

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431 and 457

[CMS-6026-IFC2]

RIN 0938-AN77

Medicaid Program and State Children's Health Insurance Program (SCHIP) Payment Error Rate Measurement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period sets forth the State requirements to provide information to us for purposes of estimating improper payments in Medicaid and SCHIP. The Improper Payments Information Act of 2002 (IPIA) requires heads of Federal agencies to estimate and report to the Congress annually these estimates of improper payments for the programs they oversee, and submit a report on actions the agency is taking to reduce erroneous payments.

This interim final rule with comment responds to the public comments on the October 5, 2005 interim final rule and sets forth State requirements for submitting claims and policies to the Federal contractor for purposes of conducting FFS and managed care reviews. This interim final rule also sets forth and invites further comments on the State requirements for conducting eligibility reviews and estimating payment error rates due to errors in eligibility determinations.

DATES: *Effective Date:* These regulations are effective on October 1, 2006.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 27, 2006.

ADDRESSES: In commenting, please refer to file code CMS-6026-IFC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word,

WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6026-IFC2, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6026-IFC2, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of Comments on Paperwork Requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Janet E. Reichert, (410) 786-4580.

Elizabeth Pham, (410) 786-7703.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on the State

requirements for conducting eligibility reviews and estimating payment error rates due to errors in eligibility determinations. You can assist us by referencing the file code CMS-6026-IFC.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received in a timely manner will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. The Improper Payments Information Act of 2002

The Improper Payments Information Act of 2002 (IPIA), Public Law 107-300, enacted on November 26, 2002, requires the heads of Federal agencies annually to review programs they oversee that are susceptible to significant erroneous payments, and to estimate the amount of improper payments, to report those estimates to the Congress, and to submit a report on actions the agency is taking to reduce erroneous expenditures. The IPIA directed the Office of Management and Budget (OMB) to provide guidance on implementation. OMB defines significant erroneous payments as annual erroneous payments in the program exceeding both 2.5 percent of program payments and \$10 million (OMB M-03-13, May 21, 2003). For those programs with significant erroneous payments, Federal agencies must provide the estimated amount of improper payments and report on what actions the agency is taking to reduce them, including setting targets for future erroneous payment levels and a timeline by which the targets will be reached.

According to OMB directives, Federal agencies must include in the report to the Congress: (1) The estimate of the

annual amount of erroneous payments; (2) a discussion of the causes of the errors and actions taken to correct those problems, including plans to increase agency accountability; (3) a discussion of the amount of actual erroneous payments the agency expects to recover; (4) limitations that prevent the agency from reducing the erroneous payment levels, that is, resources or legal barriers; and (5) a target for the program's future payment rate, if applicable.

The Medicaid and SCHIP programs were identified by OMB as programs at risk for significant erroneous payments. OMB directed the Department of Health and Human Services (DHHS) to report the estimated error rates for the Medicaid and SCHIP programs each year for inclusion in the Performance and Accountability Report (PAR).

Through the Payment Accuracy Measurement (PAM) and Payment Error Rate Measurement (PERM) pilot projects that CMS operated in Fiscal Years (FYs) 2002 through 2005, we developed a claims-based review methodology designed to estimate State-specific payment error rates for all adjudicated claims within 3 percent of the true population error rate with 95 percent confidence. An "adjudicated claim" is a claim for which either money was obligated to pay the claim (paid claims) or for which a decision was made to deny the claim (denied claims).

B. CMS Rulemaking

We published a proposed rule on August 27, 2004 (69 FR 52620) to comply with the requirements of the IPIA and the OMB guidance. Based on the methodology developed in the pilot projects, the proposed rule set forth provisions for all States annually to estimate improper payments in their Medicaid and SCHIP programs and to report the State-specific error rates for purposes of our computing the national improper payment estimates for these programs. The intended effects of the proposed rule were to have States measure improper payments based on fee-for-service (FFS), managed care, and eligibility reviews; to identify errors to target corrective actions; to reduce the rate of improper payments; and to produce a corresponding increase in program savings at both the State and Federal levels.

After extensive analysis of the issues related to having States measure improper payments in Medicaid and SCHIP, including public comments on the provisions in the proposed rule, we revised our approach. Our revised approach adopted the recommendation to engage Federal contractors to review State Medicaid and SCHIP FFS and

managed care payments (we define the term "claims" to include both managed care capitation payments and FFS line items) and to calculate the State-specific and national error rates for Medicaid and SCHIP. (States will calculate the State-specific eligibility error rates. Based on these rates, the Federal contractor will calculate the national eligibility error rate for each program.) We also adopted the recommendation to sample a subset of States each year rather than to measure every State every year. We adopted these recommendations primarily in response to commenters' concerns with the cost and burden to implement the regulatory provisions that the proposed rule would have imposed on States.

Since our revised approach deviated significantly from the approach in the proposed rule, we published an interim final rule with comment period on October 5, 2005 (70 FR 58260). The October 5th interim final rule with comment period responded to the public comments on the proposed rule, and informed the public of our national contracting strategy and of our plan to measure improper payments in a subset of States. Our State selection will ensure that a State will be measured once, and only once, every 3 years in each program.

The October 5, 2005 interim final rule also set forth the types of information that States would submit to the Federal contractors for the purpose of estimating Medicaid and SCHIP FFS improper payments. The October 5, 2005 interim final rule invited further comments on methods for estimating eligibility and managed care improper payments. We received very few comments regarding managed care and a number of comments regarding eligibility. Based on the public comments, we developed an approach to measuring eligibility errors and, through this second interim final rule, invite further public comments on this eligibility methodology. Section 1102(a) of the Social Security Act (the Act) authorizes the Secretary to establish such rules and regulations as may be necessary for the efficient administration of the Medicaid and SCHIP programs. Medicaid statute at section 1902(a)(6) of the Act and SCHIP statute at section 2107(b)(1) of the Act require States to provide information that the Secretary finds necessary for the administration, evaluation, and verification of the State's program. Also, section 1902(a)(27) of the Act (and 42 CFR 457.950) requires providers to submit information regarding payments and claims as requested by the Secretary, State agency, or both.

Under the authority of these statutory provisions, this second interim final rule requires those States selected for review in any given year for the Medicaid or SCHIP improper payments measurement to provide the Federal contractors with information needed to conduct medical and data processing reviews on FFS claims and data processing reviews on managed care claims. (Managed care claims are not subject to medical review because managed care payments are based on capitated payments made per enrollee, not on the individual services provided.)

The States selected for PERM must provide:

(a) All adjudicated FFS and managed care claims information from the review year, on a quarterly basis, with FFS claims stratified by type of service;

(b) Upon request from the contractor, provider contact information that has been verified by the State as current;

(c) All medical and other related policies in effect and any quarterly policy updates;

(d) Current managed care contracts, rate information, and any quarterly updates to the contracts and rates for the review year for SCHIP and, as requested, for Medicaid;

(e) Data processing systems manuals;

(f) Repricing information for claims that are determined to have been improperly paid;

(g) Information on claims that were selected as part of the sample, but which changed in substance after selection, for example, successful provider appeals;

(h) Adjustments made within 60 days of the adjudication dates for the original claims or line items with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items;

(i) A corrective action report for purposes of reducing the payment error rate in the FFS, managed care and eligibility components of the program; and

(j) Other information that the Secretary determines is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP.

C. IPIA Implementation

We expect to be compliant with IPIA requirements by 2008. We are measuring Medicaid FFS improper payments in FY 2006 and plan to have all components (FFS, managed care and eligibility) of Medicaid and SCHIP measured in FY 2007 and beyond. We delayed announcing a methodology for

measuring errors in managed care and eligibility in the October 5, 2005 interim final rule; and instead, we invited comments on methods for measuring these types of improper payments in both Medicaid and SCHIP. We determined that the Federal contractor would review managed care claims similar to the review process used in the PERM pilot. We published the information collection request for SCHIP and Medicaid managed care error measurements on February 3, 2006 (71 FR 5851) and again on April 14, 2006 (71 FR 19522) for public comment. We are describing the State information submission requirements in this interim final rule.

In the October 5, 2005 interim final rule, we stated that it was still possible that States sampled for review would be required to conduct eligibility reviews as described in our approach to the proposed rule. We also announced in the October 5, 2005 interim final rule our intentions to establish an eligibility workgroup to make recommendations on the best approach for reviewing Medicaid and SCHIP eligibility within the confines of current statute, with minimal impact on States and additional discretionary funding. We convened an eligibility workgroup comprised of DHHS [including CMS and, in an advisory capacity, the Office of the Inspector General (OIG)], OMB, and representatives from two States. We determined that States should conduct the eligibility measurement based on the workgroup's consideration of public comments and the examination of various approaches proposed in such comments. We also developed a review methodology, which we have outlined in this interim final rule with comment period and invite further public comment on these eligibility error measurement provisions.

Thus, in FY 2007 and beyond, we expect to have Federal contractors

measure improper payments in the FFS and managed care components of Medicaid and SCHIP, and have States selected for these reviews in any given year measure the error rate in their respective determinations of program eligibility. These measurements will produce State-specific error rates for the three components—FFS, managed care and eligibility—as well as composite program error rates for the State's Medicaid and SCHIP programs. From the State-specific error rates, we will calculate national error rates for each of the components and for the Medicaid and SCHIP program.

ANNUAL PERM ERROR RATES PRODUCED	
State-specific: Four error rates per selected program (for 17 states)	National: Eight error rates
1. FFS	1. Medicaid FFS.
2. Managed care	2. SCHIP FFS.
3. Eligibility	3. Medicaid managed care.
4. Medicaid/SCHIP Program Error Rate.	4. SCHIP managed care.
	5. Medicaid eligibility.
	6. SCHIP eligibility.
	7. Medicaid Program.
	8. SCHIP Program.

We expect State corrective actions to address the causes of error in each of the three program components. As a result, we expect States will reduce their error rates over the course of each measurement cycle which, in turn, should reduce the national error rates.

II. Provisions of the October 5, 2005 Interim Final Regulations

We published an interim final rule with comment period on October 5, 2005 that responded to comments on the August 27, 2004 proposed rule and informed the public that we will use a national contracting strategy to estimate

improper payments in Medicaid and SCHIP FFS in a subset of States rather than every State every year. We adopted this approach based on public comments on the proposed rule.

A. Selecting States for Review

Medicaid State Selection. We will use a rotational approach to review the States in Medicaid. For each fiscal year, we expect to measure 17 States. The result is that each State will be measured once, and only once, every 3 years. The rotation allows States to plan for the reviews because States know in advance in which year they will be measured.

In determining the Medicaid State selection, we grouped all States into three equal strata of small, medium, and large based on the States' most recently available FFS annual expenditure data. We randomly selected up to six States from each stratum each year, until we selected all States for review over the current and next 2 fiscal years (that is, FY 2006 through FY 2008). (The third stratum with the large States (based on annual expenditures) was substratified into two strata of 8 and 9 States. Two States were selected from one substratum and three States were selected from the other substratum. We selected 6 States each from the "small" and "medium" strata for a total of 17 States.)

The States selected for Medicaid FFS review in FY 2006, and Medicaid FFS, managed care, and eligibility reviews in FY 2007 and FY 2008 are listed below. At the end of the 3-year period, the rotation will repeat so that the Medicaid FY 2006 States will be reviewed in FY 2009; the Medicaid FY 2007 States will be reviewed in FY 2010; and the Medicaid FY 2008 States will be reviewed in 2011. We announced the Medicaid State selection rotation through a State Health Official Letter transmitted November 18, 2005.

MEDICAID STATE SELECTION	
FY 2006	Pennsylvania, Ohio, Illinois, Michigan, Missouri, Minnesota, Arkansas, Connecticut, New Mexico, Virginia, Wisconsin, Oklahoma, North Dakota, Wyoming, Kansas, Idaho, Delaware.
FY 2007	North Carolina, Georgia, California, Massachusetts, Tennessee, New Jersey, Kentucky, West Virginia, Maryland, Alabama, South Carolina, Colorado, Utah, Vermont, Nebraska, New Hampshire, Rhode Island.
FY 2008	New York, Florida, Texas, Louisiana, Indiana, Mississippi, Iowa, Maine, Oregon, Arizona, Washington, District of Columbia, Alaska, Hawaii, Montana, South Dakota, Nevada.

SCHIP State Selection. Subsequent to the Medicaid State selection for PERM reviews, we completed the SCHIP State selection. We determined that SCHIP can be measured in the same States selected for Medicaid review each fiscal year with a high probability that the

SCHIP error rate will meet OMB requirements for confidence and precision levels. Since SCHIP and Medicaid will be measured in the selected States at the same time, each State will be measured for SCHIP once and only once every three years. We

will send a State Health Official Letter regarding the SCHIP State selection as we did on the Medicaid State selection.

We believe that paralleling the SCHIP and Medicaid measurements will minimize administrative complexities for both CMS and the States. Measuring

both programs at the same time may also reduce the State cost and burden because States are able to plan activities for both measurements and may gain efficiencies by combining staff and resources for the reviews.

As with Medicaid, we expect to measure improper payments in all components (FFS, managed care, and eligibility) of SCHIP in FY 2007 and beyond. For States measured for Medicaid FFS in FY 2006, SCHIP will be measured in FY 2009.

B. Use of Federal Contractors

Under the national contracting strategy, we will use Federal contractors to measure Medicaid and SCHIP FFS and managed care improper payments. For FY 2006, we have engaged three contractors: (1) A statistical contractor (SC); (2) a documentation/database contractor (DDC); and (3) a review contractor (RC). The use of three Federal contractors allows for the award of contracts in areas of specialization and expertise, minimizes potential problems if one contractor experiences operational difficulties, and provides CMS with optimum oversight.

The SC collects adjudicated claims data, determines the sample size, draws the sample, and calculates the State and national error rates. The DDC collects and stores State medical and other related policies, and requests the medical records from providers for the FFS medical reviews. The RC conducts the medical and data processing reviews.

Statistical Contractor

The States selected for review will submit to the SC the following information for Medicaid and SCHIP:

- All adjudicated FFS and managed care claims information from the review year on a quarterly basis, with FFS claims stratified into seven strata by service type and one additional stratum for denied claims;

- Information on claims that were selected as part of the sample, but which changed in substance after selection (for example, successful provider appeals); and

- Adjustments made within 60 days from the adjudication dates for the original claims or line items, with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items.

States are requested to provide stratified FFS claims data because stratifying the claims by service type improves the efficiency of the sampling methodology by distributing the claims in the sample in proportion to the dollar

share in the universe. Stratification allows services with a larger dollar share to compose a larger share of the sample and reduces the variance in the sample. Stratifying the claims also allows for smaller sample sizes and for the identification of errors in specific service types so that States can systematically target causes of errors.

The SC will work with States and will compare the data submitted to recent data to help establish that the data are complete. Based on the annual expenditure data, the SC will determine the State's sample size and, for FFS claims, the sample size for each of the eight total strata. These strata were established during the pilot projects based on the total share of dollars. In addition, States had already grouped their claims similarly in their Medicaid Management Information System (MMIS); therefore, we believe that the stratification of claims for submission should not be burdensome to States. Stratification of the claims also provides States with information regarding the service areas where the errors are concentrated so that States can better target corrective actions.

The strata are: (1) Hospital services; (2) long term care services; (3) other independent practitioners and clinics; (4) prescription drugs; (5) home and community based services; (6) other services and supplies (for example, durable medical equipment, clinical lab tests, and x-rays); (7) primary care case management; and (8) denied claims. We expect that the average sample size will be 1,000 FFS claims and 500 managed care claims per State program in order to achieve a 3 percent precision level at the 95 percent confidence level (based on a range estimated during the PAM/PERM pilots).

From the State's quarterly adjudicated claims data, the SC will randomly select a sample of FFS and managed care claims each quarter. The State will stratify the FFS claims before submitting the data to the SC. Each selected FFS claim will be subjected to a medical and data processing review. Managed care claims will not be stratified and will not be subject to medical reviews because the payments that are made to a managed care plan are based on a set fee from a predetermined capitation agreement, rather than for the specific service(s) provided.

Documentation/Database Contractor

States selected for review will provide the DDC the following information for Medicaid and SCHIP:

- All medical and other related policies in effect for the review year and any quarterly policy updates;

- Current managed care contracts, rate information, and any quarterly updates to contracts and rates for the review year for SCHIP and, as requested, for Medicaid; and

- Upon request from the contractor, provider contact information that has been verified by the State as current.

Review Contractor

States selected for review will provide the RC the following information for Medicaid and SCHIP:

- Systems manuals for data processing reviews. (If a State's medical and data processing policies are intertwined, the State may send the policies to the DDC. The DDC will then identify the data processing policies so the RC can access them through the DDC.

- Repricing information, as requested by the RC, for claims that the RC determines to be improperly paid. The RC will request that States reprice claims that are found to be in error so that the RC is able to determine the amount of the improper payment.

The RC will use the information collected by the DDC to conduct the medical reviews. The RC will conduct the data processing reviews, most likely on-site, using the systems information provided by the State. The RC will, at a minimum, send monthly disposition reports to the States. The disposition reports will list the contractor's review findings for each sampled claim. States can review these findings and notify the RC if they identify errors they believe should be reversed. The RC will work with States to resolve differences in findings. If the State finding prevails, the RC will reverse the error finding. If the RC's finding is upheld, the error finding will stay in the calculation of the error rate.

When the reviews are completed, the SC will estimate the State-specific error rates for the FFS and managed care components of the Medicaid and SCHIP programs, as well as national program error rates and national component error rates. The States will review their error rates; determine root causes of error-prone areas and develop corrective actions to address the error causes for purposes of reducing the payment error rates.

CMS

States selected for review will provide us with the following information for Medicaid and SCHIP:

- A corrective action report for purposes of reducing the State's payment error rates in the FFS, managed care, and eligibility components of the program; and

• Other information that the Secretary determines necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP.

We will notify selected States regarding any additional information that may be necessary for determining error rates in Medicaid and SCHIP. We do not expect to request additional information other than the information we have specified in this interim final rule with comment period. However, we would necessarily request information we find during the course of measuring each program that would improve the process, produce more accurate error rates, or reduce the cost and burden on

either or both the State and Federal governments. Similarly, if we determined that we are collecting specific information that does not add value to the error rate measurement or is not productive to collect, we would discontinue that collection. Once the State-specific and national error rates are estimated, the States will develop and send to us corrective action reports describing corrective actions that the States will implement to reduce the incidence of improper payments.

C. Review Process

The process for measuring improper payments, called the “production cycle,” under the national contracting

strategy will take approximately 23 months per cycle. For example, the measurement for FY 2006 (which involves the reviews of adjudicated Medicaid FFS claims during October 2005 through September 2006) begins October 1, 2005 and will be completed by August 30, 2007. The results will be included in the FY 2007 PAR, which is published in November 2007. Using FY 2006 as an example, the following table provides an approximate overview of the PERM process. It is important to note that the process is fluid, so timeframes may fluctuate slightly depending on such factors as the complexities of the reviews.

EXAMPLE OF THE PERM PRODUCTION CYCLE: FY 2006

[Note: only includes Medicaid FFS]

Timeframe	Event
December 1, 2005	• States submit medical policies in effect for the review period to the DDC.
January 15, 2006	• States submit 1st quarter FY 2006 (October–December 2005) adjudicated claims to the SC.
February 1, 2006	• State submits 1st quarter FFS policy updates to the DDC.
April 15, 2006	• States submit 2nd quarter FY 2006 (January–March 2006) adjudicated claims to the SC.
May 1, 2006	• States submit 2nd quarter policy updates to the DDC.
July 15, 2006	• States submit 3rd quarter FY 2006 (April–June 2006) adjudicated claims to the SC.
August 1, 2006	• States submit 3rd quarter policy updates to the DDC.
October 15, 2006	• States submit 4th quarter FY 2006 (July–September 2006) adjudicated claims to the SC.
November 1, 2006	• States submit 4th quarter policy updates to the DDC.
Throughout PERM process	• States identify and resolve differences in review findings with the RC.

D. Eligibility Measurement

In the October 5, 2005 interim final rule, we invited comments on methods for measuring improper payments in eligibility in Medicaid and SCHIP. We stated in the October 5, 2005 interim final rule that the States sampled for the Medicaid or SCHIP FFS and managed care reviews in any year may be required to conduct eligibility reviews as set out in the proposed rule. To develop the eligibility measurement, we convened a workgroup comprised of DHHS (including CMS and, in an advisory role, the OIG), OMB, and representatives from two States. The workgroup considered public comments and made recommendations on the best method to measure Medicaid and SCHIP eligibility improper payments within the confines of current law, and with minimal impact on States and on additional discretionary funding.

We also invited comments on managed care review. We received few comments on measuring this component. We developed a plan for measuring managed care improper payments in a manner similar to the managed care reviews conducted under the PERM pilot. We have addressed comments received on eligibility and managed care in this interim final rule.

III. Analysis of and Responses to Public Comments

CMS received a total of 30 comments: 27 from State agencies (including one territory) and 3 from consumer advocacy and other groups. These commenters reiterated many of the comments from the proposed rule to which we responded in the October 5, 2005 interim final rule. Although we are not required to respond to these comments again, we are summarizing the comments in this interim final rule and providing our responses for the convenience of the reader. However, it is important to note that we are bound by, and therefore cannot change, the requirements of the IPIA, the OMB guidance (such as inclusion of denied claims), and section 1903(d)(2) of the Act governing recoveries. Current regulations at 42 CFR part 433, subpart F and 42 CFR part 457, subparts B and F are not addressed by this rulemaking. Below are the comments on the October 5, 2005 interim final rule, grouped by topic, and our responses as follows:

- A. Purpose, Basis and Scope
 1. Payment Error Rates
 2. State Selection
 3. Use of National Contractor
 4. State Impact
- B. Methodology

1. Exclusions From the Claims Universe
 - a. Denied Claims
 - b. Provider Appeals/Provider Fraud
2. Sampling Issues
3. Overpayments and Underpayment Errors
4. Adjustments
5. Medical and Data Processing Reviews
 - a. Methodology
 - b. Medical Reviews
 - c. Data Processing Reviews
6. Payment Error Rate and Reporting
- C. Expanded FY 2007 Error Rate Measurement
 1. Eligibility
 - a. Cost and Burden
 - b. Eligibility Workgroup
 - c. Methodology
 2. Managed Care
 3. SCHIP
- D. Appeals
- E. State Requirements
 1. Collection of Information
 - a. State's Role
 - b. State Cost and Burden
 - c. Information Collection
 - d. Repricing
 2. Technical Assistance
 3. Corrective Action Plans
 4. Recoveries
- F. Regulatory Impact Statement
- G. Anticipated Effects

Overall, comments on the October 5, 2005 interim final rule supported our efforts in assuring that Medicaid and SCHIP payments are correct. Many commenters indicated that although the

October 5, 2005 interim final rule significantly reduced the burden on the States by using a Federal contracting strategy and limiting State selection to once every 3 years, they believed that the October 5, 2005 interim final rule still placed an undue technical and financial burden on the States to assist the Federal contractors. Many commenters believed that the October 5, 2005 interim final rule underestimated the amount of resources that would be necessary to provide information and technical assistance to the Federal contractors for the estimation of State payment error rates. Commenters were also concerned with the States' ability to review and challenge the contractor's error determinations and estimates of State error rates before they were reported to OMB.

A. Purpose, Basis, and Scope

1. Payment Error Rates

Comment: Many commenters stated that the IPIA did not require State-specific error rate estimates and that State-specific error rates went beyond the requirements of the IPIA. Several commenters proposed that CMS abandon the State-level error rates in favor of having the national contractor select a nationwide statistical sample, after which the contractor would review those claims with the assistance of the individual State.

Response: We did not adopt the recommendation to select a nationwide sample because we believed that it was not the best overall method to meet the requirements of the IPIA and OMB guidance.

There is no national sampling framework for SCHIP claims, and the Medicaid Statistical Information Statistics (MSIS) data for Medicaid are too old to produce meaningful data on which States could base effective corrective actions. As such, we are not abandoning State rates for only a national rate. We will use the State rates as the basis for the national rates and States can use their individual results as the basis for corrective actions.

Comment: One commenter stated that State-specific error rates would lead to the unwarranted comparisons of States when there was wide variation in States' Medicaid and SCHIP programs.

Response: We agree and will caveat in our reporting of the error rates that comparisons among States should not be made since each program and its policies vary. State error rates will be used to measure each State's progress in reducing improper payments (that is, individual State error rates will be compared over time).

Comment: Some commenters believed that CMS' adoption of a payment error methodology that includes State-specific error rates constitutes an unnecessary burden on the States.

Response: We believe that our adoption of the recommendation to engage Federal contractors has significantly reduced the cost and burden by limiting State involvement to providing information and technical assistance to the contractor. States are required to provide information necessary for the Secretary to monitor program performance under the Medicaid statute at section 1902(a)(6) of the Act, and the SCHIP statute at section 2107(b)(1) of the Act. Therefore, we believe that it is reasonable that States provide State-specific information to assist in the national improper payment measurements.

Comment: Some commenters believed that since the IPIA is a Federal obligation, State participation should be 100 percent fully funded by CMS rather than at the Federal match rate.

Response: Our adoption of the commenters' recommendation to engage Federal contractors to estimate several components of the improper payment measurement should reduce the cost and burden that States would have otherwise incurred to conduct medical and data processing reviews on FFS and managed care claims. States will not pay for the national contractor. Only those States selected for review each year will incur costs by providing information necessary for claims sample selections and reviews, providing technical assistance, as needed, and developing a corrective action plan to reduce the error rates.

The States selected will also conduct the eligibility measurement. The States will be reimbursed for these activities at the applicable administrative Federal match under Medicaid and SCHIP. As part of the rulemaking process, we have evaluated and determined that the burden and cost of these responsibilities will not significantly impact the States.

Comment: One commenter questioned the likelihood of achieving an accurate national error rate, by aggregating error rates from all the States' programs with their inherent variations.

Response: We will be using a statistical sampling methodology to obtain an estimate of a national error rate and the "margin of error" around that rate. By drawing a stratified random sample of States and then reviewing a random sample of claims within each of those States (using each State's program policies), we are able to obtain an estimate of the national error rate without having to conduct reviews on

all claims. This methodology will produce the estimate and the precision level of the estimated national error rate, within the parameters set by OMB.

Comment: Several commenters stated that the rule is silent on how PERM relates to existing State Medicaid program integrity functions and asked if it is CMS' intent for PERM to supplant or enhance existing audit programs. They argued that PERM activities should not create duplication of States' existing audit programs and Medicaid Eligibility Quality Control (MEQC). One commenter stated that the rule should not result in any change to these practices.

Response: The PERM program is intended to fulfill the requirements of the IPIA and is not intended to supplant, enhance, or change other program integrity activities in which the States are currently engaged. We are considering methods to minimize duplication of efforts regarding the eligibility reviews.

Comment: Several commenters stated that the PAM/PERM pilots have demonstrated that State-level error rates have a negative return on investment (ROI). One commenter stated that PERM is based upon calculation of the number of claims that had any type of error, which would have minimal cost impact. The commenter recommended that CMS support expansion of State payment integrity programs that use sophisticated algorithms and models to identify targeted leads for investigation and audit that have demonstrated a positive ROI. Another commenter stated that they have found their error rate to be quite low and given that they have a relatively high Federal match rate, this means that State's resources will be expended disproportionately to the State's ROI.

Response: We do support the States' use of sophisticated algorithms and models to identify targeted leads for investigation and audit. However, the IPIA requires error rate measurement for these programs and does not cite lack of cost savings as a circumstance which would excuse us and the States from measuring improper payments. Since we are estimating improper payments in a select number of States, primarily through a Federal contracting strategy, we believe the State cost to measure error rates has been substantially reduced. We anticipate that savings will be realized over time through disseminating findings from selected States, States' corrective action measures, and modeling best practices.

Comment: One commenter asked the following questions regarding CMS targets for future improper payment

levels and a timeline by which the targets would have to be reached:

- Will CMS set an arbitrary target level or use baseline empirical data, when available?
- Will each State be measured against its individual past performance or a national average?
- What are the incentives for having a lower error rate or disincentives for a higher estimate?
- What recourse will a State have if, due to understated CMS cost estimates coupled with the State's budgetary constraints, it is unable to satisfy its PERM process obligation?

Response: CMS will use baseline empirical data, when available, to set targets for future error rate levels. States will be measured against their individual rates rather than a national average. We believe that States strive to be fiscally responsible and will work with us to lower their payment error rates because it will benefit both State and Federal governments.

We aim to work in partnership with States in this endeavor. Thus far, in collecting claims data and medical policies for the FY 2006 measurement, States have been very cooperative and helpful and have not experienced any insurmountable problems in submitting the information.

We believe our cost estimates are accurate and we have minimized the burden as much as possible through the use of Federal contractors and reviewing a subset of States rather than every State every year.

Comment: One commenter stated that there is nothing in the October 5, 2005 interim final rule that would protect a non-sampled State from having a payment error rate applied to it, based upon results from sampled States, and from CMS seeking "recoveries."

Response: Section 1903(d)(2) of the Act, 42 CFR part 433, subpart F and 42 CFR part 457, subparts B and F, solely govern recoveries for overpayments identified through the medical and data processing reviews. We will not seek PERM recoveries from States not selected for PERM in that year based on results from other sampled States.

2. State Selection

Comment: Several commenters stated that the proposed selection of States in PERM on a three-year cycle will make it difficult to predict what resources a given State will need in advance to conduct PERM. Other commenters requested that CMS consider alternative methodologies that would permit States to know the schedule for PERM audits in advance so that the States can make

staffing and funding plans for the years their program is selected for review.

Response: We agree with these comments and have adopted a State rotation that will provide States with advance notice of which fiscal years they will be participating in PERM. As we described in the preamble to this interim final rule, we randomly selected 17 States from the three strata for PERM measurement in FY 2006 through FY 2008. We announced the State selections for PERM reviews for FY 2006, FY 2007, and FY 2008 through a State Medicaid Director's letter dated November 18, 2005. We have also included the list of States selected for these fiscal years above in the preamble of this interim final rule with comment period. We also indicated that the SCHIP State selection will be based on the Medicaid State selection in that States selected for Medicaid will also be measured for SCHIP in the same year. We expect to measure improper payments in all components of SCHIP in FY 2007 and beyond. We plan to use a rotational basis for subsequent years so each State will know which fiscal year they will be participating in the PERM review of Medicaid and SCHIP.

3. Use of National Contractors

Comment: Several commenters believed the adoption of Federal contractors to measure the improper payments for one-third of the States each year and the phased-in implementation of the components to be reviewed would substantially reduce the burden on State Medicaid and SCHIP agencies. They stated that it would ensure greater consistency across States and reliability in the review process and outcome.

Response: We agree and appreciate the support of our adoption of the recommendations as a result of public comments.

Comment: One commenter stated that the national contracting methodology was not tested in the PAM or PERM studies. They argued that States' extensive knowledge is not easily transferred to a Federal contractor and the implementation of this knowledge transfer has not been designed or tested, but is germane to generating an accurate error rate estimate.

Response: Many States that participated in the PAM and PERM pilots used contractors to implement the reviews and compile the findings. It is important to note that CMS engaged one of the contractors used in the PAM and PERM pilots as the statistical contractor (SC) because of its experience with developing the sampling strategy and calculating error rates. Similarly, we

engaged the documentation/database contractor (DDC) based on its experience with information collection for Medicare's Comprehensive Error Rate Testing (CERT) program and a review contractor (RC) that has demonstrated knowledge and experience with claim reviews. Therefore, we believe that the Federal contractors, working closely with States, will be able to produce accurate error rate estimates.

Comment: A number of commenters believed that the use of three contractors places an additional and unreasonable burden on States to ensure timely and coordinated responses to contractor questions, requests, etc. The comments included:

- The contractors will need to learn States' policies, including States' waivers, which would mean the States would have to educate each one of the contractors;
- The fact that three different contractors may have three different standards or procedures is problematic and may skew the error rates;
- The separate contractors may not share data and communicate effectively to complete the reviews; and
- The work should be consolidated for one main contractor or for one lead national contractor to coordinate the processes of the other subcontractors to give consistency to the requirements.

Response: States will be required to provide technical assistance on State policies only to the RC, who will examine State policies and the medical records to determine if payment for a FFS claim was medically necessary and paid correctly. States will also provide technical assistance to the RC on the data processing reviews. The SC will perform the sampling of claims and the calculation of the State and national error rates. The DDC will collect, store, and provide the review contractor with access to the State policies and medical records. The contractual agreements have been written to assure that the contractors will share information and communicate with each other. We will provide coordination and oversight.

Comment: Several commenters believed that the contractor's operational success is heavily contingent on information and technical assistance provided by participating States. The comments included:

- Success would require the contractors to have extensive knowledge of State policies and procedures to be aware of what might constitute special handling of a particular claim, and to know where to find documentation or authority to approve the service or item for payment;

- The contractor may not be well situated to fully grasp the nuances of each individual State program without a very close working relationship with State staff; and

- The rule should require the national contractor to collaborate with each program being reviewed during each stage of the review process (medical records, processing, and eligibility).

Response: We recognize that Medicaid and SCHIP programs are unique to each State. We agree that the contractor may need State assistance with nuances of each State program and as a result, the RC will work closely with the State. In addition, States will have the option to review the contractor's decision on the claims indisposition reports and discuss with the contractor any difference of opinion in the contractor's error determinations through the difference resolution process. Our goal is to work in partnership with the States to produce the most accurate State-specific rates.

Comment: Citing the intricacies inherent within each State's programs and systems, one commenter preferred that States be fully funded to conduct the processing and medical review at the State level. The commenter stated that States have the ability to conduct those reviews more efficiently, more accurately, and at a lower cost than a Federal contractor. The commenter believed that this is an opportunity for the States to learn additional ways to improve the programs and save Federal and State dollars that otherwise would be lost.

Response: We engaged in a national contracting strategy to implement the PERM program based on comments to the proposed rule regarding State cost and burden. We also believe that having the Federal contractor conducting the processing and medical reviews will provide consistency in reviews across States. Therefore, we are not adopting this recommendation. States will be able to identify additional ways to improve the programs and save State and Federal dollars through the contractor's review findings.

Comment: A number of commenters stated that they did not believe that the use of a national contracting strategy exempts CMS or its contractors from having any public review of the procedures on how medical reviews are conducted and how an error is determined. The comments included:

- Since the States are required to share all of their claims processing procedures, policies and provider enrollment, and payment methodologies with the Federal contractor(s), there is a need for a clear process to enable States

to know what steps are taken by the contractor(s) working on the PERM project and to re-review error findings.

- CMS should make arrangements for a public review of the PERM protocols and the contractor's performance, including input from State agencies, provider organizations and other public entities.

- The use of a Federal contractor increases the need for outside oversight and review because the procedures will be less transparent to States and other parties who are affected by the policies.

Response: We described in the preamble of this interim final rule what each contractor's roles and responsibilities are in the implementation of the PERM program. We will be using the review and error rate calculation methodologies that we used in the PERM pilot, which States worked with us to design and refine. The contractors will work closely with the States to understand the State's policies such as special handling of claims.

States will also be able to review the contractor's claim determinations and resolve any differences in findings through the difference resolution process, which provides States with a level of outside oversight and review.

Comment: Several commenters argued that unlike Medicare, which is a single national program, reviewers for Medicaid and SCHIP must be experts in the policy, policy application, administration, and claims processing systems of 102 different State programs. The commenters stated that they wanted more opportunities for input in the development and monitoring of the PERM contractors, work plans, work statements, and protocol. Also they believed that the rule should describe the performance standards of the contractors and the ways that CMS will monitor compliance of those standards to ensure that States are not required to devote unnecessary resources in providing assistance to the Federal contractors.

Response: We recognize the complexities of reviewing Medicaid and SCHIP claims, and we have engaged a review contractor (RC) with experience in conducting claims reviews. The RC is required to have clinical experts perform the medical reviews. The RC will perform reviews in 17 States per year for the Medicaid and SCHIP measurements and will work with each State to clarify questions on the application of the policies in the medical review and also will work with States when questions on the data processing reviews arise.

Information regarding the procurement of Medicaid PERM contractors was posted on FedBizOpps.gov during the procurement process for public review. Information regarding the statistical contract was posted on August 4, 2005, the documentation/database contract on August 10, 2005, and the review contract on August 18, September 19, and October 14, 2005. We anticipate using the same standards set in the Medicaid procurement to engage the contractors (statistical, documentation/database, and review) for the SCHIP measurement. The performance and monitoring of the PERM contractors is a Federal responsibility, and we will oversee their work.

Comment: One commenter recommended that CMS employ an independent contractor to evaluate the final results of the PERM process for accuracy and cost effectiveness.

Response: As part of the Chief Financial Officer (CFO) audit, the PERM program may be audited by an independent agency, similar to Medicare's Comprehensive Error Rate Testing (CERT) program, which was established to monitor and report the accuracy of Medicare FFS payments.

4. State Input

Comment: Several commenters stated that CMS should establish a steering committee or other advisory group that includes State representatives to help ensure that the PERM contractors consider all the logistical and data collection issues to reduce demands on State staff.

Response: For the FY 2006 measurement, we have held several conference calls with States clarifying the collection process for the requested information. Due to the wide variation in the States' programs, the contractors have followed up individually with each State selected for the FY 2006 measurement. We believe that this one-on-one communication between the contractor and each selected State has worked well to address any issues the State may have related to data collection. We will continue to have informational conference calls and the contractors will follow up with each State selected for review, as necessary.

Comment: Several commenters expressed concern with the States' inability to actively participate in the rulemaking process, particularly for development of the eligibility and managed care components of PERM. They stated that CMS should not publish a final rule until CMS can draft the eligibility and managed care claims review processes, estimate realistic cost

assessments of the burden to States of the untested national contractor model, and the States can examine these processes, estimates, and other issues regarding PERM. These commenters expected that any rules that are formulated regarding eligibility or managed care reviews related to PERM will be published in the **Federal Register** and be subject to public comment.

Response: We agree and believe that States have been active participants in this process. States commented in the proposed rule, and we invited further comments on eligibility and managed care measurements in the October 5, 2005 interim final rule. We also provided the opportunity for public comment on the information collection requests for FFS (70 FR 42324 and 70 FR 50357), managed care (71 FR 5851 and 19522), and eligibility (71 FR 30410) and believe that our estimates of cost and burden to the States are realistic. Finally, we are publishing this as an interim final rule with an additional comment period to provide the opportunity for further public comment on the PERM eligibility review requirements before publishing a final rule.

Comment: One commenter stated that CMS should open workgroup participation on SCHIP, eligibility, or managed care to any State having an interest. CMS should share the options under consideration with the States. Workgroup minutes should be circulated to all parties.

Response: We solicited representatives through the American Public Human Services Association (APHSA) to participate on the eligibility workgroup. We believe that at least one State representative apprised States of the eligibility workgroup's recommendations through at least one Eligibility Technical Advisory Group conference call. We did not conduct managed care or SCHIP workgroups but we provided opportunity for State input through the proposed rule and the October 5, 2005 interim final rule as well as the information collection requests for FFS and managed care. We note that this workgroup, which was primarily internal, is exempt from FACA requirements under 2 U.S.C. sec. 1534. We are also soliciting further comments on the eligibility reviews through this subsequent interim final rule.

Comment: One commenter asked whether the text of the October 5, 2005 interim final rule with comment at 70 FR 58273, third column, was intended to reference § 437.978 and § 437.982 of

the rule or whether these were typographical errors.

Response: Yes, these were technical errors.

Comment: One commenter stated it is imperative that the final eligibility review rules be published as quickly as possible to give States the necessary time to obtain legislative authority to create and fund new positions.

Response: We alerted States in the October 5, 2005 interim final rule that we expect that eligibility would be included in the PERM program beginning in FY 2007 and that it was possible that States would be conducting the eligibility error measurement. This interim final rule with comment period sets out the eligibility review requirements. We expect States selected for review in FY 2007 will conduct eligibility reviews for Medicaid and SCHIP. However, we invite further comments on these eligibility provisions before publication of the final rule.

B. Methodology

1. Exclusions From the Claims Universe

a. Denied Claims

Comment: Some commenters noted that the inclusion of denied claims in the sample is questionable and conflicts with the definition of *payment* in the October 5, 2005 interim final rule since Federal funds are not used to pay denied claims. Therefore, the commenters believe that denied claims should be removed from the sampling universe.

Response: The IPIA defines an improper payment as “* * * any payment that should not have been made or that was made in an incorrect amount including overpayments and underpayments.” Additionally, OMB guidance M–03–13, published May 21, 2003, states that “* * * incorrect amounts are overpayments and underpayments including inappropriate denials or payment of services.” Therefore, we must include denied claims in the error rate measurement process.

Comment: A number of commenters stated that CMS' response that denied claims are included to comply with OMB guidance does not resolve the State concerns regarding the inclusion of denied claims in the estimation of improper payments. The commenters noted that “improper” and “error” as used throughout the notice indicate misspent funds and to count non-payments with payments is misleading. One commenter argued that to include unspent dollars with misspent dollars attempts to change the definition of

error payment and would result in a meaningless statistic. They recommended that overpayments, underpayment, and denied payment errors should be calculated and reported separately.

Response: The commenters are correct that “improper” and “error” refers to misspent funds. However, we believe the incorrect denials of claims that should have been paid are payment errors in the same manner that payments of claims that should not have been paid are payment errors and should be measured. Additionally, we are bound by the requirements of the IPIA and OMB guidance and must include denied claims in the error rate measurement process. Therefore, denied claims made in error are included in the estimation of improper payments. We will provide an analysis of these errors in the PERM report.

b. Provider Appeals and Provider Fraud Investigations

Comment: One commenter believed that unresolved disputed claims should be excluded from the PERM measurement to avoid interfering with the resolution.

Response: We believe the commenter's use of “unresolved disputed claims” is referring to claims that are in the appeals process at the time data analysis begins. Claims that are appealed by providers are potentially underpaid claims or denied claims, so we must include them in the payment universe as required by OMB guidance. We do not believe that inclusion of these claims will interfere with the State's resolution with the provider. Independent of the State's appeals process, the contractor will review the claim and make its determination as to whether it was correct or in error and provide the State with the disposition of the claim. The State can review the contractor's determination in the difference resolution process but will not be bound by it.

Comment: Many commenters expressed concerns regarding claims from providers and beneficiaries that are under active fraud investigation. Their comments include:

- CMS needs to adopt specific procedures for how fraudulent claims and providers under investigation will be handled.
- Such claims should be excluded from the PERM process to avoid interfering or compromising the investigation.
- The contractor should consult with the States before contacting providers so

as not to jeopardize ongoing fraud investigations.

- Including such claims under active investigation would result in a decrease in response rate and skew the error rate.

- The contractor could over-sample the strata on a quarterly basis to allow for the substitution of claims under investigation; and that CMS should allow for at least 5 percent of the claims sample to be dropped for claims that are under active investigation.

Response: Fraudulent provider claims or claims under active provider fraud investigation will be included in the universe. We believe that the PERM review will not compromise the investigation since requests for medical records are an expected part of the provider's participation in the Federal medical assistance programs. The intent of the IPIA is to measure the extent to which Medicaid and SCHIP payments were made improperly, regardless of whether potential fraud exists.

However, we are allowing States to exclude beneficiary cases under active fraud investigations from the eligibility reviews because we believe that, in most cases, payments are not being made directly to the beneficiary.

Comment: One commenter believed that dropping claims under fraud investigation could skew the results if these types of claims were always dropped.

Response: We agree and will include these claims in the FFS and managed care reviews.

Comment: One commenter recommended that States be notified of the list of medical records requested from providers so that the States could notify the contractor of any claims flagged for review that have already been identified as overpayments and addressed by their State Surveillance and Utilization Review Systems (SURS) or Medicaid Fraud Control Unit (MFCU).

Response: Once the quarterly claims sample is completed, the SC will provide the State with a list of the selected claims for which the DDC will be requesting records. However, claims selected for PERM will be reviewed for improper payments regardless of whether overpayments have already been identified by other State review systems.

2. Sampling Issues

Comment: One commenter asked whether CMS or the Federal contractor selects the participating States.

Response: The Federal contractor randomly selected the sample of States for PERM reviews in Medicaid. A table of the States selected for FY 2006, FY

2007, and FY 2008 is provided above in the preamble of this interim final rule.

For the SCHIP State selection, we determined that SCHIP will be measured in the same year that States are selected for the Medicaid measurement. We will send a State Health Official Letter announcing the SCHIP State selection.

Comment: One commenter believed that CMS could achieve the IPIA requirements and reduce the State sample size by allowing a larger standard error for each State's sample. The commenter argued that it is possible for States to identify vulnerabilities and to implement corrective actions because States are already performing activities to eliminate reimbursement weaknesses through SURS, Peer Review Organizations, and payment integrity program activities.

Response: Although we agree with the commenter that we could reduce State sample size by allowing for a larger standard error and still achieve the national IPIA requirements, we are not adopting this recommendation. We want to ensure a large enough sample size to provide enough information to the States on where the errors occurred so that States can efficiently and effectively target their efforts to address these vulnerabilities.

We intend for the PERM program to be an independent measurement; however, States can use the information from PERM in conjunction with information from their own payment integrity programs to efficiently and effectively target corrective actions and improve program performance.

Comment: One commenter is concerned that the previous year's data already provided to CMS, which are to be used for determining sample size per stratum, may not agree with the same type of stratification as submitted in the quarterly data.

Response: The SC has determined that it can base the actual sample size per stratum on the stratified quarterly claims data submitted by the States. Therefore, we will not request data from the previous fiscal year on which to approximate the sample.

3. Overpayment and Underpayment Errors

Comment: Several commenters stated a true error rate could only be determined by identifying overpayments and underpayments, and offsetting or netting one against the other to determine the sum of errors. Moreover, aggregating overpayments and underpayments provides a false

indicator of overpayments and payment error, and distorts the results.

Response: We must comply with OMB guidance (M-03-13) on IPIA, which defines improper payments as including overpayments and underpayments and requires that these payments be measured separately. Further, we view overpayments and underpayments each as sources of payment error since the amount of payment that should have been made was made incorrectly by virtue of the fact that the State either paid too much or too little for the service provided.

4. Adjustments to Claims

Comment: Several commenters argued that the proposed 60-day limit for adjustments to claims would overstate the amount of the payment error since adjustments occur later than 60 days after the payment adjudication date. They believed that all adjustments to the claims should be included in the review at the time when the sample is drawn and do not believe that the 60-day limit has been adequately tested.

Response: Consistent error rate measurement requires a specified timeframe for considering adjustments. The 60-day limit provides a consistent time period across States since States have varying timeframes for adjustments of claims. We believe that the 60-day timeframe has been adequately tested through the PAM/PERM pilots.

5. Medical and Data Processing Review Procedures

a. Methodology

Comment: Several commenters stated that CMS responded to a number of comments requesting clarification of the review procedures by stating that the comments were "no longer relevant since States will not be conducting the medical or data processing reviews." Although the States will not be conducting the reviews, these commenters believed that:

- CMS has obligated States to provide whatever technical assistance is needed for the contractor to perform the reviews. Clear guidelines will enhance State and provider understanding. This in turn will improve cooperation, compliance, quality, and accuracy;
- States need to understand the processes, standards and requirements in order to develop and implement effective corrective action plans that will address the payment errors identified in the reviews; and

- The guidance already developed cooperatively with CMS and the States should be used along with nationally recognized review criteria.

Response: The contractors will work closely with States during the review process. Most States have participated in the pilots and are familiar with how the reviews are conducted. The contractors will generally follow the guidelines that were developed in the PAM/PERM pilots. Additionally, State corrective action plans are based on the sources of errors rather than the review process.

Comment: One commenter argued that without specifying the methodology in the regulation text, CMS could change the methodology at will, including increasing the sampling precision, thus increasing the response burden on the States, especially for the eligibility component. The commenter asserted that CMS should not be permitted to unilaterally change any element of the methodology without affording the public an opportunity to comment on it through applicable administrative review requirements.

Response: We have tested the methodology within the three pilot programs and may make changes, as needed, to improve the payment error rate measurement. We have specified in the rule that each State error rate must be within the 3 percent precision level at a 95 percent confidence interval level. However, we do not anticipate making significant changes to the methodology unless revisions are necessary to produce accurate error rates that meet the statistical requirements. We will be able to request any further information necessary from the States through our authority under the current Medicaid and SCHIP regulations.

Comment: One commenter stated that CMS should revise the October 5, 2005 interim final rule to allow States' continuing involvement in establishing review procedures and to base these procedures on the best practices already identified through the PAM and PERM pilot projects.

Response: During the PAM/PERM pilots, we sought extensive feedback from the participating States on the review procedures. We used this feedback to help develop the review guidelines. We have based the review procedures for the Federal contractors on the procedures and the best practices identified through the pilots. We also invited and considered public comments on the managed care and eligibility review procedures through the October 5, 2005 interim final rule. Finally, we are publishing this interim final rule with comment period to provide the opportunity for further public comments regarding the PERM eligibility review requirements.

b. Medical Reviews

Comment: One commenter expressed concern about the amount of information that must be gathered and reviewed in context for an adequate error determination. Contract medical reviewers would need access to recipient case histories and provider claim patterns over a number of years to make a full and complete assessment of claims. The commenter stated that they could make available onsite access to the contractor, if requested.

Response: We agree that for some cases, the RC will need to contact the States for additional information for the medical reviews, for example, to determine whether the maximum number of services has been met. For these cases, if necessary, the RC can obtain more information during the data processing reviews, which will be done on-site. However, we do not anticipate that the RC will need additional information to this extent for the majority of the medical reviews.

Comment: One commenter asked if "no documentation" would be considered an error. The commenter stated that States should not be penalized because of non-responsive providers who fail to produce records or respond to follow-up questions.

Response: Yes, an error will be cited in cases in which there is no documentation because there is no evidence to adequately determine whether the services were provided, were medically necessary, and were properly coded and paid. The contractors will follow up a number of times with the providers in order to obtain the medical records. States can, at any time, proactively educate their providers about submitting the information for the PERM program. We have posted a "provider education" letter at <http://www.cms-perm.org/> that States can use to educate their providers. States need not wait until they are selected for the PERM reviews to begin this activity. In addition, the selected States will be able to obtain information identifying which providers have not submitted the requested medical records within the first 45 days of the initial request from the DDC, so that such States may do their own follow-up, if they choose.

Comment: Some commenters expressed their concerns regarding the inclusion of any documentation error as an improper payment. The inclusion would produce a higher error rate, especially in States that are the most demanding in their documentation requirements. They suggested that CMS could alleviate their concerns by

including, in its final report, a comprehensive explanation of what is included as a payment error and distinguish between inadequate documentation and provider non-response to documentation requests.

Response: We agree and the findings will distinguish errors due to no documentation and insufficient documentation from other types of errors. However, the total payment error rate will include these errors.

Comment: Many commenters believed that the contractors will have limited incentives to work to obtain near-complete provider records for the sampled claims and stated that the final rule should clearly indicate the contractor's responsibilities to assure complete receipt of medical records and the accurate review of each and every sampled claim.

Response: According to our contractual agreement with the DDC, the DDC will make a number of attempts to obtain the medical records and will send up to three letters and make up to three phone calls, if necessary, to the providers. As for the accuracy of review, the RC will work closely with States to clarify policies. Also, the RC will conduct a second level review on all errors and on 10 percent of the claims sampled. States also have the option of reviewing and requesting reconsideration of the RC's findings through the difference resolution process discussed below.

Comment: Several commenters stated that labeling a claim an error after a provider exceeded an arbitrarily imposed response deadline does not make a payment improper, and recommended that guidelines allowing an additional 30 days for efforts to be made by the Federal contractor to obtain medical records.

Response: We believe that the 90-day timeframe is a reasonable amount of time for the collection of medical records, given that the DDC will make up to 6 contacts to the provider.

Comment: A number of commenters asked for clarification as to what role States will play in the record collection process. They believed that States will need to commit significant resources to assist the Federal contractor in obtaining the required records and documentation in order to minimize payment error rates resulting from records not received within the 90-day timeframe.

Response: The DDC will contact providers directly to request medical records. States are not required to be involved in the collection of medical records unless they opt to follow up

with providers who do not respond to the DDC's requests.

Comment: Several commenters indicated that States must be considered a partner in the efforts to ensure a reliable error rate determination. They believed that States should be involved in the development of model letters requesting records, establishing provider guidance, and working with the provider to ensure that the contractor has the full record for review.

Response: We agree. We view the States as partners in this effort. States can choose to participate in follow-up discussions with providers who have not responded to requests for medical records. We have placed the provider education letter regarding the requirements of medical records submission on the PERM Web site, <http://www.cms-perm.org/>. States can use this letter and its contents, as appropriate, to educate providers on this program.

Comment: Since some providers may be guarded about confidentiality of medical records, several commenters asked how the contractors will handle complaints about health privacy concerns regulated under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191, enacted August 21, 1996) (HIPAA), many of which will be directed to State Medicaid staff. They recommended that the records request letter clearly set forth the business relationship that permits disclosure under HIPAA, the obligation to provide records without compensation, and indicates that HIPAA explicitly allows this type of collection.

Response: We will indicate in the provider letters: (1) That CMS has authority to collect the medical records under section 1902(a)(27) of the Act; (2) that the information collection complies with the Privacy Act and HIPAA; and (3) that we will comply with the Privacy Act, HIPAA and the regulations at 45 CFR parts 160 and 164.

Comment: Several commenters suggested that when the contractor is unable to obtain sufficient information to determine whether a claim was an error, the case should be eliminated from the sample. They stated that the contractor should continue to keep track of the insufficient documentation cases as an incentive to improve future performance of medical record collection.

Response: We are not adopting this recommendation because a claim with either no documentation or insufficient documentation does not have evidence to support that the payment was correct. The RC will record the cases of no

documentation and insufficient documentation; States may use the information to educate providers on the importance of submitting adequate documentation.

Comment: One commenter noted that some States verify medical necessity determinations by calling the physicians that delivered the services, and encouraged CMS to include this step in the contractor workplans.

Response: We are not adopting this recommendation because, as part of standard medical practice, providers should include full documentation in the medical records.

Comment: A number of commenters stated that the rule should specify that the contractor will submit to the State agency all erroneous claims with all appropriate documentation, so that the State can decide whether to re-review the case. If the State can demonstrate that there is no error, the error determination should be nullified and the appropriate adjustments should be made to the State's error rate.

Response: Based on the comments to the October 5, 2005 interim final rule, we have provided for a difference-resolution process in this interim final rule. The difference-resolution process, a type of alternative dispute resolution process, will provide the States with the opportunity to review the error determinations made by the RC (through its medical and data processing reviews) and to resolve any concerns about the findings. The RC will make the documentation on which the decision was based available to the States.

Comment: As an alternative to determining claims without sufficient documentation as errors, the contractor could develop a statistically appropriate method to estimate the proportion of State claims with missing documentation which are actually in error and actually correct and use that method to adjust the error rates.

Response: We are not adopting this recommendation. Every claim must have documentation in the medical record to support payment of the claim. A provider must submit this information to support his or her claim; otherwise, the payment of the claim itself is an error.

Comment: One commenter recommended a number of changes to the medical review guidelines including:

- Explaining the difference between a medical necessity review and a comprehensive medical review, including defining the components of each type of review;
- Omitting the words, "if applicable" pertaining to prior authorizations;

- Providing more guidance on how a claim line versus a claim will be reviewed; and,

- Providing more detailed sections specific to personal care service providers.

Response: These suggestions were made to clarify areas of the medical review guidelines that some States found troublesome when using the guidelines for the medical reviews under the past PERM pilot project. These changes may no longer be needed since we anticipate the contractor that we engage to conduct the medical reviews will have a higher level of expertise than the States in evaluating medical records. However, we believe that these recommendations may offer improvements to the guidelines, and we will review and incorporate these recommendations, as applicable.

Comment: One commenter indicated that States using InterQual Level of Care criteria for inpatient stay approvals, as opposed to States that use specific length of stay by diagnosis, have a higher likelihood of a higher error rate due to inadequate documentation. The commenter asked if the CMS contractor is licensed and trained for InterQual Reviews, because States cannot provide the proprietary information to the contractor.

Response: Some States use various tools, such as InterQual Reviews, to authorize payments or conduct secondary reviews of payments. These tools are used to review items in the medical record, such as specific chart notations or notations on daily progress and nursing notes. The contractor would not need access to these tools since it will base its determinations on reviews of the underlying medical records.

c. Data Processing Review

Comment: One commenter stated that it is unclear from the October 5, 2005 interim final rule whether there will be a separate systems review component in the process and requested CMS further clarify the extent to which systems will be reviewed as part of PERM.

Response: Yes, data processing reviews, which determine whether there are errors due to the State's payment processing system, will be conducted on all sampled claims. The RC will most likely conduct these reviews on-site and will work with the State on learning its claims processing system. For both FFS and managed care claims, the processing reviews will determine if each sampling unit was processed correctly. The FFS processing reviews will determine, for example, whether the service is a duplicate item or claim;

the service is covered; the service should have been covered by a managed care organization (MCO); the service was priced correctly; whether there was a problem with the logic edits; and whether the information was entered into the system correctly. For managed care claims, the processing reviews will determine whether the capitation payment was made correctly based on the information available to the capitation payment system or to the system that processes vouchers for payment to a MCO; whether the person is in the program; and whether the claim was correctly paid.

Comment: Several commenters asked whose interpretation of the State policy would establish the standard by which payments would be measured. They stated that the contractor must consult with the State regarding all claims they determine to have errors. They believed that the program operations staff will need to provide an enormous amount of technical assistance, explanations and clarifications for non-typical situations, which are not easily found by simply consulting manuals and bulletins, or by review of system edits.

Response: The contractor will follow the State's policy and will work closely with the State to clarify the policy if it is unclear. Upon review of the contractor's determination of claims, the State can review the claims and file a difference resolution.

Comment: One commenter stated that there is no reference to beneficiaries' eligibility files, which the State found was necessary for the processing reviews in the PERM project.

Response: In the data processing review, the eligibility check will be limited to data matching to determine whether a beneficiary was enrolled in the program on the date of service.

Comment: One commenter stated that, regarding the response to third-party liability (TPL) not being reported on the line-item level, it will be necessary to review all line items of a claim (not just the sampled detail line) when TPL or patient liability is involved. They stated that this could be accomplished by using the data extracts submitted by the States.

Response: We agree that in some cases, the contractor will need to review other claim information beside the line item for TPL or patient liability. However, the contractor will not need the States to submit data extracts in these cases. The contractor will be able to review TPL information during the data processing review, which will most likely be conducted through the State's processing system.

Comment: One commenter stated that the probability of a PERM error increases with each safeguard that a State adds to its payment processes. The commenter argued that this may cast a negative light on States that have been aggressive in their efforts to protect the integrity of their payment system.

Response: The PERM program is intended to measure each State against its own standards and policies to determine if it complies with these standards and policies when making payments for services rendered in FFS and managed care settings and when making payments based on program eligibility. Therefore, we do not agree that States with high standards of operation are disadvantaged or would be cast in a negative light since the State is being measured against itself.

6. Payment Error Rate and Reporting

Comment: One commenter stated that managed care and FFS error rates are not comparable because the majority of the managed care sample would have fewer processing requirements and therefore, fewer errors. The commenter believed CMS should include in the final report an explanation of the difference in the managed care and FFS error rates.

Response: We agree. We will measure FFS claims separate from managed care capitation payments.

Comment: One commenter stated that States should receive a copy of the draft report for their State and be provided with an opportunity to respond within 30 days before publication.

Response: We provide States with the opportunity to provide input during the entire measurement process, from clarifying policies to reviewing disposition reports. Moreover, States may use the difference resolution process when States disagree with a contractor determination. States will also be provided with their error rate information before CMS reports the rates.

Comment: One commenter asked whether the State error rates would be presented in a way that provides for accurate representation of a national rate with an understanding of each State's performance.

Response: Yes, CMS will report national error rate information in the PAR and will include State information in its error rate report. We believe the reporting will accurately represent both a national rate and individual State performance.

Comment: Several commenters expressed concern that it is possible for PERM to be flawed by both dependent and independent variables. For

example, if a claim was determined to be an error in the eligibility review due to the participant having an open Medicaid number, then the State would incur a second error if it was inappropriately denied. There is no provision for preventing the double counting of error dollars.

Response: The proposed method for accounting for both eligibility errors and medical and processing review errors is to draw two independent samples. For FFS, one sample will be drawn for eligibility review and one sample will be drawn for medical and processing reviews. For managed care, one sample will be drawn for eligibility review and one sample will be drawn for processing review.

The eligibility error rate and the medical and processing review error rates will be calculated independently for the two respective samples. They will be combined into a single, total error rate under the assumption that the types of errors (that is, eligibility, medical and processing reviews) are independent. "Independence" means that the probability of a processing or medical review error on a given claim or line item is not related to the probability of an eligibility error for the recipient of the services implied by the claim or line item. In making this assumption, we considered the results from the PAM Year 3 pilot study. In those States that subjected the same sampling unit to a full eligibility review and medical and processing reviews, the data suggested that the two types of errors were independent (though this finding is limited because the sample sizes were small).

As the methodology for combining both samples for "total" error rate is implemented, we plan to monitor the individual results. In particular, over time there will be some overlap between the beneficiaries reviewed for eligibility review and the claims of those beneficiaries reviewed for medical and processing reviews. This will allow us to test the independence assumption as this type of data accumulates. In practice, the independence assumption will overstate the error rate significantly only if eligibility and medical and processing review errors are highly correlated. There is no evidence at this time that there is a dependence or correlation of the samples.

Comment: One commenter recommended using a systematic random sampling methodology in which claims are ordered before the sample is drawn to accomplish maximum precision, given the wide variation in the Medicaid benefits provided by the States, and the

corresponding variation in claims processing procedures.

Response: We agree that using a systematic sampling methodology would increase the precision. We adopted the stratification methodology, which was first used in the pilots, to substitute for the systematic sampling and to minimize the required sample size and burden on the States. Also, the stratification of the FFS claims sample provides States with information on where the errors are concentrated so that States can target corrective actions.

Comment: Several commenters stated that the proposed strata are neither mutually exclusive nor representative across all Medicaid programs and if unchanged, these methods will produce invalid estimates of the State-specific error. Also, there is considerable confusion and overlap regarding the groupings of service types among the strata. One commenter stated that using a systematic random sampling methodology would increase the validity of the estimates and reduce the confusion, or alternatively, CMS might consider reducing the number of strata.

Response: The States selected for the FY 2006 measurement were provided with a list of crosswalk codes from the MSIS for the PERM strata, and the SC will work with each State in order to stratify the claims. We intend for the strata to be mutually exclusive, but because of variations in coverage and how the services are categorized across the States, there may be overlap between the groupings of service types for some States. We believe that because the estimates are based on a sample of all services, regardless of the categories, the effect of any potential overlap on the error rates would be insignificant. Also, if we reduced the number of strata, it could result in an increase in the required sample size and would limit the ability of States to identify specific service types that were vulnerable to improper payments.

Comment: One commenter questioned whether a "one-size fits all" statistical approach works across 50 different State Medicaid programs, especially in light of the differences in the types of populations each State covers and the populations in FFS as compared to managed care. They asked whether error rates in a State with a high managed care population would be equivalent to a State with a predominantly FFS population, and whether CMS asserts that any error rate calculation in the first year is complete without managed care claim reviews and eligibility reviews.

Response: In order to produce a statistically valid national error rate, we must implement a standardized

methodology that is consistent across all States. We understand that there are great variations among State programs and will point out these variances in our reporting. We note that the FY 2006 error rates are based only on Medicaid FFS claims. The reason for this is because we solicited public comment on methods to measure managed care and eligibility. The rate reported in the FY 2007 PAR is exclusively a FFS component rate; a complete program error rate will be reported in the FY 2008 PAR based on FY 2007 reviews of FFS, managed care and eligibility.

Comment: A number of commenters requested the opportunity to allow State statisticians to review and comment on the relevance and reliability of the methodology for determining the error rates.

Response: We appreciate the commenters' offers to review the relevance and reliability of the error rate methodology. However, we believe that, in consultation with our contracted statisticians, the method developed to produce the error rate calculations is valid and reliable. The PERM program, including its statistical aspects, will be subject to an independent audit and we believe this audit would reveal any issues that may need to be addressed.

C. Expanded FY 2007 Error Rate Measurements

1. Eligibility

a. Cost and Burden

Comment: One commenter observed that if CMS' intent was to implement the eligibility component of PERM within existing Medicaid and SCHIP law, then 42 CFR part 431 subpart P would have to be revised to substitute the existing MEQC requirements with PERM eligibility requirements. Another commenter acknowledged that MEQC and PERM have different methodologies and are in separate areas of the law. However, the commenter believed that the PERM reviews could be substituted for the MEQC reviews in years when a State was selected to participate in PERM. This would eliminate duplication of efforts and enable States to convert MEQC resources to PERM eligibility resources.

Response: We agree that duplication of effort should be minimized to the extent possible. However, we cannot waive the MEQC statutory requirements and substitute the PERM eligibility reviews for the MEQC reviews. In light of States' expressed concern regarding duplication of effort and cost to operate two eligibility review systems, we will consider this suggestion.

Comment: Several commenters believed that there are significant resource implications to conducting eligibility reviews for PERM. They stated that the Federal government must be responsible for the resource and logistical implications of the eligibility reviews and that the expense of eligibility reviews should be fully federally funded. A number of commenters expressed concern that State-conducted eligibility reviews will be costly and inherently duplicate MEQC activities. One commenter stated that if the eligibility measurement followed what was planned in the proposed rule, CMS would not have responded adequately to State concerns regarding burden. One commenter believed that it was incumbent on CMS to look at other regulations already in place and make every attempt to incorporate established requirements rather than overburden States with redundant policies.

Response: We have determined that States will be conducting the eligibility reviews for Medicaid and SCHIP. We are considering public comments to eliminate or reduce duplication of effort. However, since State submission of information on Medicaid and SCHIP program performance is an ongoing administrative requirement, States will be reimbursed at their normal administrative match for conducting the eligibility reviews and associated activities.

Comment: One commenter questioned CMS estimates that the burden of the eligibility review component will be no greater than the traditional MEQC effort. The demands on State staff to educate the contractor staff are uncertain at best since the contractor's capabilities are unknown.

Response: Since the States, rather than the Federal contractor, will be conducting the eligibility reviews, the State will not need to educate the contractor; thus eliminating this demand on State staff.

Comment: One commenter anticipated that its actual cost for performing eligibility reviews similar to MEQC reviews would exceed CMS' previous estimate of \$570 per eligibility review. The commenter suggested that the eligibility workgroup consider this figure as a starting point when developing the eligibility review methodology.

Response: We based our estimated cost to perform the review on State-reported costs from PAM Year 2.

Comment: One commenter believed that because the eligibility component of PERM has not yet been developed, it

is premature to conclude that the impact on State resources will be minimal.

Response: As stated in the October 5, 2005 interim final rule, we strove to develop a review process that has minimal impact on the States.

Comment: Stressing that eligibility reviews are extremely time-consuming and labor-intensive, several commenters believed that CMS should consider conducting eligibility reviews on a statistically valid sub-sample of the claims selected for the PERM review.

Response: We are not adopting this recommendation. The PAM and PERM pilots used this approach and the review results indicated that claims-based eligibility reviews had inherent problems predominantly due to the inability to verify eligibility information as of the date the service was received, which could be up to two years prior to when the claim was sampled. Therefore, we developed a case-based sample and methodology that reviews recent cases at less cost and burden, and provides more current information on which States can base corrective actions.

Comment: One commenter stated that the PERM rule should address the organizational structures that are applicable for conducting the PERM eligibility reviews. Since PERM identifies improper payments, the commenter believed that a possible conflict of interest may occur if a Quality Control (QC) Unit is contained within a Medicaid Policy Office or Division.

Response: We agree and will adopt this recommendation. We will provide in the regulation that the agency conducting the PERM eligibility reviews must be functionally and physically separate and independent from the State agency responsible for Medicaid and SCHIP policy and operations, including eligibility determinations.

b. Eligibility Workgroup

Comment: A number of commenters stated that they believed that members of the public, including State officials and other interested parties, should be able to participate in the eligibility workgroup. Their comments include:

- CMS should comply with requirements under the Sunshine Act;
- The workgroup has been formed without the opportunity for public participation and no information has been sent to States on it, nor was there an opportunity for interested States to participate in the workgroup;

- There should be an opportunity for States to submit their comments to the workgroup and a procedure for input before the promulgation process;

- States included in the workgroup (that is, New Jersey) have not participated in previous PERM pilots; and,

- The eligibility workgroup should include presentations from States with and without PAM or PERM pilot experience in Medicaid and SCHIP.

Response: The “Government in the Sunshine Act” (Pub. L. 94–409, codified at 5 U.S.C. section 552b) (“Sunshine Act”), defines “agency” under (a)(1) as a collegial body. This definition applies to independent commissions rather than Cabinet agencies. Therefore, DHHS is exempt from the requirements of the Sunshine Act. Generally, meetings of workgroups of this kind would be covered by the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2. However, under 2 U.S.C. 1534(b), as promulgated by section 204 of the Unfunded Mandates Reform Act (Pub. L. 104–4, enacted March 22, 1995), the workgroup did not need to comply with the FACA requirements because meetings between Federal officials and designated State employees are FACA-exempt under the statute.

Nonetheless, States and the public were offered the opportunity, through the rulemaking process of both the proposed rule and the October 5, 2005 interim final rule, to submit comments and recommendations on the best measurement for eligibility errors and to express concerns. Public comments were considered by both the workgroup in making recommendations, and by CMS in crafting this interim final rule to incorporate the views of the public. Moreover, we are publishing this rule as an interim final rule with comment period rather than a final rule to provide the opportunity for further public comment on the PERM eligibility review requirements.

To solicit State participation in the workgroup, we contacted the American Public Human Services Association (APHSA) and we were notified of two States they selected for the workgroup. We believe that participation in the PAM or PERM pilots was not necessary to provide valuable input in the workgroup because the pilots demonstrated many problems with a claims-based sample and the States commented on these problems.

c. Methodology

Comment: One commenter stated that having the contractor conduct the eligibility review raises confidentiality issues both in State and Federal law concerning Social Security Administration and Internal Revenue Service information in the case records.

Response: We believe these concerns are addressed by having the States rather than the Federal contractor conduct the reviews.

Comment: A few commenters expressed concern about the lack of an administrative period to allow for the reporting of changes in beneficiary status. One commenter stated that measuring eligibility solely based on the date of service was inconsistent with CMS regulations at 42 CFR 431.211, which requires the State to mail the Medicaid recipient a notice 10 days before withdrawing Medicaid eligibility for an individual, and is also inconsistent with quality control policies in other programs. One commenter recommended that as part of the review, the administrative period be applicable to eligibility determinations and that failure to do so will result in an artificially inflated eligibility error rate.

Response: As defined under § 431.804, the administrative period is a timeframe under the MEQC program that provides States with a reasonable period of time to reflect changes in the beneficiary’s circumstances without an error being cited. This period consists of the review month and month before the review month. The administrative period is not applicable for those cases where the review is the month of the State’s most recent action (application or redetermination cases). For all other cases, eligibility is also reviewed as of the State’s most recent action so the administrative period would not be applicable in this instance either. However, if the State did not redetermine eligibility timely, the review will assess eligibility as of the sample month. We will not apply the administrative period to these cases because we do not believe the State should be held harmless when it has not demonstrated good case management by redetermining eligibility at least annually as required by Federal regulations at 42 CFR 435.916(a) and 457.960.

Comment: One commenter stated that, under the pilot projects, a relatively large percentage of improper payments were due to “lack of documentation” errors. The commenter believed that if full documentation were provided, it is possible that the error findings would decrease. Regarding eligibility samples, the commenter argued that caseloads larger than those selected in traditional MEQC were not needed to identify and address problem areas.

Response: In the past PAM and PERM pilot projects, “insufficient documentation” errors were determined with respect to lack of documentation to

support the medical reviews, not to support eligibility determinations. Regarding eligibility samples, we will base the number of eligibility reviews on an estimated sample size projected to be within 3 percent precision level at the 95 percent confidence interval level. We estimate an average of 500 reviews per year, which is less than the sample sizes for half the States under the traditional MEQC program.

Comment: Several commenters agreed with CMS' response that the State should be accountable for all Medicaid eligibility determinations regardless of which State agency made the determination but believed that Medicaid recipients who receive Supplementary Security Income (SSI) and whose Medicaid eligibility were determined by the Social Security Administration pursuant to section 1634 agreements should be excluded.

Response: We agree and have excluded from the Medicaid universe SSI cases in States with a section 1634 agreement, as well as Title IV–E foster care and adoption cases in all States.

Comment: One commenter noted that the PERM rule provided for adjustment to the error rate due to the provider appeals process. The commenter argued that adjustments should also be made to eligibility determinations under a fair hearing process and that decisions from such process should cause the error to be backed out of the error rate.

Response: If a State is properly continuing coverage due to a beneficiary appeal, the case would be counted as correct. There are no dollars associated with an improper denial or termination, so these cases would not have been included in the payment error rate and therefore would not need to be reversed. Note that for Medicaid, there are no adverse consequences associated with eligibility error rate computations under the IPIA. Disallowances of misspent Federal Medicaid funds are statutorily required for MEQC under section 1903(u) of the Act. For identified improper payments based on eligibility errors in SCHIP, the general recoveries statute at section 2105(e) applies.

Comment: One commenter expressed concern for conducting the Medicaid and SCHIP reviews independently and recommended that the issue be considered by the eligibility workgroup. The commenter stated that, in some States, families applying for SCHIP are first reviewed to determine if they are Medicaid eligible and if they are Medicaid eligible, they do not have the choice to be enrolled in SCHIP. In the above situation, the commenter argued that it is counterproductive to pursue repayment of Medicaid overpayments,

especially for families who applied using only SCHIP applications.

Response: We are measuring SCHIP and Medicaid dollars separately and, therefore, must conduct these program reviews independent of each other. Under SCHIP regulations at 42 CFR 457.350, States are required to screen SCHIP applicants for Medicaid eligibility. If a State erroneously determines a person eligible for Medicaid, the payments for the Medicaid services made by the State are improper regardless of whether the eligibility determination was made as a result of an SCHIP application or a Medicaid application. The statutory provisions requiring recoveries of misspent Federal funds due to Medicaid eligibility errors are at section 1903(u) of the Act. The general recovery provisions for misspent Medicaid Federal funds other than those due to eligibility errors are at section 1903(d) of the Act. For SCHIP, the recovery provisions are at section 2105(e) of the Act. These statutory provisions do not permit us to make exceptions to recoveries of misspent funds on the basis that such recoveries are counterproductive.

Comment: Several commenters expressed concern about citing eligibility errors for participants sampled for one program (SCHIP) while found eligible for the other program (Medicaid). The commenters believed that the difference between the levels of Federal matching should be considered erroneous and that adjustments to Federal claims should be allowed simply as adjustments to claims.

Response: As we previously stated, we are measuring improper payments in each separately funded program. The OMB guidance requires a statistically valid error rate that meets specified confidence and precision levels for estimating improper payments in each individual program. Therefore, for purposes of measuring improper payments in a program under PERM, adjustments in Federal claiming will not be made between a State's Medicaid and SCHIP programs.

Comment: One commenter stated that while he believed that CMS does not intend the payment error rate measurements to affect beneficiary eligibility or program coverage through State actions (such as States imposing more restrictive documentation requirements to prove eligibility) it is a possible outcome of PERM.

Response: States may take actions to avoid errors in eligibility determinations in any of a number of ways, including by making the application or redetermination process more stringent. For example, States may require a

higher level of proof of eligibility or require face-to-face interviews which could discourage program enrollment. This interim final rule does not require States to change their eligibility policies and procedures. However, if analysis of a State's error rate reveals weaknesses in its policies or procedures, the State may decide to address the causes in a manner that could require a higher level of beneficiary participation in substantiating his or her eligibility.

Comment: One commenter stated that a possible solution to address the barriers in eligibility verification as of the date the service was received, which can be 12 months prior to the date the claim is sampled for review, is to impose a maximum date of service of no earlier than 3 to 6 months from when the claim is sampled.

Response: We are using a case-based methodology for eligibility reviews to avoid situations where the reviewer is attempting to verify eligibility factors for a year or more in the past. The case-based sample reviews eligibility as of the State's most recent action rather than as of the date of service.

Comment: One commenter stated that CMS should eliminate the multiple month reviews for individuals within a continuous eligibility period; the review requirements should be limited to the month of service only. The commenter argued that this would support the intent of the PERM process, which is to determine if the individual was eligible for the service at the time the service was provided. The commenter stated that it also clearly highlights areas where the eligibility determination process could be improved to more accurately reflect the participants' continuing eligibility. The errors could be categorized as disqualifying or non-disqualifying depending on which eligibility factor was determined to be in error (that is, income, age, and/or residency). The commenter believed that this generally would move the review month closer to the month in which the eligibility review itself is completed.

Response: The review month is the month when the State took its last action to grant or redetermine eligibility and is the month in which the State will verify eligibility for the purposes of PERM. If the State's last action was taken beyond 12 months before the sample month, the review month will be the sample month. Each month, a State will divide its universe of cases into three strata and draw a random sample of cases from each stratum. The strata are as follows: (1) All applications (2) all redeterminations on which the State took an action to continue eligibility,

and (3) all other cases. For cases in stratum one, the review month is the month of the State's last action to grant eligibility. For stratum two, the review month is the month of the State's last action to redetermine eligibility. Therefore, for continuous eligibility cases in strata one and two, eligibility will be determined as of the first month of the 12-month continuous eligibility period. The same concept is true for cases in stratum three unless the State's last action was taken prior to 12 months from the sample month. In those instances, eligibility is reviewed as of the sample month. These review procedures eliminate the multiple month reviews for continuous eligibility cases.

Comment: One commenter is interested in how eligibility errors will translate into dollars.

Response: For purposes of computing an eligibility error rate (as opposed to the FFS and managed care error rates), the amount of improper payments is the amount paid improperly for services received, if any, either in the first 30 days of eligibility or in the review month (for cases in strata 1 and 2) or during the sample month (for cases in stratum 3). Each State will compute its error rate as a result of the reviews and associated claims. Disallowances of Federal funds due to Medicaid eligibility errors are governed by section 1903(u) of the Act as part of the MEQC program. The general recoveries statute at section 2105(e) of the Act applies to identified improper payments based on eligibility errors in SCHIP. States must attempt recoveries on identified errors under these statutory requirements.

2. Managed Care

Comment: One commenter stated that for managed care reviews there are two considerations: whether the individual was eligible when payment was made to the MCO and whether the payment to the MCO was in the proper amount (for example, capitation code and amount). With respect to SCHIP, CMS must additionally consider whether any applicable cost-shares were correctly assessed for the enrollee's family (for those in premium assistance programs).

Response: Medicaid and SCHIP managed care data processing reviews will determine whether: (1) the beneficiary was enrolled in Medicaid or the SCHIP program; (2) the capitation amount was correct according to State policy; and (3) the capitation payment was paid correctly. Cost-sharing will not be reviewed because generally the State has built these cost sharing amounts into their rate structures and CMS is not reviewing the accuracy of the cost-

sharing calculations as part of the review.

Comment: One commenter expressed concern regarding the potential additional expenses incurred in connection with medical reviews, which may erode provider participation in Medicaid/SCHIP managed care programs due to increases in response burdens.

Response: The managed care measurement does not include medical reviews; thus, provider participation in the managed care programs should not be affected since providers would not need to send in medical records.

Comment: One commenter expressed an interest in an opportunity to participate in any discussions about the methodology and procedures for calculating errors in managed care. Another commenter stated that the guidance and instructions from CMS for the PERM pilot managed care reviews would serve as a thorough and appropriate methodology for managed care reviews.

Response: We invited comments on managed care in the proposed rule and the October 5, 2005 interim final rule; the respective comment periods provided the opportunity to participate in discussions about the methodology and procedures for calculating errors. A number of commenters availed themselves of those opportunities. We concluded that it was best to base the managed care reviews and error calculations on the general methodology used in the PERM pilot project.

3. SCHIP

Comment: One commenter stated that, in the event the State exceeded its allotment, for every dollar the State used to provide information to support the measurement of a SCHIP payment error rate (or, in the instance of eligibility, actually makes such determinations), a dollar would be taken away from providing insurance coverage to the target population. The commenter used CMS' estimate of \$620,000 per State to argue that the State would need to cut 344 individuals from SCHIP (at an average cost of \$1,800 per individual per year) in order to comply with the October 5, 2005 interim final rule.

Response: The cost estimate of \$620,000 per State that we indicated in the October 5, 2005 interim final rule is the Federal cost, not the State cost, for PERM activities related to the medical and data processing reviews of FFS claims. We estimated that the cost to submit the information requested would not be significant, since States should have this information on hand. Therefore, we do not believe that

complying with the PERM requirements would necessarily result in termination of individuals from the State's program.

D. Appeals

Comment: Most commenters were concerned that the PERM regulation does not provide a process for States to review the contractor's findings for accuracy. Their comments include:

- The rule should allow States to formally review all errors using the documentation, including State reimbursement or billing policies used by the contractor to determine errors, before a final set of State-specific or national estimates are made;
- States will need a report with error codes to evaluate whether the error determination was appropriate;
- The Federal contractor should be required to hold an exit conference with the State before the findings are categorized as errors; and,
- CMS should revise the rule to clarify how and when the contractor would be able to validate the errors and resolve any discrepancies with the States.

Response: In responding to these comments, we have incorporated a "difference-resolution" process (a type of alternative dispute resolution) in this interim final rule, which provides States with the opportunity to review the RC's error findings and resolve instances where the State believes the claims were not erroneously paid.

At least monthly, the RC will provide the State with a disposition report. The disposition report includes the review determinations of the medical and data processing reviews for each sampled claim reviewed for the time period covered by the disposition report. The RC will make available information on which it based its findings so that the State can agree or disagree with the findings. A State can file a disagreement with a finding by sending a written request to the RC. If the RC agrees with the State, the RC will send the corrected findings to the SC. The SC will then delete the error and recalculate the error rate. If the State and the RC cannot resolve the difference in findings, the State may appeal to CMS for final resolution.

Comment: Several commenters expressed their concern that it was unclear who would make the final decision on the error determinations. One commenter stated that an appeals process, consisting of a neutral independent party to review potential errors that could not be mutually agreed upon by the State and the national contractor, should be incorporated in the final rule.

Response: This interim final rule provides that we will make the final decision on claims that cannot be resolved between the RC and the State.

Comment: One commenter stated that clarification is needed on whether States have appeal rights. Since CMS did not indicate whether States could appeal the contractor's error determinations, the commenters believed that appeals would fall upon the providers when the State implemented recovery efforts based on the contractor's findings of overpayments. However, if a provider receives a notice of overpayment and it is a small amount, the provider may not feel it worthy of an appeal, but the error would nonetheless affect the State error rate.

Response: States may work with the RC to resolve differences in findings on claims that are determined by the RC to have been paid in error (except for errors caused by no documentation). In addition, we would reverse errors based on successful provider appeals. However, whether or not a provider chooses to appeal an overpayment is a factor that we believe should not be influential on error determinations or error rates.

Comment: One commenter stated that CMS' description of the appeals process, in which States provided any adjudication changes due to successful provider appeals of the State's determinations, was unclear, and that more clarification is required in order for States to correctly submit the requested information. The commenter believed that CMS was referring to sampled denials by the State agency that the provider appealed. However, in those cases the commenter observed that entire new claims were created (not adjustments to prior claims). The commenter argued that, by regulation, providers must accept the payment that Medicaid sends them; providers can only appeal notices of recoupment of overpayment.

Response: Under our regulations at 42 CFR 447.15, providers participating in the Medicaid program must accept, as payment in full, the amount paid for the service by the State (plus any beneficiary cost-sharing required to be paid by the beneficiary). Thus, the provider cannot appeal the rate set by the State for each service. However, this does not preclude a provider from appealing partial payments, incorrect payments, or denied payments for services delivered to Medicaid beneficiaries. As part of the PERM process, States will provide the SC with information regarding the resolution of sampled claims that enter their appeals

process. As the commenter noted, in many States an entirely new claim is created after a successful provider appeal and is not associated with the original claim. If the resolution affects the contractor's disposition on the sampled claim, the error rate calculation will be revised to reflect that change.

Comment: Several commenters stated that CMS' response of adjusting the State's error rate if a provider's appeal reverses the decision would not be feasible for some States where the appeal process can take at least 2 years. They asked how transaction errors would be handled when a provider appealed an error and the State had an appeal process that was not exhausted before the completion of the PERM audit.

Response: The contractor will adjust the error rate in instances where the provider appeals the adjudication decision, the claim is adjusted and it affects the review finding so long as this process is completed earlier than 45 days before the error rate calculation. For claims adjustments due to provider appeals that occurred after the error rate calculation, the State may request that we adjust the State's error rate and issue a revised error rate.

Comment: Several commenters expressed their concerns regarding their ability to respond to provider appeals of overpayments identified through PERM. The commenters noted that in their States' respective provider appeal and repayment process, they could not rely on the contractor's determination as the sole reason for collection of an overpayment. Other commenters stated that the national contractor should be responsible for defending its decisions related to all provider appeals in the appeals process and that States should not have to expend time and effort to defend the error findings of the national contractor when State staff did not participate in the reviews. Otherwise, they argued that the States would have to make their own determinations, which puts additional burden on States.

Response: We have provided States with the opportunity to review the RC's error findings on all claims and have these errors reversed if the State can demonstrate the claims were correctly paid through the difference-resolution process. This is the vehicle we intend the States to use to participate in the reviews. For claims where error findings stand, the State must recover the overpayment from the provider under section 1903(d) or section 2105(e) of the Act. The RC will make available to the State the information on which the RC made its determination that a claim was improperly paid.

E. State Requirements

1. Collection of Information

a. State's Role

Comment: One commenter stated that it appeared that the information collection notice listing State responsibilities in the **Federal Register** (70 FR 50357) was different than the list of State responsibilities sent to the State Health Officials by letter on October 6, 2005.

Response: The October 6, 2005 letter addressed to State Health Officials listed the information to be submitted by the sampled States as outlined in the October 5, 2005 interim final rule. The letter did not include the requirement that States provide "other information" that the Secretary may need to estimate error rates; we apologize for this omission. In response to public comments regarding the burden of information collection, we have reduced the burden by making one change in this interim final rule. We have provided that States will no longer need to submit the previous year's claims data. The contractor can use the quarterly claims data to determine sample size and, therefore, we determined that the collection of this information would be superfluous.

Comment: One commenter asked whether CMS would require States to establish data use agreements with each of the three national contractors.

Response: States do not need to establish data use agreements with the national contractors. The contractors will collect the required information for us under the authority in the Medicaid statute at section 1902(a)(6) of the Act and the SCHIP statute at section 2107(b)(1) of the Act. The contractors would be business associates of CMS pursuant to 45 CFR 164.502(e), and would be required to sign a business associate agreement as specified at 45 CFR 164.504(e). Our contractors must abide by terms and conditions of these contractual agreements, which incorporate HIPAA and Privacy Act provisions requiring security measures and imposing limitation on use.

Comment: Several commenters were concerned with the open-ended language used in describing the information States would need to submit. Their comments included:

- The use of the language "that include but are not limited to" in conjunction with the language in 42 CFR 431.970(g) means that CMS could require States to report State-specific payment error rates for Medicaid and SCHIP. The commenter argued that § 431.970 should reflect CMS' intention

as expressed in the preamble to the October 5, 2005 interim final rule that States would not be required to submit State-specific payment error rates to CMS.

• Section 431.971, paragraph (g) would require States to provide “other information that the Secretary deems necessary for, among other purposes, estimating improper payments, and determining error rates.” The commenter believed that the rule was intended to govern only estimating improper payments and error rates and that CMS had other authority under Federal law to demand information necessary for the administration of the Medicaid program. The commenter argued that the phrase “among other purposes” is not within CMS’ authority under the IPIA, is unnecessary, and should be deleted.

Response: The phrase, “that include but are not limited to,” in the information submission requirements enables us to collect information that is not specifically listed so that we could include any information that could help improve the process or would produce more accurate error rates. “Among other purposes” is included to allow us to use the information for other purposes if needed without duplicating our request for information from the States.

Comment: One commenter stated that requiring its territory to meet error rate standards without the territory having comparable access to technology support is a serious challenge that places financial strain on the territorial government.

Response: As stated in the August 27, 2004 proposed rule and the October 5, 2005 interim final rule, we have excluded the territories from payment error rate measurements.

Comment: Several commenters noted that for States to provide the Federal contractors with the requested information would require constant communication between the State and the Federal contractors. The commenters recommended that CMS assure States that the Federal contractors and States will have systematic and regular contact and communication for the duration of the project. To facilitate the communication, one commenter asked whether States planned to use staff from the State’s Program Integrity or Program Operations as the designated contact persons.

Response: A State can designate, at its own discretion, State contacts for PERM. Once the State contacts are established, the contractors will communicate with the designated person regarding specific State

information that is needed for the program. We have provided the Federal contractor and CMS contact information at <http://www.cms-perm.org/>.

Comment: Several commenters stated that it would be difficult to obtain approval for additional staff when PERM activities occur only once every 3 years. They stated that even temporary positions are time consuming to establish at the State level, and retention of knowledgeable and experienced staff for the PERM project will not be possible if they are utilized only once every 3 years.

Response: Since the Federal contractors will conduct the reviews for managed care and FFS, the selected State will only provide the required State policies and claims information, technical assistance on the State’s program, and the State’s corrective action plan to reduce improper payments. We believe the submission of information would not require experts or experienced staff since the information that we are requesting (for example, State medical policies and updates) should be available in-house for submission. With respect to eligibility reviews, staff for PERM will be needed longer than once every 3 years because the process to measure one fiscal year takes approximately 23 months. In the interim time before a State’s next PERM measurement activities (approximately 13 months), a State could use the staff for other quality assurance initiatives, such as enhancing its MEQC and/or SCHIP program integrity activities.

b. State Cost and Burden

Comment: Many commenters believed that the October 5, 2005 interim final rule underestimates the amount of resources that will be needed to comply with the proposed rule. Their comments include:

• Experience with the PERM pilot project indicates that this work will require more than 1,630 hours, with one commenter believing that it would require 4,000 to 5,000 hours of State effort.

• The estimation of 800 hours for the sole purpose of submitting the quarterly stratified claims data (200 FTE hours per quarter) leaves only 830 budgeted hours left for each State’s program to perform all other functions, which seems inadequate.

• The estimates do not incorporate the appropriate sample sizes, or account for the expanded scope of PERM or other tasks.

Response: We believe our estimates are accurate based on the experience with the past PAM/PERM pilots. Under

the national contracting strategy, the Federal contractors will conduct the reviews. We agree that the estimates do not account for the expanded scope of PERM. The October 5, 2005 interim final rule only included estimates for the FFS measurement.

Comment: Several commenters stated that the rule does not take into account that each State will need to dedicate a substantial amount of personnel and resources to ensure that the payment error rate is accurate. The commenter requested that the rule be amended to consider the resources that will be required for this task.

Response: We have provided estimates of State burden and cost in this interim final rule with comment. However, ensuring that the FFS and managed care payment error rates are accurate is not a State requirement under PERM. Reviewing the RC’s findings is the State’s option. We believe that our monitoring of the contractor’s quality assurance plan is sufficient to provide for accurate and reliable findings. The quality assurance plan includes, at a minimum, that the RC:

• Become International Organization for Standardization (ISO) compliant and registered within one year of being awarded its contract;

• Perform a second level review on each sampling unit determined to have a payment error and on a 10 percent random sample of all other sampling units.

Comment: Some commenters stated that CMS’ cost and burden estimates of the information collection and technical assistance requirement are understated. Their comments included:

• CMS assumes that the contractor will operate with minimal State technical assistance. Because of the complexities of State programs, the commenters believed that it will be difficult for a Federal contractor to become proficient in evaluating how claims are processed and reviewed in all 50 States without constant guidance from the States.

• This will require a substantial commitment of the States’ resources, from multiple program areas and from the States’ contractors, to support initial contractor start-up and follow-up with contractors on State policies.

• It is difficult to gauge the technical assistance that States must provide because the contractor’s capabilities are unknown.

Response: As previously stated, we have engaged, and will continue to engage, a review contractor that has demonstrated knowledge and experience with claims reviews. In this

way, we have tried to minimize the burden on States.

Comment: Some commenters believed that implementing the PERM requirements as described in the October 5, 2005 interim final rule will compete with State resources that are directed toward more promising quality control projects. They stated the rule will create a diversion of staff from program integrity and MEQC, which target known areas of vulnerability, and could result in a decline in recoupments, fewer ineligible recipients being detected, and fewer corrective actions implemented.

Response: The purpose of the PERM program is to fulfill the requirements of the IPIA. PERM does not serve as a waiver of other Medicaid and SCHIP program requirements. States have a responsibility to comply with those other requirements.

Comment: Since resources will be pulled from various State program areas and from multiple State program contractors, the State will be faced with a significant responsibility as it attempts to coordinate the work efforts of multiple State and contractor staff that will be interfacing with multiple CMS contractors.

Response: We believe that the need for State coordination will be minimal for medical and data processing reviews since each Federal contractor will contact the appropriate State staff members to obtain the information requested for the PERM reviews. Also, we will be coordinating efforts of the Federal contractors.

Comment: One commenter questioned whether the estimated State burden of 200 FTE hours per quarter for submitting claims data is adequate given that fiscal intermediaries must write new data programs for each stratum and the data must be reviewed for quality. They argued that due to the unique design of the data extracts, significant burden may be placed on States if the Federal contractor requests multiple data extracts because of incorrect data queries provided by the fiscal intermediaries.

Response: The 200 hours per quarter is an estimate for the FFS measurement. We anticipate the majority of the hours required for submitting the claims data will be in the initial quarter of review. Once the statistical program, which stratifies the claims information for the first quarter, is created, that same statistical program will be used for the subsequent quarters. The SC can provide technical assistance to the State or fiscal intermediary so the State correctly submits the quarterly claims information. We do not anticipate

multiple requests for data extracts. The SC will provide detailed instructions and technical assistance to each selected State or its fiscal agent on the stratification process. Through our experience with the past PAM/PERM pilots, stratification will require minimal data programming since we have based the strata on the MSIS categories. We do not believe this will substantially burden the States or their fiscal agents.

Comment: Several commenters expressed concern about the 10 percent cap on SCHIP administrative expenditures and recommended that CMS consider exempting the cost of PERM-related SCHIP activities. One commenter believed that the PERM-related SCHIP activity costs should be 100 percent federally-funded. A number of commenters asked whether the enhanced Federal funding would be available for the State to meet this obligation and some commenters requested a 90 percent enhanced match. Other commenters asserted that providing full funding or increasing the FFP to 100 percent would alleviate the burden on States for the hours and resources necessary for the State to support this Federal initiative.

Response: States will be compensated at the SCHIP match rate, similar to other Federal audits. We are not considering exempting the costs of PERM-related activities from the 10 percent cap on SCHIP administrative expenditures.

Comment: Several commenters expressed concerns regarding the start-up costs for PERM. Their comments included:

- CMS should consider additional support to States during the start-up phase; the initial time would be most onerous since States are transferring a large body of information for medical reviews, systems, and provider information to PERM contractors; and
- Since CMS did not issue final plans for the PERM model until recently, States have not received budgetary approval to support this initiative. CMS should consider fully funding these costs until such time that they can be included in an approved State budget.

Response: Our adoption of the commenters' recommendation to engage a Federal contractor to estimate several components of the improper payment measurement significantly reduces the cost and burden. States will not pay for the Federal contractors. Only those States selected for review each year will provide information necessary for the sample selections and reviews, provide technical assistance as needed, and implement and report on the corrective actions to reduce the error rate. The

States will be reimbursed for these activities at the applicable Federal SCHIP match rate for SCHIP and at the Medicaid administrative match rate for Medicaid. Our estimates of the burden and cost of these responsibilities can be found in this interim final rule at Section VI, Regulatory Impact.

We understand that States may need to receive budgetary approval in advance and we have selected States for review in a manner that allows for States to plan for the reviews.

Comment: Some commenters stated that the stratification of quarterly claims data by service is a burden to the States. They believed that the contractor will need substantially more data files from the States than specified in the notice, which will increase the burden to States. They stated that States should not be responsible for the costs of formatting the data into required format and delivering the data to the contractor. One commenter stated that to comply with the minimum data sets, a State will have to pay their fiscal agents for any and all work that amends the fiscal agent's scope of work.

Response: The SC will provide detailed instructions and technical assistance to each selected State or its fiscal agent on the stratification process. Through our experience with the past PAM/PERM pilots, stratification will not require more information than we have specified in the rule since we have based the strata on the MSIS categories. We have determined that this will not substantially burden the States or their fiscal agents.

Comment: One commenter stated that providing the universe of denied claims data to the Federal contractor will be time-consuming and the cost of this activity may not have been properly estimated since it was not included in the PAM cost study.

Response: The strata were used in the PERM pilot and we must include the denied claims in the universe. We incorporated the cost of including denied claims in the universe when we estimated the impact on States and do not believe that including denied claims would be a burden to the States.

c. Information Collection

Comment: Several commenters noted that the resources needed by the States to meet the information requirements vary considerably depending on the level of detail required and expressed that it is critical that States have a clear understanding of the CMS requirements, so that States can more accurately assess the resources needed to support PERM.

Response: We have provided cost estimates and more specific details

regarding the methods and timeframe for the submission of information in Section IV, Regulatory Impact, of this interim final rule.

Comment: One commenter stated that since only the States selected for review are required to provide the information needed by the Federal contractor, the body of the regulation should explicitly state that States should not have to report any information if the State's program has not been selected in the sample to be reviewed.

Response: The information collected through this rule applies only to the PERM program and does not relieve States, whether or not they are selected for the PERM program, of their responsibilities to report to the Secretary for this or other purposes, as required under Medicaid law at section 1902(a)(6) of the Act and SCHIP law at section 2107(b)(1) of the Act. Both Medicaid and SCHIP statutes require States to provide information necessary for the Secretary to monitor program performance. We do not anticipate situations that would require a State to report information not related to its error rate in the off years to satisfy PERM requirements.

Comment: One commenter cited the statement in the rule that CMS will be reporting the error rates in the FY 2007 and FY 2008 PAR and believed that States could be asked to submit all required information delineated in the regulation whether or not the information will actually be used for reporting in the PAR. The commenter asserted that the body of the regulation should explicitly indicate that States should not have to report any information if a program will not be reported in the PAR.

Response: The information collected through the October 5, 2005 interim final rule will be necessary for producing the national Medicaid and SCHIP improper payment estimates that will be reported in the PAR. Otherwise, as noted above, we retain a statutory right to collect information from States to effectively administer the Medicaid and SCHIP programs.

Comment: One commenter argued that the timelines associated with the States submitting the quarterly data are unclear and asked when the quarterly claims data would be due. They believed there may not be sufficient time for the Federal contractor to receive the data for the last quarter of FY 2006 (July through September 2006) and then request medical documentation, review the claims for processing errors, and report on the findings by August 2007.

Response: The FY 2006 measurement timeline runs from October 2005 through August 2007. This timeline is aggressive; however, we believe we will be able to report the FY 2006 error rates in August 2007.

Comment: Several commenters pointed out that CMS will direct the Federal contractors on stratification issues; however, they argued that States will also need to know these directions in a timely fashion so they can properly submit their data in the required stratified format. They asked whether the States would need to reformat their claims data using standard headings before submission, since the States' data systems are different.

Response: The stratification of FFS claims will be similar to the classification system used in the PERM pilot, in which the claims were stratified into the eight strata: (1) Hospital services; (2) long-term care services; (3) other independent practitioners and clinics; (4) prescription drugs; (5) home and community based services; (6) other services and supplies, for example, labs, x-rays; (7) fixed payments, such as Medicare Parts A and B premiums; and (8) denied claims. States can submit the claims information using the following formats: A portable flat file, CD/DVD, or tapes. The SC will also work with the States to determine the best format for each individual submission of the stratified claims data.

Comment: Several commenters stated that the proposed rule would not require States to provide the contractor with States' Medicaid Management Information System (MMIS) (the claims processing system for the State) data and that this would add substantial State staff burdens. They recommended that the contractor use data by extracting Medicaid Statistical Information System (MSIS) data (which summarizes historical claims payment information from the different MMIS systems and stores it in a centralized CMS database) that the Federal government already collects, to avoid duplication with information already reported by the States.

Response: States are not required to submit MMIS data to the contractor, but rather the adjudicated claims from the previous quarter stratified into eight strata. The MSIS data that we have in-house are too old to produce meaningful data on which States could base effective corrective actions. Also, we note that there is no similar national sampling framework which could be used to process SCHIP claims.

Comment: One commenter stated that CMS should provide a "preprint" for

the States to fulfill PERM requirements in order to minimize the response burden on the States in this regard.

Response: States are not required to submit State plan amendments for PERM purposes. Therefore, a preprint is not necessary.

d. Repricing

Comment: One commenter stated that the re-pricing of claims which were determined by the national contractor to have been underpaid or overpaid would require the contractor to copy all medical records associated with the claims reviewed and provide them to the States.

Response: The repricing of claims will be performed by the national contractor during the data processing reviews or through other available State information. If the contractor cannot determine a reprice, the contractor will provide the States with the appropriate information (for example, billing code, place of service) for the States to use to reprice the claim.

Comment: One commenter stated that in a particular State, providers have a year to submit valid claims and 18 months to adjust their claims.

Response: We recognize that States have varying time period for adjustments. In order to have a consistent timeframe and to allow for timely completion of the error rate estimates, only adjustments made to claims within 60 days of adjudication or payment will be considered in the error rate calculation.

Comment: One commenter asked whether States can factor in both provider and Department of Medical Assistance adjustments in the re-pricing of claims.

Response: In this context we intend "re-pricing" to mean the Federal contractor's determination of the correct payment amount (according to the State's payment rate) that should have been paid for a claim so that the Federal contractor can calculate the amount of improper payment. The Federal contractor will determine the correct payment amount during the data processing review or through other available State information. If the contractor is unable to determine the correct payment amount, the contractor will contact the state for re-pricing.

Comment: One commenter asked whether the re-pricing of errors identified by the Federal contractor would provide an opportunity for each State to review the Federal contractor's work and for the State to dispute a potential error and provide more information. The commenter argued that this review by the State is necessary

considering the Federal contractor's work is final and that the State's review is a crucial component of obtaining a valid national error rate that States can agree with and support.

Response: The repricing of claims is not meant to occasion a review of the national contractor's findings. However, the re-pricing of errors will offer the State an early indication that there may be an error determination by the contractor. States will have the opportunity to review the contractor's determination of the claims and resolve differences through the difference-resolution process.

2. Technical Assistance

Comment: Several commenters noted that section IV of the October 5, 2005 interim final rule stated that selected States would provide technical assistance to the CMS contractors as needed to "allow the contractor to fully and effectively perform all functions necessary to produce the program error rates." They argued that if the provision of technical assistance by the States is required or expected, those expectations should be expressed more clearly.

Response: The States must provide technical assistance to assist the RC in conducting the medical and data processing reviews. For instance, the State may need to explain or clarify unusual policies or procedures, and the State may need to provide training on its MMIS or claims processing system.

Comment: One commenter observed that data processing reviews will be an additional cost to States because the IT staff would have to provide manual and technical assistance to the federal contractors. The IT staff would have to interpret fields for the Federal contractor's process reviews and provide answers in a timely manner.

Response: We agree that the State must provide technical assistance to the contractor for the processing reviews. However, the data processing reviews will most likely be performed on-site, which will allow the State to work directly with the contractor when questions or issues arise. We believe this assistance provided to the contractor will not result in additional costs and estimate that the burden will be minimal.

3. Corrective Action Plans

Comment: Several commenters stated that the October 5, 2005 interim final rule contains little detail on the required corrective action plans, such as what is required in the plans and how they will be monitored and evaluated. One commenter stated that CMS should clarify the reporting requirements for

corrective action, including the source and the consequences of the corrective action components. Another commenter stated that CMS should be required to enter into a dialogue with States to identify the components of model corrective action plans so that these can be refined and agreed upon before the PERM information collection process begins.

Response: States will submit a report to CMS. The corrective action plan format should include the following:

- Data analysis—an analysis of the findings to identify where and why errors are occurring.
- Program analysis—an analysis of the findings to determine the causes of errors in program operations.
- Corrective action planning—steps taken to determine cost-effective actions that can be implemented to correct error causes.
- Implementation—plans to operationalize the corrective actions, including milestones and a timeframe for achieving error reduction.
- Monitoring and evaluation—to assess whether the corrective actions are in place and are effective at reducing or eliminating error causes.

States will monitor implemented corrective actions to determine whether the actions are effective and whether milestones are being reached.

Comment: Several commenters stated that it would be impossible to determine the costs and resources that would be needed to comply without clarifying the corrective action requirements. They stated that if States prepare and implement corrective action plans, these plans could constitute a significant workload beyond the 500 hours identified in the supporting statements for the information collection notices published July 22, 2005 (70 FR 42324) and August 26, 2005 (70 FR 50357). For example, the development and implementation of a provider outreach program could entail considerable staff time.

Response: The corrective action requirements are to evaluate the findings from the PERM reviews, plan and implement actions to be taken to address the major causes of identified payment errors, and monitor those actions to evaluate their effectiveness on error rate reduction. The State may have to discontinue corrective actions that are determined to be ineffective and implement new actions. All of this information will be contained in the State's corrective action plan. CMS intends such plans to be carried out within the restrictions of the ongoing program.

Comment: One commenter believes that the rule did not describe how the corrective action plans would improve the national error rate over time. The commenter believes that by the time the States were re-sampled, their corrective action plans for the initial errors found would be stale. The commenter argued that CMS should allow States flexibility in developing corrective action plans in order for these plans to be of maximum use to the States.

Response: We agree. We believe that it will take time for the implementation of corrective actions to impact States' error rates. We also agree that States should have flexibility in developing their corrective action plans.

Comment: One commenter asked what would be the appropriate corrective action if a provider miscoded a claim or failed to adequately document a service in his or her medical records. The comment asked what would be expected by CMS beyond education of that provider's staff.

Response: We believe that determining the appropriate corrective actions to correct error causes is a State action. If, in this instance, provider education is working to reduce the incidence of errors, the State may determine that actions beyond this are not needed. However, if the education is not effective, we would expect the State to develop new corrective actions to address the problem.

Comment: A commenter asked whether corrective actions would be required for all errors, or whether CMS planned to set a percentage point or dollar threshold at which corrective actions would be required. Another commenter asked at what point States that had low error rate estimates would be exempt from submitting a corrective action plan or participating in PERM.

Response: Corrective actions will be required from each State being measured, as will PERM participation. States should target corrective actions to the major causes of errors identified by PERM in order to improve payment accuracy. "Major causes" are not necessarily tied to a percentage point or dollar threshold and, therefore, we are not promulgating such thresholds. In planning corrective actions, States can estimate the cost-effectiveness in evaluating what actions to implement.

Comment: The commenter believed that States with low error rates should be given the same consideration offered through MEQC—to develop and operate pilot projects that identify and resolve payment and eligibility issues that have improved program performance and administration. The commenter argued

that Medicaid pilot projects allow States to concentrate on identified problems and are a much better use of limited resources.

Response: We are required to report Medicaid and SCHIP error rates by the IPIA and must use a standard measurement process to ensure the reliability of those rates. Furthermore, the improper payments for medical and processing reviews in FFS and managed care will be measured by the Federal contractor, so States do not need to conduct pilot programs.

4. Recoveries

Comment: Some commenters were concerned about recoveries of overpayments. Their comments and suggestions are as follows:

- Claims with only "technical errors" that do not affect payment should not be disallowed;

- The date of discovery of overpayments should be the date that the State agency confirms that an error had occurred;

- The Federal share of the overpayments should be offset by the amount of underpayments identified by the review, and overpayments should be returned to CMS within 60 days after the actual recovery of the overpayments and not 60 days after the overpayment is identified;

- CMS should not be permitted to offset any alleged overpayments until a State's appeal has been resolved;

- Any offset amount should be further reduced by an agreed-upon factor to represent the actual claims adjustments that were made but were not included in the payment error rate methodology that would inflate or exaggerate the amount of overpayments made;

- Identified overpayments should not be subject to the 60 day rule until such time that the State agreed that an overpayment had occurred or administrative remedies available to the State had been exhausted; and

- It is problematic that States would be required to return Federal funds even when recoupment on claims proved impossible (for example, when a provider was terminated or could not be located).

Response: In the regulation text at the conclusion of this preamble, we have cross-referenced the recoveries provisions in existing Federal regulations for the convenience of the reader. As previously stated, recoveries of overpayments are governed by the existing statutory and regulatory requirements (section 1903(d)(2) of the Act; 42 CFR part 433, subpart F; and 42 CFR part 457, subparts B and F). We are

not proposing to amend these regulations and, therefore, are not accepting recommendations for revisions or exceptions to its provisions.

Comment: Some commenters discussed possible alternatives to recoveries in the PERM measurement. Their comments included:

- CMS should not require States to repay the Federal share of erroneous payments identified via PERM reviews;

- It would pose significant problems to States' budgets and accounting systems if CMS applied States' error rates to the total expenditure of the States' Medicaid programs and sought recoupment at the universe level, rather than on specific claims found to have been paid inaccurately;

- The corrective action plan to reduce the error rate is the intended output of this study, not recoveries;

- If CMS pursues an alternative payment recovery from the States, States should be provided an opportunity to review, comment, and if necessary, appeal CMS findings in accordance with existing Federal regulations; and

- CMS could adopt an error threshold similar to existing standards for the Single Audit, which requires a dollar threshold of \$10,000 for a reportable condition to be found.

Response: As previously stated, recoveries of Federal funds are governed under current law and regulation. This interim final rule with comment does not seek to make revisions, so we are not accepting these recommendations.

Comment: One commenter has found strict adherence to the wrong date of service policy results in recoupment of funds for which the provider cannot rebill because the timeframe had ended for filing a new claim for the service. The State has allowed a discrepancy in dates in past audits if the service or procedure is only a day off and is not duplicated in the claims history for that timeframe.

Response: We will follow the State payment policies to determine how the State deals with incorrect dates of services. However, any special payment conditions, such as special treatment of dates of service, should be stated in the State policies submitted to the Federal contractor.

F. Regulatory Impact Statement

Comment: One commenter stated that the cost estimates for the reviews, in their entirety, seem exorbitant. They argued that it would use resources that would be better spent on the provision of services for recipients rather than for a review that will recoup possibly significant funds from the State and will

ultimately lead to smaller budgets for the administration of services.

Response: The cost estimate in the October 5, 2005 interim final rule is for the Federal contractor to review FFS claims in Medicaid and SCHIP. There, we estimated the FFS review cost to be \$11.16 million per program, per year. These costs are the Federal costs to fund the contractor; the States would not pay for the Federal contractor. In the October 5th rule, we estimated the State's cost to be \$1,524,506 total computable (\$42,348 per State per program) to submit information needed to review Medicaid or SCHIP FFS claims.

We believe that we have reduced the burden on States from the proposed rule by engaging Federal contractors to conduct the medical and data processing components of PERM review and by reviewing these components in a State once every 3 years. Regarding the recoupment of funds from States, this regulation does not supersede current law and regulations governing the recovery of misspent funds.

Comment: Several commenters stated that the amounts of State time and resources required for the reviews have been underestimated. Their comments included:

- Many States that participated in the PERM pilot process strongly believed that the burden and cost estimates should be higher;

- CMS underestimated the time and cost required to obtain medical records from providers;

- The CMS rule associated with formulating cost estimates was based on incomplete data; CMS utilized these rules to exclude time and effort estimates for both eligibility and managed care claims reviews; and

- CMS' impact estimate on States ignored the resources that would be needed to develop, submit, monitor, and evaluate the required corrective action plans.

Response: We based the cost estimates on the information provided by the States participating in the PAM Year 2 pilot, and believe that our estimates for States to provide requested information and technical assistance to the Federal contractor are reasonable. The October 5, 2005 interim final rule did not estimate the costs for measuring improper payments in managed care and eligibility because we postponed issuing a final methodology on the measurement of these components and invited further public comments. We have included the estimate for the costs of providing information for managed care, conducting eligibility reviews, and developing a corrective action plan in

this interim final rule. Estimates of this burden and these costs are indicated in section VI of this interim final rule. However, we believe that the costs of monitoring and evaluating the corrective plan are part of the States' overall operating procedures and, therefore, we did not include these costs in our estimates.

Comment: One commenter argued that States would incur additional undocumented costs to meet PERM requirements. At a minimum, CMS should require all 17 initial FFS States to track all attendant costs for staff time and effort in FY 2006. They argued that final PERM regulations should not be issued until a more realistic cost baseline can be ascertained and a revised regulatory impact assessment performed.

Response: We have revised the estimated program costs, including State costs, based on a rate of pay that incorporates fringe and overhead costs. The revised estimates have been included in section V of this preamble. Based on our experience in the past PAM and PERM pilot projects, we believe our estimates are accurate and we do not anticipate that the State burden will be more than what is specified in this rule. We will not adopt the recommendation to require States to track costs for staff time and effort because we limited the information collection requirements to the minimal information needed to measure improper payments. Collection of more information would place an additional burden on States.

Comment: One commenter stated that although CMS indicated in its response to comments in the October 5, 2005 interim final rule that it has analyzed the cost and burden on providers as part of this rule and determined that there would not be a significant impact, no such analysis appears anywhere in the October 5, 2005 interim final rule.

Response: We described our reasoning for determining that there would not be a significant cost or impact on providers on pages 58274 and 58275 of the October 5, 2005 interim final rule. As we stated in the October 5, interim final rule's regulatory impact statement, a request for medical documentation to substantiate a claim for payment is not a burden on individual providers nor is the request outside the customary and usual business practice of Medicaid and SCHIP providers. Since not all States will be reviewed every year, it is highly unlikely that a provider selected to provide supporting documentation will find it burdensome or incur significant additional cost.

Also, such information should be readily available and the response should take minimal time and cost since the response requires gathering the documents and either copying and mailing them or sending them by facsimile. States are free to reimburse their providers for the cost of submitting this information. Thus, the request for medical documentation from providers is within the usual practice of a provider who accepts payment from an insurance provider, whether it is a private organization, Medicare, Medicaid or SCHIP, and should not have a significant impact on the provider's operations.

Comment: One commenter stated that whether or not the RFA requires CMS to conduct an impact analysis, States that have never participated in the PAM or PERM pilots should have an opportunity to review the analysis to which CMS referred so that these States could make their own determinations of potential response burden on providers.

Response: We stated in the October 5, 2005 interim final rule that we believe that the impact on providers will be minimal. States are free to make their own determinations by conducting their own impact study.

G. Anticipated Effects

Comment: The commenter agreed that the anticipated effects of the rule would not be evident for several years. The PERM process is a large and labor-intensive activity that will have high costs in paying contractors and in the use of States' staff for information-sharing and liaison activities. These costs may ultimately have a very large, negative impact on the State should the review show a high error rate.

Response: In meeting the requirements of the IPIA, the purpose of PERM is to measure improper payments and identify vulnerabilities in State programs, which States can address in their corrective action plans. We believe that this effort will improve the States' program performance. Insofar as the process discloses overpayments, both the Federal and State shares can be recouped from providers.

IV. Provisions of This Interim Final Regulation

We published an interim final rule on October 5, 2005 because we significantly revised the approach we originally proposed to implement the IPIA. Based on recommendations received in response to the August 27, 2004 proposed rule, we adopted the recommendation to engage a Federal contractor to estimate improper payments in Medicaid and SCHIP for

reviews of adjudicated FFS and managed care claims. We also adopted the recommendation to review a subset of States each year rather than measuring every State every year. However, we continued to propose that the States selected for review in any given year would measure improper payments based on eligibility reviews rather than delegating this responsibility to a Federal contractor. The national contracting strategy significantly deviated from the provision in the proposed rule so the October 5, 2005 interim final rule provided the opportunity for further public comment. We also specifically invited comments on methods for estimating improper payments for managed care and program eligibility.

In the preamble, we describe the national contracting strategy for review of FFS and managed care claims and list the States selected for Medicaid review in FY 2006 through FY 2008. We also describe the State eligibility review requirements. Additionally, this interim final rule with comment period—

- Retains the State requirements for information submission laid out in the October 5, 2005 interim final rule;
- Adds a new information collection from States in order to measure improper payments in managed care; and
- Adds a new section on the State requirements for measuring payment errors through eligibility reviews and providing this information to CMS.

Descriptions of the measurement process for managed care and eligibility improper payments are set forth below.

1. Managed Care

In commenting on the proposed rule, States objected to conducting the reviews, including managed care reviews. We invited further comments in the October 5, 2005 interim final rule on methods for measuring managed care claims in Medicaid and SCHIP. Commenters recommended that we measure: (1) Whether the individual was eligible when payment was made; and (2) whether the State's payment to the managed care organization was made according to State policy and in the proper amount. An additional consideration would be whether any applicable cost-shares were correctly assessed.

For this interim final rule, we determined that the Federal contractor will measure improper payments in Medicaid and SCHIP managed care by:

- Measuring managed care improper payments in the same States that are selected in any given year for FFS and eligibility reviews; and

- Using a claims-based sample to determine whether the beneficiary was enrolled in the Medicaid or SCHIP program and whether that State's capitation payment to the managed care organization was made correctly according to the State's policies.

We are limiting the review of managed care enrollment to program enrollment since other factors such as eligibility for the plan will be determined as part of the program eligibility reviews. We are not adopting the recommendation to review whether cost-shares were correctly assessed since these payments do not offset or otherwise affect the State's payment to the plan.

The Federal contractor will measure managed care in the same year that a State is selected for FFS reviews in Medicaid and SCHIP. Beginning in FY 2007 each State will be measured for managed care payment errors Medicaid and SCHIP, once and only once every 3 years. We will calculate a separate managed care error rate for each State under review and will merge the State's managed care and FFS error rates together with the State's eligibility error rate to produce State-specific error rates for Medicaid and SCHIP. The following is an overview of the managed care measurement process.

a. Claims Universe

For each program, the universe will consist of all capitation payments made on behalf of beneficiaries in Medicaid or SCHIP. Capitation payments are payments made by the State to a managed care plan for a set fee that is based on a pre-determined agreement rather than on the actual cost of care and services delivered. Excluded from the universe are FFS payments to the managed care plan on behalf of managed care beneficiaries (for example, services such as childbirth); these payments instead will be subject to sampling in the FFS review.

b. Sample Size

For the managed care error rate measurement, we estimate an annual sample size of 500 claims per State per program will be reviewed. This estimate is based on the experience in the past PAM and PERM pilots. Since the variances for capitation payments are low, we believe that this estimated sample size will allow us to produce a State-level error rate that meets 3 percent precision level at a 95 percent confidence interval level.

c. Managed Care Review Process

The review of managed care payments will be similar to the managed care data

processing reviews under the past PAM and PERM pilots. The review will determine whether the capitation payments are correctly paid based on the information available from the claims processing system or the system that processes vouchers for payment to a managed care organization. We anticipate the managed care data processing reviews will be conducted on-site, along with the FFS claims data processing reviews. Managed care claims are not subject to medical reviews.

The purpose of the managed care review is to verify that:

- The beneficiary was enrolled in the Medicaid or SCHIP program;
- The capitation payment was made in accordance with State policies; and
- The capitation payment was made in the correct dollar amount.

The review contractor will identify and report on errors found through these reviews and the statistical contractor will calculate and report to CMS State-specific error rates, which will be used to determine a national managed care error rate for Medicaid and SCHIP.

2. Eligibility

States objected to conducting eligibility reviews primarily because these reviews substantially duplicate the eligibility reviews required by the Medicaid Eligibility Quality Control (MEQC) program as well as the cost to operate a separate eligibility measurement program. We invited further comment in the October 5, 2005 interim final rule on methods for measuring eligibility in Medicaid and SCHIP. We stated in the October 5 interim final rule that it could be possible that States sampled for Medicaid and SCHIP FFS and managed care reviews may be required to conduct eligibility reviews in a manner similar to the provisions set forth in the proposed rule. We have responded to specific comments in this second interim final rule, and have set out the requirements for eligibility reviews in the regulation text following.

As we stated in the October 5, 2005 interim final rule, we assembled an eligibility workgroup comprised of CMS and OIG (which acted in an advisory capacity) within the DHHS, OMB, and two State representatives to review public comments and recommend a method for measuring program eligibility. The eligibility workgroup reviewed Federal Medicaid and SCHIP laws, regulations, and policies and public comments from the proposed rule and October 5, 2005 interim final rule. Considering the workgroup's

recommendations and public comments, we have determined that:

- States will administer the Medicaid and SCHIP eligibility reviews.

- In response to comments regarding the relationship of the FFS and managed care reviews to eligibility, we have provided that States will measure eligibility improper payments in the same fiscal year that they are selected for FFS and managed care reviews in Medicaid and SCHIP;

- In response to comments regarding the barriers to reviewing eligibility at the time of service, States will sample individual beneficiaries, rather than claims or capitation payments.

- In response to comments regarding duplication of effort and costs, we have stated that we will consider recommendations.

- In response to comments regarding measuring progress in serving eligible people, the eligibility measurement will review two eligibility samples. One sample will include beneficiaries enrolled in Medicaid or SCHIP (that is, active cases) to ensure that the person was eligible. The other sample will include denied and terminated cases (that is, negative cases) to ensure that eligible persons are not erroneously denied or terminated from Medicaid or SCHIP.

- In response to comments regarding application of the administrative period to account for a time period in which States react to case changes, we have provided that States will review eligibility as of the latest action taken by the State to determine eligibility. States will review Medicaid and SCHIP eligibility in the month of (1) application, (2) redetermination, or (3) as of the last action taken by the State for all other cases (providing the last action was taken within 12 months of the month the case is sampled; otherwise States review eligibility as of the month the case is sampled). Since the review will focus on the month in which the State took an action on a case, application of the administrative period is not necessary.

- Based on public comments regarding dropping cases when eligibility cannot be determined, we have provided that States can designate these cases as "undetermined." Though a payment error rate will not be associated with these cases, the State will report and CMS will track the percentage of "undetermined" cases.

- In response to comments regarding potential conflicts of interest, we have provided that the eligibility reviews must be conducted by a State agency independent of the State agency responsible for Medicaid and SCHIP

policy and operations (that is, is functionally and physically separate) including making the program eligibility determinations.

- The State must, at a minimum, produce an error rate within a 3 percent precision level at a 95 percent confidence interval level.

The procedures for eligibility review in this interim final rule differ from those in the August 2004 proposed rule in the following ways:

- Under proposed § 431.982(a) and § 431.986(a), the proposed rule would have required an eligibility review on all sampled claims. This interim final rule at § 431.980(a) and (b) revises the review process to sample individual beneficiary cases rather than claims or capitation payments made by the State.

- Section 431.982(a)(2)(i) and (ii) of the proposed rule would have required the reviewer to verify eligibility as of the day or month the claimed service was provided.

Under this interim final rule at § 431.980(d)(i) and (ii), States will review eligibility as of the State's most recent action to grant eligibility based on an eligibility determination at application or at redetermination, and, for all other cases, the most recent action providing that action is within 12 months of the month the case is sampled; otherwise States will review eligibility as of the sample month.

- Under § 431.982(a)(2)(iii), the proposed rule stated that the eligibility review would have followed the MEQC procedures established by sections § 431.812(e)(1) through (e)(4), except that the States would not apply the administrative period. This interim final rule changes the focus of the reviews to eliminate the need for the administrative period and does not otherwise rely on MEQC procedures.

- Section 431.982(a)(2)(iv) of the proposed rule had included reviews of Medicaid recipients who receive Supplemental Security Income (SSI) in certain States where the Social Security Administration (SSA) determines Medicaid eligibility. Based on comments to the proposed rule and the October 5, 2005 interim final rule, this interim final rule at § 431.978(d)(1)(i) excludes these cases from review in these States. In addition, we are excluding Title IV—E adoption assistance and foster care cases that receive Medicaid from review in all States.

- Under § 431.982(a)(2)(v), the proposed rule would have required States to take appropriate action on individual error cases that could affect eligibility. This interim final rule deletes this provision, since

§ 435.916(c)(1) of our rules already requires a prompt redetermination of eligibility when the agency learns of changes that may affect eligibility.

a. Eligibility Universe

The Medicaid and SCHIP universes will consist of both active cases (individuals enrolled in the program) and negative cases (individuals denied or terminated from the program). For purposes of the PERM reviews, we define “case” as an individual; not as families or groups of more than one person. For Medicaid active cases, the universe will include all individuals enrolled in the program in the sample month. The universe will exclude SSI recipients in States with an agreement with the SSA whereby, under section 1634 of the Act, SSA determines Medicaid eligibility for SSI cases. The universe also will exclude, in all States, Title IV—E foster care and adoption assistance cases that receive Medicaid, due to the complexities of obtaining information for verifying eligibility, which is often subject to strict parameters of confidentiality (for example, sealed adoption records). Finally, States shall exclude Medicaid cases that are under active fraud investigation from the universe; if these cases cannot be identified before sampling, States can drop these cases from review.

For the Medicaid negative cases, the universe will include all individuals denied or terminated in the sample month. Individuals denied due to incomplete applications or terminated because they did not complete the eligibility redetermination process according to State policy will be excluded.

The SCHIP universe also will consist of both active and negative cases. For SCHIP active cases, the universe will consist of all individuals enrolled in the program for the sample month. States shall exclude SCHIP cases that are under active fraud investigation from the universe; if these cases cannot be identified before sampling, States can drop these cases from review. There are no other SCHIP cases excluded from the SCHIP active universe, because SCHIP eligibility is not determined by a Federal agency, such as Medicaid eligibility for SSI cases in certain States.

For SCHIP negative cases, the universe will consist of all individuals denied or terminated in the sample month and will exclude individuals denied due to incomplete applications or terminated because they did not complete the eligibility redetermination process according to State policy.

b. Sample Selection and Sample Size

Medicaid and SCHIP cases in the active universe will be stratified into three strata:

- Stratum 1—Applications approved in the sample month;
- Stratum 2—Cases where eligibility was redetermined in the sample month; and
- Stratum 3—All other cases.

Each month, an equal number of cases will be selected from each stratum. Negative case action samples will not be stratified in either program.

For active case reviews, we estimate an annual sample size of 501 cases will be reviewed per State per program. We believe this estimated sample size will produce error rates within a 3 percent precision level at a 95 percent confidence interval level for the State. However, the annual sample size may vary and a State may have a sample that contains more than 501 active cases in order to meet this statistical requirement. The sample will be selected each month. We estimate that a State will select and review approximately 42 cases each month.

If not excluded from the universe, States shall drop a case from review when the case is currently under an active fraud investigation. “Active fraud investigation” means a beneficiary's name has been referred to the State Medicaid (or SCHIP) Fraud and Abuse Control Unit or similar investigation unit and the unit is currently and actively pursuing an investigation to determine whether fraud was committed by the beneficiary. States must drop these cases from the eligibility reviews because we believe that, in most cases, payments are not being made directly to the beneficiary.

The State will classify any case in which eligibility cannot be conclusively verified as “undetermined.” These cases will not be considered eligible or ineligible when calculating the error rate but the number and rate of undetermined cases will be noted in our reporting of the error rates.

For negative case reviews, we estimate the annual sample size will be 200 cases per program. As above, we believe this should produce an estimate that is within a 3 percent precision level at a 95 percent confidence interval level. However, the sample size may vary and a State may have a sample that contains more than 200 negative cases in order to meet this statistical requirement. The sample will be selected each month. We estimate that a State will select and review approximately 17 cases each month.

c. Eligibility Review Process

We determined that a State will review program eligibility in the year it is scheduled for review for FFS and managed care improper payments. Based on recommendations from public comments and the eligibility workgroup, we developed a review process that is less burdensome than the review requirements under the proposed rule and that follow State procedures. We have designed the review process to minimize the effect on States regarding cost and burden.

Finally, to provide objective review findings and error rate calculations, we adopted the recommendation that the eligibility reviews be conducted by a State agency which is independent of the State agency making the program eligibility determinations.

In preparation for the PERM measurement, we will provide the

selected States with advance implementation guidelines attached to a State Health Official letter to all States being measured in FY 2007. Essentially, States will conduct eligibility reviews on a sample of active cases that are stratified as follows: (1) Current applications; (2) current redeterminations; and (3) other cases. States will measure eligibility as of the latest action taken by the State to determine eligibility for Medicaid and SCHIP (providing the action for all "other cases" is within 12 months of the sample month; otherwise, States will review eligibility as of the sample month). We expect eligibility can be established primarily through desk reviews of the case records, although there are instances when States would be required to verify information (for example, information missing from the file, outdated, or likely to change).

The review process will apply to both Medicaid and SCHIP cases. However, for all SCHIP cases, the reviewer will further verify that the case is not eligible for Medicaid by following the SCHIP requirements at 42 CFR 457.350 to screen SCHIP applicants for potential Medicaid eligibility.

d. Eligibility Error Rate Calculation

The State will determine:

- State-specific case and payment error rates for active cases;
- State-specific case error rates for negative cases; and
- The number of undetermined cases in each sample (with associated paid claims for each case) and the total amount of payments for all undetermined cases in the active case sample.

These rates will be computed using the following general calculations:

$$\text{Case error rate} = \frac{\text{Total number of cases in error}}{\text{Total number of cases in the sample}}$$

$$\text{Payment error rate} = \frac{\text{Total amount of dollars in error}}{\text{Total amount of dollars in the sample}}$$

Once the State reports the State-specific eligibility rates, the national contractor will combine the State specific eligibility error rates to produce national eligibility error rates for each program.

e. Reporting

For purposes of eligibility information collection and reporting, States will submit to CMS and its contractors:

- A sampling plan for approval 60 days prior to the beginning of the fiscal year selected for review. States selected for the measurement for FY 2008 and beyond will submit a sampling plan by August 1. States selected for the FY 2007 measurement will submit the sampling plan by November 15, 2006;
- A monthly sample selection list that identifies the cases selected for review, to be submitted each month and before commencing the reviews;
- Summary eligibility findings on all case reviews to be submitted by July 1 following the fiscal year under review; and
- State-specific case and payment error rates for active cases, case error rates for negative cases, the number and amount of undetermined cases in the samples, and the total amount of payment from all undetermined cases in

the active case sample to be submitted by July 1 after the end of the fiscal year under review.

3. Difference Resolution Process

We received many comments on the October 5, 2005 interim final rule regarding State opportunity to review the contractor's findings on FFS and managed care claims. In response to these comments, we developed a difference-resolution process to provide States with the opportunity to review the RC's reconsideration of its error determinations (on its medical and data processing reviews) and to resolve the differences in findings.

On at least a monthly basis, the RC will provide each State under review with a disposition report. This report includes the review findings of the medical and data processing reviews for each FFS claim, and the findings of the data processing reviews for each managed care claim completed that month. Towards the end of the review period, the RC will provide these disposition reports on a bi-weekly basis to the State. Information on which the RC based its findings will be made available to the State so that the State can determine whether it agrees with the findings.

A State can notify the RC in writing that it has a difference in finding on a claim in error. To support the State's position that the claim was properly paid, the State: (1) Must have a factual basis for filing the difference on any claim; and (2) must present valid evidence to support its position that the claim was correctly paid. If the RC agrees with the State, the error will be adjusted or backed out of the error rate calculation. The difference resolution process is the only means by which the State and the Federal contractor can consider differences in findings and reverse the RC's error findings.

For cases in which the State and the RC cannot resolve the differences in findings, the State may file a written appeal to CMS for final resolution. However, for CMS to review the claim, the difference in findings must be in the amount of \$100 or greater. The State must provide CMS with the specific reasons and necessary documentation to support its determination that the claim was correctly paid as well as the review contractor's justification for upholding its initial error finding. CMS will make the final determination on the sampled claim.

Claims with "no documentation" errors or "insufficient documentation"

errors due to the provider not submitting the requested information will not be considered in the difference resolution process because all medical documentation must be provided within the 90-day timeframe. We have provided an opportunity for the States to participate in ensuring that the provider submits the necessary documentation within the 90-day timeframe; and the difference resolution process is not intended to extend this timeframe for the collection of medical documentation. Additionally, we allow for adjustments to claims to be made pending completion of the reviews; the difference resolution process is not intended to extend the timeframe for adjustments. Therefore, subsequent adjustments to claims will not be considered as a valid reason to reverse findings on claims. All differences in findings between the State and the RC on any claim not resolved in time to be included in the error rate calculation will be considered as errors for meeting the reporting requirements of the IPJA. However, at State request, we will calculate a subsequent State-specific rate that reflects any reversed disposition of the unresolved claims.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This interim final rule with comment sets forth requirements for States to provide information for purposes of estimating improper payments through FFS, managed care and eligibility reviews in Medicaid and SCHIP. Therefore, we solicited public comment on each of the issues listed above for the following sections of the rule that contain information collection requirements.

It is important to note that subsequent to the information collection notices, which estimated cost and burden for 34 States, we have determined that SCHIP will be measured in the same year that States are measured for Medicaid. Thus, the estimate for “34 States” should be interpreted to mean “34 State programs” in 17 States.

Section 431.970(a) Information Submission Requirements

Section 431.970(a)(1)–(11) sets forth requirements for States to provide information to the Secretary for purposes of estimating improper payments in FFS and managed care based on medical and data processing reviews in Medicaid and SCHIP. Those States selected for review in any given year will be required to provide, at a minimum, the following information for Medicaid and SCHIP:

(a)(1) All adjudicated fee-for-service (FFS) and managed care claims information, on a quarterly basis, from the review year with FFS claims stratified by type of service;

(a)(2) Upon request from CMS, provider contact information that has been verified by the State as current;

(a)(3) All medical and other related policies in effect and any quarterly policy updates;

(a)(4) Current managed care contracts, rate information, and any quarterly updates to both for the review year for SCHIP and, as requested, for Medicaid;

(a)(5) Data processing systems manuals;

(a)(6) Repricing information for claims that are determined to have been improperly paid;

(a)(7) Information on claims that were selected as part of the sample, but changed in substance after selection, for example, successful provider appeals;

(a)(8) Adjustments made within 60 days of the adjudication date for the original claim or line item with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claim or line items;

(a)(9) For the eligibility improper payment measurement, information as set forth in § 431.978 through § 431.988;

(a)(10) A corrective action plan for purposes of reducing erroneous payments in FFS, managed care, and eligibility; and

(a)(11) Other information that the Secretary determines is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP.

The burden described at § 431.970(a) represents the total State information collection burden for PERM. Based on

our estimates of State participation burden for both Medicaid and SCHIP, for 34 States (17 States per Medicaid and 17 States for SCHIP), for the FFS reviews (55,420 hours), the managed care reviews (22,100 hours), and eligibility (448,120 hours), we calculated that the annual State burden for the PERM program is 525,640 hours (262,820 hours per program). The burden associated with these requirements is the time and effort necessary for States to collect this information and provide it to CMS or the Federal contractor. We estimated these costs through three information collection notices based on the information needed for the FFS, managed care, and eligibility review as follows:

Estimate for FFS reviews. A notice of the FFS proposed collection was previously published in the **Federal Register** for public comment on July 22, 2005 (70 FR 42324). That document was available for public inspection at the Office of the Federal Register beginning on July 15, 2005 and comments were requested by August 15, 2005 (30 days from date of display). We republished the notice of the FFS proposed collection on August 26, 2005 (70 FR 50357), which was available for public inspection for an additional comment period ending September 26, 2005 (30 days from date of publication). The shortened timeframe for public comment was essential so that CMS could proceed with the FFS data collection from States and providers by October 2005 to initiate reviews for timely reporting of a FY 2006 Medicaid FFS error rate to OMB. We received OMB approval of this information collection on October 3, 2005. The OMB approval number is 0938–0974 with an expiration date of October 31, 2008.

Initially, in the information collection notice for the FFS reviews, we estimated that the annualized number of hours that would be required for up to 36 States (18 States for Medicaid and 18 States for SCHIP) to respond to the requests for information would be 58,680 hours (1,630 hours per State per program). Subsequent to the notice, we revised our estimates of the burden to reflect that 17 States would be selected for each program (rather than “up to 18 States” per program). The revised annualized number of hours that would be required for 34 States (17 States for Medicaid and 17 States for SCHIP) to respond to the requests for information for the FFS measurement is 55,420 hours (1,630 hours per State per program).

It is important to note that subsequent to the notice and initiation of the FY

2006 FFS measurement in Medicaid, we determined that each State's FFS sample sizes for Medicaid and SCHIP could be determined by the annual expenditure data that States already report to CMS. Therefore, States do not need to resubmit the annual expenditure data to CMS for the purposes of PERM.

Estimate for managed care reviews. A notice of the proposed collection of managed care information was previously published in the **Federal Register** for public comment on February 3, 2006 (71 FR 5851). Comments were requested by April 4, 2006 (60 days from date of display). We republished the notice of proposed collection on April 14, 2006 (71 FR 19521), which was available for public inspection for an additional comment period ending May 17, 2006 (30 days from date of publication).

Initially, in the information collection notice for the managed care reviews, we estimated that the annualized number of hours that would be required for up to 36 States (18 States for Medicaid and 18 States for SCHIP) to respond to the requests for information would be 23,400 hours (650 hours per State, per program). Subsequent to the notice, we revised our estimates of the burden to reflect the 17 States selected for each program (rather than "up to 18 States" per program). The revised annualized number of hours that would be required for 34 States to respond to the requests for information for the managed care reviews is 22,100 hours (650 hours per State per program).

Estimate for eligibility reviews. A notice of this proposed collection was previously published in the **Federal Register** for public comment on May 26, 2006 (71 FR 30409). Comments were requested by July 26, 2006 (60 days from date of display). We expect to republish the notice of proposed collection on August 25, 2006, which will be available for public inspection for an additional comment period ending 30 days from date of publication.

In the information collection notice for the eligibility reviews, we estimated: (1) The annualized number of hours needed to respond to the information request for the purpose of Medicaid and SCHIP eligibility reviews; and (2) the number of respondents, 34 States (17 States for Medicaid and 17 States for SCHIP). Based on these estimates, we determined that the total annualized number of hours required for the eligibility reviews for 34 States would be 448,120 hours (13,180 hours per State per program).

For the specific information requests in § 431.978 (referenced at § 431.970(a)(9)) and § 431.992 (as

referenced at § 431.970(a)(10)), the burden includes the following estimated annualized hours: (1) Up to 1,000 hours required for a State to develop and submit a sampling plan; (2) up to 1,200 hours for a State to submit 12 monthly sample lists detailing the cases selected for review; and (3) up to 1,000 hours for a State to develop a corrective action report for purposes of reducing the eligibility payment error rate.

For the requirements for eligibility reviews in § 431.980 and the reporting of findings in § 431.988, as referenced at § 431.970(a)(9), we estimated that each State would need to review an annual sample size of 501 active cases to achieve within 3 percent precision at a 95 percent confidence interval level in the State-specific error rates. We also estimated that States would need to review 200 negative cases to produce a case error rate that meet similar standards for statistical significance. We therefore estimate that the annualized number of hours required for 34 States to complete the eligibility case reviews and report the eligibility-based error rates to CMS will be 339,320 hours (9,980 hours per State per program).

Section 431.970(b) Information Submission Requirements

Section 431.970(b) requires providers to submit medical record information to the Secretary for estimating improper payments in Medicaid and SCHIP. In the "Anticipated Effects" section of the impact statement in the August 27, 2004 proposed rule, we stated that providers could be required to supply medical records or other similar documentation that verified the provision of medical services to beneficiaries as part of reviewing paid and denied claims under PERM. We believed this action would not have a significant cost impact on providers. We continue, as stated in the regulatory impact section, to estimate this burden to be part of a provider's usual and customary business practices.

Section 431.978 Eligibility Sampling Plan and Procedures

This section requires that the selected States submit a Medicaid and a SCHIP sampling plan (or revisions to the current plans) for both active and negative cases to CMS for approval at least 60 days before the beginning of the review year (for the FY 2008 measurement and beyond). (States will submit the sampling plans by November 15, 2006 for the FY 2007 review year.) The State must receive approval of the plans before implementation.

As stated above, the burden associated with this requirement will be the time and effort it will take for the

States to prepare and submit a sampling plan to CMS for approval. We estimate that the annual burden associated with this requirement for 34 States (17 States for Medicaid and 17 States for SCHIP) will be 34,000 hours (1,000 hours per State per program).

Section 431.988 Eligibility Case Review Completion and Submittal of Reports

Sections 431.988(a) and (b) require the selected States to submit reports of findings and error rates in accordance with paragraphs (b)(1) through (b)(2) beginning with the FY 2007 measurement.

As stated above, the burden associated with this requirement is the time and effort it would take for the States to produce the required material and submit a report to CMS. We estimate that the annual burden associated with this requirement for 34 States (17 States for Medicaid and 17 States for SCHIP) will be 339,320 hours (9,980 hours per State per program).

Section 431.992 Corrective Action Plan

This section requires the selected States to submit to CMS a corrective action plan to reduce improper payments in Medicaid and SCHIP based on the major causes of the errors in the FFS, managed care, and eligibility components.

The burden associated with this requirement is the time and effort put forth by the selected States to develop and submit a corrective action plan to CMS. In the information collection notices, we estimated that it would take each selected State up to 500 hours for the FFS component, up to 500 hours for the managed care component, and up to 1,000 hours for the eligibility component of the corrective action plan for each program. Therefore, we estimate that the total annual burden associated with this requirement for 34 States (17 States for Medicaid and 17 States for SCHIP) will be 68,000 hours (2,000 hours per State per program).

Section 431.998 Difference Resolution Process

Section 431.998(b)(2) provides the selected States the option to enter the difference resolution process. States wishing to do so must notify the Federal contractor and submit documentation to support its determination that the claim was incorrectly paid.

We have included this State option in this interim final rule in response to public comments on both the proposed rule and the October 5, 2005 interim final rule. The burden associated with

this requirement would be the time and effort it would take for a State to gather the facts and valid documentation and submit it to the Federal contractor or, upon appeal, to CMS. We anticipate that 34 States will request a difference resolution for each fiscal year and that it will take up to 5 hours per claim to request a difference resolution and present evidence to support the State's disagreement with the Federal contractor's determination.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Melissa Musotto (Attn: CMS-6026-IFC2), Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Katherine Astrich, CMS Desk Officer, CMS-6026-IFC2, or Katherine_T._Astrich@omb.eop.gov. Fax (202) 395-6947.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132. Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

1. Cost Estimate for FFS Reviews

We have estimated that it will cost approximately \$23.3 million annually (\$22,367,088 in Federal cost and \$951,326 in State cost) to review FFS claims and estimate error rates in 34 States (17 States for Medicaid and 17 States for SCHIP). This estimate is based on the Federal cost of engaging the

Federal contractors to conduct the reviews and calculate the error rates, and the State cost to submit requested information to support the reviews. We estimated these costs as follows:

Through the use of Federal contractors, we estimated that for the FFS measurement it would cost approximately \$21,080,000 in Federal funds (\$10,540,000 per program). This estimate is based on the cost per State of \$383.80 per claim multiplied by an average of 1,000 claims; \$66,147 for travel and administrative expenses; \$133,488 for overhead and other expenses; and \$36,565 for systems hardware and software. Based on \$620,000 per State to estimate FFS error rates in Medicaid and \$620,000 per State to estimate FFS error rates in SCHIP, the FFS error rate estimates for 34 States would cost approximately \$21,080,000 in Federal funds for the Federal contracting cost.

Under the national contracting strategy, we anticipate State cost to be the cost associated with submitting information. As we indicated in the information collection section of this rule, we estimated the cost to respond to requests for information for the Medicaid and SCHIP FFS reviews is \$2,238,414 (\$1,287,088 in Federal cost and \$951,326 in State cost). Therefore, the estimated total Federal cost is approximately \$22,367,088 and total State cost is \$951,300 for FFS measurement.

2. Cost Estimate for Managed Care Reviews

We have estimated that it will cost approximately \$7.5 million annually (\$7,153,256 in Federal cost and \$379,363 in State cost) to estimate managed care error rates for 34 States (17 States for Medicaid and 17 States for SCHIP). This is based on the Federal cost of engaging the Federal contractors to conduct the reviews and calculate the error rates, and the State cost to submit requested information to support the reviews. We estimated these costs as follows:

We estimated that it will cost \$6,640,000 in Federal funds annually for a Federal contractor to estimate the error rates for 34 States. This is based on FY 2006 FFS estimates that were used as baseline assumptions for the managed care reviews. We assumed that we will use the same statistical contractor and the same review contractor for managed care and FFS reviews in each program to gain cost efficiencies in administration, overhead and systems. Based on an average of 500 claims reviewed plus travel and other administrative expenses, we estimate

that it would cost \$6,640,000 in Federal funds for the Federal contracting cost.

Under the national contracting strategy, we anticipate State cost to be the cost associated with submitting information, similar to the cost for FFS reviews. As we indicated in the information collection section of this rule, we estimated the cost to respond to requests for information for the managed care reviews would be \$892,619 (\$513,256 in Federal cost and \$379,363 in State cost). Therefore, the estimated total Federal cost is approximately \$7,153,256 and total State cost is \$379,363 for managed care measurement.

3. Cost Estimate for Eligibility Reviews

Beginning in FY 2007, States will review eligibility in the same year they are selected for FFS and managed care reviews in Medicaid and SCHIP. We estimated that total cost for eligibility review for 34 States is approximately \$18.1 million (\$10,407,251 in Federal cost and \$7,692,316 in State cost). This cost estimate is based on the cost for States to submit information to CMS and the cost for States to conduct eligibility reviews and report rates to CMS. These costs are estimated as follows:

We estimated in the information collection section, that the annualized number of hours required to respond to requests for information for the eligibility review (for example, sampling plan, monthly sample lists, the eligibility corrective action report) for 34 States will be 108,800 hours (3,200 hours per State per program). At the 2006 general schedule GS-12-01 rate of pay that includes fringe and overhead costs (\$40.39/hour), we calculated a cost of \$4,394,432 (\$2,526,798 in Federal cost and \$1,867,634 in State cost). This cost estimate includes the following estimated annualized hours: (1) Up to 1,000 hours required for States to develop and submit a sampling plan; (2) up to 1,200 hours for States to submit 12 monthly sample lists detailing the cases selected for review; and (3) up to 1,000 hours for States to submit a corrective action plan for purposes of reducing the eligibility payment error rate.

For the eligibility review and reporting of the findings, we estimated that each State would need to review an annual sample size of 501 active cases to achieve a 3 percent margin of error at a 95 percent confidence interval level in the State-specific error rates. We also estimated that States would need to review 200 negative cases to produce a case error rate that met similar standards for statistical significance. We

estimated that for 34 States the annualized number of hours required to complete the eligibility case reviews and report the eligibility-based error rates to CMS would be 339,320 hours (9,980 hours per State, per program). At the 2006 general schedule GS-12-01 costs that include fringe and overhead (\$40.39/hour), we calculated a cost of \$13,705,135 (\$7,880,453 in Federal cost and \$5,824,682 in State cost).

Therefore, the total annual estimate of the cost for 34 States to submit information and to conduct the eligibility reviews and report the error rate to CMS is approximately \$18,099,567 (\$10,407,251 in Federal cost and \$7,692,316 in State cost).

4. Cost Estimate for Total PERM Costs

Based on our estimates of the costs for the FFS, managed care and eligibility reviews for both the Medicaid and SCHIP programs at approximately \$49 million (\$39,927,595 in Federal cost and \$9,023,005 in State cost), this rule does not exceed the \$100 million or more in any 1 year criterion for a major rule, and a regulatory impact analysis is not required.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year.

We stated in the August 27, 2004 proposed rule that providers could be required to supply medical records or other similar documentation that verified the provision of Medicaid or SCHIP services to beneficiaries as part of the PERM reviews, but we anticipated this action would not have a significant cost impact on providers. Providers would only need to provide medical records for the FFS component of this program. A request for medical documentation to substantiate a claim for payment would not be a burden to providers nor would it be outside the customary and usual business practices of Medicaid or SCHIP providers. Not all States would be reviewed every year and medical records would only be requested for FFS claims, so it would be unlikely for a provider to be selected more than once per program to provide supporting documentation, particularly in States with a large Medicaid or SCHIP managed care population.

In addition, the information should be readily available and the response should take minimal time and cost since

the response would merely require gathering the documents and either copying and mailing them or sending them by facsimile. Therefore, we have concluded in this interim final rule with comment that the provision of medical documentation by providers is within the customary and usual business practice of a provider who accepts payment from an insurance provider, whether it is a private organization, Medicare, Medicaid, or SCHIP and should not have a significant impact on the provider's operations. Individuals and States are not included in the definition of a small entity. Therefore, an impact analysis is not required under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. 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 100 beds.

These entities may incur costs due to collecting and submitting medical records to the contractor to support medical reviews; but, like any other Medicaid or SCHIP provider, we estimate these costs would not be outside the limit of usual and customary business practices. Also, since the sample is randomly selected and only FFS claims are subject to medical review, we do not anticipate that a great number of small rural hospitals would be asked for an unreasonable number of medical records. As stated before, a State will be reviewed only once, per program, every 3 years and it is highly unlikely for a provider to be selected more than once per program to provide supporting documentation. Therefore, we believe that an impact analysis is not required under section 1102(b) of the Social Security Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$120 million or more. This interim final rule does not impose costs on States to produce the error rates for FFS and managed care payments, but only requires States and providers to submit information already on hand to the contractor so that the error rates can be calculated. The costs associated with submitting information for copying and mailing the information or for sending

the information by facsimile are minimal.

Based on our estimates of State participation burden for both Medicaid and SCHIP, for 34 States (17 States per Medicaid and 17 States for SCHIP), for the FFS reviews (\$951,326), the managed care reviews (\$379,363), and eligibility (\$7,692,316), we calculated that the annual State burden for the PERM program is approximately \$9,023,005 in State cost for both programs. Thus, we do not anticipate State costs to exceed \$120 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements on State and local governments, preempts State law, or otherwise has Federalism implications. The proposed rule, which would have imposed significantly more cost burden on States to measure improper payments, had estimated costs of \$1 million to \$2 million per State. This interim final rule significantly reduces these costs by requiring States only to submit information to support the medical and data processing reviews. The cost and burden associated with submitting this information is the time and cost to copy and mail the information or, at State option, submit the information electronically.

This interim final rule does require States selected for review to submit an eligibility sampling plan, monthly sample selection information, summary review findings, State error rate calculations, and other information in order for CMS to calculate the eligibility national error rate. We estimated that the burden to conduct the eligibility measurement for Medicaid and SCHIP for 34 States will be approximately \$18,099,567 (\$10,407,251 in Federal cost and \$7,692,316 in State cost). As a result, we assert that this regulation will not have a substantial impact on State or local governments.

B. Anticipated Effects

The interim final rule is intended to measure improper payments in Medicaid and SCHIP. States would implement corrective actions to reduce the error rate, thereby producing savings over time. These savings cannot be estimated until after the corrective actions have been monitored and determined to be effective, which can take several years.

C. Alternatives Considered

We considered the alternatives recommended by the public commenting on the October 5, 2005 interim final rule with comment and

adopted the recommendation to include a difference-resolution process through which States can express and resolve a difference of opinion with the error determinations made by the review contractor through its medical and data processing reviews.

We considered the other alternatives, which were recommended in the proposed rule and reiterated in the October 5, 2005 interim final rule, and determined that these recommendations were not viable or were not the best approach to meet the requirements of the law. We received comments on the October 5, 2005 interim final rule regarding the national contracting strategy that recommended allowing States to have input on CMS operational issues and evaluation of the Federal contractors. We did not adopt these recommendations because we believe that these are operational issues that are outside the scope of the rulemaking process. Comments considered and not adopted include:

- States should administer the Medicaid and SCHIP FFS and managed care measurement at an enhanced match rate;
- CMS should abandon State-level error rates in favor of national sampling, pooling State data across years or accepting larger standard errors;
- States should receive 100 percent Federal match for any State technical assistance on this effort; and
- CMS should provide more transparency on its methodologies by promulgating rules for the Federal contractor and CMS' procedures or by establishing an advisory committee.

We believe the national contracting strategy is superior to these proposals because it provides a standardized review methodology that is applied objectively and consistently to the States under review. Under the contracting strategy, each State is measured against its own standards, which we believe provides better information for States to reduce erroneous payments than using a national sample, pooling State data across years or accepting larger standard errors. We have the statutory authority to collect the claims data and policy information. The technical assistance that States provide to the contractors should be limited primarily to the claims processing reviews and will help ensure the accuracy of these reviews and the error rates. We do not believe 100 percent Federal match should be provided for technical assistance to the contractors since the PERM reviews are similar to other Federal audits for which States do not receive enhanced match. Finally, we believe the national

contracting strategy provides transparencies such as our review methodologies, cost and burden estimates, when States will be reviewed, and State responsibilities as we have stated in the October 5, 2005 interim final rule and this interim final rule. We do not believe an advisory committee is needed since we have provided States ample opportunities to comment through the rulemaking process.

D. Conclusion

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 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 457

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

- For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

- 1. The authority citation for part 431 continues to read as follows:

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

- 2. Part 431 is amended by revising subpart Q to read as follows:

Subpart Q—Requirements for Estimating Improper Payments in Medicaid and SCHIP

Sec.

- 431.950 Purpose.
- 431.954 Basis and scope.
- 431.958 Definitions and use of terms.
- 431.970 Information submission requirements.
- 431.974 Basic elements of Medicaid and SCHIP eligibility reviews.
- 431.978 Eligibility sampling plan and procedures.
- 431.980 Eligibility review procedures.
- 431.988 Eligibility case review completion deadlines and submittal of reports.
- 431.992 Corrective action plan.
- 431.998 Difference resolution process.
- 431.1002 Recoveries.

Subpart Q—Requirements for Estimating Improper Payments in Medicaid and SCHIP

§ 431.950 Purpose.

This subpart requires States and providers to submit information

necessary to enable the Secretary to produce national improper payment estimates for Medicaid and the State Children's Health Insurance Program (SCHIP).

§ 431.954 Basis and scope.

(a) *Basis.* The statutory bases for this subpart are sections 1102, 1902(a)(6), and 2107(b)(1) of the Act, which contain the Secretary's general rulemaking authority and obligate States to provide information, as the Secretary may require, to monitor program performance. In addition, this rule supports the Improper Payments Information Act of 2002 (Pub. L. 107–300), which requires Federal agencies to review and identify annually those programs and activities that may be susceptible to significant erroneous payments, estimate the amount of improper payments, report such estimates to the Congress, and submit a report on actions the agency is taking to reduce erroneous payments. Section 1902(a)(27)(B) of the Act requires States to require providers to agree to furnish the State Medicaid agencies and the Secretary with information regarding payments claimed by Medicaid providers for furnishing Medicaid services.

(b) *Scope.* (1) This subpart requires States under the statutory provisions cited in paragraph (a) of this section to submit information as set forth in § 431.970 for, among other purposes, estimating improper payments in the fee-for-service (FFS) and managed care components of the Medicaid and SCHIP programs and to determine whether eligibility was correctly determined. This subpart also requires providers to submit to the Secretary any medical records and other information necessary to disclose the extent of services provided to individuals receiving assistance, and to furnish information regarding any payments claimed by the provider for furnishing such services, as requested by the Secretary.

(2) All information must be furnished in accordance with section 1902(a)(7)(A) of the Act, regarding confidentiality.

(3) This subpart does not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands or American Samoa.

§ 431.958 Definitions and use of terms.

Active case means a case containing information on a beneficiary who is enrolled in the Medicaid or SCHIP program in the month that eligibility is reviewed.

Active fraud investigation means a beneficiary's name has been referred to the State Fraud and Abuse Control or

similar investigation unit and the unit is currently actively pursuing an investigation to determine whether the beneficiary committed fraud.

Adjudication date means either the date on which money was obligated to pay a claim or the date the decision was made to deny a claim.

Agency means, for purposes of the PERM eligibility reviews and this regulation, the agency that performs the Medicaid and SCHIP eligibility determinations under PERM and excludes the State agency as defined in the regulation.

Application means an application form for Medicaid or SCHIP benefits deemed complete by the State, with respect to which such State approved or denied eligibility.

Beneficiary means an applicant for, or recipient of, Medicaid or SCHIP program benefits.

Case means an individual beneficiary.

Case error rate means an error rate that reflects the number of cases in error in the eligibility sample for the active cases plus the number of cases in error in the eligibility sample for the negative cases expressed as a percentage of the total number of cases examined in the sample.

Case record means either a hardcopy or electronic file that contains information on a beneficiary regarding program eligibility.

Eligibility means meeting the State's categorical and financial criteria for receipt of benefits under the Medicaid or SCHIP programs.

Improper payment means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and includes any payment to an ineligible recipient, any duplicate payment, any payment for services not received, any payment incorrectly denied, and any payment that does not account for credits or applicable discounts.

Last action means the most recent date on which the State agency took action to grant, deny, or terminate program benefits based on the State agency's eligibility determination; and is the point in time for the PERM eligibility reviews unless the last action occurred outside of 12 months prior to the sample month.

Medicaid means the joint Federal and State program, authorized and funded under Title XIX of the Act, that provides medical care to people with low incomes and limited resources.

Negative case means a case containing information on a beneficiary who

applied for benefits and was denied or whose program benefits were terminated, based on the State agency's eligibility determination or on a completed redetermination.

Payment means any payment to a provider, insurer, or managed care organization for a Medicaid or SCHIP beneficiary for which there is Medicaid or SCHIP Federal financial participation. It may also mean a direct payment to a Medicaid or SCHIP beneficiary in limited circumstances permitted by CMS regulation or policy.

Payment error rate means an annual estimate of improper payments made under Medicaid and SCHIP equal to the sum of the overpayments and underpayments in the sample, that is, the absolute value of such payments, expressed as a percentage of total payments made in the sample.

Payment review means the process by which payments for services are associated with cases reviewed for eligibility. Payments are collected for services received in the review month or in the sample month, depending on the case reviewed.

PERM means the Payment Error Rate Measurement process to measure improper payment in Medicaid and SCHIP.

Provider means any qualified provider recognized under Medicaid and SCHIP statute and regulations.

Review cycle means the complete timeframe to complete the improper payments measurement including the fiscal year being measured; generally this timeframe begins in October of the fiscal year reviewed and ends in August of the following fiscal year.

Review month means the month in which eligibility is reviewed and is usually when the State took its last action to grant or redetermine eligibility. If the State's last action was taken beyond 12 months prior to the sample month, the review month shall be the sample month.

Review year means the Federal fiscal year being analyzed for errors by Federal contractors or the State.

Sample month means the month the State selects a case from the sample for an eligibility review.

State agency means the State agency that is responsible for determining program eligibility for Medicaid and SCHIP, as applicable, based on applications and redeterminations.

State Children's Health Insurance Program (SCHIP) means the program authorized and funded under Title XXI of the Act.

States means the 50 States and the District of Columbia.

Undetermined means a beneficiary case subject to a Medicaid or SCHIP eligibility determination under this regulation about which a definitive determination of eligibility could not be made.

§ 431.970 Information submission requirements.

(a) States must submit information to the Secretary for, among other purposes, estimating improper payments in Medicaid and SCHIP, that include but are not limited to—

(1) All adjudicated fee-for-service (FFS) and managed care claims information, on a quarterly basis, from the review year with FFS claims stratified by service;

(2) Upon request from CMS, provider contact information that has been verified by the State as current;

(3) All medical and other related policies in effect and any quarterly policy updates;

(4) Current managed care contracts, rate information, and any quarterly updates applicable to the review year for SCHIP and, as requested, for Medicaid;

(5) Data processing systems manuals;

(6) Repricing information for claims that are determined during the review to have been improperly paid;

(7) Information on claims that were selected as part of the sample, but changed in substance after selection, for example, successful provider appeals;

(8) Adjustments made within 60 days of the adjudication dates for the original claims or line items with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items;

(9) For the eligibility improper payment measurement, information as set forth in § 431.978 through § 431.988;

(10) A corrective action plan for purposes of reducing erroneous payments in FFS, managed care, and eligibility; and

(11) Other information that the Secretary determines is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP.

(b) Providers must submit information to the Secretary for, among other purposes, estimating improper payments in Medicaid and SCHIP, which include but are not limited to, Medicaid and SCHIP beneficiary medical records.

§ 431.974 Basic elements of Medicaid and SCHIP eligibility reviews.

(a) *General requirements.* (1) States selected in any given year for Medicaid

and SCHIP improper payments measurement under the Improper Payments Information Act of 2002 must conduct reviews of a statistically valid random sample of beneficiary cases for such programs to determine if improper payments were made based on errors in the State agency's eligibility determinations.

(2) The agency and personnel responsible for the development, direction, implementation, and evaluation of the eligibility reviews and associated activities, including calculation of the error rates under this section, must be functionally and physically separate from the State agencies and personnel that are responsible for Medicaid and SCHIP policy and operations, including eligibility determinations.

(3) Any individual performing activities under this section must do so in a manner that is consistent with the provisions of § 435.901, concerning the rights of recipients.

(b) *Sampling requirements.* The State must have in effect a CMS-approved sampling plan for the review year in accordance with the requirements specified in § 431.978.

(c) *Review requirements.* The State must conduct eligibility reviews in accordance with the requirements specified in § 431.980.

§ 431.978 Eligibility sampling plan and procedures.

(a) *Plan approval.* For the review year beginning October 1, 2006, the agency must submit a Medicaid and a SCHIP sampling plan for both active and negative cases to CMS for approval by November 15, 2006. For review years beginning October 1, 2007 and beyond, the agency must submit a Medicaid or SCHIP sampling plan (or revisions to a current plan) for both active and negative cases to CMS for approval by the August 1 before the review year and must receive approval of the plan before implementation. The agency must notify CMS that it will be using the same plan from the previous review year if the plan is unchanged.

(b) *Maintain current plan.* States must keep the plan current, for example, by making adjustments to the plan when necessary due to fluctuations in the universe. The State must review and determine that the approved plan is unchanged from the previous review year and submit a revised plan for CMS approval if changes have occurred.

(c) *Sample size.* Total sample size must be estimated to achieve within a 3 percent precision level at 95 percent confidence interval for the eligibility component of the program.

(d) *Sample selection.* The sample must be stratified in accordance with § 431.978(d)(3). Cases must be selected each month throughout the fiscal year under review. Each month throughout the year and before commencing the eligibility reviews, States must submit to CMS a monthly sample selection list that identifies the cases selected in that month.

(1) *Eligibility universe-active cases—*

(i) *Medicaid.* The Medicaid active universe consists of all active Medicaid cases funded through Title XIX for the sample month. Cases for which the Social Security Administration, under a section 1634 agreement with a State, determines Medicaid eligibility for Supplemental Security Income recipients are excluded from the universe. All foster care and adoption assistance cases under Title IV-E of the Act are excluded from the universe in all States. Cases under active fraud investigations shall be excluded from the universe. If the State cannot identify cases under active fraud investigations for exclusion from the universe previous to the sample selection, the State shall drop these cases from review if they are selected in the sample and are later determined to be under active fraud investigation at the time of selection.

(ii) *SCHIP.* The SCHIP active universe consists of all active SCHIP and Medicaid expansion cases that are funded through Title XXI for the sample month. Cases under active fraud investigations shall be excluded from the SCHIP active universe. If the State cannot identify cases under active fraud investigations for exclusion from the universe previous to sample selection, the State shall drop these cases from review if they are selected in the sample and are later determined to be under active fraud investigation at the time of selection.

(2) *Eligibility universe-negative cases.* The Medicaid and SCHIP negative universe consists of all negative cases for the sample month. Cases denied or terminated based upon incomplete applications or cases where beneficiaries who do not complete the redetermination process are excluded. The negative case universe is not stratified.

(3) *Stratifying the universe.* Each month, the State stratifies the Medicaid and SCHIP active case universe into three strata:

(i) Program applications completed by the beneficiaries in which the State took action in the sample month to approve such beneficiaries for Medicaid or SCHIP based on the eligibility determination.

(ii) Redeterminations of eligibility in which the State took action in the sample month to approve the beneficiaries for Medicaid or SCHIP based on information obtained through the completed redetermination.

(iii) All other cases.

(4) *Sample selection.* Each month, an equal number of cases are selected from each stratum for review, unless otherwise provided for in the plan approved by CMS.

§ 431.980 Eligibility review procedures.

(a) *Active case reviews.* The agency must verify eligibility for all selected active cases for Medicaid and SCHIP for the review month for compliance with the State's eligibility criteria.

(b) *Negative case reviews.* The agency must review all selected negative cases for Medicaid and SCHIP for the review month to determine whether the cases were properly denied or terminated.

(c) *Payment review.* The agency must identify all Medicaid and SCHIP payments made for services furnished, either in the first 30 days of eligibility or in the review month for applications under § 431.978(d)(3)(i) and redeterminations under § 431.978(d)(3)(ii) in accordance to State policy or from the sample month for all other cases under § 431.978(d)(3)(iii), to identify erroneous payments resulting from ineligibility for services or for the program.

(d) *Eligibility determination.* The agency must verify program eligibility for all active cases in the sample based on acceptable documentation contained in the case file or obtained independently through the review process.

(1) *Active cases—Medicaid.* The agency must—

(i) Review the cases specified at § 431.978(d)(3)(i) and § 431.978(d)(3)(ii) in accordance with the State's categorical and financial eligibility criteria as of the review month and identify with a specific beneficiary payments made on behalf of such beneficiary for services received in the first 30 days of eligibility or in the review month;

(ii) For cases specified in § 431.978(d)(3)(iii), if the last action was 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria as of the last action and identify with a specific beneficiary payments made on behalf of such beneficiary for services received in the sample month. If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility

criteria as of the sample month and identify payments made on behalf of the specific beneficiary for services received in the sample month;

(iii) Examine the evidence in the case file that supports categorical and financial eligibility for the category of coverage in which the case is assigned, and independently verify information that is missing, older than 12 months, likely to change, based on self declaration, or otherwise as needed, to verify eligibility; and

(iv) For managed care cases, also verify residency and eligibility for and actual enrollment in the managed care plan during the month under review.

(v) If the case is ineligible under paragraphs (d)(1)(i) through (d)(1)(iv) of this section, review the case to determine whether the case is eligible under any coverage category within the program.

(vi) As a result of paragraphs (d)(1)(i) through (d)(1)(v) of this section—

(A) Cite the case as eligible or ineligible based on the review findings and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month or sample month, as appropriate; or

(B) Cite the case as undetermined if after due diligence an eligibility determination could not be made and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month or sample month, as appropriate.

(2) *Active cases—SCHIP.* In addition to the procedures for active cases as set forth in paragraphs (d)(1)(i) through (d)(1)(v) of this section, once the agency establishes SCHIP eligibility, the agency must verify that the case is not eligible for Medicaid by determining that the child has income above the Medicaid levels in accordance with the requirements in § 457.350 of this chapter. Upon verification, the agency must—

(i) Cite the case as eligible or ineligible based on the review findings and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the review month or sample month, as appropriate; or

(ii) Cite the case as undetermined if after due diligence an eligibility determination could not be made and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the review month or sample month, as appropriate.

(e) *Negative cases—Medicaid and SCHIP.* The agency must—

(1) Identify the reason the State agency determined ineligibility;

(2) Examine the evidence in the case file to determine whether the State agency's denial or termination was correct or whether there is any reason the case should have been denied or terminated; and

(i) Record the State agency's finding as correct if the case record review substantiates that the individual was not eligible; or

(ii) Record the case as an error if there is no valid reason for the denial or termination.

§ 431.988 Eligibility case review completion deadlines and submittal of reports.

(a) States must complete and report to CMS the findings, including the error causes if known, for all active case reviews listed on the monthly sample selection lists, including cases dropped from review due to active fraud investigations and cases for which eligibility could not be determined. States must submit a summary report of the active case eligibility and payment review findings to CMS by July 1 following the review year.

(b) The agency must report by July 1 following the review year, information as follows:

(1) Case and payment error rates for active cases.

(2) Case error rates for negative cases.

(3) The number and amounts of undetermined cases in the sample and the total amount of payments from all undetermined cases.

(4) The number of cases dropped from review due to active fraud investigations.

§ 431.992 Corrective action plan.

The State agency must submit to CMS a corrective action plan to reduce improper payments in its Medicaid and SCHIP programs based on its analysis of the error causes in the FFS, managed care, and eligibility components.

§ 431.998 Difference resolution process.

(a) The State may file, in writing, a request with the Federal contractor to resolve differences in the Federal contractor's findings based on medical or data processing reviews on FFS and managed care claims in Medicaid and SCHIP. The State must have a factual basis for filing the difference and must provide the Federal contractor with valid evidence directly related to the error finding to support the State's position that the claim was properly paid.

(b) For a claim in which the State and the Federal contractor cannot resolve the difference in findings, the State may appeal to CMS for final resolution.

(1) The difference in findings must be in the amount of \$100 or greater; and

(2) The agency must provide CMS with the facts and valid documentation to support its determination that the claim was correctly paid, as well as the Federal contractor's justification for upholding its initial error finding.

(3) CMS will make the final decision on the claim. There will be no further judicial or administrative review of CMS' decision.

(c) All differences, including those pending in CMS for final decision that are not resolved in time to be included in the error rate calculation, will be considered as errors for meeting the reporting requirements of the IPIA. Upon State request, CMS will calculate a subsequent State-specific error rate that reflects any reversed disposition of the unresolved claims.

§ 431.1002 Recoveries.

(a) *Medicaid.* States must return to CMS the Federal share of overpayments based on medical and processing errors in accordance with section 1903(d)(2) of the Act and related regulations at part 433, subpart F of this chapter. Payments based on erroneous Medicaid eligibility determinations are addressed under section 1903(u) of the Act and related regulations at part 431, subpart P of this chapter.

(b) *SCHIP.* Quarterly Federal payments to the States under Title XXI of the Act must be reduced in accordance with section 2105(e) of the Act and related regulations at part 457, subpart B of this chapter.

SUBCHAPTER D—STATE CHILDREN'S HEALTH INSURANCE PROGRAM

PART 457—ALLOTMENTS AND GRANTS TO STATES

Subpart G—Strategic Planning, Reporting, and Evaluation

■ 4. The authority citation for part 457 continues to read as follows:

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

■ 5. Section 457.720 is revised to read as follows:

§ 457.720 State plan requirement: State assurance regarding data collection, records, and reports.

A State plan must include an assurance that the State collects data, maintains records, and furnishes reports to the Secretary, at the times and in the standardized format the Secretary may

require to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under Title XXI of the Act. This includes collection of data and reporting as required under § 431.970 of this chapter.

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

(Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program)

Dated: April 17, 2006.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: May 25, 2006.

Michael O. Leavitt,
Secretary.

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