicaid eligibility is automatic without a separate Medicaid

application. For other eligibility groups, such as low-income pregnant women, infants, and children under age 19 with incomes related to the Federal poverty level, eligibility for Medicaid is not associated with AFDC eligibility.

In an effort to make the Medicaid application process more accessible to low-income pregnant women, infants, and children under age 19, Congress enacted section 4602 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508, on November 5, 1990. Section 4602(a)(3) amended the Social Security Act to add a new Medicaid State plan requirement under section 1902(a)(55) relating to the application process for these eligibility groups. The new section 1902(a)(55) requires that a State Medicaid plan provide for receipt and initial processing of Medicaid applications from the following groups of individuals at locations other than those used for processing applications for AFDC and for using at these locations an application form for Medicaid that is not the AFDC application form:

- Individuals specified under section 1902(a)(10)(A)(i)(IV) of the Act (the mandatory eligibility group of pregnant women or infants with incomes up to 133 percent of the Federal poverty level);
- Individuals specified under section 1902(a)(10)(A)(i)(VI) of the Act (the mandatory eligibility group of children age 1 up to age 6 with incomes at 133 percent of the Federal poverty level);
- Individuals specified under section 1902(a)(10)(A)(i)(VII) of the Act (the mandatory eligibility group of children age 6 up to age 19 born after September 30, 1983, with incomes up to 100 percent of the Federal poverty level);
- Individuals specified under section 1902(a)(10)(A)(ii)(IX) of the Act (the optional eligibility groups of pregnant women or infants, children age 1 up to age 6, and children age 6 up to age 19, who are not eligible as a mandatory group, with incomes up to 185 percent of the Federal poverty level).

Section 1902(a)(55) provides that the outstation locations for receipt and initial processing of applications for these individuals must include facilities defined as disproportionate share hospitals under section 1923(a)(1)(A) of the Act and Federally-qualified health centers described in section 1905(1)(2)(B) of the Act.

The provisions of section 1902(a)(55) apply to Medicaid payments for calendar quarters beginning on or after July 1, 1991, without regard to whether final regulations to carry out the provisions have been promulgated by that date.

##### II. Provisions of the Regulations

We are amending the Medicaid regulations under 42 CFR parts 435 and 436 to incorporate the provisions of section 1902(a)(55) of the Act. Specifically—

##### 1. Outstation Locations

We have added a new § 435.904 to require that the State Medicaid agency provide an opportunity for the designated groups of low-income pregnant women, infants, and children under age 19 to apply for Medicaid and have their application initially processed at locations other than those at which AFDC applications are received and processed. The statutory language of section 1902(a)(55) of the Act, as added by section 4602 of OBRA '90, requires that States provide an opportunity to apply for Medicaid at locations other than welfare offices, including Federally-qualified health centers and disproportionate share hospitals. By specifying that certain types of facilities be among the outstation locations, Congress clearly intended that, at a minimum, Federally-qualified health centers and disproportionate share hospitals would be among the outstation locations.

We consulted extensively with States and related organizations and agencies before developing these interim final regulations. During this consultation, we considered the option of requiring States to outstation staff at every site operated by each Federally-qualified health center and disproportionate share hospital. However, we rejected this requirement because we believe that it would be burdensome on the States. Therefore, to provide States with as much flexibility as possible, especially in this era of restricted resources, we have chosen to offer States two choices for implementing the outstationing requirement. A State may establish outstation locations at each Federally-qualified health center and each disproportionate share hospital participating in the State's Medicaid program and providing services to Medicaid-eligible pregnant women and to children, but not at every site operated by these entities. As an alternative, a State may submit a plan that provides for outstation locations which include at least some Federally-qualified health centers and disproportionate share hospitals, but not all such entities that provide services to the target populations. For the alternative plan to be approved by HCFA, the State must demonstrate that it is equally or more effective in outreach than a plan that would meet

the general requirement, including the same level of staffing and funding by the State as the State would be required to commit to implement outstationing under the general requirement.

We are requiring that the outstations include Indian health clinics operated by a tribe or tribal organization, as these clinics are specifically included in the definition of Federally-qualified health centers under section 1905(1)(2)(B) of the Act, and included in the definition of rural health clinics under 42 CFR part 491, subpart A. If a Federally-qualified health center or disproportionate share hospital has more than one site, the State must ensure that applications for Medicaid can be taken at an outstation location.

In addition to placing outstationed eligibility workers at Federally-qualified health centers and disproportionate share hospitals (or locations under an approved alternative plan) that provide services to Medicaid-eligible pregnant women and to children, States may consider other locations that are frequently visited by the targeted populations. For example, States may consider family support centers or school-linked service centers in addition to other sites operated by Federally-qualified health centers as suitable outstation locations.

To permit additional flexibility, we are allowing a State, at its option, to enter into reciprocal agreements with adjoining States to ensure that the population living in border areas of a State have the opportunity to apply for Medicaid at the health care locations they normally frequent when those facilities are in another State (§ 435.904(c)(4)).

## 2. Initial Processing

Section 1902(a)(55) provides for "initial processing" of applications for the designated low-income pregnant women, infant, and children groups. However, the phrase "initial processing" is ambiguous and is not defined in the statute. The House Report accompanying OBRA '90 states that the "entire application process would be conducted at [an outstation]," and that the final eligibility determination could also be made there. The language of the House Report goes further to state that "even if the eligibility worker were an employee of the hospital or clinic, the pregnant woman or child would not be required to go to the welfare office for a face-to-face interview in order to complete the eligibility determination process. Instead, the simplified application form, along with necessary documentation, would then be forwarded to the welfare office for final

determination." (H. Rept. No. 881, 101st Cong., 2d Sess. 105 (1990)). We are, therefore, defining "initial processing" to mean taking applications, assisting applicants in completing the application, providing information and referrals, obtaining required documentation to complete processing of the application, assuring that the information contained on the application form is complete, and conducting any necessary interviews. Initial processing does not include evaluating the information contained on the application and the supporting documentation nor making a determination of eligibility or ineligibility § 435.904(d)(2). Even though the phrase "initial processing" is not defined to include determinations of eligibility or ineligibility, State eligibility workers who are assigned to outstation locations may perform these tasks if they are authorized to do so in the regular Medicaid agency intake office, as discussed in detail below. If we were to define initial processing to include making a determination of eligibility, the definition would conflict with the requirement of section 1902(a)(5) of the Act. Under section 1902(a)(5), the plan must be administered by a single State agency and determination of eligibility is restricted by this section to the Medicaid agency, the title IV-A agency, or SSA when administering the SSI program.

## 3. Staffing

The State must assure HCFA that staff are available at each outstation location to accept applications and assist applicants with the application process during the hours that the regular State Medicaid offices are normally open (§ 435.904(e)). In addition, we are providing an exception to this requirement for staffing, and hours when staff are available, at locations that are infrequently used by the designated groups of low-income pregnant women, infants, and children. To fulfill the spirit of this legislation, we also encourage States to make outstation workers available at additional hours in the evening or on weekends beyond the minimum staffing requirement set forth in these regulations, thereby making access and the opportunity to apply for Medicaid as easy as possible for the designated groups.

In order to provide the States with as much flexibility as possible, we are allowing States to target and conserve their resources while complying with the requirement on availability of staff. We are not requiring outstation intake workers to be employees of the State

Medicaid agency, which is consistent with our regulations under 42 CFR Part 432. However, all staff that perform this function must be trained to assist applicants in filing applications and to accurately answer questions that applicants may have or to refer such questions to the State agency's regular office for answers. At a minimum, staff must be available at all Federally-qualified health centers and disproportionate share hospitals that provide services to Medicaid-eligible pregnant women and to children. Proper application forms must be on hand at all locations.

We are permitting States to staff outstation locations with State employees, provider or contractor employees, or volunteers under certain conditions and limitations. When a State places staff at outstation locations, the State may schedule persons to either work at a specific location or rotate among several locations. State employees who are placed at outstation locations may perform any tasks in connection with the receipt of, and processing of, an application for Medicaid at the outstation location that the employee would be authorized to perform at the State agency office, including the eligibility determination. Provider or contractor employees at these locations may only perform initial processing. This includes taking all actions in receiving and processing applications and excludes evaluating information provided on applications and supporting documentation and making eligibility determinations. If contractor or provider employees, including provider contractors, are used, the State must ensure, whether by contract or other means, that these employees adhere to State and Federal confidentiality of information provisions concerning applicant and recipient information as specified in 42 CFR 431.300 through 431.307, to the prohibition on reassignment of provider claims, as specified in 42 CFR 447.10, and to all State and Federal laws concerning conflicts of interest. Volunteers may be used in the same manner as provider or contractor employees, with the same requirements for adherence to confidentiality of information and conflict of interest prohibitions. These provisions are consistent with our regulations at 42 CFR 431.10 (c) and (e) which specify the entities authorized to make determinations of eligibility for Medicaid and the authority of the single State agency.

At locations that are infrequently used by low-income pregnant women, infants, and children under 19, States

may use volunteers, provider or contractor employees, or State agency staff, or telephone assistance. At these locations, the State must display a notice in a prominent place advising potential applicants about when outstation intake staff will be available. The notification methods must take into account the needs and characteristics of the population served. The notice must provide a telephone number that applicants may call for assistance with initial processing of an application when staff are not available. The notice also must comply with Federal and State laws and regulations concerning the provision of adequate notice to persons who are blind or deaf or who cannot read or understand the English language. The notice must adequately inform these people of the opportunity to apply for Medicaid at locations other than the welfare office.

#### 4. Application Forms

Section 1902(a)(55)(B) specifies that the application form that is to be used by the designated groups of low-income pregnant women, infants, and children under 19 at the Medicaid outstation locations must be an application other than that used to apply for AFDC. The legislative history for OBRA '90 states that the House Committee bill would require States to provide for the use of applications for Medicaid-only coverage at outreach locations. It also states that "States would develop application forms for use at designated hospitals, health centers, and other outreach locations. These simplified forms would contain only those information requirements necessary to determine eligibility for Medicaid." (Emphasis added.) H. Rept. No. 881, 101st Cong., 2d. Sess. 105 (1990). The legislative history language further lists the items which should appear on the application form.

To permit as much flexibility as possible within the scope of the statutory language, we are specifying in § 435.907(c) that the application form, including any computerized application form, used at outstation locations be an application designed for the designated groups of low-income pregnant women, infants, and children under age 19, an application already used by Medicaid for applicants seeking Medicaid only, or a multiple-program application form in which only that information appropriate for the Medicaid program is obtained from the designated low-income eligibility groups. The application form used may not be the application form used to apply for AFDC. In response to expressed concerns, we are permitting States to continue to use an application

form that is designed to accommodate all assistance programs under certain circumstances. States may continue to use a multiple-program application form if the form contains Medicaid-only application sections or parts and it is clear to Medicaid applicants that they can choose to complete only those sections or parts of the application relating to Medicaid information requirements. The person assisting the applicant at the outstation location must make it clear to the applicant before the application is completed that only the information pertinent to Medicaid eligibility for the groups described in section 1902(a)(55) needs to be completed.

#### III. Federal Financial Participation

Federal financial participation (FFP) is available for costs associated with the outstation locations, regardless of who provides the services. However, effective October 1, 1992, under the provisions of section 1903(w) (as added by section 2(a) of the Medicaid Voluntary Contribution and Provider Specific Tax Amendments of 1991, Public Law 102-234, December 12, 1991), FFP is limited if a State receives donations for outstationed eligibility workers made by a hospital, clinic, or similar entity for the direct costs of State or local agency personnel who are stationed at a facility to determine Medicaid eligibility or to provide outreach services to eligible (or potentially eligible) individuals. Direct costs include salaries and fringe benefits for outstationed workers and the cost of pamphlets and materials distributed by outstationed eligibility workers at the site. These donations may not exceed 10 percent of the State's total Medicaid administrative costs, excluding costs for family planning services. Donations in excess of this 10-percent limit will be deducted from the State's medical assistance expenditures prior to calculation of FFP. Outstationed worker donations are also included in an overall limitation (computed in accordance with a formula specified in section 1903(w) of the Act) on permissible donations that a State may receive.

The administrative functions of taking and processing applications are reimbursed at the 50 percent rate under the provisions of section 1903(a)(7) of the Act as costs found necessary by the Secretary for the proper and efficient administration of the State plan. Subject to the limitations for outstationed eligibility worker donations discussed above, this rate includes costs incurred by the State to implement and provide outstationing of intake workers who are

State employees, provider employees, volunteers, or provider contractors. FFP is available for necessary administrative costs such as salaries, fringe benefits, travel, training, equipment, and space directly attributable to the outstationing of intake workers.

Existing regulations under §§ 432.50, 433.15, and 435.1001 already contain provisions for FFP for staffing and training costs and for administrative costs that States incur in determining and redetermining Medicaid eligibility.

#### IV. Application of Rules in Territories

The requirements of section 1902(a)(55) are applicable in Guam, Puerto Rico, and the Virgin Islands. Our existing regulations on eligibility determinations in the Territories cross-refer to the regulations under Part 435. Therefore, no further major changes in the regulations are necessary to make these interim final regulations applicable in the Territories. We have made a minor conforming change to § 436.2.

#### V. Waiver of Proposed Rulemaking

The statutory effective date of section 1902(a)(55) of the Act (as added by section 4602(a)(3) of OBRA '90) is July 1, 1991, without regard to whether regulations have been promulgated. Section 4207(k) of OBRA '90 gives the Secretary authority to issue regulations on an interim or other basis as may be necessary to implement the amendments made by the provisions of OBRA '90. Thus, we are utilizing the authority given by section 4207(k) and publishing this rule as an interim final rule. As stated earlier in this preamble, we have had extensive consultation with States and related organizations and agencies in developing the regulations. We are also providing a 60-day comment period for public comments on this interim final rule.

#### VI. Response to Public Comments

Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date specified in the "Comment Period" section of this preamble and respond to them in the preamble to any subsequent rule that we issue.

#### VII. Paperwork Burden

Section 435.907(c) of these interim final regulations with comment period contains a revised information collection requirement that is subject to review by the Office of Management and Budget under the Paperwork Reduction

Act of 1980 (44 U.S.C. Chapter 35). State agencies may be required to develop a separate Medicaid-only application form for the designated groups of low-income pregnant women, infants, and children who may apply for Medicaid at outstation locations if a Medicaid-only application is not currently available, or to amend their existing multiple-program application form to conform it to the requirement that there must be a clearly identified Medicaid-only application section. We estimate that the burden hours for States to develop or revise this application format will be 20 hours.

We do not anticipate any additional reporting burden hours on applicants in the designated groups, as they are required under currently approved reporting requirements to complete a Medicaid application form for a determination of eligibility for Medicaid.

We do, however, anticipate an increased reporting burden for those States that choose the option of submitting an alternate plan for the establishment of outstation location sites under § 435.904(c). These States will have to demonstrate that the alternate plan compares favorably to a plan to establish outstation locations at each disproportionate share hospital and each Federally-qualified health center. The State must demonstrate that the alternative plan, at a minimum, is equally effective and commits an equal amount of staffing and funding. We estimate that it will require a minimum of 40 additional hours to develop an alternative plan.

We will publish a notice in the *Federal Register* when the approval of the information collection requirements is obtained.

#### VIII. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, individuals and States are not included in the definition of a small entity.

We do not believe that this interim final rule will have a significant effect on a substantial number of small entities. The statutory changes increase Medicaid program expenditures independently of the promulgation of this rule and are effective on the statutory established date, regardless of whether we have issued final regulations. Costs associated with the

interim final rule are the result of legislation or due to interpretation of statutory changes already in effect. We estimate that the Federal Medicaid costs associated with implementation of the legislative changes will be approximately \$40 million per fiscal year, and the State costs to be approximately \$30 million per fiscal year.

This interim final rule incorporates, and, in some cases, interprets in regulations statutory changes that are already in effect. In cases where it was necessary to provide interpretations, we have relied on the available legislative history of the statutory provisions to reach the best reading of the provision. Therefore, we have not prepared a regulatory flexibility analysis under the RFA.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 50 beds and is located outside a Metropolitan Statistical Area.

We have determined, and the Secretary certifies, that this interim final rule with comment period will not have a significant economic impact on the operations of a substantial number of small rural hospitals, and, therefore, have not prepared a rural hospital impact statement.

The statute requires that all State Medicaid agencies must provide an opportunity for the designated groups of low-income pregnant women, infants, and children under age 19 to apply for Medicaid and to have their applications initially processed at locations other than welfare offices, including locations at Federally-qualified health centers and disproportionate share hospitals. Although this provision appears to be prescriptive, a majority of the States consider this to be a worthwhile option and have provided outstation locations in their respective States. Not only do we consider these provisions to be cost effective for potential Medicaid recipients through savings from travel, we expect State costs to be limited as a result of the availability of FFP. However, to the extent that these requirements may be burdensome, we request comments on any alternative approaches.

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

#### List of Subjects

##### 42 CFR Part 435

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

##### 42 CFR Part 436

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

42 CFR Chapter IV, Subchapter C is amended as follows:

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

A. Part 435 is amended as follows:

1. The authority citation for part 435 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act, 42 U.S.C. 1302.

2. Section 435.3 is amended by republishing the introductory text of paragraph (a) and adding a new citation in numerical order to read as follows:

##### § 435.3 Basis.

(a) This part implements the following sections of the Act and public laws that state eligibility requirements and standards:

\* \* \* \* \*

1902(a)(55) Mandatory use of outstation locations other than welfare offices to receive and initially process applications of certain low-income pregnant women, infants, and children under age 19.

\* \* \* \* \*

§ 435.902 [Redesignated as § 435.901]

§ 435.903 [Redesignated as § 435.902]

§ 435.904 [Redesignated as § 435.903]

3. Sections 435.902, 435.903, and 435.904 are redesignated as §§ 435.901, 435.902, and 435.903, respectively.

4. A new § 435.904 is added to read as follows:

**§ 435.904 Establishment of outstation locations to process applications for certain low-income eligibility groups.**

(a) *State plan requirements.* The Medicaid State plan must specify that the requirements of this section are met.

(b) *Opportunity to apply.* The agency must provide an opportunity for the following groups of low-income pregnant women, infants, and children under age 19 to apply for Medicaid at outstation locations other than AFDC offices:

(1) The groups of pregnant women or infants with incomes up to 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(IV) of the Act;

(2) The group of children age 1 up to age 6 with incomes at 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VI) of the Act;

(3) The group of children age 6 up to age 19 born after September 30, 1983, with incomes up to 100 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VII) of the Act; and

(4) The groups of pregnant women or infants, children age 1 up to age 6, and children age 6 up to age 19, who are not eligible as a mandatory group, with incomes up to 185 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(IX) of the Act.

**(c) Outstation locations: general requirements.**

(1) The agency must establish either—

(i) Outstation locations at each disproportionate share hospital, as defined in section 1923(a)(1)(A) of the Act, and each Federally-qualified health center, as defined in section 1905(l)(2)(B) of the Act, participating in the Medicaid program and providing services to Medicaid-eligible pregnant women and children; or

(ii) Other outstation locations, which include at least some, disproportionate share hospitals and federally-qualified health centers, as specified under an alternative State plan that is submitted to and approved by HCFA if the following conditions are met:

(A) The State must demonstrate that the alternative plan for outstationing is equally effective as, or more effective than, a plan that would meet the requirements of paragraph (c)(1)(i) of this section in enabling the individuals described in paragraph (b) of this section to apply for and receive Medicaid; and

(B) The State must provide assurances that the level of staffing and funding committed by the State under the alternative plan equals or exceeds the level of staffing and funding under a plan that would meet the requirements of establishing the outstation locations at the sites specified in paragraph (c)(1)(i) of this section.

(2) The agency must establish outstation locations at Indian health clinics operated by a tribe or tribal organization as these clinics are specifically included in the definition of Federally-qualified health centers under section 1905(l)(2)(B) of the Act and are also included in the definition of rural health clinics under part 491, subpart A of this chapter.

(3) The agency may establish additional outstation locations at any other site where potentially eligible pregnant women or children receive services—for example, at school-linked service centers and family support centers. These additional sites may also include sites other than the main outstation location of those Federally-qualified health centers or disproportionate share hospitals providing services to Medicaid-eligible pregnant women and to children and that operate more than one site.

(4) The agency may, at its option, enter into reciprocal agreements with neighboring States to ensure that the groups described in paragraph (b) of this section who customarily receive services in a neighboring State have the opportunity to apply at outstation locations specified in paragraphs (c)(1) and (2) of this section.

(d) **Outstation functions.** (1) The agency must provide for the receipt and initial processing of Medicaid applications from the designated eligibility groups at each outstation location.

(2) "Initial processing" means taking applications, assisting applicants in completing the application, providing information and referrals, obtaining required documentation to complete processing of the application, assuring that the information contained on the application form is complete, and conducting any necessary interviews. It does not include evaluating the information contained on the application and the supporting documentation nor making a determination of eligibility or ineligibility.

(3) The agency may, at its option, allow appropriate State eligibility workers assigned to outstation locations to evaluate the information contained on the application and the supporting documentation and make a determination of eligibility if the workers are authorized to determine eligibility for the agency which determines Medicaid eligibility under § 431.10 of this subchapter.

(e) **Staffing.** (1) Except for outstation locations that are infrequently used by the low-income eligibility groups, the State agency must have staff available at each outstation location during the regular office operating hours of the State Medicaid agency to accept applications and to assist applicants with the application process.

(2) The agency may station staff at one outstation location or rotate staff among several locations as workload and staffing availability dictate.

(3) The agency may use State employees, provider or contractor employees, or volunteers who have been properly trained to staff outstation locations under the following conditions:

(i) State outstation intake staff may perform all eligibility processing functions, including the eligibility determination, if the staff is authorized to do so at the regular Medicaid intake office.

(ii) Provider or contractor employees and volunteers may perform only initial processing functions as defined in paragraph (d)(2) of this section.

(4) Provider and contractor employees and volunteers are subject to the confidentiality of information rules specified in part 431, subpart F, of this subchapter, to the prohibition against reassignment of provider claims specified in § 447.10 of this subchapter, and to all other State or Federal laws concerning conflicts of interest.

(5) At locations that are infrequently used by the designated low-income eligibility groups, the State agency may use volunteers, provider or contractor employees, or its own eligibility staff, or telephone assistance.

(i) The agency must display a notice in a prominent place at the outstation location advising potential applicants of when outstation intake workers will be available.

(ii) The notice must include a telephone number that applicants may call for assistance.

(iii) The agency must comply with Federal and State laws and regulations governing the provision of adequate notice to persons who are blind or deaf or who are unable to read or understand the English language.

3. Section 435.907 is revised to read as follows:

**§ 435.907 Written application.**

(a) The agency must require a written application from the applicant, an authorized representative, or, if the applicant is incompetent or incapacitated, someone acting responsibly for the applicant.

(b) Subject to the conditions specified in paragraph (c) of this section, the application must be on a form prescribed by the agency and signed under a penalty of perjury.

(c) The application form used at outstation locations for low-income pregnant women, infants, and children specified in § 435.904 must not be the application form used to apply for AFDC. The application form (including any computerized application form) for these designated eligibility groups may be—

(1) A Medicaid-only form prescribed by the agency specifically for the designated eligibility groups;

(2) An existing Medicaid-only application; or

(3) A multiple-program application that contains clearly identifiable Medicaid-only sections or parts.

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

B. Part 436 is amended as follows:

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

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

2. Section 436.2 is amended by revising the introductory text and adding a new entry in numerical order to read as follows:

#### **§ 436.2 Basis.**

This part implements the following sections of the Act and public laws that state requirements and standards for eligibility:

\* \* \* \* \*

1902(a)(55) Mandatory use of outpatient locations other than welfare offices to receive and initially process applications of certain low-income pregnant women, infants, and children under age 19.

\* \* \* \* \*

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

Dated: July 15, 1994.

**Bruce C. Vladeck,**  
*Administrator, Health Care Financing Administration.*

Dated: July 28, 1994.

**Donna E. Shalala,**  
*Secretary.*

[FR Doc. 94-23279 Filed 9-22-94; 8:45 am]

BILLING CODE 4120-01-P

#### **42 CFR Part 456**

[MB-050-F]

RIN 0938-AF67

#### **Medicaid Program; Drug Use Review Program and Electronic Claims Management System for Outpatient Drug Claims**

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

**ACTION:** Final rule.

**SUMMARY:** This final rule revises some of the regulatory requirements for the drug use review (DUR) program for covered outpatient drugs furnished to recipients under the Medicaid program. The

regulatory requirements became effective on January 2, 1993, as a result of an interim final rule with comment period that we published on November 2, 1992. Specifically, these revisions—

- Clarify the definitions of overutilization, underutilization, consensus process, peer-reviewed literature, adverse medical result, adverse drug-drug interaction, appropriate and medically necessary, and individual medical history;

- Change the requirements for licensure of DUR board members, and telephone counseling arrangements for mail order pharmacies;

- Include non-prescription drugs in the consideration of alteration of therapeutic effect;

- Require hospitals to give assurances that they have met the requirements of the statute before claiming the hospital exemption from DUR;

- Specify the issues that State agencies must address when formulating counseling standards;

- Clarify the bases for DUR board recommendations;

- Clarify the distinction between DUR and surveillance and utilization review (SUR); and

- Make certain technical and editorial corrections.

The November 1992 interim final rule with comment period incorporated and interpreted certain provisions of section 4401 of the Omnibus Budget Reconciliation Act of 1990.

**DATES:** These regulations are effective on October 24, 1994.

**FOR FURTHER INFORMATION CONTACT:**  
Thomas Fulda, (410) 966-3343.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 1927(g) of the Social Security Act (the Act), as added by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), provides that, for Federal financial participation (FFP) payment to be made for covered outpatient drugs under the Medicaid program, the State must have in operation a drug use review (DUR) program. The DUR program must consist of prospective drug review, retrospective drug use review, the application of explicit predetermined standards, and an educational program. The purpose of the DUR program is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate and medically necessary, and that they are not likely to result in adverse medical effects. Section 1927(g) of the Act specifies detailed requirements for conducting drug use reviews under the DUR program, and

requirements for the establishment, composition, and functions of State DUR boards.

Section 1927(h) of the Act (also added by OBRA '90) requires the Secretary to encourage each State Medicaid agency to establish a point-of-sale electronic claims management (ECM) system for processing claims for covered outpatient drugs. The ECM system must be capable of performing on-line, real-time eligibility verifications, claims data capture, and adjudication of claims and assisting pharmacists and other authorized persons in applying for and receiving payment. If the State acquired, through the applicable competitive procurement process, the most cost-effective telecommunications network and automatic data processing services and equipment, FFP at a matching rate of 90 percent was available for expenditures made in calendar quarters during fiscal years 1991 and 1992 for the development of the ECM system.

Section 1927(j)(1) of the Act exempts covered outpatient drugs dispensed by health maintenance organizations (HMOs) from the requirements of section 1927 of the Act. Section 1927(j)(2) further requires that the Medicaid State plan provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the State plan at no more than the hospital's purchasing costs are not subject to the requirements of section 1927 of the Act.

In an interim final rule with comment period, published in the **Federal Register** on November 2, 1992 (57 FR 49397), we established regulations to incorporate and interpret the provisions of sections 1927 (g), (h), and (j) of the Act under 42 CFR part 456, subpart K. In the interim final rule, we prescribed requirements for—

- An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;
- The establishment, composition, and functions of a State DUR Board; and
- An optional point-of-sale ECM system for processing claims for covered outpatient drugs.

In response to the November 2, 1992, interim final rule, we received comments from 72 pharmacists and organizations on a timely basis. We summarize these comments and present our responses to them under section II of this preamble. Prior to discussion of the public comments, we present a summary of the individual provisions of the interim final regulations related to each grouping of comments.

**Note:** Sections 1927 (g) and (h) of the Act use the term "drug use review" to describe