Federal Register

Wednesday,
October 5, 2005

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 431 and 457

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431 and 457

[CMS–6026–IFC]

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 sets forth the State requirements to provide information to us for purposes of estimating improper payments in Medicaid and the State Children's Health Insurance Program (SCHIP), as required under the Improper Payments Information Act (IPIA) of 2002. The IPIA requires heads of Federal agencies to annually estimate and report to the Congress these estimates of improper payments for the programs they oversee and, submit a report on actions the agency is taking to reduce erroneous payments. We published a proposed rule on August 27, 2004 to propose that States measure improper payments in Medicaid and SCHIP and report the State-specific error rates to us for purposes of computing the improper payment estimates for these programs.

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 are revising our proposed approach. Our new approach incorporates commenters' suggestions to engage a Federal contractor by contracting with that entity to complete the data processing and medical reviews and calculate the State-specific error rates. Based on the States' error rates, the contractor also will calculate the improper payment estimates for these programs which will be reported by the Department of Health and Human Services as required by the IPIA. This interim final rule sets out the types of information that States would need to submit to allow CMS to conduct medical and data processing reviews on claims made in the fee-for-service (FFS) setting. CMS will address estimating improper payments for Medicaid managed care and eligibility and SCHIP FFS, managed care and eligibility at a later time.

This rule responds to the public comments on the proposed rule, sets forth the requirements for States to assist us and the contractor to produce State-specific error rates in Medicaid and SCHIP which will be used as the basis for a national error rate, and outlines future plans for measuring eligibility, which may include greater State involvement than the level required for the medical and data processing reviews.

DATES: *Effective date:* These regulations are effective on November 4, 2005.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 4, 2005.

ADDRESSES: In commenting, please refer to file code CMS–6026–IFC. 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/regulations/ecomments*. (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–IFC, PO Box 8012, Baltimore, MD 21244–8012.

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–IFC, 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: Christine Jones, (410) 786–3722; or Janet E. Reichert, (410) 786–4580.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–6026–IFC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

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 electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be 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

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

The Improper Payments Information Act of 2002 (IPIA), Public Law 107–300,

enacted on November 26, 2002, requires the heads of Federal agencies to review annually programs they oversee that are susceptible to significant erroneous payments 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 subsequent guidance. 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, 05/21/03). 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.

In the report to the Congress, Federal agencies must include: (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 causes; (3) a discussion of the amount of actual erroneous payments the agency expects to recover; and (4) limitations that prevent the agency from reducing the erroneous payment levels, that is, resources or legal barriers.

The Medicaid and SCHIP programs were identified by OMB as programs at risk for significant erroneous payments. OMB has directed the Department of Health and Human Services (DHHS) to report the estimated error rate for the Medicaid and SCHIP programs to OMB by November 15 of each year.

There currently is no systematic means of measuring payment errors at the State and national levels for Medicaid and SCHIP. Through the Payment Accuracy Measurement (PAM) and Payment Error Rate Measurement (PERM) pilot projects that operated in Fiscal Years (FYs) 2002 through 2005, we determined that it is feasible to estimate improper payments for Medicaid and SCHIP and refined a claims-based review methodology. This methodology was designed to estimate State-specific payment error rates within +/−3 percent of the true population error rate with 95 percent confidence. Moreover, through weighted aggregation, the State-specific estimates can be used to make national level error rate estimates for Medicaid and SCHIP that meet OMB's confidence and precision requirements.

Since Medicaid and SCHIP are administered by State agencies according to each State's unique program characteristics, State participation in estimating improper payments was critical during the pilot projects and continues to be necessary and important for the Secretary to comply with the requirements of the IPIA. Obtaining and considering State input in IPIA requirements has necessarily been time-consuming; however, the end result is an interim final rule with comment period that is more responsive to our stakeholders' concerns.

II. Provisions of the Proposed Rule

We published a proposed rule on August 27, 2004 (69 FR 52620) that contained provisions for all States to annually estimate total improper payments in Medicaid and SCHIP. Based on medical, data processing, and eligibility reviews on a monthly random selection of a total of approximately 800 to 1,200 fee-for-service (FFS) and managed care claims (stratified between the components) each for Medicaid and SCHIP, States would produce and report to us State-specific payment error rates in Medicaid and SCHIP. We would then calculate a national error rate for these programs. States would take actions to address causes of errors identified through the claims reviews. States also would submit an annual report to us detailing the causes of errors and specifying actions to be taken to reduce the level of improper payments. The process for recoveries of improper payments under Medicaid is already set in statute. States must return the Federal share of overpayments identified through the medical and data processing reviews of the sampled claims within 60 days in accordance with existing statutory and regulatory requirements governing recoveries (section 1903(d)(2) of the Social Security Act (Act) and 42 CFR part 433, subpart F). Recoveries of the Federal share of improper payments based on eligibility errors are subject to the provisions of section 1903(u) of the Act and related regulations at 42 CFR part 431, subpart P.

The intended effect of the proposed rule was to have States measure improper payments, to target corrective actions in response to identified errors, to reduce the rate of improper payments, and to produce a corresponding increase in program savings at both the State and Federal levels. The proposed rule would have allowed us to comply with the IPIA requirements.

This rule is being promulgated as interim final with comment period due to the significant departure in the approach to estimate improper payments in Medicaid and SCHIP by engaging a Federal contractor rather than requiring States to produce error rates. We plan to publish a final rule that responds to comments made on this interim final rule. We expect the determination of the eligibility error rate to require State participation and seek comments through this interim final rule on how such a rate could best be calculated within current Medicaid and SCHIP laws and regulations, and with minimal imposition on State resources. We anticipate producing a Medicaid FFS error rate for the FY 2007 Performance and Accountability Report (PAR) based on reviews conducted in FY 2006. In FY 2007, we expect to measure improper payments in the FFS, managed care and eligibility components of Medicaid and SCHIP to be reported in the FY 2008 PAR. We are also seeking comments on how best to determine an error rate for managed care in Medicaid and SCHIP.

III. Analysis and Response to Public Comments on the Proposed Rule

Public comments on the proposed rule expressed concerns predominantly with the cost and burden that States would incur and the potential adverse effect that error rate measurement could have on beneficiaries' access to care. Although many commenters supported the general need for program integrity, they offered alternatives that they believed would better achieve compliance with the IPIA requirements. Many commenters made the following recommendations to allow us to achieve compliance with IPIA by other means:

- Utilize national sampling using Medicaid Statistical Information System (MSIS) data.
- Pool State-specific data across the years, or accept larger standard errors to generate a national estimate, particularly for SCHIP.
- Use the Medicaid Eligibility Quality Control (MEQC) program as a sampling process. States could change their sampling methodology from case to claim, stratify the claims and sample monthly to determine eligibility and perform a medical review. Regulations for MEQC are in place and implementing the additional requirements within an existing structure would be easier. The MEQC error rates could also be used to produce a national eligibility error rate to prevent the redundancy of conducting PERM and MEQC, along with minimizing financial burdens.
- Use existing State methodologies and compare them to the results of other samples to determine whether they contribute to the goal of a national program error rate.

- Hire a Federal contractor.
- Use gathered information to provide technical assistance to States to improve program integrity, rather than penalize States.

We considered all of the recommendations and adopted several of the recommendations. The new approach to error rate measurement will rely on a Federal contractor to conduct medical and data processing reviews and produce State-specific and national Medicaid and SCHIP error rates. The contractor will sample selected States each year to estimate improper payments in Medicaid and SCHIP and create a national error rate. We have not made a final determination about how eligibility errors will be measured. It is likely, however, that States would be active participants in this process. For example, though several options remain under consideration, it is possible that the States sampled for the medical and data processing reviews would be required to test for eligibility errors in a manner similar to that presented in the proposed rule.

We did not adopt the other recommendations, either because they would not achieve compliance with OMB guidance, or because we believed that they were not the best methods to meet the requirements of OMB guidance. We did not adopt the first recommendation because there is no national sampling frame for SCHIP claims, and the MSIS data for Medicaid are too old to produce meaningful data on which States could base effective corrective actions. Pooling State-specific data across the years or accepting larger standard errors to generate a national estimate would not generate an error rate that was based on an annual standardized measurement of improper payments and therefore would not provide a basis on which an annual national error rate that was compliant with OMB guidance could be calculated. Although accepting State samples with larger standard errors may produce a national error rate that was compliant with OMB guidance, those estimates would not provide the States with sufficient information to identify vulnerabilities and to implement corrective actions. We also did not adopt the recommendation to use MEQC as a sampling process because the MEQC statute does not apply to SCHIP stand-alone programs under Title XXI. Also, many States have their MEQC programs attached to the section 1115 research and demonstration waivers that, while allowing them the flexibility to tailor their eligibility oversight efforts, have the effect of preventing comparability and aggregation for a national rate.

We also did not adopt the recommendation to use existing States' methodologies to produce a national program error rate. Commenters stated that, in addition to MEQC, States use the Surveillance and Utilization Review System (SURS), program integrity, and checks and balances in the claims processing systems and suggested that the States submit proof of program savings that equaled a percentage of the program's current costs. We believe this recommendation would not result in a standardized approach since the information that States would submit would be based on varying methodologies and that submitting cost savings information is not a measurement of improper payments, as required by IPIA. Also, not all States may apply these systems to SCHIP. Therefore, this approach may not produce a national error rate that would meet the confidence and precision requirements contained in OMB guidance. The proposed rule did not provide for States to be penalized through this error rate measurement. Finally, we are always available to provide technical assistance to States.

After consideration of the proposed alternatives, we are adopting the recommendations to hire a Federal contractor to conduct the medical and data processing reviews and calculate the State-specific and national error rates for Medicaid and SCHIP. We also are adopting the recommendation to sample a subset of States each year. Each State will have a State-specific error rate which will be the basis for a national error rate. Adopting these recommendations addresses commenters' concerns with State cost and burden.

By FY 2008, we hope to be compliant with the IPIA requirements by producing error rates for both Medicaid and SCHIP FFS, managed care and eligibility. In FY 2006, we will use a Federal contractor to estimate improper payments from medical and data processing reviews in the fee-for-service component of Medicaid and establish a workgroup to make recommendations on the best approach for reviewing Medicaid and SCHIP eligibility, within the confines of current statute and with minimal budgetary impact for purposes of meeting IPIA requirements to measure improper payments based on payments to ineligibles.

Under the national contracting strategy, a number of States will be selected for review. In FY 2006, the Federal contractor will group all States into three equal strata of small, medium and large based on States' annual FFS Medicaid expenditures from the previous year, and select a random sample of an estimated 18 States to be reviewed. The error rates produced by this selection methodology will provide the State with a State-specific error rate estimated to be within 3 percent precision at the 95 percent confidence level. For subsequent years, our sampling methodology will ensure that each State will be selected once, and only once, every 3 years for each program.

The States selected for review will submit the previous year's claims data and expenditure data, not otherwise already provided by CMS, on which the contractor will determine each State's sample size and the sample size for each stratum. The strata we are considering 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, labs, x-rays; (7) primary care case management; and (8) denied claims. These States also will submit quarterly stratified claims data to the contractor who will pull a statistically valid random sample, each quarter, by strata and medical and data processing reviews will be performed. State-specific error rates will be based on the results of these reviews.

In FY 2006, contingent on available funding, we plan to estimate improper payments in the FFS component of Medicaid. In FY 2007, we expect to measure improper payments in both the FFS and managed care components of Medicaid and SCHIP. We will measure the error rate in each component (FFS and managed care) separately due to their differing nature. For example, FFS has a wide variance in payments amounts, whereas managed care payments do not. We expect to be able to produce the Medicaid and SCHIP FFS, managed care and eligibility national error rates for reporting in the FY 2008 PAR to the Congress.

We received a total of 121 comments: 43 from State agencies and 78 from consumer advocacy and other groups. Overall, commenters expressed concern with the proposed methodology for measuring improper payments, although many also expressed support for the general need for program integrity. Areas of greatest concern were burden and cost, the requirement for States to construct error rates to meet a legal requirement imposed on Federal agencies, and the impact on beneficiaries. States did not believe the proposed rule's methodology would be

cost-effective or realize savings. Some States and the advocacy groups were concerned that the proposed methodology would have an adverse effect on access to care as States increased or imposed new requirements on applicants for documented proof of eligibility to avoid errors. Following are the comments on the proposed rule, grouped by topic, and our responses.

A. Purpose and Basis

Comment: Many commenters expressed concern with the cost and burden that the proposed rule would have imposed on States, particularly since they believe the IPIA imposes the requirement to measure improper payments on Federal agencies rather than the States. States are also concerned that:

- Critical staff would need to be diverted to perform the reviews;
- It would be difficult to implement corrective actions while measuring error rates at the same time;
- The rule places an added burden on States at a time when some are struggling to maintain and expand coverage to currently uninsured individuals; and,
- Forces States to shift funds from other programs. Providers need the States to invest additional resources in provider outreach, education, and resource material that would improve the entire system, not to shift funds away from activities to calculate error rates.

The commenters stated that, if States must estimate improper payments in Medicaid and SCHIP, these activities should be fully federally funded.

Response: We agree that the IPIA imposes the requirement on Federal agencies rather than the States to measure improper payments. Although Medicaid and SCHIP are jointly funded by the Federal and State governments, the programs are fully administered and operated by the States. Also, there is wide variation in States' Medicaid and SCHIP programs due to the flexibility States have in developing the coverage, benefit, and reimbursement aspects of the programs. As a result, we must measure improper payments on a State-specific basis in order to produce a national payment error rate.

Regarding the cost and burden that the proposed rule would have imposed on States, our adoption of the commenters' recommendation to engage a Federal contractor to estimate a component of improper payments significantly reduces the cost and burden and addresses this concern. States will not pay for the national contractor. In addition, only those States selected for review each year will provide information necessary for claims sample selections and reviews, will provide technical assistance as needed, and will implement and report on the corrective actions to reduce the error rate. 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 the burden and impact that these responsibilities will have on States and determined that there was significantly less impact on States and providers. We plan to measure SCHIP FFS, managed care and eligibility in FY 2007, and we acknowledge that the 10-percent cap on SCHIP administrative expenditures could be a concern in the future, particularly depending on the nature of reviews necessary to produce SCHIP eligibility error rates. Though the burden and cost States would bear for eligibility testing in both Medicaid and SCHIP fee-for-service and managed care remains uncertain, the eligibility workgroup will make every effort to minimize both while establishing a useful and worthwhile methodology.

Finally, due to the minimal additional activity required by the regulation, we believe that States selected for review should not need to divert staff from other areas of program activities.

Comment: Some commenters stated that the proposed rule goes beyond the requirements of law and lacks details needed for States to determine requirements and resource commitments. A few commenters recommended that CMS postpone the proposed rule until more details could be given or revise the regulation to establish key principles to make the reviews fair and accurate based on public comment.

Response: The Federal contractor's responsibility for medical and data processing reviews should lift a substantial portion of the burden from States. Since Medicaid and SCHIP are partnerships between the Federal and State governments, we will rely on States' assistance throughout the error measurement process. This interim final rule provides the opportunity for States and other interested parties to comment on the States' responsibilities in this revised approach.

Additionally, we will request that some States and/or their representatives be part of the eligibility workgroup. We look forward to their input and participation as we continue through the process.

Comment: A few commenters were highly supportive of the proposed rule and recommended that any modification to the rule focus on the measurement of monies lost to fraud and abuse. The commenters emphasized prevention strategies centered on education, data mining, prospective flags, as well as recovery of erroneous payments and cooperation with law enforcement to facilitate criminal prosecution.

Response: We are not adopting this recommendation. We currently conduct fraud and abuse oversight activities, which include data analysis through the Medicare-Medicaid data match, to identify potential fraud and abuse. Other activities, such as education, prospective flags, recovery of erroneous payments, and cooperation with law enforcement are currently conducted at the State level. We believe additional actions are not necessary at this time.

Comment: Several commenters urged CMS to reconsider its proposal and develop a system under which the error reporting requirements are clear and identical for all States. They are concerned that differing State rules for reviews will contribute to the administrative burden and potential inefficiencies in the system, especially for providers operating facilities in many States.

Response: We have reconsidered our approach and believe this strategy will provide more standardized measures across States. The States' requirements for the medical and data processing reviews are clearly stated in this regulation text, and the public is afforded the opportunity through this rule to comment on them.

Any additional State requirements will be described in a proposed rule with an opportunity for public comment. We invite comments on how a system that relies, in part, on State measurement could be standardized across States.

Comment: A few commenters stated that some States should be given special consideration such as States that have limited or no previous error rate experience; and CMS should exclude States with SCHIP minimal allotments, similar to excluding the Territories due to minimal funding.

Response: State burden and cost are significantly reduced under this revised strategy, so we believe the basis to consider excluding States with small SCHIP allotments no longer exists. Therefore, we are not adopting this recommendation.

Comment: A few States inquired as to: (a) the legal obligation of States to institute payment error rate measurement; and (b) the consequences if a State could not comply with the regulatory requirements.

Response: Current law at section 1102 of the Act authorizes the Secretary to establish regulations as may be necessary for the efficient administration of the Medicaid and SCHIP programs. The Medicaid statute at section 1902(a)(6) of the Act, and the SCHIP statute at section 2107(b)(1) of the Act, require States to provide information necessary for the Secretary to monitor program performance. Section 1902(a)(27) of the Act requires providers also to submit information as requested by the Secretary. These statutory provisions provide the bases for requiring States and providers to submit information needed to produce Medicaid and SCHIP error rates. Regarding compliance, the regulations that govern State compliance with Federal requirements in Medicaid and SCHIP are 42 CFR 430.35 and 457.204, respectively. Under these regulations, the Administrator has the discretion to enforce the compliance regulations by withholding Federal matching funds in whole or in part until a State complies with Federal requirements.

Comment: Some commenters stated that savings will not be realized since the cost of conducting error rate measurement will exceed savings.

Response: The IPIA requires error rate measurement for these programs and does not include lack of cost savings as a reason for not measuring improper payments. Since we are estimating improper payments in a select number of States through a Federal contracting strategy, we believe the State cost to measure error rates has been drastically reduced. We will analyze the cost/savings benefits when we have reliable findings, but we anticipate that savings will be realized over time through efficiencies gained by experience in estimating error rates, through disseminating findings from selected States, States' corrective action measures, and modeling best practices.

Comment: A few commenters recommended that payment error rate measurement use a claims-based sampling methodology and be administered electronically, since a paper-based model would prove burdensome to States and providers and could lead to lower provider response rates.

Response: The proposed rule provided for a claims-based sampling methodology as does the interim final rule for the medical and data processing reviews. Since States and providers have different levels of systems sophistication, the contractor will work with States to determine the format for States to submit information.

Comment: A number of commenters believe that working with Medicaid and SCHIP will be more difficult for providers because of increasing paperwork burdens, higher rates of denied claims, delays in payments, and sanctions.

Response: The providers who would submit medical documentation to support the medical reviews are participating providers in Medicaid and/or SCHIP. We have analyzed the cost and burden on providers as part of this rule and determined that there will not be a significant cost or impact. We believe we have further minimized the burden on providers nationwide by reviewing only a selection of States rather than all States every year. Also, providers only need to submit medical records for FFS claims since managed care claims are not subject to medical reviews.

Comment: Several commenters were concerned that the proposed rule would place a unique burden on providers who serve a disproportionately large share of Medicaid and SCHIP enrollees. The negative impact of additional time and practice cost that would be required of providers to respond to requests for medical records and error rate measurement efforts should be considered as the final rule is drafted.

Response: As stated above, we have analyzed the burden on providers as part of this rule. We believe that utilizing a sample of States will reduce the burden on providers nationwide since only those Medicaid and SCHIP providers in States selected for review will submit medical records and, in each State, only providers whose FFS claims were selected would need to submit records, as managed care claims are not subject to medical review.

Comment: A few commenters wanted to know what would be considered an acceptable State error rate percentage.

Response: Unlike the statute at section 1903(u) of the Act which sets a 3-percent error rate tolerance for Medicaid eligibility errors before a disallowance of the Federal share of improper payments can be imposed, the IPIA and subsequent OMB guidance does not set a State-specific error rate percentage. IPIA is merely a reporting requirement; it neither penalizes nor rewards States for acceptable or unacceptable error rates. However, States would still be required to reimburse CMS for the Federal portion of all improper payments identified through the medical and data processing reviews.

Comment: A few commenters suggested that CMS develop an internal taskforce to review the progress of the States in implementing payment error rate measurement, including CMS regional office representatives. The taskforce could seek feedback from stakeholders on the process for improvements in moving forward.

Response: Since we are engaging a Federal contractor rather than the States to produce error rates, the recommendation to convene a taskforce to track States' progress on medical and data processing reviews no longer applies. However, the eligibility workgroup may decide to have a taskforce track States' progress on the eligibility reviews, when implemented.

B. Definitions

Comment: A few commenters recommended replacing the definition of ''total estimated improper payments'' with a definition of ''Federal estimated improper payments'' that is based on the Federal share of improper payments, as computed using the appropriate Federal matching rate for Medicaid or SCHIP.

Response: We agree with the commenter that the IPIA and OMB guidance refer only to Federal improper payments. We have deleted this definition from the interim final rule.

C. Claims Universe and Sampling

1. Exclusions From the Universe

a. Denied Claims

Comment: Many commenters objected to the inclusion of denied claims in the sampling process. They believe that a denied claim is not included in the IPIA definition of improper payment as defined in the IPIA or the proposed rule. Some commenters questioned OMB's interpretation of an improper payment which includes denied claims. Some commenters stated that denied claims are not improper payments since payments have not actually been made.

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

Comment: Some commenters stated it may be difficult for States to find a standard definition of denied claim and wanted to know whether the amount of a denied claim should be a zero amount or the amount billed.

Response: A denied claim is a claim or line item that was submitted by a provider for services furnished, was accepted by the claims processing or payment system, was adjudicated for payment, and was not approved for payment. The amount of a denied claim when part of the universe for sampling purposes is zero dollars. The amount of improper payment, if a claim was denied erroneously, would be the amount that should have been paid as a result of the review.

Comment: Some commenters asked what documentation supports a denied claim. States may not have the authority to demand a medical record for a denied claim.

Response: Documentation to support a denied claim depends on the reason the claim was denied. For example, if the reason for the denial was based on the claims processing, a processing review would be done to verify the denial. If the reason for the denial was medically based, a medical record would support whether or not the claim was correctly denied. If the provider does not submit the record or if the submitted record does not substantiate the service billed, then the denial would be correct. Since we are utilizing a Federal contractor, States will not be requesting medical records for denied claims, so this point is no longer applicable.

Comment: Some commenters asked what would constitute an adjustment to a denied claim (similar to when a paid claim is adjusted to, for example, correct the billing amount or coding) and whether it would be possible to identify these adjustments to claims denied for payment.

Response: Denied claims are not subject to adjustments because, when a claim is denied for payment, the provider will resubmit a new claim for payment. The claim resubmitted for payment would not be associated with the claim that was originally denied. Therefore, adjustments to denied claims are not included in this interim final rule.

Comment: Some commenters stated that inclusion of denied claims will affect the precision levels. Denied claims have a greater chance of selection since a large portion will reappear in the universe as a paid claim. They inquired why denied claims will be used to increase the amount of misspent dollars.

Response: Denied claims include claims accepted by the claims processing or payment system, adjudicated for payment and not approved for payment. This definition excludes many or most of the types of claims that are rejected from the claims payment system, corrected and resubmitted, and ultimately approved for payment. This reduces the chance that a claim for a single service would show up in the sample as both a denial and a paid claim. The inclusion of denials is consistent with guidance from OMB, which has stated that improper payments include inappropriate denials of payment or service.

Comment: Some commenters questioned how an error rate would be determined for a denied claim specifically inquiring as to the nature of the numerator and denominator.

Response: There are multiple approaches for including denials in the error rate. If denials are included as a separate stratum, the ''difference'' version of the error rate calculation would be applied. Errors from denials are included in the total error rate, projected to the population or universe using the inverse of the sampling frequency. In the denominator, the non-stochastic (that is, deterministic) value of all line items paid over the sampling period is included, and denials enter the denominator as zero.

Comment: Some commenters asked what denial explanation of benefits will be used to identify denied claims that will be included or excluded from the universe.

Response: All denied claims are included in the universe. Therefore, it is not necessary to categorize denials based on the explanation of benefits.

Comment: Some commenters asked if eligibility determinations will need to be conducted on denied claims.

Response: If a claim is denied on the basis that the person is not eligible, we believe an eligibility review should be done to confirm the claim was correctly denied. This issue is likely to be considered by the eligibility workgroup.

b. Medicare Claims and Other Premium Payments

Comment: Some commenters stated that it was not clear if Medicare crossover claims were included in the proposed rule methodology.

Response: We believe the commenter defines crossover claims as payment authorization for Medicare coinsurance and deductible amounts. The proposed rule intended to include Medicare crossover claims in the reviews since these are considered part of the universe of claims. The universe includes all claims submitted by providers, insurers, and managed care organizations for which a decision to pay or deny was made by Medicaid or SCHIP. Under this interim final rule, these claims would be included in the universe and subject to sampling and review to the same extent as any other claim.

Comment: A few commenters stated that Medicare crossover claims should be excluded because the buy-in claims are paid directly to a Federal agency and have the unintended outcome of having States determine the accuracy of Medicare claims, when the primary Medicare claims are already measured by CMS. The commenters stated these claims were not tested in the PAM pilots.

Response: The commenter is correct that Medicare Parts A and B crossover claims were not tested in the PAM pilots. At that time, CMS and the participating States were still refining the methodology to estimate error rates. In the FY 2005 pilot (PERM pilot), both Medicare crossover claims and denied claims were included in the reviews. Medicare crossover claims are included in the universe for sampling because they are considered Medicaid payments made to insurers, similar to Medicaid payments for employee health care premiums. This methodology measures the accuracy of the Medicaid payment on the claim rather than the accuracy of the Medicare payment.

Comment: A few commenters stated that buy-in claims should be excluded from sampling because these payments are made to a Federal agency and, furthermore, buy-in overpayments or payments made on behalf of ineligible participants are unrecoverable.

Response: Although the Medicare program is administered by a Federal agency, it is considered an insurer, as noted above. Moreover, it is immaterial whether an erroneous payment is recoverable or non-recoverable.

Comment: A few commenters stated that Parts A and B premiums are not processed as claims through MMIS and stated they believe that the sampling was intended to test claims submitted by providers and processed by the States' MMIS systems. If these claims were included, they argued other contracts with Federal match, such as disproportionate payments, rent and salary should be included.

Response: The methodology in the proposed rule would have reviewed only claims paid to providers, insurers and managed care organizations. Payments not falling within these categories would be excluded from the universe. Medicare crossover claims would be included because Medicare is considered an insurer for this purpose. We acknowledge that most claims are processed by the States' MMIS systems; however, the proposed rule did not provide for States to exclude any claims that were not processed through the

MMIS. The data processing review in the proposed rule, as well as in the revised approach discussed in this interim final rule, is intended to ensure the claim was correctly paid regardless of the system making the payment.

Comment: A few commenters stated that States may not have the necessary understanding of Medicare payment policies.

Response: Although we are available to provide technical assistance to States that do not understand Medicare payment policies, under the proposed rule, States would not be required to verify the accuracy of Medicare payments. The States would only verify that the State had paid its own portion correctly. However, since States are no longer conducting the medical or data processing reviews, this fact is no longer relevant.

Comment: A few commenters stated that ''improper payment'' needed further definition and asked what impact uncollected, incorrect, or disputed (official complaint on file) premium payments would have on the error rate (for example, for SCHIP participants who prepay a monthly premium).

Response: We believe the definition of ''improper payment'' in the proposed rule as well as this interim final rule is clear. The error rate methodology in the proposed rule would have required States to review claims to determine if the payment amount was correct. An uncollected, incorrect, or disputed premium amount in a sampled claim would have been determined to be an over-or underpayment in the amount that was either the participant's liability or the State's liability to pay, depending on the circumstances of the specific claim being reviewed.

c. Other Exclusions

Comment: A few commenters asked if FFS or managed care components with less than 10 percent of program expenditures will be excluded.

Response: For purposes of the pilot programs, we did exclude such FFS or managed care components from review but we did not anticipate in the proposed rule or in this interim final rule that components would be excluded on this basis.

2. Sampling Issues

Comment: Some commenters wanted to know if CMS had adequate staff to approve States' sample plans in a timely manner and asked that ''timely manner'' be defined.

Response: At this time, States will not need to submit sampling plans to us for approval under the national contractor approach. Should the eligibility testing require States to do any sampling, those issues would be addressed in a subsequent issuance.

Comment: A few commenters expressed concern with the large sample sizes and asked that we identify the percent of error assumed to develop the methodology. Commenters suggested that States be allowed to submit alternative sampling plans that have an equal or better precision than required.

Response: Under the proposed rule, the Federal contractor would determine the sample sizes needed to achieve the required precision levels for Medicaid and for SCHIP, which is an estimate that is within +/−3 percentage points of the true population payment error rate with 95 percent confidence. When we originally estimated the range of sample sizes to be between 800 to 1,200 for each program in each State, we did not assume a particular error rate; rather, we assumed a variance in payment size. Experience now shows that the 800–1200 sample size results in States achieving the precision level of +/−3 percent. It is important to note that the sample sizes could be larger or smaller in each State or in the SCHIP program. Since States will not need to submit sampling plans for selecting claims for medical and data processing reviews or review these claims under the national contracting strategy, we believe these concerns have been addressed.

Comment: A few commenters suggested that as a way to reduce the sample size, the Medicaid and SCHIP claims be combined or suggested that the sample sizes should not be the same for Medicaid and SCHIP.

Response: The Medicaid and SCHIP claims cannot be combined because the OMB guidance requires a statistically valid error rate that meets specified confidence and precision levels for each individual program. The sample sizes for Medicaid and SCHIP will be estimated to achieve +/−3 percent precision within 95 percent confidence. Although we estimated the Medicaid and SCHIP sample size to be within the same range, the actual sample size may or may not be the same. Combining Medicaid and SCHIP claims or arbitrarily reducing the sample sizes for either program to calculate error rates would not meet the OMB requirements.

Comment: Some commenters noted that the sample size required of the SCHIP program is the same required for the Medicaid program, even though the SCHIP programs are far smaller. They stated that imposing such large burdens on SCHIP programs, which have fewer administrative funds, would necessitate diversion of resources away from areas like outreach and enrollment processing. These commenters suggested relaxing sampling and precision estimates for smaller States or programs.

Response: We cannot adopt this recommendation. As noted above, reducing the State sample sizes to achieve less than 3 percent precision with a 95 percent confidence level would (1) not provide the State with sufficient information to determine vulnerabilities and to initiate corrective action; and (2) not achieve a national error rate that meets the OMB confidence and precision requirements when rolling up the State error rates.

Comment: Some commenters stated the stratified sample is a complicated feature and expressed concern with the cost and resource burden to pull a large sample for review, particularly for the SCHIP program, which has limited administrative funding, or for States with smaller populations.

Response: Stratification of the claims is necessary to improve precision, reduce sample size, and identify the areas of greatest vulnerability. We believe it is necessary for each selected State to submit stratified claims data because the contractor otherwise would not be able to complete the statistical aspect of the measurement process in a timely manner. We have reevaluated the burden associated with States submitting adjudicated and stratified claims data for each current quarter and estimated the burden to be up to 200 FTE hours per quarter. Details regarding States' role in eligibility testing will be described in a subsequent issuance.

Comment: A few commenters suggested reducing the sample size to minimize the burden on providers.

Response: The sample size is determined by the number of claims that need to be reviewed to meet our State-specific confidence and precision levels and cannot be reduced to minimize the burden on providers. We analyzed the impact on providers as part of the proposed rule and determined it was not significant. It should be noted that only providers whose FFS claims were selected would submit medical records, as managed care claims are not subject to medical review.

Comment: A few commenters stated that it was not clear if the sample size considers cases where eligibility cannot be verified due to death or non-cooperation of the client.

Response: The sample sizes in the proposed rule would not have excluded these cases. Under the pilot projects, we allowed States to oversample to account for these cases that are dropped from the

eligibility review if the State could not verify eligibility due to these reasons. We will ask the eligibility workgroup to consider this issue for measuring eligibility error rates and will clarify how these cases will be treated in a subsequent issuance.

Comment: A few commenters believe that monthly samples would be complicated and were not pulled under the PAM pilots.

Response: Since States will not need to pull monthly samples for the data processing and medical reviews under the national contractor approach, we believe this issue is no longer applicable for these reviews. To the extent that the final eligibility testing methodology involves State sampling, as stated above, we will address this issue in a subsequent issuance.

Comment: A few commenters pointed out that the proposed rule did not mention whether Medicaid FFS claims would be stratified into seven strata by service, as was done in the PAM pilots.

Response: Under the proposed rule, the intent was to stratify the Medicaid FFS claims. We are considering the following strata: (1) Inpatient hospital, (2) long term care, (3) practitioners and clinics, (4) pharmacy, (5) home and community-based services, (6) other services and supplies, and (7) fixed payments such as Medicare Parts A and B premiums, and an eighth stratum for denied claims. This is the stratification model that is being used for the current PERM pilot. The methodology under the national contracting strategy described in this interim final rule would stratify the FFS claims in a similar manner with variations for SCHIP, as appropriate. However, CMS will direct the national contractor on all implementation issues.

Comment: A few commenters stated that a dollar weighted sample would cause an over sampling of high-cost, low-error services like nursing home and hospital care, rather than lower-cost services that have historically higher error incidence.

Response: This method improves the precision of the estimate if the variance of the accuracy rate across strata is proportional to the Medicaid payment share represented by the stratum. When calculating the final payment error rate, this oversampling and undersampling by stratum is taken into account and the sample is reweighted to calculate an unbiased estimate of the overall payment error rate.

Comment: Many commenters recommended that the reviews have a more balanced approach between FFS and capitated payments. The concern is that FFS claims will have a higher level of scrutiny than managed care claims, which unfairly characterizes FFS as more prone to fraud and error. They expressed concern that higher error rates would inevitably be detected for fee-for-service claims than for managed care payments, even though undetected Medicaid payment errors may also occur under capitated managed care.

Response: Under the proposed rule, the sample is drawn proportional to the State's spending. For example, if two-thirds of the State's funds are spent in FFS, then two-thirds of the dollar share of the Medicaid sample in the State would be FFS claims. In this manner, the measurement would be more representative of total Medicaid spending and we believed would produce a more accurate error rate. However, in this interim final rule, as previously stated, when we begin measuring both the FFS and managed care components of Medicaid and SCHIP, as we expect to in FY 2007, we will estimate separate error rates for FFS and managed care. We will also produce a combined FFS and managed care error rate for each State for each program in addition to providing a national error rate for each program.

Comment: Some commenters suggested that CMS should require that data presented on error rates explain that the errors computed for FFS claims and capitated payments are not comparable because of measurement differences and that fewer errors are detected for managed care because the review is less intensive.

Response: We agree with this comment. However, since States will not be estimating FFS error rates, the recommendation that we require States to provide an explanation on the measurement differences is no longer relevant.

3. Overpayment and Underpayment Errors

Comment: Many commenters stated that adding overpayments and underpayments together will count unspent dollars as misspent dollars and recommended an error rate for each type of payment.

Response: The IPIA specifically provided that OMB set implementation guidelines for Federal agencies. The OMB guidelines state that the annual estimated amount of erroneous payments is the gross total of both overpayments and underpayments. In order to be in compliance with IPIA, we must follow OMB guidelines regarding total gross overpayments and underpayments to derive error rate estimates. However, we also intend to report separately the amount of overpayment and underpayments.

Comment: Some commenters believe that only overpayments are the appropriate gauge of misspent dollars.

Response: We must estimate improper payments according to the IPIA and OMB guidelines. OMB guidelines require the inclusion of both overpayments and underpayments in the error rate estimate. As such, we must measure and report both overpayments and underpayments.

Comment: A few commenters asked if the sum of both underpaid and overpaid claims exceeds 2.5 percent or more than $10 million, would this be considered ''significant'' or must the error rate meet just one or both of these conditions to be considered ''significant.''

Response: The IPIA states that significant improper payments are payments that exceed $10 million. OMB guidance defines significant erroneous payments as annual erroneous payments exceeding both 2.5 percent of program payments and $10 million. However, these thresholds refer to the national error rate for the program rather than State-specific error rates. Neither the IPIA nor OMB guidelines set target State-specific error rates.

4. Adjustment to Claims

Comment: Some commenters stated that the 60-day timeframe to allow for adjustments to claims is arbitrary and should be extended to 120 calendar days to give providers and the States' payment systems more time to identify and correct adjudicated claims issues.

Response: The 60-day timeframe was agreed upon by States and CMS during the development of the review methodology under the PAM pilot projects as a reasonable timeframe that allows for adjustments while maintaining a timeline that also allows for completion of the reviews and to compute and report the error rates in time for inclusion in the next PAR. If we extend the timeframe to a point beyond 60 days, we could not be assured that the error rate measurement process would be completed in time to report the error rate. Therefore, we are not adopting this recommendation.

Comment: Other commenters stated that identification and review of adjustments are complicated and increase the complexity of the error rate measurement process.

Response: Reviewing adjustments to claims provides a more accurate error rate because adjustments reflect a more accurate final amount paid.

Comment: A few commenters stated that, in the current Health Information Portability and Accountability Act (HIPAA) claim format, information on the allocation of third party liability

(TPL) amounts is not required at the line level. There is no way to know if TPL calculations are correct for a specific line if the provider reported the information in the aggregate and asked whether this is what is meant by ''line items that are not individually priced.''

Response: Line items that are not individually priced are generally bundled into a service. Under the proposed rule, the service is the sampling unit. States were not required to sample at the line item. This concept would remain the same under the national contracting strategy as described in this interim final rule.

5. Other Comments

Comment: A few commenters stated that CMS should ensure that all payment information from CMS that States depend on to pay providers is given to States at least 60 days before the expected implementation date.

Response: We strive to work with States on a myriad of complicated financial issues and respond to issues in a timely manner. To that extent, we also make every effort to provide policy guidance to States in a timely manner but, due to the complexity of issues, we would not commit the agency to a 60-day timeframe for providing all payment information.

D. Review Procedures

1. Medical Reviews

Comment: Some commenters stated that requiring a medical review increases the cost and logistical complexity of the review effort due to the review time and follow-up necessary to obtain provider records.

Response: Since States are no longer performing the medical reviews and will not incur the cost of the reviews, we believe this concern has been addressed.

Comment: A few commenters stated that obtaining records for denied claims may prove more problematic than for paid claims.

Response: As stated above, since States are not performing the medical reviews and will not need to obtain records for the reviews, we believe this concern has been addressed.

Comment: A few commenters stated that providers should not have to submit records for denied claims since there is no incentive for them to copy records for services that Medicaid did not reimburse.

Response: If providers chose not to submit medical records for denied claims, we would consider the State to have properly denied the claim.

Comment: Some commenters recommended that States be allowed to contract with external quality review organizations to do the reviews.

Response: Since States will not be conducting the medical and data processing reviews, they will not need to contract with external organizations.

Comment: Some commenters stated that projected costs to conduct the reviews will exceed the $300 per review due to the type and number of FFS claims to be sampled.

Response: We estimated the costs of review based on information given by States participating in the PAM pilot projects. However, since we will engage a contractor to perform the medical and data processing reviews and States will not incur these costs, this comment is no longer relevant. Once the details of eligibility testing are finalized, we will address cost estimates in a subsequent guidance.

Comment: A few commenters stated that requesting, receiving and performing medical reviews is a time-consuming process. There is not enough time allocated to completing the review process prior to having to return the Federal share for overpayments identified within 60 days.

Response: States are no longer being asked to conduct the medical reviews for purposes of this interim final rule. Therefore, we believe the concern with concluding the medical reviews timely in relation to returning recoveries is no longer relevant.

Comment: Some commenters made recommendations that only medically unnecessary services and services not covered or delivered, as well as over and underpayments due to improper coding, should be counted as errors and other error types such as technical errors, such as minor coding and clerical errors, should be excluded.

Response: It is not clear what the commenters believe to be a minor coding or clerical error. We believe that if the error has any effect on the payment, then it must be included in the error rate calculation.

Comment: A few commenters acknowledged that inadequate documentation is a problem and agreed it should be measured but recommended that it be measured separately from clearly improper payments.

Response: We disagree with this comment. If documentation is inadequate to support the correctness of the claim, we believe it would be unreasonable to consider these claims as correct. Otherwise, any claim with inadequate documentation could be deemed correct which would undermine the purpose and reliability of the improper payment measurement.

Comment: A few commenters suggested that the method for determining medical necessity should be clearly stated in regulation, and recommended using the InterQual level of care criteria or similar product to reduce error rates and improve relationships with providers.

Response: As stated above, since the States are not performing the medical reviews, it is no longer necessary to define or clarify review procedures.

Comment: A few commenters noted that hospitals can be large organizations where mail with no addressee could take weeks to get to the appropriate person or could get lost and suggested that there should be a phone and e-mail address on the notification where receipt of the request can be confirmed. They also recommended follow-up to no responses from providers.

Response: We appreciate this suggestion but believe it is no longer relevant since States will not be conducting the medical reviews.

Comment: Some commenters wanted to know whether the claims for which providers did not respond should be discarded from the sample and how they should proceed with providers who are no longer in the program and refuse to provide medical records.

Response: As stated above, clarification of the review procedures is not necessary since States are not conducting the medical reviews.

Comment: A few commenters stated that it may be difficult to obtain records on Medicare cross-over claims and SCHIP claims when Medicaid has no agreement with the provider.

Response: We agree with the commenter and Medicare crossover claims will not be subject to medical review. The Medicare crossover claims will be subject to the data processing review.

Comment: Some commenters suggested that medical records should be requested only as a last resort since it is labor intensive for providers. Instead, commenters suggested that information be gleaned from claims.

Response: We are unclear as to how one would perform a comprehensive medical review based on the information provided on the face of the claim. In addition, we analyzed the burden on providers as part of the proposed rule and determined that there is no major impact on them to provide medical records.

Comment: A few commenters stated that the current medical review process accomplished under the Surveillance and Utilization Review Subsystem (SURS) program is more than adequate.

Response: We believe this point is not applicable since States will not be conducting the medical reviews. However, we encourage States to continue with reviews that uncover payment errors and other program weaknesses.

2. Data Processing Reviews

Comment: A few commenters stated that most claims are submitted by electronic media and asked whether the review can be accomplished through software that duplicates MMIS processing.

Response: Since States will not be conducting the data processing reviews, we believe this question is no longer relevant.

Comment: A few commenters asked whether the State should review the capitation fee or the actual claims for SCHIP when it is administered by a capitated per member per month fee.

Response: Since States will not be conducting the data processing reviews, we believe this question also is no longer relevant.

Comment: A few commenters commented that the specific review items for managed care claims, for example, non-covered services, third party liability, invalid pricing seemed to be inappropriate since the States would not be reviewing managed care encounters.

Response: Since States will not be conducting the data processing reviews, we believe this comment is no longer relevant.

3. Eligibility

Comment: Many commenters stated that the eligibility reviews in the proposed rule are expensive in both funds and staffing needs and duplicate current efforts under the MEQC program and SCHIP eligibility audit processes. They recommended that the eligibility reviews be eliminated or merged with MEQC.

Response: As previously stated, we cannot eliminate the eligibility reviews because the IPIA includes payments to ineligibles in defining improper payments. We have previously addressed the reasons why we chose not to merge the reviews with MEQC. When we convene the eligibility workgroup, we will ask for recommendations about how to estimate eligibility errors while minimizing burden, cost, and duplication with MEQC.

Comment: Many commenters had suggestions and recommendations on the eligibility review process and procedures, such as retaining the administrative period, allowing for technical errors, using the same rules as the application process, such as self-declaration, and excluding Supplemental Security Income (SSI) cases.

Response: We are not adopting these suggestions in this interim final rule since we have not yet finalized a method for eligibility reviews and plan not to conduct eligibility reviews in Medicaid and SCHIP in FY 2006. We will consider these recommendations as CMS and the workgroup determine the best method to measure eligibility errors and will address these suggestions and the requirements for eligibility reviews in a later issuance.

Comment: Most commenters stated that the proposed eligibility reviews have flaws that would produce overestimates of Medicaid eligibility errors. The eligibility review should be further clarified.

Response: As stated above, we are not adopting these suggestions in this interim final rule time since we have not yet finalized a method for eligibility reviews and will not conduct eligibility reviews in FY 2006. We will convene a workgroup to consider the best approach to eligibility reviews under the IPIA. We invite public comments on this issue.

Comment: Most commenters stated that payment errors should not be determined for a beneficiary who is certified on the basis of presumptive eligibility for Medicaid or SCHIP during the period of presumptive eligibility, so long as the presumptive eligibility determination has been conducted properly.

Response: Under the proposed rule, cases of presumptive eligibility under Federal law would have been excluded from review. We believe that the intent of the Congress is to hold States harmless for the limited time that presumptive eligibility is in effect for pregnant women and children under sections 1920, 1920A and 1920B of the Act. Since we have not determined how best to conduct the eligibility reviews at this time, we cannot state for certain that these cases will be excluded when we implement the reviews but we will raise this concern to the eligibility workgroup for their consideration and will address this issue in a subsequent issuance.

Comment: Many commenters suggested that if the review found a person to be ineligible under the Medicaid or SCHIP eligibility category in which they were enrolled, the review should have assessed whether the person was eligible under another Medicaid or SCHIP eligibility category. If a person was eligible under another category, then no overpayment would have occurred.

Response: The eligibility reviews in the proposed rule were intended to look at eligibility under the Medicaid program, not just the category of coverage within the Medicaid program. The same concept holds true for SCHIP. As such, no overpayment would have occurred if the review determined that the person was eligible for the program and that the beneficiary was eligible to receive the service under that program. We will apply this same concept when we implement eligibility reviews. However, since we have been and will continue to be estimating error rates for Medicaid and SCHIP separately, if a person was ineligible for one program or ineligible for a service under the program, the claim would have been in error regardless of whether the person was eligible for the other program or that the service was covered under the other program. In other words, if a person is determined ineligible for Medicaid or for a Medicaid service, eligibility for SCHIP is not relevant to whether or not an improper payment for Medicaid was made for the person.

Comment: Some commenters stated that beneficiaries, whose eligibility is based on information provided by another program, including Food Stamps, Temporary Assistance for Needy Families, or Medicare low-income drug benefit, should be exempt similar to the proposed rule's exemption of SSI beneficiaries.

Response: We do not agree with this comment. We believe that, in measuring improper payments, the State should be accountable for all Medicaid eligibility determinations regardless of which State agency is making the determination or regardless of which State agency provides the information. While the eligibility reviews would not have required the State to verify, for example, TANF eligibility, the information obtained by the TANF agency on which a Medicaid eligibility determination was made should be verified if there is no evidence that the TANF agency verified the information as part of its eligibility determination. The proposed rule did not exempt SSI cases from the eligibility reviews (see proposed § 431.982(a)(2)(iv), 69 FR 52631).

Comment: A few commenters asked how the eligibility reviews would coordinate with the medical and data processing reviews.

Response: Under the proposed rule, all three reviews would have been conducted on each FFS claim (there would not have been a medical review on managed care claims). We expect the

eligibility reviews will be coordinated with the medical and data processing reviews being done in those States selected for review so that an error rate for Medicaid and SCHIP FFS, managed care and eligibility can be concurrently calculated for each State under review. We will address this issue in a later issuance.

Comment: Many commenters stated that determining eligibility at the time of service is stringent and raises difficulties and significant barriers for States in verifying eligibility for a time so far in the past and pointed out that corrective actions would be meaningless.

Response: We agree with this comment. We have not determined at this time how eligibility reviews will be conducted under IPIA. We invite public comment on this issue and will respond in a subsequent issuance.

Comment: Some commenters stated that State remedies to improve error rates, such as more frequent redeterminations, will exacerbate involuntary disenrollment and churning without providing any meaningful fiscal impact.

Response: We do not agree with this comment. States should strive to improve the accuracy of their eligibility determinations as part of their prudent fiscal management responsibilities regardless of whether or not we are specifically measuring eligibility errors. As such, States can improve their eligibility processes in many ways beyond more frequent eligibility determinations without necessarily creating an adverse effect on program enrollment.

Comment: A few commenters argued that error rates would be skewed upward by children who are ineligible at a particular point in time but who are eligible over the course of a year.

Response: We believe this comment means to be asking about the issue of continuous eligibility and its impact on improper payment measurement. The eligibility workgroup will be addressing the issues of defining the universe, sampling techniques and other review variables regarding an eligibility error rate.

Comment: A few commenters argued that SCHIP participants who are eligible for Medicaid and vice versa should not be cited as totally ineligible and only the difference in the error amount between the two programs should be cited as an error for a service obtainable through both programs.

Response: We disagree with this comment because the IPIA requires estimates of improper payments for each program. As such, the rule provides for separate measurements of improper payments in Medicaid and SCHIP and would have cited the improper payment amount for the claim being reviewed.

Comment: A few commenters stated that some States will face difficulties with respect to coordination among agencies, record retention, and storage.

Response: We agree that the proposed rule presented States with many challenges for measuring improper payments in their programs. We believe adopting the recommendation to engage a Federal contractor to conduct medical reviews addresses many of the commenters' concerns and alleviates, to the extent reasonably possible, challenges that States would have faced.

Comment: A few commenters wanted to know how the MEQC findings would coordinate with the deadlines for reports to OMB for the following year, and any possible corrective action plans between agencies.

Response: The provisions of MEQC were not coordinated with or affected by the proposed rule. Based on the recommendations of the eligibility workgroup, we will address any coordination between MEQC and the eligibility reviews under IPIA in a subsequent issuance. Finally, we believe that States should have the flexibility to coordinate corrective action plans among their agencies as appropriate.

Comment: Most of the commenters expressed concern that if the proposed rule were implemented, the regulations could harm the coverage and well-being of low-income children, families, seniors, and people with disabilities in Medicaid and SCHIP by encouraging restrictive policies that could have made it harder for low-income beneficiaries to enroll and stay enrolled in Medicaid and SCHIP.

Response: Neither the proposed nor this interim final rule requires States to reduce or terminate a beneficiary's program benefits in any way or require States to impose more restrictive requirements that would create barriers to the programs. The eligibility workgroup will take into consideration the possible impact that any proposed recommendations for eligibility error rate measurement may have on beneficiaries, including this concern.

Comment: Many commenters were concerned that the restrictive policies that would require more participation by the recipients to prove eligibility, for example, providing documentation or attending interviews, would threaten enrollment simplification and access for beneficiaries and individuals who might have been eligible for Medicaid or SCHIP and could also increase the ''churning'' of recipients in and out of Medicaid or SCHIP coverage in cases where beneficiaries failed to complete the redetermination process, which would disrupt the patient-provider relationship, leading to higher health care costs and increasing the potential for quality concerns.

Response: The eligibility workgroup will take into consideration the possible impact that any proposed recommendations for eligibility error rate measurement may have on beneficiaries, including this concern.

Comment: Many commenters stated that the eligibility review, which would have required the beneficiary to be eligible on the date of service and provided no administrative period to allow for report of changes in beneficiary status, would have created a significant burden for beneficiaries of these programs and would likely have resulted in disenrollment of many eligible individuals and families.

Response: We disagree with this comment. The eligibility review is to verify eligibility at the time of service to determine whether the claim was correctly paid. The review would ask for the recipient's cooperation only if eligibility could not be verified through the case record review or through other sources. Recipients have a responsibility to cooperate in the eligibility determination process, whether at application, during redetermination or through a quality control review. Recipient cooperation during a MEQC review is longstanding. Also, the proposed rule would not have required States to terminate program eligibility as a result of the reviews. As such, we do not agree that the review would have created a significant burden for beneficiaries or resulted in disenrollment. When we determine the type of eligibility reviews for Medicaid and SCHIP to be implemented under IPIA, we will address this issue.

Comment: Many commenters expressed concern that the regulation would have barred reviewers from counting the ''administrative period'' which is currently used in MEQC to account for the time permitted for a person to submit changes in eligibility information and for the time for the State to process these data.

Response: We will consider this comment in the context of the workgroup in determining the best approach to eligibility reviews under the IPIA and we will address it in a subsequent document.

Comment: Many commenters noted that if eligibility reviews remained in PERM, CMS and the States would need to develop a system to review for errors in denials of eligibility or recertification,

in order to comply with the IPIA. They argued that the OMB guidance for IPIA stated that payment error estimates should include estimates of inappropriate denials of services; PERM included no efforts to measure erroneous denials of eligibility or to measure progress in serving eligible people.

Response: Current Federal regulations require States to review a sample of Medicaid denials and terminations under MEQC which helps protect beneficiaries against erroneous denials and terminations of Medicaid. SCHIP agencies can institute a similar review. OMB guidance did not include erroneous denials of eligibility as eligibility decisions do not always drive Medicaid or SCHIP payment. However, we will revisit this concern with the eligibility workgroup and will address it in a subsequent issuance.

E. Reporting and Recordkeeping

Comment: A few commenters stated that medical records do not lend themselves to replication for record retention, for example, x-rays, and asked if scanning is allowed for any and all records.

Response: Those States selected for reviews will submit information that the contractor will scan and retain. Therefore, States will not be required to retain this information for purposes of error rate measurements under the OMB guidance. The collection of this information is permitted (subject to privacy restrictions) under the HIPAA provisions and our regulations at 45 CFR Part 164.

Comment: In commenting on retaining records for Federal re-review or audits, a few commenters asked whether there will be some level of tolerance that will keep Federal re-reviews and audits from occurring. The commenters stated that it is becoming difficult to accommodate the various audits from internal and external sources.

Response: The proposed rule would have required States to retain records for Federal re-review and future audits on the basis that the States were conducting the reviews and calculating the State-specific error rates. However, since the records to support the medical determinations and the calculation of the State-specific error rates and the national error rate will be retained by the national contractor, the Federal re-reviews (for example, OIG review) will be conducted at the national contractor location(s).

Comment: A few commenters asked that the final rule verify the assumption that the States' electronic files and records meet the requirements of the rule regarding supporting the testing and statistical calculation of the Medicaid and SCHIP error rates.

Response: We would be unable to verify any assumption that States' documentation retained for purposes of supporting the error rate is adequate since we would have no control over what documentation the States retained and if States retained all documentation in good and full form for the required period of time. We are proposing that under our Federal contractor's methodology insufficient documentation to support a determination that the claim was correctly paid would be considered an error for the purposes of the IPIA.

F. Recoveries

Comment: A few commenters stated that the Federal share of any overpayment be returned within 60 days of the actual recovery of the payment, rather than identification of the payment, and that the States should decide whether pursuing recovery is cost effective since pursuing recoveries against providers on a claim-by-claim basis is administratively burdensome.

Response: As stated earlier, the requirement to return the Federal share of erroneous payments within 60 days of identification is longstanding in statute and regulation and does not allow for only cost-effective recoveries. The provisions of the recovery regulation were open to public comment at the time of its publication. It is outside the scope and intent of this regulation to amend provisions of separate, existing regulations.

Comment: A few commenters asked how the recovery is affected by the MEQC statute under which improper payments based on eligibility errors are recouped, particularly if a State is conducting MEQC pilots or has its MEQC program attached to its research and demonstration waiver under section 1115 of the Act.

Response: Improper payments based on eligibility determinations are subject to recovery under section 1903(u) of the Act which governs the MEQC program. Thus, these payments are not subject to recovery under section 1903(d)(2) of the Act.

Comment: A few commenters asked how erroneous eligibility determinations, though exempt from Medicaid overpayments, will be reported.

Response: The proposed rule did not exempt the reporting of erroneous eligibility determinations or overpayments on this basis. The proposed rule merely stated that section 1903(u) of the Act governs the recovery of overpayments based on eligibility errors. As stated in this interim final rule, we will determine the eligibility review process with the assistance of the workgroup and will respond to the reporting of improper eligibility determinations under the IPIA in a later document.

Comment: A few commenters recommended that CMS consider that overpayments may be part of fraud investigations and the Medicaid Fraud and Control Unit (MFCU) may not want State intervention in an active investigation.

Response: Because the proposed rule has been substantially altered through the use of a Federal contractor, State intervention in an active CMS fraud investigation is no longer a relevant issue. Conversely, the Federal contractor will not know which claims in the sample are under State fraud investigation nor would the contractor be working directly with the MFCUs during the course of the medical and data processing reviews.

Comment: A few commenters stated that, since States return the Federal share of overpayments, States should receive additional funds for underpayments.

Response: We agree with the commenters. States that make adjustments for underpayments would draw down the appropriate Federal matching funds.

Comment: A few commenters suggested that measuring improper payments in Medicaid and SCHIP should include adequate safeguards to prevent against repayments of Federal funds when genuine errors do not exist, for example, an incorrect date of service that, if corrected, would not affect the amount of payment.

Response: The recoveries provision in the proposed rule was a cross-reference to existing State requirements to refund the Federal share of payments when an overpayment occurred. It is outside the scope of this rule to make exceptions or changes to another regulation. Therefore, we are not adopting this recommendation in the interim final rule.

Comment: A few commenters recommended that States be required only to return the Federal share of any payments after all the overpayments and underpayments are taken into consideration.

Response: The proposed rule was not intended to make exceptions or changes to another regulation. Therefore, we are not adopting this recommendation.

Comment: A few commenters recommended that small overpayments

that resulted in an expanded investigation would reap more Federal share of funds returned. Therefore, the commenters recommend that overpayments should be returned as one large payment rather than two separate payments.

Response: We are unable to adopt this recommendation because it would violate the current requirement that States return the Federal share within 60 days of identification of an overpayment.

G. Appeals

Comment: A few commenters stated that the proposed rule is devoid of any discussion of provider notification and appeal rights when an error has been determined, nor does it provide an opportunity to appeal or indicate how the process would use the existing notification and appeals process for both beneficiaries and providers.

Response: Appeals procedures are not modified by this rule and therefore have not been addressed. To summarize, if the State retrospectively denied the claim, the provider could appeal the denial under the existing State appeal process. If the provider won the appeal, we would back the error out of the error rate calculation, either at the time of the error rate calculation or, for claims reviewed towards the end of the year, subsequent to the error rate calculation.

Regarding beneficiaries, we do not make payments to beneficiaries except in limited circumstances permitted by CMS regulation or policy, so we do not anticipate that they will be impacted by this rule. Also, States must, under current regulations at § 435.916, redetermine Medicaid eligibility prior to terminating program benefits. Therefore, the State cannot terminate program benefits based on any eligibility errors found through these reviews without first doing a redetermination. If the redetermination concludes the person is no longer eligible, the normal beneficiary appeals process would occur at that time. Similarly, the SCHIP program provides for beneficiaries to appeal any proposed termination action.

IV. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption ''PROVISIONS of the INTERIM FINAL RULE'' at the beginning of your comments.]

The IPIA requires the Secretary to annually review all programs and activities that are susceptible to significant improper payments, estimate the amount of improper payments, and report those estimates to the Congress. OMB has identified Medicaid and SCHIP as programs at risk for significant improper payments. Because of the wide variation in States' Medicaid and SCHIP programs due to the flexibility States have in developing coverage, eligibility determination policies, benefit, and reimbursement aspects of the programs, we rely on State-specific information to develop State-level estimates.

Based on comments and recommendations received on the August 27, 2004 proposed rule, we will adopt the recommendation to use a Federal contractor to estimate medical and data processing error rates for Medicaid and SCHIP based on reviews of adjudicated claims. By FY 2008, we expect to be compliant with the IPIA requirements. In FY 2006, we will use a Federal contractor to estimate improper payments from medical and data processing reviews in the fee-for-service component of Medicaid and establish a workgroup to make recommendations on the best approach for reviewing Medicaid and SCHIP eligibility within the confines of current statute and with minimal budgetary impact for purposes of meeting IPIA requirements to measure improper payments based on payments to ineligibles.

Under the national contracting strategy, a number of States will be selected for review. Our sampling methodology will ensure that each State will be selected once, and only once, every 3 years for each program. The error rates produced by this selection methodology will provide the State with a State-specific error rate estimated to be within 3 percent precision at the 95 percent confidence level.

The contractor will select a number of States to be reviewed. States selected for review will submit the previous year's claims data and expenditures, not already otherwise provided by CMS, after which the contractor will determine each State's sample size and the sample size for each stratum. These States also will submit quarterly adjudicated and stratified claims data to the contractors who will pull a statistically valid random sample, each quarter, by stratum. Based on previous estimates, the average sample size per State is expected to be 1,000 claims (based on a previous estimate of range of 800 to 1,200 claims per State).

The contractor will conduct medical and data processing reviews. Initially, the eligibility reviews will not be conducted. We will convene a workgroup that will consider the best approach to measure improper payments based on eligibility errors within the confines of current law and with minimal budgetary impact. It is possible that States will be required to conduct at least part of the eligibility tests, should the workgroup recommend it. Any additional requirements placed on States will be detailed in a subsequent issuance.

This interim final rule sets forth the State requirements to provide information to us for purposes of estimating medical and data processing improper payments in Medicaid and SCHIP. Section 1102 of the Act authorizes the Secretary to establish regulations as may be necessary for the efficient administration of the Medicaid and SCHIP programs. Medicaid law at section 1902(a)(6) of the Act and SCHIP law at section 2107(b)(1) of the Act require States to provide information necessary for the Secretary to monitor program performance. Through these statutory provisions, this interim final rule with comment period requires only those States selected for review to provide the contractor with the following information needed to monitor program performance by submitting, at a minimum, the following information:

- The previous year's claim data and expenditures, not already otherwise provided by CMS from which the contractor will stratify claims and determine sample sizes.
- Quarterly adjudicated and stratified claims data from the review year that are needed to select a random sample of claims for review in each State.
- All medical policies in effect and quarterly medical policy revisions needed to review claims.
- Systems manuals needed for data processing reviews.
- Current provider contact information; verified and/or updated as necessary to have providers submit medical records needed for medical reviews.
- Repricing of claims the contractor determines to be in error.
- Claims that were included in the sample, but the adjudication decision changed due to the provider appealing the determination and the State overturning the original decision.
- An annual report on corrective actions to reduce the error rate.
- Other information that the Secretary determines is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP.

States selected for review also will provide technical assistance as needed to allow the contractor to fully and effectively perform all functions necessary to produce the program error rates.

In addition, regulations at § 430.35 and § 457.204 govern State compliance with Federal requirements in Medicaid and SCHIP, either because the State plan does not comply with Federal requirements or because the State is not complying in practice. Under these regulations, the Administrator notifies a State that it is in noncompliance with a particular regulation and that no further payments will be made to the State or that only partial payments will be made, that is, in areas not affected by the noncompliance, until the Administrator is satisfied that the State has come into compliance. The Administrator has the discretion to enforce these regulations in instances when States do not cooperate in a timely and efficient manner with us in producing Medicaid and SCHIP program error rates for IPIA purposes. Finally, section 1902(a)(27) of the Act requires providers to retain records necessary to disclose the extent of services provided to individuals receiving assistance and furnish the Secretary with information regarding any payments claimed by the provider for furnishing the services as the Secretary may request.

This interim final rule with comment period does not require States to estimate the annual total improper medical and data processing payments and produce payment error rates in Medicaid and SCHIP using the methodology described in the proposed rule. The provisions of this interim final rule with comment period will be set forth in 42 CFR part 431, subpart Q and in part 457, subpart G, as in the proposed rule, with the following changes:

Section 431.950 in the proposed rule would have required States to estimate improper payments and produce payment error rates in Medicaid and SCHIP. This section will be revised by the interim final rule with comment period to state that the purpose of the rule is to require States to submit information necessary to enable the Secretary to produce a national improper payment error rate for the Medicaid and SCHIP programs. This interim final rule includes the types of information that States would need to submit in order for CMS to estimate improper payments in Medicaid fee-for-service (FFS) beginning in FY 2006 by conducting medical and data processing reviews on claims made in the FFS setting. CMS will address estimating improper payments for Medicaid managed care and eligibility and SCHIP FFS, managed care and eligibility at a later time.

Section 431.954(a) in the proposed rule set forth the statutory basis for the Secretary's general rulemaking authority and the States' obligation to provide information for monitoring program performance. This section will be revised to add the statutory reference of section 1902(a)(27) of the Act, which requires providers to retain and provide medical records necessary to disclose the extent of services provided to individuals receiving assistance and any payments claimed by the provider for furnishing the services as the Secretary may request.

Section 431.954(b) in the proposed rule would have set forth the scope of the statutory provisions as requiring States to annually estimate total Medicaid and SCHIP improper payments in their States and submit to the Secretary the payment error rates. This section will be revised by the interim final rule with comment period to set forth the types of information that the States and providers are required to submit to the Secretary for the purposes of estimating improper payments in Medicaid and SCHIP.

Section 431.958 which, in the proposed rule, would have set forth the definitions and use of terms, will be revised by the interim final rule to strike all definitions except the following definitions: improper payment; payment; and payment error rate.

Section 431.962 in the proposed rule would have set forth the State plan requirements for providing and submitting to the Secretary estimates of the payment error rates for Medicaid and SCHIP. This section is removed in the interim final rule because States are no longer required to submit estimates of the payment error rates for Medicaid and SCHIP. However, existing Medicaid and SCHIP regulations require: (1) State plans to include assurance that the State collects data, maintains records and furnishes reports to the Secretary (see § 457.720 for SCHIP and § 431.16 and § 431.17 for Medicaid; and, (2) that the SCHIP and Medicaid programs must include methods of administration that the Secretary finds necessary for the proper and efficient operation of the program (see § 457.910 for SCHIP and § 431.15 and § 435.903 for Medicaid). Therefore, to avoid States incurring additional cost and burden, we believe it is not necessary to require States to submit new State plan material requiring submission of information to the Secretary since we believe these requirements are covered under these current regulations and are included in this interim final rule.

Section 431.970 in the proposed rule would have set forth the requirement that States provide annually to the Secretary payment error rates for both Medicaid and SCHIP. That section is replaced by a new § 431.970 in this interim final rule with comment period to specify the information that States would be required to provide to the Secretary that is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP and for submitting a corrective action report for purposes of reducing the error rate.

Sections 431.974, 437.978, 437.982, 431.986, and 431.990, which prescribe the basic elements of PERM and set forth the methodology by which States would sample and review claims, report the error rates, and retain records are removed.

Section 431.1002 in the proposed rule reiterates for the reader's convenience current regulations at § 433.312 that requires States to return the Federal share of overpayments identified through the State reviews. This section is revised in the interim final rule with comment period to remove the phrase ''in the sampled claims reviewed for data processing and medical necessity'' and to cross-reference the existing regulatory requirement for States to return the Federal share of overpayments within 60 days of identification. This section is for the reader's convenience only and is not intended to revise the existing regulatory requirement at § 433.312.

Section 457.720 is revised to include the same requirements in this section that are included in § 431.970.

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.

Therefore, we are soliciting public comment on each of these issues for the following sections of this document that

contain information collection requirements:

Section 431.970 of this document contains information collection requirements. This section sets forth requirements for States to provide information to us for purposes of estimating medical and data processing improper payments in Medicaid and SCHIP. Only those States selected for review will be required to provide the contractor, at a minimum, with the following information needed to monitor program performance:

- The previous year's claim data and annual expenditures, not already otherwise provided by CMS, from which the contractor will stratify claims and determine sample sizes.
- Quarterly adjudicated and stratified claims data from the review year that are needed to select a random sample of claims for review in each State.
- All medical policies in effect and quarterly medical policy revisions needed to review claims.
- Systems manuals needed for data processing reviews.
- Current provider contact information; verified and/or updated as necessary to have providers submit medical records needed for medical reviews.
- Repricing of claims the contractor determines to be in error.
- Claims that were included in the sample, but the adjudication decision changed due to the provider appealing the determination and the State overturning the original decision.
- An annual report on corrective actions to reduce the error rate.
- 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 associated with this requirement is the time and effort necessary for States to collect this information and provide it to the Federal contractor. The number of respondents is estimated to be up to 36 States (up to 18 Medicaid and up to 18 SCHIP States). The annualized number of hours that may be required to respond to the requests for information equals 58,680 hours (1630 hours per State per program).

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to the Office of Management and Budget (OMB) for its review of these information collection requirements.

A notice of this 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 public display). The shortened timeframe for public comment is essential so that CMS can proceed with data collection from States and providers by October 2005 to meet the deadlines for reporting national Medicaid error rate to Congress.

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: William Parham 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–IFC, *KAstrich@omb.eop.gov*. Fax (202) 395–6974.

VI. Response to Comments

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

VII. Regulatory Impact Statement

[If you choose to comment on issues in this section, please include the caption ''REGULATORY IMPACT STATEMENT'' at the beginning of your comments.]

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). We estimate that it will cost up to $11.16 million in Federal funds for a Federal contractor to estimate Medicaid FFS error rates in up to 18 States. Contingent on available funds, we plan to implement reviews to produce a Medicaid FFS error rate to be reported in the FY 2007 PAR.

We estimated it would cost $620,000 per State per program based on a cost of $360 per claim multiplied by an average of 1,000 claims plus $260,000 for travel and other administrative expenses. Based on $620,000 per State to estimate error rates in Medicaid and $620,000 per State to estimate error rates in SCHIP, error rate estimates for up to 18 States would cost a total of up to $22.3 million (up to $11.16 million in each program).

Since we have not determined the type of eligibility review that will be done to gather eligibility error rates under IPIA, we cannot state for certain what State and Federal costs will be added to the approximate $22.3 million Federal amount. We have determined that the interim final rule with comment period will not exceed the annual $100 million threshold impact criterion and an impact analysis is not required under E.O. 12866.

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. A request for medical documentation to substantiate a claims payment is not a burden to individual providers nor is the request outside the customary and usual business practice of a Medicaid and/or SCHIP provider. Not all States will be reviewed every year so it is highly unlikely for a provider to be selected more than once, per program per year to provide supporting documentation. In addition, the information should be readily available and the response should take minimal time and cost since the response requires gathering the documents and either copy and mail them, send by facsimile or transmit electronically. Therefore, the request for medical documentation from 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 Core-Based 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 and/or SCHIP provider, we estimate these costs would not be outside the usual and customary business practice nor do we anticipate that a great number, if any, small rural hospitals would be asked for medical records. As stated above, not all States will be reviewed every year so it is highly unlikely for a provider to be selected more than once, per program per year to provide supporting documentation. Therefore, 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 $110 million. In the proposed rule, we estimated that the total computable cost will range from $1 million to $2 million (total computable) for States to measure Medicaid and SCHIP error rates. States commenting on the proposed rule estimated the costs to be higher, and a few States estimated the costs at three times that amount. In this interim final rule with comment period, we are not requiring States to measure the error rates but rather are using a national contractor. This rule is not imposing a cost on States to produce the error rates but rather requires States and providers to submit information already on hand to the contractor so that activities needed to estimate the error rates can be performed. Since the information is on hand and States and providers are not being required to develop new materials, the costs associated with submitting information are for copying and mailing the information although States and providers have the option to send the information electronically. Finally, States will be required to develop, submit and implement corrective action plans designed to reduce the error rates, if necessary.

Under the proposed rule the costs could have been as high as $6 million total computable by States' estimation to conduct reviews and calculate States' error rates. This interim final rule with comment period eliminates all but two of the State requirements contained in the proposed rule. As the interim final rule with comment period drastically reduces the costs and burden to States, we do not anticipate State costs to exceed $110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs 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 than this interim final rule with comment period, had an estimated costs of $1 million to $2 million per State. As the remaining costs will be significantly lower than these, we assert this regulation will not have a substantial impact on State or local governments.

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.

B. Anticipated Effects

The interim final rule with comment period is intended to measure errors in Medicaid and SCHIP. States would implement corrective actions to reduce the error rate, thereby producing savings. However, 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 proposed rule and adopted the recommendations for a Federal contractor to review a subset of States. We considered the other alternatives to be not viable or were not the best approach to meet the requirements of the law. If sufficient data are available to estimate these impacts in the final rule, it will be included there. In constructing the methodology to measure Medicaid and SCHIP error rates, we considered other alternatives. We considered different sampling methods in an effort to meet both the requirements in OMB guidance and our goal of being able to compare error rates from year to year while providing States with advance knowledge of when they would be selected for review. We considered random sampling, rotational sampling, sampling on a stratified probability proportional to size and randomly selecting States based on probability proportional to size. We concluded that statistically valid (random) sampling and a stratified or random probability proportional to size basis would meet OMB guidelines but would not provide States with the desired predictability of selection.

In FY 2006, the Federal contractor will group all States into three equal strata of small, medium and large based on States' annual FFS Medicaid expenditures from the previous year, and select a random sample of an estimated 18 States to be reviewed. The error rates produced by this selection methodology will provide the State with a State-specific error rate estimated to be within 3 percent precision at the 95 percent confidence level. For subsequent years, our sampling methodology will ensure that each State will be selected once, and only once, every 3 years for each program.

Regarding the eligibility reviews, because the majority of the cost and burden are attributable to verifying eligibility, we considered limiting the reviews to confirming that persons were actually enrolled in the program at the time of service. We considered augmenting this review with strengthening the current MEQC eligibility oversight activities. However, we determined that an eligibility workgroup should be convened to make recommendations on the best approach to Medicaid and SCHIP eligibility reviews. We plan to have recommendations from the workgroup in FY 2006 so that eligibility reviews can commence in FY 2007 for error rate reporting in the FY 2008 PAR.

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 ADMINSTRATION

■ 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 adding new subpart Q to read as set forth below:

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.
431.1002 Recoveries.

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

§ 431.950 Purpose.

This subpart requires States to submit information necessary to enable the Secretary to produce a national improper payment estimate 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 annually review and identify those programs and activities that may be susceptible to significant erroneous payments, estimate the amount of improper payments, and report those estimates to the Congress and, submit a report on actions the agency is taking to reduce erroneous payments. Section 1902(a)(27) of the Act requires providers to retain records necessary to disclose the extent of services provided to individuals receiving assistance and furnish the Secretary with information regarding any payments claimed by the provider for furnishing services, as the Secretary may request.

(b) *Scope.* This subpart requires States under the statutory provisions in paragraph (a) of this section to submit Medicaid and SCHIP expenditures and claims data, medical policies, data processing manuals and other information as necessary for, among other purposes, estimating improper payments in Medicaid and SCHIP. This subpart also requires States to submit corrective action reports as prescribed by the Secretary for purposes of reducing their payment error rates. This subpart also requires providers to submit medical records and other information necessary to disclose the extent of services provided to individuals receiving assistance and furnish the information regarding any payments claimed by the provider for furnishing the services, to the Secretary as requested.

§ 431.958 Definitions and use of terms.

As used in this subpart, the following definitions apply:

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.

Payment means any payment to a provider, insurer, or managed care organization for a Medicaid or SCHIP recipient for which there is Medicaid or SCHIP Federal financial participation. It may also mean a direct payment to a Medicaid or SCHIP recipient 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 (including payments to ineligible recipients) and underpayments, that is, the absolute value, expressed as a percentage of total payments made over the sampling period.

§ 431.970 Information submission requirements.

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—

(a) Claims data and annual expenditures from previous year;

(b) Quarterly, stratified adjudicated claims data from the review year;

(c) All medical and other policies in effect and quarterly updates as needed to perform claims reviews;

(d) Data processing systems manuals;

(e) Current provider contact information that is verified and/or updated to contain current provider contact information;

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

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

(h) A corrective action report as prescribed by the Secretary for purposes of reducing the payment error rate.

§ 431.1002 Recoveries.

States must return to CMS the Federal share of overpayments identified within 60 days 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 exempt from this provision because they are addressed under section 1903(u) of the Act and related regulations at part 431, subpart P of this chapter.

SUBCHAPTER D—STATE CHILDREN'S HEALTH INSURANCE PROGRAM

PART 457—ALLOTMENTS AND GRANTS TO STATES

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

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

Subpart G—Strategic Planning, Reporting, and Evaluation

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

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

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. 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: August 16, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 22, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–19910 Filed 9–30–05; 11:03 am]

BILLING CODE 4120–01–P