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]

BILLING CODE 6560–50–F

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)(ii)(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(1)(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)(l) 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 outstation 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

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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

the total program (prospective review, retrospective review, and education) and in speaking of the retrospective review activity. These same sections use the term "drug review" to mean the prospective review activity. We maintain that distinction in terminology in the following discussion.

II. Public Comments and Departmental Responses

A. Definitions

In § 456.702 of the interim final regulations we define several terms that are used in the DUR program to assess drug use, including "adverse medical result", "appropriate and medically necessary", "overutilization", and "underutilization".

Comment: Five commenters suggested that the definition of "appropriate and medically necessary" be expanded to permit the use of professional prerogatives to allow for individualized drug therapy. (We defined the term to mean drug prescribing and dispensing that is in conformity with predetermined standards established in accordance with provisions in the regulations under § 456.703.) The commenters had a concern that a specific criterion might identify one approach as appropriate and, by omission, indicate that an equally acceptable approach is inappropriate.

Response: Section 456.703 states that the goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy. We believe that predetermined standards are necessary to identify provider outliers whose prescribing, dispensing, and drug use practices may not conform to accepted medical practice. Without predetermined standards, each provider may claim "professional prerogative" for any action taken. Within this system for developing criteria and standards, there is adequate room for the exercise of professional prerogatives because States may adopt standards to modify criteria. Also, during retrospective DUR, States may use peer review to recognize professional prerogatives in the prescribing and dispensing of drugs. We do not believe that it is necessary to change this definition.

Comment: Four commenters suggested that the definition of "overutilization" should be changed to conform with the definition of "underutilization". "Overutilization" is defined as the use of a drug in quantities or for durations that put the recipient at risk of an adverse medical effect while "underutilization" is defined as the use of a drug by a recipient in insufficient quantity to achieve a desired therapeutic goal. The commenters suggested that the definitions indicate the use of a drug in quantities or duration greater than necessary to achieve a desired therapeutic goal, and only when the use of the drug puts the recipient at risk of a clinically significant undesirable effect.

Response: We concur with the commenters and have revised these definitions to incorporate their suggested language.

Comment: Two commenters suggested that the definition of "underutilization" also include a statement regarding insufficient duration for drug therapy.

Response: We concur and have revised the regulation accordingly.

B. Exception for Nursing Facilities and HMOs

Section 456.703(b) of the interim final regulations provides an exception to the DUR requirements for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review requirements specified in regulations at § 483.60, and an exception for drugs dispensed by HMOs.

Comment: One commenter suggested clarification of § 456.703(b) to state that pharmacies owned by nursing homes, where reimbursement of drugs is not included in the per diem rate, are subject to the DUR requirements.

Response: We do not believe that this section needs any further clarification. The regulation already states that the nursing facilities exception applies only to drugs given to patients in a nursing facility that is in compliance with the drug regimen review requirements in § 483.60. Ownership of the pharmacy by the nursing home is not a factor.

Comment: Two commenters asked for clarification of the applicability of DUR requirements to various types of residential care facilities.

Response: The term "facility", as it applies to the exception to the DUR requirements, is described at § 483.5 and means a nursing facility (NF) as defined in section 1919(a) of the Act. Drugs dispensed by any facilities not meeting this definition would not be exempt from drug use review. Residential care facilities for the treatment of mental diseases do not meet the definition of section 1919(a) of the Act. These facilities are subject to the DUR requirements and do not qualify for the nursing facility exception.

Comment: One commenter suggested clarification that the nursing facility exception also applies to rural health clinics and Federally qualified health centers.

Response: Rural health clinics and Federally qualified health centers do not meet the requirements for nursing facilities as defined in section 1919(a) of the Act. Therefore, the DUR requirements under section 1927(g) apply to these facilities.

Comment: One commenter suggested that States should not be able to apply additional nursing home requirements without appropriate Federal guidelines.

Response: The statute precludes Federal action to require DUR for drugs dispensed by nursing facilities meeting the section 1927(g)(1)(D) guidelines but leaves the States free to issue additional requirements. The interim regulations that we issued explain the DUR requirements and include guidelines for the States to implement the DUR requirements.

Comment: Four commenters suggested that HMOs not be excluded from the DUR requirements.

Response: The exemption of drugs dispensed by HMOs from the DUR requirements is in the statute and can only be changed by the Congress. We are removing the HMO exception provision under § 456.703(b), because this is a technically incorrect location, and adding a paragraph (c)(2) under § 456.703 which specifies the exemption for HMOs.

Comment: One commenter suggested that the nursing facility exception to the DUR requirement be mandatory, rather than making the exception optional.

Response: The Act precludes the Federal Government from requiring States to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities in compliance with the drug regimen review requirements specified at section 1919 of the Act, as set forth in § 483.60. States may nonetheless impose DUR requirements on nursing facilities (see § 456.703(b)).

C. Exemptions for Certain Covered Outpatient Drugs Dispensed by Hospitals

Section 456.703(c) of the interim final regulations specifies that a State plan must provide that covered outpatient drugs dispensed by hospitals using a formulary system and billing Medicaid no more than the hospital's purchasing cost are not subject to the DUR requirements.

Comment: One commenter suggested that a hospital pharmacy that is separate from the inpatient pharmacy should be subject to the DUR requirements as are other retail pharmacies.

Response: Section 1927(j) of the Act applies the exemption to outpatient covered drugs dispensed by hospitals

under certain specified conditions. Pharmacies located on the hospital premises that are separate in terms of ownership and fill only outpatient prescriptions are not entitled to the exemption.

Comment: Two commenters suggested that outpatient prescription drugs dispensed by hospital pharmacies should not be exempt from the DUR requirements.

Response: Pharmacies that operate as part of a hospital and also fill outpatient prescriptions are, by statute, entitled to the exemption. We have amended § 456.703(c)(1) to indicate that hospitals which apply for the exemption must provide the State agency with an assurance that they qualify for the exemption by meeting the requirements at section 1927(j)(2).

Comment: One commenter suggested the need for clarification of § 456.703(c) by defining "hospital's purchasing cost" and "formulary system".

Response: The statute permits States, if they wish, to define the terms "formulary system" and "hospital's purchasing cost". We do not believe that it is necessary to do so in the regulations.

D. Predetermined Standards

Section 456.703(d) of the interim final regulations specifies that the DUR program must assess drug use information against predetermined standards as provided for in section 1927(g)(1)(B) of the Act. Sections 456.703 (e)(1) through (e)(4) specify the sources of predetermined standards. Section 456.703(f) lists eight specific requirements that predetermined standards must meet, including the requirement that the source material for development of the standards must be consistent with peer-reviewed medical literature. Section 456.703(g) requires that predetermined standards be available to the public, and that pharmacists and physicians must be informed of their existence and how they may obtain copies.

Comment: One commenter requested clarification of the distinction between criteria and standards.

Response: Section 1927(g)(1)(B) indicates that the DUR program is to assess drug use, based on predetermined standards that are consistent with three compendia and the peer-reviewed medical literature. The compendia and the peer-reviewed literature are source materials for criteria, but additional work is necessary to resolve differences of opinion in source material and to consider the input of professional experts. "Criteria", as defined in § 466.1 and cross-referenced in § 456.702, are the predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared. "Standards", as defined in § 466.1, are professionally developed expressions of the range of acceptable variation from a norm or criterion, which may be developed by the States. If, for example, a criterion for the use of H2 receptor antagonists indicates that acute therapy should not exceed 62 days, a standard might indicate that acute therapy of up to 67 days would not warrant consideration of intervention. Although section 1927(g)(1)(B) of the Act does not define predetermined standards, we believe that the definitions of criteria and standards at § 466.1 provide an adequate base to interpret the meaning of predetermined standards.

Comment: One commenter suggested that § 456.703(e)(3) should delete specific examples of independent organizations from which predetermined standards may be obtained to broaden the sources of independent standards. This comment also indicated a typographical error in paragraph references at § 456.703(e)(4).

Response: We need to specify certain organizations in the regulations to indicate that criteria should be developed by organizations which have no vested interest in the sale of drugs covered by the criteria. Organizations with a vested interest would have an opportunity to provide input during the DUR board approval process. Therefore, we have retained the specific organization names.

We have corrected § 456.703(e)(4) to refer to paragraphs (e)(1) through (e)(4) rather than (f)(1) through (f)(4).

Comment: One commenter suggested the inclusion of additional sources of predetermined standards, including relevant guidelines from professional groups, experience of practitioners with expertise in drug therapy, information from pharmaceutical manufacturers, and data as well as experience from the DUR program.

Response: The statute provides that criteria developers are to place primary reliance on compendia and peer-reviewed literature. They may rely on other source materials to supplement what is in the compendia and the peer-reviewed literature. In the event of conflicts between primary materials and supplementary information, such as professional experience, if the professional consensus process (as specified in § 456.703(f)(2)) is unable to resolve the conflict, the supplementary information must not be relied on by the criteria developer.

Comment: One commenter suggested an amendment to require Food and Drug Administration (FDA) labeling as the primary source of DUR criteria.

Response: The statute is specific regarding the primary sources for predetermined standards. FDA labeling is not included as a primary source.

Comment: Five commenters requested clarification of § 456.703(f)(2) regarding the consensus process and what to do if consensus cannot be reached. Several commenters suggested resolving disagreements with additional input from professional or medical organizations or other outside sources. Others indicated that if consensus is not reachable because of insufficient data or lack of sufficient knowledge of therapeutic outcomes, it would be satisfactory to have no criteria or to have more than one standard. One of these commenters recommended taking into account community practice standards in seeking consensus. One commenter suggested that the DUR board have final authority in the case of disagreements.

Response: We have amended § 456.703(f)(2) to specify that consensus process means that the criteria developers should rely on professional experts in drug therapy to consider differences in criteria source materials and come to agreement on how differences should be resolved. It is expected that the differences would be resolved before a criterion was submitted to the DUR board for approval. The DUR board must know the sources, decision guidelines used in developing criteria, and any other information necessary to evaluate criteria.

Comment: One commenter suggested a revision of § 456.703(f)(5) to consider patient as well as provider outliers in identifying problems and to consider both dispensing and consumption practices. In addition, the commenter suggested that standards may be considered in deciding if in-depth review is needed to determine whether to intervene, once potential therapeutic problems have been identified through the use of clinical criteria.

Response: We agree and have revised § 456.703(f)(5) to consider recipients' consumption practices.

Comment: One commenter suggested that § 456.703(f)(6) should be clarified to indicate that testing against claims data should be to test the accuracy and ability of criteria to detect significant problems without undue levels of false positives.

Response: We have amended § 456.703(f)(6) to specify that criteria be tested against claims data prior to adoption by the developer in order to validate the level of possibly significant therapeutic problems without undue levels of false positives.

Comment: Two commenters suggested that criteria for predetermined standards should be modified to conform to State standards of practice. Four commenters were concerned with the process used to modify criteria. One commenter suggested that the State should be required to establish a process for review and modification of criteria which provides a mechanism to get input from providers. One commenter suggested an annual period for receipt of petitions for modification of criteria. Another commenter suggested that the DUR board issue public notice when it considers changing criteria. Another commenter suggested that there is a risk of bogging down the process by establishing procedures.

Response: The State may require DUR Boards to specify the procedures suggested by the commenters. The DUR board would then establish the mechanisms to obtain input, where appropriate, from providers, the public, and other interested parties concerning modification of the criteria or the approval of the criteria. To avoid the possibility that these procedures might impede the efficient operation of the DUR program, the State may use informal mechanisms that it deems appropriate. There is no Federal requirement for the use of notice and comment procedures during the criteria development process.

Comment: Two commenters suggested that standards be accessible during development, and public comment should be obtained during criteria development. Two commenters suggested that it is unnecessarily burdensome to have to furnish providers with criteria. One of these commenters suggested providing only a general description, not the complete criteria. One commenter suggested giving criteria to providers and allowing reasonable time for compliance.

Response: We believe that making criteria and standards accessible for public comment during the development period would impede the development process. Section 456.703(g) does not require distribution of the criteria to the public or to providers; nor does it require that the State distribute the predetermined standards to the public. The regulations, however, do require that predetermined standards must be made available to the public after they are adopted by the State. They also require that physicians and pharmacists be informed of what predetermined standards have been adopted and how they can obtain copies.

Comment: One commenter suggested that criteria should consider the needs of the geriatric population. Another commenter suggested that peer reviewers, not criteria and standards, determine what is necessary and appropriate. One commenter suggested that professional prerogatives, to allow for individualized therapy, be linked to the use of criteria and standards.

Response: To the extent that the peer-reviewed medical literature and the three compendia specified in the statute reflect the results of the testing of drugs on elderly subjects, the needs of the geriatric population will be taken into consideration. Criteria and standards involve peer reviewers in the development and approval process. Also, standards provide a basis for State DUR boards to decide the degree of variation from a criterion which is acceptable to allow for such things as individualized therapy. In most instances where retrospective drug use review is conducted, peer reviewers evaluate the results of the screening process to decide which types of interventions should be applied to particular situations.

Comment: One commenter suggested that the description of "peer-reviewed" medical literature in § 456.703(f)(1) be revised to indicate that original manuscripts are "accepted" for publication rather than "rejected".

Response: We agree that if a manuscript was rejected, it would mean that the manuscript had not become peer-reviewed literature. We have deleted the words "rejected or" from the description of peer-reviewed medical literature.

Comment: One commenter suggested that the § 456.703(f)(1) provision on "peer-reviewed" medical literature should address conflicts between such literature and compendia.

Response: We realize that there will be conflict between peer-reviewed medical literature and compendia. However, the resolution of any such conflict will occur in the consensus process described in § 456.703(f)(2).

E. Confidentiality

Section 456.703(h) of the interim final regulations requires States to establish policies concerning the confidentiality of patient-related data consistent with Federal confidentiality requirements at part 431, subpart F of the Medicaid regulations, State Pharmacy Practice Acts, and guidelines adopted by the State Board of Pharmacy or other relevant licensing authority.

Comment: Six commenters suggested that § 456.703(h) should be more detailed and should require that States provide pharmacies with detailed information on how to comply with confidentiality requirements. The commenters suggested that the section include guidelines on protection of patient confidentiality in the electronic claims environment and physician-to-pharmacist confidentiality; and specify that confidentiality requirements which apply to medical records also apply to patient profiles maintained by pharmacists.

Response: We believe that the Federal confidentiality requirements in the regulations at part 431, subpart F, the State requirements contained in Pharmacy Practice Acts, and the policies developed by State bodies which regulate the practices of medicine and pharmacy should be sufficient to protect the confidentiality of patient-related data and at the same time allow providers access to data to make informed judgments necessary to effectively conduct DUR. With regard to the problem of maintaining confidentiality in an electronic environment, the Workshop on Electronic Data Interchange (WEDI) is studying these issues but has not yet developed policy recommendations. In the interim, since use of the electronic drug claims processing systems may present unique confidentiality problems, particularly with prospective DUR, States may wish to establish policies to address these problems.

Comment: One commenter indicated that, as important as confidentiality is, it should not be allowed to be used to restrict pharmacist access to relevant data needed to permit accurate assessment of patient needs so the pharmacist can make informed medication-related judgments.

Response: Section 456.703(h) of the regulations requires States to establish policies concerning the confidentially of patient-related data which is consistent with Federal confidentiality requirements and State Pharmacy Practice Acts and State Pharmacy Board guidelines. We believe that this can be accomplished in a manner which both protects patient confidentiality and allows for access to data needed to efficiently administer the Medicaid DUR program.

Comment: One commenter asked how HCFA will ensure that patient confidentiality rules are adequate and how HCFA will monitor compliance with them.

Response: Since States are primarily responsible for regulating pharmacy and medical practice, they must determine the adequacy of confidentiality rules and ensure compliance with them. HCFA will monitor compliance with the confidentiality requirements through its review process conducted by regional offices and through review of the DUR annual reports required by § 456.712.

Comment: Two commenters requested an explanation of why Federal confidentiality requirements do not apply to patient profile requirements at § 456.705(d).

Response: The Federal Privacy Act requirements do not apply where the Federal Government does not control the records in question.

F. Prospective DUR

Section 456.705(a) of the interim final regulations requires review of drug therapy before each prescription is filled or delivered to a recipient. This review, as described in § 456.705(b)(1) through (7), is done at the point of sale, based on predetermined standards, before a prescription is filled or delivered to the recipient or the recipient's caregiver. Reviews are to detect drug-disease contraindications, therapeutic duplication, adverse drug-drug interaction, incorrect drug dosage or duration of therapy, drug-allergy interactions, and clinical abuse and/or misuse. Counseling and maintenance of patient profiles by the pharmacist are required by §§ 456.705(c) and (d).

Comment: One commenter suggested that the word "prescription" be changed to "drug" in the description of drug-disease contraindications because contraindications can also occur with over-the-counter drugs. The commenter also suggested that the term "clinically significant" be used to describe adverse medical effect. This latter terminology would ensure that only significant events would be reviewed and these regulations would not identify all adverse effects as contraindications.

Response: We have revised § 456.705(b)(2)(i) to incorporate the commenter's suggestions.

Comment: Two commenters suggested that the definition of "adverse drug-drug interaction" include the phrase "clinically significant" to describe "adverse medical effect". Again, this would ensure that only significant effects would meet this definition, since all adverse effects need to be reviewed.

Response: We have revised § 456.705(b)(3) to incorporate the commenters' suggestion. We have made a conforming change to § 456.703(f)(5).

Comment: One commenter suggested that the definition of "adverse drug-drug interaction" should prohibit substitution of the FDA orange book "B" rated drugs.

Response: It is not HCFA's responsibility to require generic substitution of the FDA orange book "B" rated drugs. State laws regarding product selection will determine the requirements regarding generic substitution.

Comment: One commenter suggested an error in the definition of "incorrect drug dosage" at § 456.705(b)(4) as a potential drug therapy problem type that must be included in the screening in point-of-sale or point-of-distribution reviews. The commenter pointed out that the reference to "daily dosage range" should be "daily dosage" as the term "range" applies to the standard and is not a part of the definition. A second commenter suggested that the correct "duration" of drug treatment was hard to assess as a potential drug therapy problem type under § 456.705(b)(5).

Response: We have deleted the references to "range" in § 456.705(b)(4), since we believe that the term is redundant. We agree with the commenter that duration, in some instances, may be difficult to assess. However, ranges provided in the predetermined standards would allow for some variance in individual cases.

Comment: One commenter suggested that the definition of "drug-allergy interactions" include a statement that such problems can only be identified based upon history obtained from the patient or the physician.

Response: We agree that information regarding drug- allergy problems may be only available through contact with the physician or the patient. However, such a statement is not a proper part of the definition.

Comment: One commenter suggested that the prospective DUR screening elements definitions should be consistent with definitions developed by the National Council for Prescription Drug Programs (NCPDP).

Response: We did review the definitions of prospective DUR, retrospective DUR, and concurrent DUR developed and recommended by the NCPDP in developing the interim final regulations. Section 456.705 describes prospective DUR in detail and § 456.709 describes retrospective DUR in detail. We see no reason to define these terms in § 456.703. Because the statute does not refer to concurrent DUR, we have no reason to include this term in the regulation.

Comment: Four commenters were concerned about performing prospective DUR in an on-line electronic drug claims management environment. Two commenters suggested not implementing prospective DUR in an on-line ECM environment until demonstration projects required by the statute have been completed. Another commenter suggested a comparison of ECM-based DUR and pharmacy on-site DUR and the implementation of the most effective approach. One commenter warned against making prospective DUR too automated because the pharmacist is essential as a problem solver. One commenter suggested that detailed prospective DUR rules are unnecessary because prospective DUR can be performed based on the pharmacist's professional judgment manually, or electronically, or a combination of the two.

Response: Establishing electronic drug claims management systems and including prospective DUR as part of such systems are options available to the States; they are not required. Therefore, prospective DUR can be done electronically or on site by each pharmacy. The purpose of the demonstration project required by Congress at section 4401(c)(1)(d) of OBRA '90 is to determine the relative effectiveness of the ECM-based prospective DUR versus the on-site pharmacy prospective DUR, and thus assure implementation of ECD-based DUR. We recognize that, even with automation, prospective DUR cannot be done without the pharmacist because his or her professional judgment determines whether and how to respond to an automated alert of a potential problem.

Comment: One commenter suggested that if electronic prospective DUR is implemented, a professional oversight committee should work to keep focus on serious problems and to avoid false positives.

Response: We agree that if an electronic prospective DUR is implemented, a professional oversight committee is needed to ensure that prospective DUR is focused on serious problems and avoids false positives. We believe that the State DUR board would be the appropriate entity to provide such oversight.

Comment: One commenter suggested that in the course of the prospective DUR, prescriptions should not be changed or denied without the physician's knowledge.

Response: Except for the quantity dispensed, State law prohibits changing a prescription. It would be appropriate for the pharmacist to notify the physician if the prescription is not filled for therapeutic reasons. Establishing rules requiring such notification is in

the province of State boards of pharmacy and could be included in the State Pharmacy Practice Acts. In the absence of such rules, the State Medicaid agency could, where appropriate, establish them.

Comment: One commenter suggested that we define a prescription.

Response: The definition of a prescription is included in the State Pharmacy Practice Acts.

Comment: One commenter suggested that approval of State plans for DUR should be contingent on the State providing adequate financial incentives for pharmacist interventions.

Response: There is no prohibition in the statute or the regulations against the State providing financial incentives for pharmacist interventions. The State is free to include, in its reimbursement for the cost of filling a prescription, consistent with the requirements of section 1902(a)(30)(A) of the Act with regard to efficiency, economy and quality of care, amounts to compensate for DUR services.

Comment: One commenter suggested that instructions for compliance with prospective DUR should go to the pharmacist, not the pharmacy.

Response: We believe that the instructions for compliance with prospective DUR should be directed to the pharmacies since they are the Medicaid providers. It would be more burdensome to furnish this information to pharmacists in part because changes in the pharmacy staff occur more frequently than do changes in the status of pharmacies. The owners or managers of pharmacies, as Medicaid providers, are responsible for furnishing their staff with information pertaining to DUR.

Comment: One commenter suggested that pharmacists should not be required to take medical histories.

Response: Nothing in the statute or the regulations requires pharmacists to take medical histories. Pharmacists must make a reasonable effort to maintain patient profiles and may, based on their professional judgment, seek patient specific information for those profiles.

Comment: Seven commenters pointed out the importance of diagnosis information and the difficulty of conducting prospective DUR screening to identify drug-disease and drug-allergy screening without patient-specific information. One commenter suggested that inaccurate diagnosis information would generate needless communication between physicians and pharmacists.

Response: We agree that it is difficult to screen for drug-disease contraindications and drug-allergy interactions without access to patient-specific information. Clearly, access to such information improves the ability to conduct prospective DUR, and obtaining accurate information is a difficult technical problem. There is also the question of the relationship of the diagnosis to the use of the prescription, for example, the diagnosis may be cancer and the prescription may be for pain. Given these difficulties, problems associated with access to patient-specific information can best be resolved by pharmacists cultivating relationships with physicians so that it becomes possible for the pharmacist to seek patient-specific information about diagnosis, allergies, and other matters when, in his professional judgment, it is appropriate for counseling.

Comment: One commenter suggested that HCFA require physicians to submit diagnosis information, while another suggested that physicians not be required to provide diagnosis information. Other commenters pointed to the difficulty of getting diagnosis information from providers.

Response: Since States regulate the practice of medicine, placing diagnosis information on prescriptions is a matter for States to decide.

G. Counseling

Section 456.705(c) of the interim final regulations provides that applicable State law, or other method satisfactory to the State, must establish standards for counseling of the recipient or the recipient's caregiver. The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements, including guidelines on counseling, profiling, and documentation of prospective DUR activities by the pharmacists. The State law, or other method satisfactory to the State, must specify how counseling requirements apply to mail order pharmacies.

The standards must specify whether the pharmacist or an ancillary person may make the offer to counsel; must specify what documentation must be maintained on refusals of counsel; and must include in the counseling those matters considered significant by the pharmacist. The standards need not require a pharmacist to provide consultation when a recipient or recipient's caregiver refuses such consultation.

Comment: Five commenters addressed the physician-pharmacist relationship concerning the provision of counseling services. One commenter stated that counseling that involves the pharmacist contacting the physician would create a hassle factor for the physician. Four commenters suggested the expansion of § 456.705(c) to include specific statements regarding the physician-pharmacist relationship: the physician should be able to direct the pharmacist to include or exclude specific topics for specific patients; the pharmacist should notify the physician if the patient refuses the prescription after counseling. In addition, if the pharmacist identifies a significant risk of an adverse medical result, he or she should consult the physician prior to counseling. The commenters indicated concern that inappropriate counseling would result without the addition of these requirements.

Response: The individual State has the responsibility of establishing standards of counseling for the pharmacist. Some States may want to incorporate requirements regarding physician-pharmacist interaction in their standard; others may not. We believe these interactions will occur in the normal day-to-day relationships between physicians and pharmacists. In any event, States should be given the flexibility of either including, or not including, the suggested requirements.

Comment: Seven commenters suggested that mail order pharmacies should be treated the same as all other pharmacies. Counseling requirements should apply equally to all pharmacy providers of outpatient drugs.

Response: We concur and have removed the statement concerning mail order pharmacies from § 456.705(c). Since delivery of a prescription to a person at home by a pharmacy and mail order prescriptions raise the same issues about how to offer and provide counseling, we have amended § 456.705(c) to require State counseling standards to address this issue.

Comment: Three commenters suggested that the regulations specify whether the offer to provide counseling is required for new prescriptions only, both new and refill prescriptions, or whether the decision to make the offer should be left to the professional judgment of the pharmacist. One commenter suggested limiting the offer to new prescriptions; one commenter suggested that it apply to both new and refill prescriptions; and the third commenter suggested leaving the decision to the professional judgment of the pharmacist. Six commenters suggested that the regulations specify the role of ancillary personnel in making the offer to counsel to the patient or the patient's representative. The commenters indicated that pharmacists may have ancillary personnel make the offer of counseling

on their behalf, but the pharmacists must personally conduct counseling if the offer is accepted.

Response: Since the statute requires each State to establish standards for counseling, these State standards rather than Federal regulations must, at a minimum, address the following issues:

- Whether the offer to counsel is required for new prescriptions only, or both new and refill prescriptions;
- Whether only pharmacists must make the offer to counsel or whether auxiliary personnel are authorized to make the offer;
- Whether only a patient's refusal of the offer to counsel must be documented or whether documentation of all offers is required;
- Whether documentation of counseling is required; and
- How counseling is to be addressed in situations where the patient's representative is not readily available to receive a counseling offer or the counseling itself.

We have amended § 456.705(c) to specify that State counseling standards must address these issues.

Comment: Seven commenters discussed the method of documenting a patient's refusal of the offer to provide counsel. Six commenters suggested that pharmacists be given the maximum flexibility in the method of documenting a patient's refusal of the offer to provide counsel. One of the six commenters suggested that documentation should not be mandatory. The seventh commenter suggested that a recipient should be able to sign a blanket refusal for all prescriptions.

Response: Again, we leave to the States decisions regarding documentation of offers to counsel.

Comment: Five commenters addressed documentation of counseling in general, although such documentation was not discussed in the interim final regulation. Two commenters suggested that guidelines on documentation be included and three commenters suggested that documentation standards should be general and not specific.

Response: The statute requires the States to establish standards for counseling. We have amended § 456.705(c)(1) (formerly the undesignated introductory paragraph of § 456.705(c)) to specify the subject matter that must be addressed by these standards.

Comment: Five commenters suggested that § 456.705(c)(1) specify that the content of counseling should be left to the professional prerogative of the pharmacist, who should be given proper flexibility in selecting how patient counseling should be administered in each circumstance. One commenter requested that the control of the content not be given to the prescriber.

Response: Section 456.705(c)(3), formerly § 456.705(c)(2), clearly specifies that the content of counseling is subject to the professional judgment of the pharmacist. Determining how counseling should be administered, that is, whether counseling must be oral or to what extent written communication may be used, depends on the State standards for counseling.

Comment: Six commenters discussed making an oral offer to counsel. Two of the six suggested that, in all instances, the offer must be oral. Three suggested that a written offer should be used where an oral offer was not possible. The sixth commenter advised that written material alone should not be substituted for the oral offer.

Response: We believe that the issue of whether the offer to counsel must be oral, and the extent to which written material may be substituted for an oral offer of counseling, are matters to be addressed by State standards for counseling.

Comment: Six commenters suggested additional requirements for offers of counseling when the patient was not available, when deliveries were made via mail service or offsite deliveries outside the area covered by the local telephone exchange. They suggested use of written instructions (offer to counsel) with the prescription plus a toll-free telephone number for the patient to call if there were any questions.

Response: We concur and have amended § 456.705(c)(2) to require mail order pharmacies to provide toll-free telephone service for all long distance calls. As stated in the regulation, other pharmacies whose primary patient population is accessible through a local measured or toll-free exchange may not be required to offer toll-free service. A State agency's counseling standards must address special situations where the patient, or the patient's representative, is not readily available to receive the offer to counsel or the actual counseling, for example, prescriptions delivered off site or through the mail.

Comment: Five commenters addressed the provision of a toll-free telephone number for the patient to use to ask questions or obtain additional information concerning his or her prescription. One commenter stated that requiring such a number was not practical. One commenter requested more information regarding toll-free numbers. One commenter stated "access to" should mean that every patient has the opportunity to telephone the pharmacist without cost to the patient. The fourth commenter stated that managed care pharmacies should provide a toll-free telephone counseling service. A fifth commenter also stated that pharmacies should provide a toll-free number on the prescription label which would, in part, meet the "offer to counsel" standard.

Response: As stated in the regulation, pharmacists whose primary patient population is accessible through a local measured or toll-free exchange may not be required to offer toll-free service. States are free to further define, under the counseling standards, the term "primary patient population", or otherwise specify under what circumstances pharmacies would or would not be required to provide toll-free telephone service. Otherwise, pharmacists whose primary population is not accessible as indicated above, would be required to provide toll-free telephone service.

Comment: Four commenters suggested that counseling requirements will alarm, confuse, or raise fears among recipients. Two commenters indicated that recipients would not understand that refusal to provide medical history or to accept counseling would not affect their eligibility for medical services under the Medicaid program.

Response: We do not agree that counseling would alarm, confuse, or raise fears among recipients. Overall, the program will increase the knowledge, and the understanding by patients, of the impact of drugs on their lives. With such increased knowledge, patients can better participate in the administration of the medical care that they are receiving. Rather than alarm patients, the offer to counsel and the actual counseling can be used to alleviate their fears by providing an explanation which could cover not only the items suggested in the law and regulations but also the impact of the counseling program on the individual's eligibility for medical services under the Medicaid program.

Comment: One commenter suggested that the regulations be amended to acknowledge what many States had done to implement model patient counseling legislation that established how the "offer to counsel" is made to the patient.

Response: We do not believe that an acknowledgement of what States have done thus far would serve any purpose. It would not be feasible to include a current list of such States in the regulations since the list would be growing constantly. If such recognition is provided for model patient

counseling legislation, then recognition should also be provided to States that have model retrospective review programs, prospective programs, and point-of-sale ECM systems. HCFA intends to share with the States information and technology that various States have found effective for administering DUR.

Comment: One commenter suggested that the regulation distinguish between the "offer to counsel" and the act of counseling itself.

Response: We believe that §§ 456.705 (c)(1) and (c)(3) already distinguish between the offer and the content of counseling.

Comment: Two commenters suggested that the counseling requirements are an unwarranted Federal intrusion and may have adverse consequences for the mentally ill. They stated that absolute confidentiality must be maintained and counseling must be done in a discreet, supportive, informative, and non-threatening manner.

Response: We agree that the protection of confidentiality and the sensitivity with which counseling is conducted are critically important. Since the States and pharmacists, not the Federal Government, are responsible for counseling, we do not believe that an unwarranted Federal intrusion has occurred.

Comment: One commenter asked whether the $1 to $2 cost estimate per prescription for counseling services was based upon the pharmacist or the ancillary personnel making the offer to counsel.

Response: This estimate was based upon the pharmacist making the offer of counseling.

Comment: One commenter noted that the timing of the issuance of the rule placed States and pharmacies at a serious disadvantage as it permitted only 60 days for the adoption of counseling standards through legislation or regulation.

Response: We agree that the timeframe for issuing the regulations was unusually short and placed a burden on the States. However, most States have successfully established counseling standards to comply with the regulations.

H. Profiling

Section 456.705(d) of the interim final regulations requires States, in the case of Medicaid recipients, to require pharmacists to make a reasonable effort to obtain, record, and maintain patient profiles. The profiles, at a minimum, must contain the following information: (1) name, address, telephone number, date of birth (or age), and gender of the patient; (2) individual history, if significant, including disease state or states, known drug reactions, and a comprehensive list of medications and relevant devices; and (3) the pharmacist's comments relevant to the individual's drug therapy.

Comment: Two commenters suggested that "individual history" rather than "individual medical history" should be one of the minimum information items.

Response: We agree and we have changed § 456.705(d)(2) to delete the word "medical". The term "medical history" is not appropriate, as "medical history" includes obtaining specific information regarding laboratory results, diagnosis, and other medical findings.

Comment: Three commenters suggested that the regulations should include a statement that profile information can be obtained by ancillary personnel, but the pharmacist must review and interpret the information obtained.

Response: We believe this is an individual State decision. A State that decides to authorize auxiliary personnel to obtain profile information may include such authorization and the appropriate requirements for the use of auxiliary personnel in their standards for counseling.

Comment: Three commenters addressed the use of the term "reasonable effort" for obtaining profile information in § 456.705(d). One commenter suggested the term should be further defined or deleted. One commenter suggested expansion of the term to state that "the pharmacist is responsible for ensuring that a reasonable effort is made to obtain profile information." The third commenter suggested expanding the statement to indicate that "reasonable effort" should not include additional burden or cost to the pharmacist.

Response: We have decided not to define reasonable effort in the regulations to allow States flexibility in implementing the DUR requirements. States and their pharmacy boards may, or may not, choose to further define "reasonable effort".

Comment: One commenter stated that § 456.705(d)(2) should be amended to make it explicit that the profiling requirements are limited to recording information concerning drugs and devices dispensed at the pharmacy where the pharmacist is employed.

Response: We have retained the phrase "a comprehensive list of medications and relevant devices" as the statute specifies in section 1927(g)(2)(A)(ii) of the Act. Neither the statute nor the regulation defines a "comprehensive list"; therefore the State, if it chooses, may further define the term according to section 1927(g)(2)(A)(ii) of the Act. Methods for securing this information could include checking the pharmacy's own record, receiving an alert message from the electronic claims management system, or asking the patient, physician, or other pharmacies for additional information if, in the professional judgment of the pharmacist, it was appropriate to do so.

Comment: One commenter suggested that HCFA study the advantages and disadvantages of requiring the collection of information for profiles.

Response: We will consider these matters as a subject for HCFA studies of the DUR program and its impact on the industry and the public.

I. Retrospective DUR

Section 456.709 of the interim final regulations requires that the State Medicaid plan provide for a retrospective DUR program for ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. This examination must involve pattern analysis, using predetermined standards of physician prescribing practices, dispensing practices of pharmacies, and drug use by individual patients. This program must be provided through the State's mechanized drug claims processing and information retrieval system or an electronic drug claims processing system that is integrated with the Medicaid Management Information System (MMIS).

Comment: Two commenters suggested peer review prior to any intervention suggested by DUR reports or outliers identified by computerized DUR programs. A third commenter suggested that the regulations state that the system should not produce punitive decisions against physicians.

Response: It is up to each State to determine whether, and under what circumstances, peer reviews of therapeutic problems identified through screening applications based upon predetermined standards, will be required. States may require peer review prior to all interventions or identify circumstances where peer reviews are, or are not, required.

We do not believe that it is appropriate to address the question of punitive decisions against physicians. The objective of the DUR is to improve pharmaceutical care through education.

J. Education Program

Section 456.711 of the interim final regulations requires that the State plan must provide for ongoing outreach programs that educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. Section 456.716(d)(5) requires the DUR Board to: (1) identify and develop educational programs if needed; (2) make recommendations regarding interventions; and (3) periodically reevaluate and, if necessary, modify interventions. Section 456.716(d)(6) specifies that the Medicaid agency, or its contractor, should apply predetermined standards to drug claims data and generate reports for use by the board and carry out educational programs specified by the board.

Comment: Five commenters suggested expanding § 456.716(d)(5) to make it more specific. One commenter suggested the creation of a fifth provision to require more in-depth review prior to intervention. Other commenters stressed "appropriate and balanced" education programs based upon program experience, matching the education program to the drug therapy problem identified, and placing more emphasis on preliminary education.

Response: We have expanded § 456.716(d)(5)(ii) to address the commenters' suggestions. The DUR Board recommendations for educational interventions must be based on an in-depth review of claims data reports. The board may decide which educational intervention approaches are suitable for the drug therapy problems identified. We have changed § 456.703(f)(5) to specify that standards (that is, exceptions to criteria) may be used in deciding whether or not to intervene after the potential therapeutic problems have been identified.

K. Annual Report

Section 456.712 of the interim final regulations provides that a State must require the DUR Board to prepare and submit annual DUR reports to the Medicaid agency. The Medicaid agency is required to prepare and submit an annual report to the Secretary of the Department of Health and Human Services that incorporates the DUR board's report and includes detailed information on the DUR program operations and an estimate of the cost savings attributable to the DUR program.

Comment: Ten commenters addressed the DUR cost savings estimate required in the annual report. Three commenters suggested that § 456.712 should specify that savings resulting from reduced physician visits and hospitalizations should be taken into account. Two commenters suggested that we require comprehensive evaluations, including both clinical and economic evaluations that would estimate total savings of DUR.

Response: The requirement that State Medicaid agencies submit a cost savings estimate refers to those savings that can be attributed to the operation of prospective and retrospective DUR. The report on cost savings must identify what is spent annually to operate the DUR program and also identify the savings to the Medicaid drug program as a result of DUR. It may include savings that result from reduced physician visits and reduced hospitalizations if the State can document such savings. We agree that evaluating both the economic and clinical impact of DUR is important and the States should, to the extent that they are able, take both types of outcomes into account when evaluating their DUR programs. Demonstration projects are also addressing outcomes, including physician visits, emergency room visits, and hospitalizations. The Agency for Health Care Policy and Research of the Public Health Service is conducting an evaluation of pharmaceutical outcomes, and may cover this topic in its study.

Comment: Three commenters stated that it would be difficult to estimate cost savings as a result of the DUR program and asked for suggestions as how to perform this task. One commenter recommended that HCFA define the word "costs" in § 456.712(b)(10) when referring to the cost savings estimates to be included in the annual report. Another commenter suggested that the cost of DUR be expressed in terms of cost per recipient.

Response: Currently HCFA is developing a cost savings methodology for use by State Medicaid agencies, at their option, when estimating the cost savings that result from DUR. These guidelines will specify data collection needs. They will also suggest what costs are to be considered and whether or not to express costs in terms of cost per recipient. The guidelines for reporting cost savings will be distributed to the States on an advisory basis.

Comment: One commenter suggested that § 456.712(b)(3) be revised to require States to include information in the annual report that describes the process and sources used for establishing and revising criteria.

Response: HCFA will provide guidance to the States about the contents of the annual reports which will include information relating to sources for criteria. We do not believe it is necessary to include this as a regulatory requirement. The State DUR Boards will have such information available if there are any questions about the selection of criteria and standards.

Comment: One commenter suggested that providing complete criteria in annual reports would be cumbersome and costly. Another questioned whether the provision of criteria in the annual report would eliminate the need for the State's cost savings estimate.

Response: Section 1927(g)(3)(D) of the Act identifies specific information that must be included in the annual report to allow us to evaluate the effectiveness of each State's DUR program. HCFA's Medicaid Bureau has provided additional informal guidance with regard to the contents of the annual reports. This guidance indicates that detailed information about DUR-approved criteria must be provided but not necessarily the criteria themselves. This approach addresses concerns about the burdensome nature of submitting complete criteria in the annual reports. The statute requires inclusion of a cost savings estimate in the annual report; therefore provision of detailed information on the criteria does not eliminate the requirement that the State must submit a cost savings estimate.

Comment: One commenter suggested that a requirement be established for adequate data to be collected by State Medicaid agencies, to prove that the DUR program is beneficial.

Response: State agencies are required to submit an annual DUR report to HCFA. As previously indicated, HCFA will provide guidance as to what data are needed to determine cost effectiveness.

L. Drug Use Review and Surveillance and Utilization Review (SUR)

Section 456.714 of the interim final regulations states that the retrospective DUR requirements parallel some portion of the Surveillance and Utilization Review (SUR) requirements in subpart A of part 456 and in part 455 of the Medicaid regulations.

Comment: Two commenters suggested that SUR and DUR activities should be completely separate and distinct.

Response: We agree with the commenters and we have revised § 456.714 to indicate that the SUR program and the DUR program have overlapping responsibilities to identify and reduce the frequency of patterns of fraud, abuse, and gross overuse of drugs. Given the historical emphasis of SUR units in this area, we believe that the DUR staffs should focus their limited resources on what constitutes appropriate and medically necessary

pharmaceutical care. It is the State's option, however, to establish what it considers to be the appropriate balance between fraud and abuse and medical appropriateness concerns.

Comment: One commenter requested clarification of § 456.714 and an explanation of how cost savings from SUR are to be taken into account in calculating DUR cost savings required by § 456.712(b)(10).

Response: HCFA is developing specific guidance to assist the States in determining DUR costs savings as required by § 456.712(b)(10). This guidance will address the issue of whether or not to include SUR cost savings.

M. DUR Board

Sections 456.716(a) and (b) of the interim final regulations require that each State establish a DUR Board and establish requirements for the composition of the DUR Board and expertise of its members. Section 456.716(c) specifies the relationship between the DUR Board and the State Medicaid agency; § 456.716(d) discusses activities of the DUR Board; and § 456.716(e) specifies funding available for DUR Boards.

Comment: Five commenters expressed concern about the relationship between the DUR Board and the State Medicaid agency as provided for in § 456.716(c). Four commenters suggested that the DUR Board be separate from the Medicaid agency or have final authority with regard to clinical issues such as approval of criteria. One commenter suggested the DUR Board should have rulemaking authority. One commenter suggested that DUR Boards should not be independent.

Response: Section 1902(a)(5) of the Act, which specifies that a single State agency must administer or supervise the administration of the Medicaid program, precludes making DUR Boards independent of the State agency. While it is expected that a State will rely heavily on the clinical expertise of the DUR Board, this does not preclude the State agency from independently assessing the DUR Board's recommendations to assist it in reaching its decisions.

Comment: Four commenters addressed the issue of procedures for DUR Board action if a State agency overrules the DUR Board. Two commenters suggested that DUR Boards have procedures to make their activities public, including possible public comment procedure for responses to outside input. Two commenters indicated that when the State agency overrules the DUR Board, it must make public the reasons for its actions and consider public comment.

Response: States may require DUR Boards to establish informal procedures through which outside parties may contribute input with regard to the application of predetermined standards. Section 456.716(c) gives the State agency the authority to overrule the DUR Board. The State agency may or may not make its reasons public, depending on the rules which it establishes for the creation of the DUR Board.

Comment: Five commenters addressed the composition of the DUR Boards. Some commenters suggested the need for more specifics about membership such as the possibility of having public members, representatives of chain pharmacies, and psychiatrists. One commenter suggested that pharmacist members have DUR experience.

Response: The State agency is free to determine the size of the DUR board and may include any types of members that it considers appropriate so long as it complies with §§ 456.716 (a) and (b).

Comment: One commenter suggested that the issue of possible conflict of interest of Board members be dealt with.

Response: Section 1927(g)(3)(b) of the Act and § 456.716 of this regulation specify that members of the DUR boards must be health professionals who have recognized knowledge and expertise in one or more of the following: the clinically appropriate prescribing of covered outpatient drugs; the clinically appropriate dispensing and monitoring of covered outpatient drugs; drug use review, evaluation, and intervention; or medical quality assurance. We are monitoring compliance with these requirements and expect that States will take whatever actions they deem appropriate, consistent with their laws and regulations concerning conflict of interest, to protect against conflict of interest in the operation of the DUR boards.

Comment: One commenter suggested that DUR Boards have the flexibility to determine appropriate interventions and when to use them. The commenter also suggested that there is no need to have all interventions reviewed by peers before they are carried out.

Response: DUR Boards do have the flexibility to determine appropriate interventions and when to perform them. It is up to the DUR Board to decide under what circumstances peer review must occur prior to interventions and when interventions may occur without such review.

Comment: Eighteen commenters responded to the request for comment on the interim final regulations about the appropriateness of having DUR Boards certify prospective DUR software. Ten of these commenters indicated that the DUR Board should not take on the task of certifying individual pharmacy prospective DUR software because of the enormity of the task, the DUR Board's lack of expertise in this area, and because the Board should not be put in a position of providing something equivalent to a seal of approval for software products. Five of the commenters suggested that DUR Boards should approve prospective DUR software. One commenter suggested that it would be more economical for HCFA to undertake evaluation of software packages. Two commenters suggested that DUR Boards should not deal with evaluation of individual pharmacy prospective DUR software but should provide guidance as to which products available to pharmacies would meet statutory requirements.

Response: We agree with those commenters who indicated that the DUR Boards should not take on the task of certifying individual pharmacy prospective DUR software. DUR Boards should know and understand the criteria upon which the software is based, but they often do not have the expertise to evaluate the quality and efficiency of the software itself. Undertaking such certification would be excessively burdensome and create the impression that some packages have State government approval while others do not.

Comment: One commenter suggested that the requirement in § 456.716(b) that pharmacists must be licensed and actively practicing in the State on whose DUR Board they serve would be burdensome to small States seeking to recruit experts from nearby States.

Response: We concur and have revised § 456.716(b) by eliminating the requirement for licensure by the State on whose DUR Board the pharmacist is serving.

N. Electronic Drug Claims Processing

Section 456.722 of the interim final regulations establishes functional requirements for those State Medicaid agencies that choose to develop an on-line, real-time point-of-sale electronic claims management (ECM) system to perform eligibility verification, claims data capture, claims adjudication, and to assist pharmacists in applying for and receiving reimbursement for services.

Comment: Four commenters addressed the costs of in-store telecommunications and the installation

and use of on-line dedicated telecommunications lines. They recommended that pharmacy providers should be compensated for the additional costs incurred One commenter suggested that the States should pay costs, charges, and fees related to on-line communication. Four commenters addressed the issue of costs associated with establishing an on-line, real-time ECM system and asked who would be responsible for the costs. They questioned whether access to the system would be toll free. They suggested that providers be compensated for costs associated with telecommunications, software enhancements, etc., that HCFA or fiscal agents, rather than pharmacies, take responsibility for telecommunication costs, and that HCFA require States to pay associated costs.

Response: State Medicaid agencies, who may receive FFP for the ECM systematic MMIS at enhanced rates if functional requirements are met, may also decide the amount of funding they will offer providers for hardware, software, and telecommunications charges, if any. A State may base this decision on such variables as what the average cost will be for pharmacies to participate, the amount of FFP received by the State for the ECM subsystem, and whether the State's budgets will enable it to compensate pharmacies who have incurred additional costs due to ECM. The State agency is free to pay transmission charges and other costs associated with participation in an ECM system or to require pharmacies to cover these costs.

Comment: One commenter stated that "ECMS" should require only the minimum data elements necessary for processing and paying claims. No variable data elements should be permitted.

Response: HCFA requires at least the minimum data set for processing and paying claims as defined in Part 2 of the State Medicaid Manual. Given the wide variation in State programs, however, we believe that it would be unwise at this time to restrict data that States may need for proper program administration. Thus, States have the option to add other data elements, as necessary.

Comment: Eight commenters suggested that HCFA require State Medicaid agencies to comply with one industry telecommunications standard. Six of the eight commenters recommend NCPDP's Version 3.2 to be incorporated into § 456.722. One commenter suggested that HCFA require the use of RFDS 3C in all State POS/ECM systems.

Response: Currently, the State may decide the format for its ECM as long as it meets the requirements of the minimum data set provided in Part 2, section 11375 of the State Medicaid Manual However, with the growing use of the Electronic Data Interchange (EDI) and the possibility of a Federal requirement that mandates its use by the Medicaid program, a standard format requirement for ECM subsystems may be forthcoming. Moreover, HCFA announced in an advance notice of proposed rulemaking in the **Federal Register** on October 19, 1992 (57 FR 47587) that it endorses electronic standards established by the American National Standards Institute (ANSI). We anticipate final adoption of the ANSI electronic standards as the required telecommunications standard.

Comment: One commenter recommended that the ECM system develop electronic payment capabilities by incorporating the electronic funds transfer (EFT) program, or it will be of little value.

Response: The States may decide whether their ECMs will have an EFT capability. HCFA requires only that ECMs take steps toward the payment of the claim, in order to receive FFP, but not that funds be sent electronically.

Comment: Four commenters addressed the establishment of ECM systems. Two commenters suggested that providers be required by HCFA to use ECM systems. One commenter suggested that participation in an ECM system be an option for the pharmacy. One commenter requested that batch processing of claims for prescriptions be included in any ECM program.

Response: State Medicaid agencies may determine whether providers will be required to use ECM systems and whether providers using the ECM system will be required to rely on the State's prospective DUR, if the State has one. At this time, HCFA does not require State Medicaid agencies to establish ECM systems or to use them to accomplish prospective DUR.

Comment: Two commenters suggested that HCFA should require mail order pharmacies' ECM systems to be on-line, real-time. One commenter suggested that the exemption allowing batch claims submission mentioned in § 456.722(b) also be available to retail pharmacies.

Response: States are responsible for determining whether mail order dispensers and other providers are required to operate a real-time ECM system, or a batch processing system at the end of each day or at a time specified by the State Medicaid agency.

Comment: One commenter recommended that HCFA not require States to obtain cost/benefit analyses prior to procuring point-of-sale ECM.

Response An analysis that shows the cost effectiveness of the ECM is required in order for the States to receive enhanced FFP for the system.

O Dispensing Physicians

The interim final regulations are silent on the subject of dispensing physicians.

Comment: One commenter pointed out that the regulations do not deal with the situation of dispensing physicians.

Response: Section 1927(k)(3) of the Act states that the term "covered outpatient drug" does not apply to drugs provided as physicians services unless there is a separate reimbursement for the drug. If there is a separate reimbursement claim for a drug dispensed by a physician, all the requirements of section 1927(g) apply to that physician, except for the requirements to offer patient counseling and to collect, record, and maintain patient profiles. This is because the Act specifically speaks to a pharmacist's responsibilities in these two areas. The State is free to develop State requirements with regard to patient counseling and patient profiles for dispensing physicians.

Comment: One commenter suggested that dispensing physicians not be allowed to submit claims through ECM systems.

Response: While the Secretary has been explicitly directed by the statute to encourage the use of ECM systems, States are free to establish policy with regard to the submission of claims through ECM systems.

P. Renal Dialysis

Section 1927(k)(3) of the Act does not include as a "covered outpatient drug" under Medicaid, drugs provided for renal dialysis unless direct reimbursement for the drug is involved.

Comment: One commenter pointed out that drugs administered to Medicaid recipients in renal dialysis centers are or are not subject to DUR, depending on whether or not there is separate reimbursement for the drug.

Response: We agree with the commenter. Section 1927 (k)(3) of the Act provides that drugs provided to Medicaid recipients in renal dialysis centers are not subject to DUR unless there is a separate reimbursement for the drug product.

Q. Liability

The Act and the interim final regulations are silent with regard to additional liability incurred by

pharmacists as a result of DUR requirements.

Comment: Three commenters suggested that the preamble language that pharmacies would not incur additional liability is not correct and pharmacists should expect to have additional liability problems.

Response: Suits may result from pharmacy practice of DUR, but we have no evidence to support or refute the contention that the level of liability suits will increase. Since the DUR requirements specified in OBRA '90 constitute standards of pharmacy practice for Medicaid recipients, compliance with these standards provides the best protection against possible liability actions.

Comment: Five commenters suggested that pharmacists be held harmless from liability associated with conducting DUR or that HCFA assume such liability.

Response: We know of no statutory basis for holding pharmacists harmless from such liability or for having HCFA assume such liability that may result from compliance with the DUR requirements.

Comment: One commenter asked about product liability.

Response: We do not believe that product liability would be impacted by the OBRA '90 DUR requirements.

R. Comments on the Regulatory Impact Analysis

Comment: Two commenters questioned the Congressional Budget Office estimate of $10 million to $40 million savings annually. One commenter suggested that the DUR provisions will cost more than they save. The other commenter stated that significant hardware and software costs will reduce cost savings.

Response: Since these commenters provided no specific data, we will not make changes to the Congressional Budget Office estimates.

Comment: Ten commenters questioned the hardware-software costs associated with the DUR program. They included estimates for software costs of: $1,500, $1,900, $2,000 to $5,000, and $3,500. One commenter suggested the cost of a new computer would be $3,600 to $6,000; a second commenter indicated that 10 percent of their group would need new computers. One commenter indicated annual upgrade and modification costs would be $995 per pharmacy.

Response: We concur with the majority opinion that our original estimates may be low and probably should reflect costs in the $1,500 to $3,500 range. However, due to the lack of any empirical data, we are unable at this time to make this determination with any degree of certainty

Comment. Four commenters questioned the cost of counseling, all indicating cost estimates should be higher; however, only two provided their own estimates. One commenter suggested that 5 minutes would be necessary for counseling and profiling at a cost of $2.50 per prescription. Another commenter indicated that the time and cost per prescription for the DUR requirements would be 4 minutes and $2.98 ($2.98 includes 50 cents for hardware- software costs). One commenter suggested that the usual and customary charge should be reimbursed to ensure adequate compensation for DUR services. Four commenters suggested that the dispensing fee will need to be changed to reflect the increased requirements for DUR. None of the commenters suggested specific cost figures.

Response: We believe that 5 minutes at a cost of $2.50 per prescription is a reasonable estimate that would raise our top estimate from $140 million to $175 million. However, as we stated earlier, we lack any empirical data to substantiate this claim.

Comment: Six commenters suggested that the estimates in the interim final regulations did not include, or consider, the cost of interventions or consultations with physicians. One commenter, using data from a study that the commenter conducted, reported that 1.9 percent of all prescriptions require interventions. Where interventions are made, 87 percent of these interventions involve contact with the physician. This commenter estimated that with 2 to 4 minutes per consultation, at a pharmacist hourly rate of $30, the total cost would be $10 to $20 million for approximately 140 million new prescriptions per year.

Response: We generally agree that some of our estimates may be low. However, we do not believe, absent any additional definitive research studies that we can make any provisional changes as a result of this study at this time.

Comment: Three commenters suggested reimbursement for "cognitive services." One commenter suggested that the cognitive fee be separate from the dispensing fee. The second commenter indicated that a cognitive fee payment would ensure that pharmacists would maximize program efficiencies. The third simply advocated payment for such services.

Response: Currently, there is no authorization in Federal statute or regulation for a separate payment for cognitive services. However, section 4401(c)(2) of OBRA '90 authorizes a demonstration project on the cost-effectiveness of reimbursement for pharmacists' cognitive services. When this demonstration project is completed consideration may be given to the inclusion of reimbursement for cognitive services in the payments made to pharmacists.

Comment: The commenters addressed various subjects, all indicating their impact on increasing costs. One commenter suggested that recordkeeping and liability costs will increase. Three commenters indicated that costs associated with establishing and maintaining profiles were not included in the estimates. Six commenters were concerned about increased costs (one comment indicated DUR costs would be shifted to other payers).

Response: Some of these costs will be considered by the State in establishing the dispensing fee. As indicated in existing §§ 447.331 and 447.332 of the Medicaid regulations, the State is authorized to include a reasonable dispensing fee in its payments to pharmacies. This area is discussed in response to the comment regarding liability costs in section II. Q. of this preamble.

Comment: One commenter stated that the regulatory impact analysis was not adequate and seriously underestimated the impact of the rule on small pharmacies. The commenter suggested a more comprehensive regulatory flexibility analysis and recommended a longer compliance schedule for small businesses and looking at other alternatives to ease the burden.

Response: We disagree with the commenter. The analysis in the interim final rule did address the impact on pharmacies, States, dispensing fees, cost of counseling, and the costs of educational outreach. Since the commenter offered no data to support the comment and did not suggest a methodology for conducting the analysis, we are not making a change in the regulation at this time.

III. Changes to the Interim Final Rule

In developing the November 1992 interim final regulations, we essentially relied on the language of sections 1927 (g) and (h) of the Act. We also sought and received advice from various national provider associations, pharmaceutical companies, States, drug utilization review firms, and others. The interim final regulations became effective on January 2, 1993.

We have reviewed all of the public comments received on the interim final

regulations and, in summary, have made the following changes.

- We have amended § 456.702 to clarify the definitions of "overutilization" and "underutilization".
- We have removed the technically incorrect HMO exception from § 456.703(b) and added a new paragraph at § 456.703(c)(2) to indicate the HMO exemption from DUR.
- We have included under § 456.703(c)(1) a provision that those hospitals that claim the exemption from DUR must give assurances to the State that they meet the requirements of section 1927(j)(2) of the Act.
- We have removed the words "rejected or" from § 456.703(f)(1) to clarify that only published peer-reviewed literature is an acceptable criterion.
- We have added a definition of "the consensus process" to § 456.703(f)(2).
- We have amended §§ 456.703(f)(5) and 456.705(b)(3) to clarify that only "clinically significant" adverse medical results warrant consideration in the prospective drug review. We also added wording under § 456.703(f)(5) to include the consideration of patient consumption practices and standards.
- We have added wording to § 456.703(f)(6) to clarify the reason for testing criteria against claims data.
- We have changed the word "prescription" to "drug" in § 456.705(b)(2)(i) in order to include consideration of non- prescription drugs with regard to alteration of therapeutic effect.
- In § 456.705(b)(4), we have specified "daily dosage" rather than "daily dosage range" in the description of what constitutes incorrect drug dosage.
- We have removed the reference to how drug counseling requirements apply specifically to mail order pharmacies from § 456.705(c) (now designated as § 456.705(c)(1)) so that we do not give the impression that they are treated differently than other pharmacies. Also, we have added language in § 456.705(c)(1) (i) through (v) to specify the issues that State agencies must address when formulating their counseling standards.
- We have added wording to § 456.705(c)(2)(i), previously § 456.705(c)(1), to require mail-order pharmacies to provide toll-free telephone service for long distance calls for counseling.
- In § 456.705(d)(2), we have replaced the phrase "individual medical history" with "individual history" since medical history would indicate the need for much more complete records, including such items as laboratory reports, X-rays, consultation reports, and unrelated surgeries and illnesses.
- We have added a paragraph to § 456.714 clarifying the distinction between the responsibilities of DUR and SUR.
- We have amended § 456.716(b) to change the requirement for licensure of a DUR board member in the State on whose board he or she serves, to licensure in any State.
- In § 456.716(d)(5)(ii) we have added wording to clarify the bases for DUR board recommendations, and we have added wording to § 456.703(f)(5) to allow the consideration of standards if an in-depth review is needed to determine whether to intervene once the potential therapeutic problems have been identified through the use of clinical criteria.
- Also, we have made certain technical corrections and corrections of typographical errors that appeared in the interim final rule.

VI. Regulatory Impact Statement

A. Regulatory Flexibility Act

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 rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all pharmacies and prescribing physicians are considered to be small entities.

B. Comments on Regulatory Impact Analysis and Regulatory Flexibility Analysis

In the interim final rule with comment period, we included a regulatory impact and regulatory flexibility analysis because of the financial impact on the operation of pharmacies, the States, and on recipients. The analysis described the effects that the interim final rule with comment period would have on these individuals and entities.

We received 35 comments concerning the costs of the drug use review program, the cost of the DUR requirements on pharmacies, and the cost estimates included in the interim final rule. All commenters indicated that the actual costs of implementing the provisions will be higher than the amounts presented. Eight of the commenters furnished specific cost figures either for their particular operation or they supplied estimates of specific costs per prescription, type of service rendered, equipment costs, or total program costs.

The comments covered the following specific areas:

- Initial hardware and software computer costs
- Upgrade costs for computer programs
- Counseling
- Cognitive services
- Dispensing fees
- Consultation with physicians
- Interventions by pharmacies
- Recordkeeping
- Additional liability for the pharmacist
- Profiles

The other commenters suggested the cost *saving* estimate was too high, advocated increased Federal funds to offset DUR costs, urged voluntary compliance of prospective DUR requirements for small fragile pharmacies, warned that DUR cost estimates were too low, and requested a comprehensive regulatory analysis for small businesses. For a complete summarization of these comments and our responses, see section II of this preamble.

We were unable to provide a more quantitative analysis due to the lack of empirical data. However, we did receive several studies from commenters. Although these data were somewhat limited, we agree that some of our estimates were low. We believe, however, that additional research in the future concerning these issues is needed to provide us with more specific results.

This final rule revises the November 2, 1992, interim final rule with comment period based on comments submitted by the public. Costs associated with implementing these regulations are a consequence of section 4401 of OBRA '90, not the regulations. We do not believe, absent any additional definitive research studies, that the changes incorporated into this final rule as a result of public comments will have any significant effect on DUR costs.

C. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This 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 is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We are not preparing a rural impact analysis since we have determined, and the Secretary certifies, that this final rule will not have a significant impact

or the operations of a substantial number of small rural hospitals. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

V. Collection of Information Requirements

Sections 456.703, 456.705, 456.709, 456.711, 456.712, 456.716, and 456.722 contain information collection or recordkeeping requirements or both that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). The information collection requirements concern the collection of information for patient profiles of Medicaid recipients, preparation by the State DUR boards of annual reports to the State agency, and preparation of annual reports by the State agency to the Secretary. These are statutory requirements. The respondents who will provide the information include Medicaid recipients who will provide information for profiles to pharmacists, State DUR boards that will provide annual report information to the State agencies and State agencies that will provide annual report information to the Secretary. Public reporting burden for the collection of profile information is estimated to be 5 minutes for each initial encounter and 2 minutes for each subsequent encounter. Public reporting burden for the collection of the annual report information, which includes activities by the DUR board and by the State agency, is estimated to be up to 60 hours a year per State.

A notice will be published in the **Federal Register** after approval is obtained.

List of Subjects in 42 CFR Part 456

Administrative practice and procedure, Grant programs—health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR part 456 is amended as set forth below:

PART 456—UTILIZATION CONTROL

1. The authority citation continues to read as follows:

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

2. In § 456.702 the definitions of "overutilization" and "underutilization" are revised to read as follows:

§ 456.702 Definitions.

* * * * *

Overutilization means use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesirable effect, or both.

* * * * *

Underutilization means use of a drug by a recipient in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesired effect, or both.

3. In § 456.703, paragraphs (b), (c), and (e)(4) are revised, the introductory text of paragraphs (e) and (f) are republished and paragraphs (f)(1), (f)(2), (f)(5), (f)(6) and (h) are revised to read as follows:

§ 456.703 Drug use review program.

* * * * *

(b) *Exception for drugs dispensed to certain nursing facility residents.* Prospective drug review and retrospective drug use review (including interventions and education) under the DUR program are not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in part 483 of this chapter. This does not preclude the State agency from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State agency makes the drugs subject to all the requirements of this subpart applicable to the respective review.

(c) *Exemption for certain covered outpatient drugs dispensed by hospitals and health maintenance organizations.*

(1) The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart. Individual hospitals requesting this exemption must provide assurances to the State agency that they meet the requirements specified in section 1927(j)(2) of the Act.

(2) The State plan must provide that covered outpatient drugs dispensed by health maintenance organizations are not subject to the requirements of this subpart.

* * * * *

(e) *Source of predetermined standards.* The predetermined standards must be—

* * * * *

(4) Any combination of paragraphs (e)(1) through (e)(3) of this section.

(f) *Requirements for predetermined standards.* The predetermined standards used in the DUR program must meet the following requirements:

(1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts) and the following compendia.

(i) American Hospital Formulary Service Drug Information;

(ii) United States Pharmacopeia-Drug Information;

(iii) American Medical Association Drug Evaluations.

(2) Differences between source materials were resolved by physicians and pharmacists developing consensus solutions. The consensus process means the reliance, by the criteria developers, on the expertise of physicians and pharmacists to evaluate differences in criteria source materials and to come to agreement on how differences should be resolved.

* * * * *

(5) The review based on clinical criteria uses predetermined standards to determine the population at risk of a clinically significant adverse medical result and applies standards, appropriate to this population, across providers and patients to determine the provider outliers whose prescribing, dispensing, or consumption practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these data. Standards may be considered in deciding if an in-depth review is needed to determine whether to intervene once the potential therapeutic problems have been identified through the use of clinical criteria.

(6) They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems without undue levels of false positives.

* * * * *

(h) *Confidentiality of patient related data.* In implementing the DUR program, the agency must establish, in regulations or through other means, policies concerning confidentiality of patient related data that are consistent with applicable Federal confidentiality requirements at part 431, subpart F of this chapter; the State Pharmacy Practice Act; and the guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies.

4. In § 456.705, paragraph (b) introductory text is republished and paragraphs (b)(2)(i), (b)(3), (b)(4), (c), and (d) are revised to read as follows:

§ 456.705 Prospective drug review

* * * * *

(b) *Point-of-sale or point-of-distribution review.*

* * * * *

(2) Drug-disease contraindication, that is, the potential for, or the occurrence of—

(i) An undesirable alteration of the therapeutic effect of a given drug because of the presence, in the patient for whom it is prescribed, of a disease condition; or

* * * * *

(3) Adverse drug-drug interaction, that is, the potential for, or occurrence of, a clinically significant adverse medical effect as a result of the recipient using two or more drugs together.

(4) Incorrect drug dosage, that is, the dosage lies outside the daily dosage specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage is the strength multiplied by the quantity dispensed divided by day's supply.

* * * * *

(c) *Drug counseling.* (1) As part of the prospective drug review program, standards for counseling by pharmacists of recipients or the recipients' caregivers must be established by State law or other method that is satisfactory to the State agency. A State agency's counseling standards must address special situations where the patient or the patient's representative, is not readily available to receive the offer to counsel or the actual counseling, for example, prescriptions delivered offsite or through the mail. The State agency, at a minimum, must also address the following issues in their counseling standards:

(i) Whether the offer to counsel is required for new prescriptions only, or for both new and refill prescriptions;

(ii) Whether pharmacists must make the offer to counsel or auxiliary personnel are authorized to make the offer;

(iii) Whether only a patient's refusal of the offer to counsel must be documented, or whether documentation of all offers is required;

(iv) Whether documentation of counseling is required; and

(v) Whether counseling is required in situations where the patient's representative is not readily available to receive a counseling offer or the counseling itself.

(2) The standards must meet the following requirements:

(i) They must require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Mail order pharmacies are required to provide toll-free telephone service for long distance calls.

(ii) They need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses that consultation.

(iii) They must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

(3) The standards must specify that the counseling include those matters listed in paragraphs (c)(3)(i) through (c)(3)(viii) of this section that, in the exercise of his or her professional judgement (consistent with State law regarding the provision of such information), the pharmacist considers significant as well as other matters the pharmacist considers significant.

(i) The name and description of the medication;

(ii) The dosage form, dosage, route of administration, and duration of drug therapy;

(iii) Special directions and precautions for preparation, administration, and use by the patient;

(iv) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) Techniques for self-monitoring drug therapy;

(vi) Proper storage;

(vii) Prescription refill information; and

(viii) Action to be taken in the event of a missed dose.

(d) *Profiling.* The State agency must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing, at a minimum, the information listed in paragraphs (d)(1) through (d)(3) of this section.

(1) Name, address, telephone number, date of birth (or age), and gender of the patient;

(2) Individual history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist's comments relevant to the individual's drug therapy.

5. Section 456.714 is revised to read as follows:

§ 456.714 DUR/Surveillance and utilization review relationship.

(a) The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455 of this chapter.

(b) A State agency may direct DUR staffs to limit review activities to those that focus on what constitutes appropriate and medically necessary care to avoid duplication of activities relating to fraud and abuse under the SUR program.

6. In § 456.716, paragraph (d) introductory text is republished and paragraphs (b), (d)(5) introductory text and (d)(5)(ii) are revised to read as follows:

§ 456.716 DUR Board.

* * * * *

(b) *Board composition.* At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed.

* * * * *

(d) *DUR Board activities.*

* * * * *

(5) *Education program (including interventions): Board's activities.* The DUR Board must perform the following activities:

* * * * *

(ii) Make recommendations as to which mix of the interventions set forth in §§ 456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy. The DUR board recommendations must be based upon an in-depth review of the results of the application of predetermined standards against claims data reports, must be appropriate based upon program experience, and must match the educational program with the drug therapy problems identified.

* * * * *

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

Dated: April 1, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: June 28, 1994.

Donna E. Shalala,

Secretary.

[FR Doc. 94–23280 Filed 9–22–94; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 61, 64, and 69

[CC Docket No. 91–115]

Tariffing Requirements for Billing Name and Address

AGENCY: Federal Communications Commission.

ACTION: Final rule; clarification.

SUMMARY: On May 13, 1993, the Federal Communications Commission adopted amendments to require local exchange carriers to provide billing name and address information on a common carrier basis to telecommunications service providers for billing purposes. On August 5, 1993, those rule amendments were suspended. By this document, the Commission clarifies that the suspension of these amendments has been lifted.

EFFECTIVE DATE: This document is effective September 23, 1994, and establishes the effective date of the rules as of January 18, 1994.

SUPPLEMENTARY INFORMATION: On May 13, 1993, the Federal Communications Commission adopted revisions to Parts 61, 64, and 69 of its Rules, 47 CFR Parts 61, 64, and 69, to require local exchange carriers to provide billing name and address information on a common carrier basis to telecommunications service providers for billing purposes. Policies and Rules Concerning Local Exchange Carrier Validation and Billing Information for Joint Use Calling Cards, 58 FR 36143–45, July 6, 1993. On August 5, 1993, those rule revisions were suspended. Policies and Rules Concerning Local Exchange Carrier Validation and Billing Information for Joint Use Calling Cards, 58 FR 42253–54, Aug. 9, 1993. By this document, the Commission clarifies that the suspension of these rule revisions has been lifted, and these revisions took effect as of January 18, 1994. *See* Policies and Rules Concerning Local Exchange Carrier Validation and Billing Information for Joint Use Calling Cards, 58 FR 65669–71, Dec. 16, 1993.

FOR FURTHER INFORMATION CONTACT: Steven Spaeth, Tariff Division, Common Carrier Bureau, (202) 418–1530.

Federal Communications Commission,

William F. Caton,

Acting Secretary.

[FR Doc. 94–23101 Filed 9–22–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 93–186; RM–8258, RM–8333 & RM –8343]

Radio Broadcasting Services; Diamond City, AR, Half Way, Humansville, and Ozark, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 225C2 for Channel 225A at Ozark, Missouri, modifies the construction permit for Station KZPF (FM), substitutes Channel 256A for Channel 226A at Half Way, Missouri, and modifies the construction permit for Station KYOO–FM, in response to a petition filed jointly by Ozark Mountain Broadcasting, Inc. and KYOO Broadcasting Company. *See* 58 FR 38548, July 19, 1993. The coordinates for Channel 225C2 at Ozark are 36–58–45 and 93–26–38. The coordinates for Channel 256A at Half Way are 37–44–35 and 93–15–00. The counterproposals filed by Lake Broadcasting requesting the allotment of Channel 224A to Diamond City, Arkansas, and Missouri Radio, Inc. proposing the allotment of Channel 256A to Humansville, Missouri, were withdrawn on March 3, 1994. With this action, this proceeding is terminated.

EFFECTIVE DATE: November 7, 1994.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 93–186, adopted September 12, 1994, and released September 20, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street NW., Suite 140, Washington, D.C. 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by removing Channel 225A and adding Channel 225C2 at Ozark and by removing Channel 226A and adding Channel 256A at Half Way.

Federal Communications Commission.

Douglas W. Webbink,

Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–23508 Filed 9–22–94; 8:45 am]

BILLING CODE 6712–01–M