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Wednesday, August 11, 2010

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 447, and 457

Medicaid Program and Children's Health Insurance Program (CHIP); Revisions to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 447, and 457

[CMS-6150-F]

RIN 0938-AP69

Medicaid Program and Children's Health Insurance Program (CHIP); Revisions to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS. **ACTION:** Final rule.

SUMMARY: This final rule implements provisions from the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3) with regard to the Medicaid Eligibility Quality Control (MEQC) and Payment Error Rate Measurement (PERM) programs. This final rule also codifies several procedural aspects of the process for estimating improper payments in Medicaid and the Children's Health Insurance Program (CHIP).

DATES: *Effective Date:* These regulations are effective on September 10, 2010. FOR FURTHER INFORMATION CONTACT: Elizabeth Lindner, (410) 786–7481. Jessica Woodard, (410) 786–9249. SUPPLEMENTARY INFORMATION:

I. Background

A. Medicaid Eligibility Quality Control Program

The Medicaid Eligibility Quality Control (MEQC) program is set forth in section 1903(u) of the Social Security Act (the Act) and requires States to report to the Secretary the ratio of States' erroneous excess payments for medical assistance to total expenditures for medical assistance. Section 1903(u) of the Act also sets a 3-percent threshold for improper payments in any fiscal year and the Secretary may withhold payments to States based on the amount of improper payments that exceed the threshold. The traditional MEQC program is based on State reviews of Medicaid cases identified through a statistically reliable Statewide sample of cases selected from the State's eligibility files and excludes separate CHIP programs. These reviews are conducted to determine whether the sampled cases meet applicable Medicaid eligibility requirements.

B. The Improper Payments Information Act of 2002

The Improper Payments Information Act of 2002 (IPIA), (Pub. L. 107-300, enacted on November 26, 2002) requires the heads of Federal agencies to annually review programs they oversee to determine if they are susceptible to significant erroneous payments. If any programs are found to be susceptible to significant improper payments, then the agency must estimate the amount of improper payments, report those estimates to the Congress, and submit a report on actions the agency is taking to reduce erroneous expenditures. The IPIA directed the Office of Management and Budget (OMB) to provide guidance on implementation. OMB defines "significant erroneous payments" as annual erroneous payments in the program exceeding both 2.5 percent of program payments and \$10 million (OMB M–06–23, Appendix C to OMB Circular A-123, August 10, 2006). For those programs found to be susceptible to 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.

The Medicaid program and the Children's Health Insurance Program (CHIP) were identified as programs at risk for significant erroneous payments. The Department of Health and Human Services (DHHS) reports the estimated error rates for the Medicaid and CHIP programs in its annual Agency Financial Report (AFR) to Congress.

C. Regulatory History

1. Medicaid Eligibility Quality Control Program

Sections 431.800 through 431.865 set forth the regulatory requirements for States to conduct the annual MEQC measurement. Currently, the MEQC program consists of the following:

• MEQC traditional—Operating MEQC under § 431.800 through § 431.865 and selecting a random sample of all Medicaid applicants and enrollees and reviewing them under guidance in the State Medicaid Manual.

• MEQC pilots—Operating MEQC under a special study or a target population and providing oversight to reduce and prevent errors and improve program administration.

• MEQC waivers—Operating MEQC as a part of a CMS approved section 1115 waiver and reviewing beneficiaries included in the research and demonstration project.

2. Payment Error Rate Measurement (PERM) Program

Section 1102(a) of the Act authorizes the Secretary to establish such rules and regulations as may be necessary for the efficient administration of the Medicaid and CHIP programs. The Medicaid statute at section 1902(a)(6) of the Act and the CHIP statute at section 2107(b)(1) of the Act require States to provide information that the Secretary finds necessary for the administration, evaluation, and verification of the States' programs. Also, section 1902(a)(27) of the Act (and §457.950 of the regulations) requires providers to submit information regarding payments and claims as requested by the Secretary, State agency, or both. Under the authority of these provisions, we published a proposed rule in the August 27, 2004 Federal Register (69 FR 52620) to comply with the requirements of the IPIA and the OMB guidance. The proposed rule set forth provisions for all States to annually estimate improper payments in their Medicaid and CHIP programs and to report the State-specific error rates for purposes of our computing the national improper payment estimates for these programs.

In the October 5, 2005 **Federal Register** (70 FR 58260), we published an interim final rule with comment period (IFC). The IFC responded to public comments on the proposed rule, and informed the public of our national contracting strategy and of our plan to measure improper payments in a subset of States. Our State selection process ensures that a State is measured once, and only once, every 3 years for each program.

In response to the public comments from the October 5, 2005 IFC, we published a second IFC in the August 28, 2006 Federal Register (71 FR 51050). The IFC reiterated our national contracting strategy to estimate improper payments in both Medicaid and CHIP fee-for-service (FFS) and managed care, and set forth and invited further comments on State requirements for estimating improper payments due to errors in Medicaid and CHIP eligibility determinations. We also announced that a State's Medicaid and CHIP programs would be reviewed in the same year.

In the August 31, 2007 **Federal Register** (72 FR 50490), we published a final rule for the PERM program, which implements the IPIA requirements. The August 31, 2007 final rule responded to the public comments on the August 28, 2006 IFC and finalized State requirements for submitting claims to the Federal contactors that conduct FFS and managed care reviews. The August 31, 2007 final rule also finalized State requirements for conducting eligibility reviews and estimating payment error rates due to errors in eligibility determinations.

D. Children's Health Insurance Program Reauthorization Act of 2009

On February 4, 2009, the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3) was enacted. (Please note, as a result of this legislation, the program formerly known as the "State Children's Health Insurance Program (SCHIP)" is now referred to as the "Children's Health Insurance Program (CHIP)"). Sections 203 and 601 of the CHIPRA relate to the PERM and MEQC programs.

Section 203 of the CHIPRA establishes an error rate measurement with respect to the enrollment of children under the Express Lane Eligibility option. The law directs States not to include children enrolled using the Express Lane Eligibility option in data or samples used for purposes of complying with the MEQC and PERM requirements. Provisions for States' Express Lane Eligibility option will be set forth in a future rulemaking document.

Section 601(a) of the CHIPRA provides for a 90 percent Federal match for CHIP expenditures related to PERM administration and excludes such expenditures from the 10 percent administrative cap. (Section 2105(c)(2) of the CHIP statute gives States the ability to use an amount up to 10 percent of the CHIP benefit expenditures for outreach efforts, additional services other than the standard benefit package for low-income children, and administrative costs.)

The CHIPRA requires a new PERM rule and delays any calculation of a PERM error rate for CHIP until 6 months after the new PERM rule is effective. Additionally, the CHIPRA provides that States that were scheduled for PERM measurement in fiscal year (FY) 2007 may elect to accept a CHIP PERM error rate determined in whole or in part on the basis of data for FY 2007, or may elect instead to consider its PERM measurement conducted for FY 2010 as the first fiscal year for which PERM applies to the State for CHIP. Similarly, the CHIPRA provides that States that were scheduled for PERM measurement in FY 2008 may elect to accept a CHIP PERM error rate determined in whole or in part on the basis of data for FY 2008, or may elect instead to consider its PERM measurement conducted for FY 2011 as the first fiscal year for which PERM applies to the State for CHIP.

The CHIPRA requires that the new PERM rule include the following:

• Clearly defined criteria for errors for both States and providers.

• Clearly defined processes for appealing error determinations.

• Clearly defined responsibilities and deadlines for States in implementing any corrective action plans.

• A provision that the payment error rate for a State will not include payment errors based on a State's verification of an applicant's self-declaration if a State's self-declaration verification policies meet regulations promulgated by the Secretary or are approved by the Secretary.

• State-specific sample sizes for application of the PERM requirements to CHIP PERM.

In addition, the CHIPRA shall harmonize the PERM and MEQC programs and provides States with the option to apply PERM data resulting from its eligibility reviews for meeting MEQC requirements and vice versa, with certain conditions.

E. CMS Response to the CHIPRA

As required by the CHIPRA, we proposed revised MEQC and PERM provisions in the proposed rule published in the July 15, 2009 **Federal Register** (74 FR 34468).

Section 601(b) of the CHIPRA states that "the Secretary shall not calculate or publish any national or State-specific error rate based on the application of the payment error rate measurement (in this section referred to as 'PERM') requirements to CHIP until after the date that is 6 months after the date on which a new final rule (in this section referred to as the 'new final rule') promulgated after the date of the enactment of this Act and implementing such requirements in accordance with the requirements of subsection (c) is in effect for all States." The CHIP error rate for the FY 2008 cycle was scheduled to be published in the FY 2009 Agency Financial Report (in November 2009), which was less than 6 months after the expected promulgation and effective date of this new final rule. Therefore, the publication of any CHIP error rates for FY 2008 (for States that elect to accept FY 2008 as their first CHIP measurement under PERM) is delaved until at least 6 months after the effective date of this final rule implementing the CHIPRA requirements for PERM.

As noted previously, section 601(d) of the CHIPRA provides that States that were scheduled for PERM measurement in FY 2007 may elect to accept a CHIP PERM error rate determined in whole or in part on the basis of data for FY 2007, or may elect instead to consider its PERM measurement conducted for FY 2010 as the first fiscal year for which PERM applies to the State for CHIP. In addition, the CHIPRA provides that States that were scheduled for PERM measurement in FY 2008 may elect to accept a CHIP PERM error rate determined in whole or in part on the basis of data for FY 2008, or may elect instead to consider its PERM measurement conducted for FY 2011 as the first fiscal year for which PERM applies to the State for CHIP.

Accordingly, a State measured in the FY 2007 cycle that elects to accept the PERM error rate for its CHIP program determined in whole or in part on the basis of data for FY 2007 is required to notify us of its intentions through an acceptance form to be provided to all States in a forthcoming State Health Official letter. Similarly, a State measured in the FY 2008 cycle that elects to accept the PERM error rate for its CHIP program determined in whole or in part on the basis of data for FY 2008 is required to notify us of its intentions through an acceptance form to be provided to all States in a State Health Official letter. If a State measured in the FY 2007 or FY 2008 cycles elects to reject the CHIP PERM rate determined during those cycles, they do not need to notify CMS of this decision. However, information from those cycles will not be used to calculate the State-specific sample sizes and we will rely on the standard assumptions for determining sample size.

It should be noted that immediately after the enactment of CHIPRA, we suspended all CHIP measurement cycles (FY 2008, FY 2009, and FY 2010). Due to the timing of the publication of this final rule for PERM, we decided that CHIP PERM will begin again with the FY 2011 measurement cycle and no retroactive reviews will be done for FYs 2009 and 2010. For this reason, States measured in FY 2007 will not have FY 2010 measured, but will be measured again in FY 2013 and will have the option to consider FY 2013 as their first or second measurement cycle for CHIP PERM as described previously.

In order for section 601(d) of the CHIPRA to be read in harmony with the IPIA, which requires a PERM error rate to be calculated annually, we believe that the appropriate reading of section 601(d) of the CHIPRA, construing the law as a whole and giving effect to all language of the CHIPRA, is that a State may only elect to reject the PERM error rate for the State's CHIP program for FY 2007 or FY 2008. A State scheduled for PERM measurement in FY 2008 still had its PERM error rate for its Medicaid program measured.

Additionally, the FY 2009 and FY 2010 Medicaid measurements are proceeding with no delays as a result of the CHIPRA. The FY 2009 Medicaid measurement was conducted according to the policies in the August 31, 2007 final rule (72 FR 50490) because the measurement process was complete prior to the publication of this rule. The FY 2010 Medicaid measurement is currently underway; therefore, parts of the measurement process that have already taken place prior to the publication of this final rule (that is, universe submission and sample size determination) will not be repeated once the final rule is effective. However, for parts of the measurement that have vet to be completed (that is, medical and data processing review, error rate calculation, corrective action plans, etc) the policies of this final rule will apply. We do not intend to recalculate any Medicaid error rates already calculated or published prior to the effective date of this final rule.

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

As a result of the CHIPRA, we proposed a nomenclature change to parts 431, 447, and 457. We revised current regulatory language to reflect the change made by the CHIPRA to refer to the program formerly known as the "State Children's Health Insurance Program (SCHIP)" as the "Children's Health Insurance Program (CHIP)." We also proposed the following revisions to the current PERM provisions:

A. Sample Sizes

Section 601(f) of the CHIPRA requires us to establish State-specific sample sizes for application of the PERM requirements with respect to CHIP for fiscal years beginning with the first fiscal year that begins on or after the date on which the new final rule is in effect for all States, on the basis of such information as the Secretary determines appropriate. In establishing such sample sizes, the Secretary shall, to the greatest extent practicable: (1) Minimize the administrative cost burden on States under Medicaid and CHIP; and (2) maintain State flexibility to manage such programs.

To comply with the IPIA, the PERM program must estimate a national Medicaid and a national CHIP error rate that covers the 50 States and District of Columbia. Consistent with OMB's precision requirements defined in its IPIA guidance, the estimated national error rate for each program must be

bound by a 90 percent confidence interval of 2.5 percentage points in either direction of the estimate. Since States administer Medicaid and CHIP and make payments for services rendered under the programs, we collect State-level information at a high level of confidence (the estimated error rate for a State should be bound by a 95 percent confidence interval of 3 percentage points in either direction). To estimate the national error rate, as well as Statespecific error rates, reviews are conducted in three areas for both the Medicaid and CHIP programs: (1) FFS; (2) managed care, and (3) program eligibility. The FFS and managed care reviews are referred to jointly as the "claims review," while the program eligibility review is referred to as the "eligibility review."

Samples of payments made on a FFS and managed care basis for the claims review and samples of beneficiaries for the eligibility review are drawn each year in order to calculate a national error rate that meets the precision requirements described in OMB Guidance (OMB M-06-23, Appendix C to OMB Circular A-123, August 10, 2006). The preferred method is to achieve the precision goal with the smallest sample size possible, so as to reduce the burden on States, the Federal government, beneficiaries, and providers. We determined that the most efficient method, statistically, is to draw a sample of States and then draw a sample of payments from the payments made by the sampled States. The process for drawing a sample of States is described in detail in the preamble to the August 31, 2007 final rule (72 FR 50490). We did not propose modifications to the current approach, which samples 17 States per year for a PERM measurement cycle. The proposed rule addressed the Statespecific sample sizes for samples of claims and beneficiaries within a State.

In response to the new CHIPRA requirements, we proposed to add new §431.972, to describe more fully the claims sampling procedures used for the claims review. In addition, we proposed to more fully describe the process for establishing State-specific sample sizes for PERM, although we note that the execution of these responsibilities would remain with CMS and the Federal contractors, not with the States. Under the Secretary's authority at section 1102(a) of the Act and in order to effectively implement the IPIA, we also proposed that these sampling procedures apply to both Medicaid and CHIP.

We proposed to revise §431.978 to provide additional guidance on State

Medicaid and CHIP eligibility sample sizes by clarifying the process for establishing State-specific sample sizes.

1. Fee-for-Service (FFS) and Managed Care

a. Universe Definition

In order to implement the IPIA and related requirements (OMB M-06-23, Appendix C to OMB Circular A-123, August 10, 2006) that require Federal agencies to estimate the amount of improper payments in programs with significant erroneous payments (which includes Medicaid and CHIP), in the current § 431.970(a)(1) we require States to submit "[a]ll adjudicated FFS and managed care claims information, on a quarterly basis, from the review year," so that a sample of payments can be reviewed and from the review findings we can estimate the amount of improper payments in each program. We proposed to remove the word "all" from § 431.970(a)(1) because certain types of payments are excluded from PERM sampling and review for technical reasons. The methodology developed by us to measure improper payments in Medicaid and CHIP focuses on payments made on behalf of or for individual beneficiaries. Accordingly, PERM has excluded certain payments for services not provided to individual beneficiaries such as Disproportionate Share Hospital (DSH) payments to facilities, grants to State agencies or local health departments, and costbased reconciliations to non-profit providers and Federally-Qualified Health Centers (FQHCs) because the basis of the payment cannot be traced back to an individual beneficiary. This exclusion from PERM sampling was further clarified through instructions issued by CMS to the States at the beginning of each measurement cycle starting with FY 2006.

For the PERM claims review component, the "claims universe" is defined in the new §431.972 as including payments that were originally paid (paid claims) and for which payment was requested but denied (denied claims) during the Federal fiscal year, and for which there was Federal financial participation (FFP) (or would have been if the claim had not been denied) through Title XIX of the Act (Medicaid) or Title XXI of the Act (CHIP). Depending on the context in which it is used, the claims universe may refer to either the adjudicated FFS claims during the fiscal year under review, or the managed care capitation payments made during the fiscal year under review, for Medicaid or CHIP. We are reiterating our long standing

position that, for PERM purposes, managed care claims are payments made by the State to entities with comprehensive risk contracts that assume full or partial risk for enrolled beneficiaries. FFS claims are claims other than managed care claims. CMS and our contractors may assign certain payments to the PERM FFS or managed care universe in order to ensure consistency across States and across cycles. Given the wide range of payment methodologies employed by States for similar programs, as well as the fact that State definitions of FFS and managed care may not align with PERM definitions as described previously, CMS and our contractors must maintain some flexibility in assigning payments to either FFS or managed care.

Due to the significant variation in State systems for processing, paying, and claiming reimbursement for medical services under Medicaid and CHIP, we did not propose to include a more specific claims universe description in regulation. Rather, States should refer to more detailed claims universe specifications that will be published by us in separate instructions at the beginning of each PERM measurement cycle. However, we proposed that States must establish controls to ensure that the FFS, managed care, and eligibility universes are complete and accurate. For example, this would include the comparisons between the PERM universes and the State's Form CMS-64 and Form CMS-21 financial reports. We are placing this requirement in the regulatory text at §431.972(a)(2).

b. Stratification

In FY 2006, we measured only the error rate for the FFS component of Medicaid. To obtain the required precision levels while minimizing the sample size, and therefore reducing the burden on States, the claims universe for FFS payments for Medicaid was stratified by service category and a stratified random sample was drawn for each State. In FY 2007 and beyond, we measure the error rates for Medicaid FFS, Medicaid managed care, CHIP FFS, and CHIP managed care separately (to the extent that a State has each of these programs). We also stratify each universe by dollars rather than service category.

Under this stratification and sampling approach, all payments in each universe are sorted from largest to smallest payment amounts. The payments are then divided into strata such that the total payments in each stratum are the same. For example, if five strata are used, the total dollars in each stratum

would equal 20 percent of the total dollars in the universe. The first stratum would contain the highest dollar-valued payments, and the last stratum would contain the smallest dollar-valued payments, including all zero-paid and denied claims (denials have a zero dollar amount, and therefore, would appear in the stratum with the smallest dollar values). An equal number of FFS claims or managed care payments are then drawn from each stratum, which means the sample would include proportionately more high-dollar payments and proportionately fewer low-dollar payments and denials, compared to their representation in the universe. This overweighting of higherdollar payments (which is taken into account when calculating error rates) enables us to draw a smaller sample size that has a reasonable probability of meeting the precision requirements, compared to a perfectly random sample or a sample stratified by service type. Similarly, it reduces the risk that a single very large claim will have a dominant effect on the error rate. In this manner, we reduce burden on States. the Federal government, beneficiaries, and providers.

c. Sample Size

In order to establish State-specific sample sizes, we proposed that the annual sample size in a State's first PERM cycle (referred to as "initial sample" or "base sample") would be 500 FFS claims and 250 managed care payments.

We determined this initial sample size based on the experience of the PERM pilot study, PERM measurement in FY 2008 and FY 2009, and our requirement that the estimated error rate for a State should be bound by a 95 percent confidence interval of 3 percentage points in either direction. Specifically, the sample size is calculated assuming that the universe is "infinite" and the error rate for FFS is 5 percent and the error rate for managed care is 3 percent. (Once the universe contains more than approximately 10,000 sampling units, it can be treated as if it were infinite. Statistically speaking, beyond a universe of approximately 10,000 sampling units, universe size does not affect sample size.) Using these assumptions and historical information on payment variation in FFS and managed care from previous PERM cycles, we have determined that an annual sample of 500 FFS and 250 managed care payments per State per program should meet our State-level precision requirements with reasonable probability.

However, States with Medicaid or CHIP PERM universes under 10,000 line items or capitation payments can notify us in order to have an annual sample size smaller than the base sample size in the initial PERM year or future years. While the universe can be treated as if it were infinite if its size exceeds 10,000 sampling units, if the total universe from which the total (full year) sample is drawn is less than 10,000 sampling units, the sample size may be reduced by the finite population correction factor. The finite population correction is a statistical formula utilized to determine sample size where the population is considered finite rather than infinite. Starting with the FY 2011 measurement cycle, a State that anticipates that the total number of payments in the FFS or managed care universe for either Medicaid or CHIP will be less than 10,000 payments over the Federal fiscal year may notify us before the fiscal year being measured and include information on the anticipated universe size for their State. Our contractor will develop a modified sampling plan for that program in that State.

The State-specific annual sample size in the base PERM year is based on an assumed error rate of 5 percent. If a State's actual PERM error rate in a cycle reveals that precision goals can be achieved in future PERM cycles with either lower or higher sample sizes than indicated by the original assumptions, sample sizes after the first PERM cycle may vary among States according to each State's demonstrated ability, based on PERM experience, to meet desired precision goals.

In subsequent years, we will provide our contractor with information on each State's error rate and payment variation in the previous cycle. Our contractor will review each State's prior PERM cycle claims error rate and payment variation to determine if a smaller or larger claims sample size will be required to meet the precision goal established for that PERM cycle. Our contractor will develop a State-specific sample size for each program in each State. If information from a previous cycle is not available for a particular State or program within the State, the contractor will use the "base sample" size of 500 FFS claims and 250 managed care payments. For States measured in the FY 2007 or FY 2008 cycle that elect to accept their State-specific CHIP PERM error rate determined during those cycles, FY 2007 or FY 2008 would be considered their first PERM cycle for purposes of sample size calculation for CHIP. Therefore, these States would be considered for an adjusted sample size

in their next year of measurement after the publication of the new final rule. For States measured in the FY 2007 or FY 2008 cycle that elect to reject their State-specific CHIP PERM error rate determined during those cycles, information from those cycles would not be used to calculate the Statespecific sample sizes, and the "base sample" size of 500 FFS claims and 250 managed care payments would be used.

We proposed to establish a maximum sample size for Medicaid or CHIP FFS or managed care of 1,000 claims. Additionally, as discussed previously, a State with a claims universe of less than 10,000 sampling units in a program may notify us and the annual sample size will be reduced by the finite population correction factor for any PERM cycle. We believe that by taking into consideration prior cycle PERM error rates, as well as the finite population correction factor in establishing Statespecific sample sizes, the States administrative cost burden will be reduced and the program will be more manageable at the State level.

We received the following comments regarding our proposed revisions to the FFS and managed care universe, stratification, and sample sizes.

i. Universe Definition

Comment: Some commenters raised concerns about the proposed definition of the universe for the claims review component ("adjudicated fee-for-service (FFS) or managed care claims information or both, on a quarterly basis, from the review year"), referencing the change that removes the word "all" from the definition used in prior PERM regulations. The commenters expressed concern that this change materially alters the definition of the universe and of a claim, while others stated that the change does not go far enough in excluding certain types of payments, such as non-emergency medical transportation payment records that are not maintained at the beneficiary level, beneficiary-specific payments that are neither FFS or managed care, and offline claims from payment sources other than the Medicaid Management Information System (MMIS). Other commenters raised concerns that allowing a more comprehensive universe definition to be included in annual program instructions rather than regulation will lead to inconsistency across cycles.

Response: The IPIA requires payments matched with Title XIX or Title XXI funds to be included in the PERM universes. Because CMS designed the PERM methodology to sample and review individual, beneficiary-level

claims and payments, we have excluded from PERM certain Medicaid and CHIP payments that States do not pay at the beneficiary level. For example, DSH payments to facilities, grants to State agencies or local health departments, and cost-based reconciliations to nonprofit providers and FQHCs are excluded from PERM because they cannot be directly tied to an individual beneficiary. These payments will continue to be excluded from PERM sampling and review. However, in addition to these payments, State Medicaid and CHIP programs may make a variety of payments for services provided to individual beneficiaries outside of typical FFS or capitated managed care arrangements, which CMS considers part of FFS or managed care arrangements for purposes of PERM. This language change is intended to give CMS the flexibility to provide clarifying guidance when working with individual States that have unique or complex payment structures for certain types of beneficiary services, while continuing to meet the requirements of IPIA.

We have issued updated versions of the PERM universe and claims detail instructions each year in order to provide States with clarifying guidance on meeting the PERM statutory and regulatory requirements. We have not changed the fundamental definition of a PERM universe, and do not intend to do so through this rulemaking, as PERM must continue to comply with IPIA. Because State programs and payment structures continue to evolve, we would like to maintain the flexibility to continue to refine the data submission specifications to make them easier for the States to interpret and apply, within the constraint of a consistent PERM universe definition.

Regarding the comment on measurement of aggregate payments such as non-emergency medical transportation payments, the regulations at § 431.958 define "payment" as "any payment to a provider, insurer, or managed care organization for a Medicaid or CHIP beneficiary for which there is Medicaid or CHIP Federal financial participation." In some cases, it is appropriate and possible to break aggregate payments down to the beneficiary level. Additionally, because some States make more aggregate payments or payments not stored in the MMIS than others, excluding these payments would result in unequal measurement across States. Accordingly, we are not excluding these payments from the claims universe. However, we will consider developing a methodology for sampling and review of these payments that can be applied

consistently across States, taking into account the many variations in State payment systems.

Comment: One commenter questioned what the impact would be of removing the word "all" from the universe and raised concerns as to whether this change could potentially mean additional work for the State in producing the universe.

Response: We appreciate the commenter's concerns. Certain types of payments are excluded from PERM sampling and review for technical reasons. Therefore, the word "all" was removed from § 431.970(a)(1) to more accurately reflect what States are required to submit. States are not required to submit all adjudicated FFS and managed care payments. Rather, certain types of payments, such as adjustments, are excluded. We do not anticipate that this change will have an impact on what States are required to submit for the PERM universe.

Comment: One commenter expressed concern over PERM regulations, guidelines, and communications to providers that use language related to "medical services", "medical documentation" and "medical review" including "medical necessity" despite the fact that there are a variety of Medicaid and CHIP services that do not fit within the medical review model. The commenter stated that this discrepancy causes confusion for State staff and providers when identifying what documentation is required. The commenter believed this issue is also confusing due to the use of the word "claim" throughout documentation pertaining to FFS samples when a variety of services that are included in the review are not generated from a "claim" but rather considered a "payment." The commenter recommended that PERM guidance should reflect this consideration and the terminology should be changed from "medical record review" to "medical and service record review", including revision of communication to providers around the use of the word "claim" to include "payment".

Response: The purpose of all documentation that we develop and provide to States and providers is intended to clarify what is required for the PERM reviews. If improvements can be made to further provide clarification, we will attempt to address these issues. In addition, we have added the following clarification in section II.A.1.a of this final rule, "for PERM purposes, managed care claims are payments made by the State to entities with comprehensive risk contracts that assume full or partial risk for enrolled beneficiaries. FFS claims are claims other than managed care claims. CMS and its contractors may assign certain payments to the PERM FFS or managed care universe in order to ensure consistency across States and across cycles." Further, we will consider reviewing current guidance and communications to assess where further changes should be made.

ii. Provider Fraud

Comment: We received several comments regarding the current policy on claims from providers under fraud investigation. Commenters recommended dropping these claims from the sample. It was observed by the commenters that beneficiaries under fraud investigation are dropped from the eligibility review and dropping claims from providers under investigation would be consistent policy. Furthermore, commenters noted that certain records may no longer be available if they have been subpoenaed. and that the PERM request for documentation may complicate an investigation.

Response: The IPIA requires Federal agencies to measure "improper payments" and does not distinguish between different types of improper payments (for example, unintentional errors versus fraud). Our current policy is to maintain claims that are from providers who are under fraud investigation in the universe and in the sample when those claims are randomly selected from the universe. If States opt to have the CMS contractor not request supporting documentation for the claims, so as not to disrupt the investigation, the claim is found to be paid in error.

While we appreciate the commenter's concern, we are not adopting the recommendation to drop claims from providers under fraud investigation from the sample. We do not believe that the PERM review will compromise or complicate an investigation because requests for medical records are an expected and routine part of a provider's participation in the Medicaid and CHIP programs. In addition, when a provider is the subject of a fraud investigation, it does not necessarily mean that all of the claims he or she submits are the subject of the investigation. By dropping every claim submitted by the provider from the PERM review, it would mean dropping claims that legitimately should be considered in the error rate.

iii. Universe Stratification

Comment: Some commenters raised concerns about the current stratification

process adopted by CMS, in which payments are stratified by dollar. One commenter remarked that dollar stratification has resulted in an oversampling of high dollar claims and an undersampling of low dollar claims. Another commenter raised the concern that stratification by dollar value will lead to an unbalanced sample of the various service categories and all providers will not have an equal chance of being selected due to variances in the dollar value of claims submitted by service providers.

Response: In addition to meeting overall national IPIA precision requirements, we have established criteria for the precision of the Statelevel estimates. Because of the need to measure each State's error rate accurately, sample sizes for the States will not be proportional to the State's program. Statistical theory suggests that, for the purpose of obtaining a given level of precision, the sample size is independent of the universe size once the universe exceeds about 10,000 units. Beginning with the FY 2007 cycle, we changed to a dollar stratification approach (from a service stratification approach) to improve the precision of the error rate estimate. By intentionally oversampling high dollar claims and undersampling low dollar claims, we were able to reduce the FFS sample size from 1,000 claims to 500 claims and still project error rates with a level of precision that meets OMB requirements. Oversampling the high dollar claims also reduces the risk that a single high dollar claim will have a dominant effect on the error rate. Although claims are sorted by dollar and divided into strata, a random sample is drawn from each stratum so that every claim has a chance of being sampled. Our primary goal in adopting the dollar stratification approach was to develop an efficient sampling plan that would allow calculation of an error rate that meets OMB precision requirements with the smallest possible sample, to reduce the burden on States, providers, and the Federal government. Because PERM estimates an overall payment error rate for FFS, it is not necessary or desirable to design a stratification approach that ensures equal representation of every provider or service type, as long as all payments have some chance of being sampled.

iv. State-Specific Sample Size

Comment: Several commenters discussed our proposed approach to vary the PERM sample size by State as required by the CHIPRA. Some commenters interpreted the CHIPRA requirement that the Secretary establish

State-specific sample sizes for application of the PERM requirements to mean that a fixed sample size for each State should be established, and stated that the proposed rule was in conflict with the CHIPRA as it did not establish a fixed sample size for any State. Some commenters questioned whether the maximum FFS sample size (1,000 claims for Medicaid and CHIP respectively) was appropriate or necessary. Other commenters raised concerns about the administrative challenges of planning around uncertain and changing sample sizes. One commenter suggested that the overall sample sizes should be proportional to program size (in most cases CHIP programs are much smaller then Medicaid programs, but the same number of claims and eligibility cases are sampled for review under PERM).

Response: As indicated previously, we are governed not only by the CHIPRA but also by the IPIA and OMB guidance, which does not mandate certain minimum or maximum sample sizes but does require CMS to estimate national error rates for Medicaid and CHIP that meet certain precision requirements. The formula for estimating a sample size highly likely to meet OMB precision requirements takes three factors into consideration: Population size; variation in payments in the universe; and expected error rate. Each of these factors can be determined on a State-specific basis using information from a prior measurement cycle. Therefore, we believe that the proposed approach of calculating a State-specific sample size prior to the beginning of each cycle, using information from the prior cycle, meets the CHIPRA goals. This approach is consistent with the CHIPRA provision that provides the Secretary with flexibility to determine which information is appropriate to use in determining sample sizes.

State sample sizes will be calculated to result in an unbiased estimate of the error rate within a certain level of precision. The State-level rates will be combined to calculate a national error rate within the IPIA-required level of precision. Variation in State sample sizes will not affect the calculation of the national error rate or comparison of the national or State rates over time (both fixed and State-variable sample sizes are designed to result in an unbiased estimate of the error rate). Smaller sample sizes will reduce the precision of the estimates at the State level somewhat but should have less effect on the precision of the national error rates (it will be slightly lower but it will not be a substantial change). The

variance in the estimates will also be slightly greater at the lower sample sizes.

As the State error rates are built up from the independent component rates, sample sizes would be calculated for all six components (for example, Medicaid FFS, Medicaid managed care, Medicaid eligibility, CHIP FFS, CHIP managed care, and CHIP eligibility), and the maximum and minimum sample sizes would apply to each component independently (there is no overall program maximum or minimum). Information specific to each program and component would be used to estimate the State-specific sample size. That is, information from the Medicaid FFS error rate measurement in the previous cycle would be used only to calculate the sample size for Medicaid FFS measurement in the subsequent cycle. Therefore, a State with a high FFS error rate and a low managed care error rate in one cycle could see a larger FFS sample size and a smaller managed care sample size in the next cycle.

The possibility of a larger than "standard" sample size (currently, 500 for FFS and 250 for managed care) is necessary because these sample sizes are not likely to meet the precision requirements if a State's rate is significantly higher than expected. (In FY 2007, 3 Medicaid programs and 8 CHIP programs did not meet the precision requirement with the standard sample sizes.) Failure to meet the Statelevel precision goals jeopardizes the precision of the national error rate. Thus, if we are to establish Statespecific sample sizes it must evaluate all three determinants of sample size (that is, population size, variation in payments in the universe, and expected error rate) for each State and increase the sample size if the error rate is expected to be higher than average, based on the prior cycle findings.

Because reviewing claims requires both staff and monetary resources, a maximum sample size puts a limit on expenditure. Statistical tests suggest that if State-level precision cannot be met with a sample size of 1,000 claims, it is unlikely to be met with any reasonable sample size (the slight increases in precision that could be achieved would be outweighed by the significant expense associated with reviewing thousands of additional claims). However, a substantial increase in the probability of reaching precision goals can be gained by increasing the sample size from 500 to 1,000, so we believe this maximum to be reasonable and prudent.

Finally, while CHIP programs are typically much smaller than Medicaid

programs, from a sampling perspective there is generally no difference between a small and large population (number of payments for claims sample, number of beneficiaries for eligibility sample). Specifically, a property of sampling is that, once the population size exceeds about 10,000, it can be treated as if it were an infinite population. Nearly every Medicaid and CHIP program has at least 10,000 payments or 10,000 beneficiaries across a fiscal year, so they are all treated as "infinite" in terms of population size. As a result, the PERM sample sizes are driven primarily by the variation in payments in the universe and the expected error rate, not by program size. If a program does have fewer than 10,000 payments or 10,000 beneficiaries across a fiscal year, the expected population size can be substituted into the calculation to determine an appropriate sample size that will probably be smaller than the "standard" sample size.

We recognize that sample sizes, particularly for eligibility, drive State resource needs. Because all of the information necessary to develop a State-specific sample size will be available to CMS once the State's error rate for the prior cycle is calculated, when CMS sends a State notice of its error rates at the end of a cycle, it will include in that notice the calculation of the sample size for the next cycle. This will provide States with the greatest advanced notice possible. We are considering developing a calculator that States can use to estimate potential sample sizes under a variety of scenarios.

Comment: Several commenters asked questions about our proposed approach regarding base years. Commenters stated that in a base year, the sample size for a State will be that specified in the regulation, not a State-specific sample size calculated using information from a prior cycle (the "base year" is, by definition, the first cycle). Some commenters asked if the Medicaid error rate from FY 2007 or FY 2008 could be used to determine State-specific sample sizes for CHIP in the next measurement cycle, if the State decided not to accept its CHIP error rate from FY 2007 or FY 2008

Response: The commenters are correct in that the "base year" refers to a State's first cycle, and therefore, the State would have sample sizes as provided in the regulation.

The CHIPRA gives States that participated in the PERM CHIP measurement in FY 2007 and FY 2008 the option of accepting the payment error rate from that cycle or not accepting that rate and treating their

next cycle as the first fiscal year for which the PERM requirements apply to the State (in effect, a new "base year"). We believe it is likely that a State with a low CHIP error rate would choose to accept that rate, and would be likely to have a sample size the same as or lower than the base sample size in the next cycle. We believe it is likely that a State with a high CHIP error rate would choose not to accept that rate, and would be allowed to use the base sample size (500 FFS claims and 250 managed care payments), rather than risk having a larger sample size. As a result, for States that have previously participated in PERM, Medicaid and CHIP program sample sizes could vary from the "base year numbers."

The CHIPRA does not provide a similar option for States to accept or reject their Medicaid error rates from previous cycles. Therefore, sample sizes for a State's Medicaid program will be based on the State's error rate from their previous cycle.

Results from FY 2007 (the only year for which CHIP error rates were calculated) indicate that State CHIP rates are not necessarily closely correlated to State Medicaid rates: that is, 7 of the 17 States had Medicaid and CHIP rates that were more than three percentage points apart. Because of differences in error rates and payment variation between Medicaid and CHIP programs, information on Medicaid error rates cannot be used to generate sample sizes for CHIP programs.

Comment: Several commenters inquired as to whether CMS would implement a minimum sample size given that the proposed regulation offers a maximum sample size. The commenters recommended that CMS set a minimum sample size in regulation in order to assist States in planning for resource needs.

Response: We appreciate the commenter's recommendation to adopt a minimum sample size for PERM, but we are not accepting this recommendation at this time. To comply with the IPIA, the PERM program must estimate a national Medicaid and a national CHIP error rate that covers the 50 States and District of Columbia. Consistent with OMB's precision requirements defined in its IPIA guidance, the estimated national error rate for each program must be bound by a 90 percent confidence interval of 2.5 percentage points in either direction of the estimate. By setting a minimum sample size, we risk having sample sizes that are too small for States that had higher error rates in their subsequent PERM cycles. If the realized variation for the State is not as

favorable as the earlier history, the State's error rate will not meet Statelevel precision requirements and may, in some cases, jeopardize meeting national precision goals. However, the States will still have the potential to reduce their sample sizes based on prior years' data. It is our intention to work closely with our contractor and the States to ensure States are informed well in advance of the measurement cycle of their sample size for planning purposes.

Comment: Commenters expressed concern about the amount of work and time it takes to complete a comparison between the PERM universe and the Form CMS-64 and Form CMS-21 reports. Furthermore, commenters noted that the differences between what States include in the Form CMS-64 and Form CMS-21 reports (for example, adjustments, non-beneficiary specific payments) and how they report the information differs greatly from the individual beneficiary-level claims and payment data provided in the PERM universes.

Commenters also offered suggestions for changes that could be made to the comparison, such as adopting a threshold above which a comparison would be considered valid, or to use the same quarter of data for comparison (which would require a short delay in the PERM universe submission).

Response: The Form CMS–64 and Form CMS–21 comparison is a component of the quality control review process to validate PERM universes, which, like other quality control processes, is discussed in more detail in the PERM universe submission instructions provided to States at the start of each cycle.

The purpose of the comparison, along with the rest of the quality control checks States are asked to complete, is to ultimately provide the most accurate and complete universe of Medicaid and CHIP payments as possible to ensure an unbiased and accurate error rate calculation. The comparison is not expected to be a dollar for dollar match but rather a means for the State and CMS to identify if, in certain areas, there are significant discrepancies that could indicate that payments were not properly included or excluded. We have found over the previous PERM cycles that States often overlook Medicaid or CHIP programs which are processed and paid outside of MMIS and/or managed by other agencies and divisions when developing the PERM universes. The Form CMS–64 and Form CMS–21 comparison serves as a tool for both States and CMS to determine if all payments for services provided to individual beneficiaries for which the

State claims Title XIX or Title XXI match are included. As we have found that this quality control step has identified potential problems with the PERM universes, we are not adopting any recommendations to eliminate this process. However, we will work with States to explore options regarding how this process can be more effective for States and CMS. Additionally, we will consider for future cycles how to provide the most detailed information possible about this process so States can plan and prepare accordingly. As a result, we are modifying §431.972 to include the requirement that States establish controls to ensure the FFS and managed care universes are accurate and complete and to require a comparison of the PERM universes to the Forms CMS-64 and CMS-21.

Comment: We received a number of comments related to universe development and sampling issues including the following:

• One commenter stated that CMS should utilize Medicaid Statistical Information System (MSIS) data for the Medicaid universe submission and if the data is not robust enough, make changes to the MSIS data so it can meet PERM requirements;

• One commenter stated that CMS should only require a universe submission and review if the universe exceeds a pre-established minimum threshold in terms of number of claims or total dollar amount;

• One commenter stated that CMS should review the current sampling methodology which oversamples high dollar claims to determine if the methodology is yielding the desired results;

• One commenter stated that CMS should provide more technical guidance to States for the submission of the claims universe data to prevent differing interpretations of the requirements.

Response: While the MSIS data will not currently fully meet the requirements of PERM, we understand that States are required to pull similar data for several CMS initiatives, resulting in redundancies with already limited State resources. We are currently beginning year two of the minimum data set pilot for PERM, in which our contractor is working with a small number of States, on a voluntary basis, to review available data fields and determine if it would be possible to create one data submission that meets the needs of multiple programs.

The IPIA and OMB guidance (OMB M–06–23, Appendix C to OMB Circular A–123, August 10, 2006) requires that all programs that are susceptible to significant erroneous payments (where

the annual erroneous payments in the program exceed both 2.5 percent of program payments and \$10 million) must participate in the error rate measurement. Only those programs whose annual erroneous payments fall below this threshold may not be subject to the error rate measurement requirements. Therefore, a single State universe, no matter what the size in terms of claims and dollars, is not eligible for omission from the national error rate measurement in a given cycle.

The current sampling methodology is yielding the desired results. The overweighting of higher dollar payments (which is taken into account when calculating error rates) enables us to draw a smaller sample size that has a reasonable probability of meeting the precision requirements, compared to a perfectly random sample or a sample stratified by service type. In this manner, we reduce burden on States, the Federal government, beneficiaries, and providers.

Finally, we appreciate the recommendation to provide States with more technical guidance on claims submission. We are in the process of developing a PERM manual, which we envision will be a single resource for all PERM-related guidance. As we develop the manual and update data submission and eligibility instructions, we will look for ways in which to improve technical guidance. We are also considering adding this as a topic for discussion with the PERM Technical Advisory Group (TAG).

2. Eligibility

The eligibility sampling requirements are described in §431.978. The universe for the eligibility component is casebased, not claims-based. The case as a sampling unit only applies to the eligibility component. For PERM eligibility, the "universe" is the total number of Medicaid or CHIP cases. which, as discussed in the proposed rule, is comprised of all beneficiaries, both individuals and families. The eligibility sampling plan and procedures state that the total eligibility sample size must be estimated to achieve within a 3 percent precision level at a 95 percent confidence interval for the eligibility component of the program.

For PERM eligibility, the initial sample size is calculated under the assumption that the error rate is 5 percent and the universe is greater than 10,000 total cases. The estimated error rate for a State should be at a 95 percent confidence interval of 3 percentage points in either direction. This means that the desired precision requirements will be achieved with a high probability if the actual error rate is 5 percent or less. For this reason, an annual sample of 504 active cases and 204 negative cases should be selected in a State's base PERM year to meet State-level precision requirements with a high probability. Appendix D of the PERM Eligibility Review Instructions elaborates on the theory of sample size at the State-level for the dollar-weighted active case error rates, and is on the CMS Web site at http://www.cms.gov/ perm/downloads/ PERM Eligibility Review Guidance.pdf.

Eligibility sampling is performed by the States, and States have the opportunity to adjust their eligibility sample size based on the eligibility error rate in the previous PERM cycle. After a State's base PERM year, we will determine, with input from the State, a sample size that will meet desired precision goals at lower or higher sample sizes based on the outcome of the State's previous PERM cycle. The sample size could either increase or decrease given the results of the previous review year. We proposed to establish a maximum sample size for eligibility at 1,000 cases. States must submit an eligibility sampling plan by August 1st before the fiscal year being measured and include a proposed sample size for their State. Our contractor will review and approve all eligibility sampling plans. The State must notify CMS that it will be using the same plan from the previous review year if the plan is unchanged. However, we will review State sampling plans from prior cycles in each PERM cycle to ensure that information is accurate and up-to-date. States will be asked for revisions when necessary.

As in the claims universe, States with PERM eligibility universes under 10,000 cases can propose a reduced eligibility sample size for either the base year or any subsequent PERM cycle.

Additionally, section 203 of the CHIPRA describes the State option to enroll children in Medicaid or CHIP based on findings of an Express Lane agency in order to conduct simplified eligibility determinations. Under sections 203(a)(1) and (2) of the CHIPRA, an error rate measurement will be created with respect to the enrollment of children under the Express Lane Eligibility option. The law directs States not to include children enrolled using the Express Lane Eligibility option starting April 1, 2009, in data or samples used for purposes of complying with MEQC and PERM requirements. Provisions for States' Express Lane option will be set forth in a future rulemaking document.

We proposed to revise § 431.814 and § 431.978 to reflect the changes and clarifications specified previously.

We received the following comments regarding our proposed revisions to the eligibility sample sizes.

Comment: A few commenters suggested that we set minimum eligibility sample sizes for active and negative cases.

Response: We cannot adopt this recommendation. By setting a minimum eligibility sample size, we risk having sample sizes that are too small to meet the IPIA's precision requirements for States that had higher error rates in their subsequent PERM cycles. If the realized variation for the State is not as favorable as the earlier history, the State's error rate will not meet State-level precision requirements and may, in some cases, jeopardize meeting national precision goals. However, the States will still have the potential to reduce their eligibility sample sizes based on prior years' data. Reduced State sample sizes will balance the results from the PERM sampling equations with the need to reliably reproduce small error rates. Sample size reductions will be based on a State's previous eligibility error rate in PERM or MEQC (depending upon the method chosen by the State for PERM), the typical margin of error for that previous error rate, and the results from simulation studies on small samples. These studies examined the point at which small samples cease to reliably return known small error rates in the targeted universes. Reduced sample sizes must also meet the confidence and precision requirements.

Comment: One commenter disagreed with setting a maximum sample size and requiring States with eligibility error rates above the 5 percent standard to increase their eligibility sample size. The commenter recommends the sample size remain constant from cycle to cycle.

Response: We disagree with the commenter. We recognize that sample sizes, particularly for eligibility, drive State resource needs. The possibility of a larger sample size is necessary because the standard sample sizes are not likely to meet the IPIA precision requirements if a State's rate is significantly higher than expected. We are setting a maximum sample size in order to keep the sample sizes manageable as CMS would find it necessary for some States to sample significantly more than 1,000 cases to meet IPIA precision requirements.

B. Error Criteria

Under the PERM program, we identify improper payments through claims reviews and eligibility reviews. For the

claims review, we perform the following: (1) a data processing review of a sample of FFS and managed care payments to ensure the payments were processed and paid in accordance with State and Federal policy; and (2) a medical review of a sample of FFS payments to ensure that the services were medically necessary, coded correctly, and provided and documented in accordance with State and Federal policy. For the eligibility review, we rely on States to review a sample of beneficiary cases to ensure that they were determined eligible for the program in accordance with documented State policies and procedures and for any services received and paid for by Medicaid or CHIP (as applicable). The PERM eligibility review also considers negative cases (cases where eligibility was denied or terminated). A negative case is in error if the case was improperly denied or incorrectly terminated in accordance with State documented policies and procedures. However, because there are no payments associated with these cases, only a case error rate is calculated. These errors are not factored into the PERM error rate, which is a payment error rate.

Under the IPIA, to be considered an improper payment, the error made must affect payment under applicable Federal policy and State policy. Improper payments include both overpayments and underpayments. A payment is also considered improper where it cannot be discerned whether the payment was proper as a result of insufficient or lack of documentation.

Consistent with the IPIA, the PERM error rate itself does not distinguish between "State" and "provider" errors; all dollars in error identified through PERM reviews contribute to the State error rate. In practice, the data processing and eligibility reviews focus on determinations made by State systems and personnel, while the medical review focuses on documentation maintained and claims submitted by providers.

Section 601(c)(1)(A) of the CHIPRA requires us to promulgate a new final rule that includes clearly defined criteria for errors for both States and providers. Accordingly, we proposed to add § 431.960, "Types of payment errors," to clarify that State or provider errors for purposes of the PERM error rate must affect payment under applicable Federal policy and State policy, and to generally categorize data processing errors and eligibility review errors as State errors and medical review errors as provider errors. The data processing errors, medical review errors, and eligibility review errors may include, but are not limited to, the types of improper payments discussed below.

1. Claims Review Error Criteria

a. Data processing errors (State errors)

i. Duplicate item

The sampled line item/claim is an exact duplicate of another line item/ claim that was previously paid (for example, same patient, same provider, same date of service, same procedure code, and same modifier).

ii. Non-covered service

The State policy indicates that the service is not payable by the Medicaid or CHIP programs and/or the beneficiary is not in the coverage category for that service.

iii. Fee-for-service claim for a managed care service

The beneficiary is enrolled in a managed care organization that should have covered the service, but the sampled service was inappropriately paid by the Medicaid or CHIP FFS component.

iv. Third-party liability

The service should have been paid by a third party and was inappropriately paid by Medicaid or CHIP.

v. Pricing error

Payment for the service does not correspond with the pricing schedule on file and in effect for the date of service.

vi. Logic edit

A system edit was not in place based on policy or a system edit was in place but was not working correctly and the line item/claim was paid (for example, incompatibility between gender and procedure).

vii. Data entry errors

A line item/claim is in error due to clerical errors in the data entry of the claim.

viii. Managed care rate cell error

The beneficiary was enrolled in managed care and payment was made, but for the wrong rate cell.

ix. Managed care payment error

The beneficiary was enrolled in managed care and assigned to the correct rate cell, but the amount paid for that rate cell was incorrect.

x. Other data processing error

Errors not included in any of the above categories.

b. Medical Review Errors (generally provider errors)

i. No documentation

The provider did not respond to the request for records within the required timeframe.

ii. Insufficient documentation

There is not enough documentation to support the service.

iii. Procedure coding error

The procedure was performed but billed using an incorrect procedure code and the result affected the payment amount.

iv. Diagnosis coding error

According to the medical record, the diagnosis was incorrect and resulted in a payment error—as in a Diagnosis Related Group (DRG) error.

v. Unbundling

The provider separately billed and was paid for the separate components of a procedure code when only one inclusive procedure code should have been billed and paid.

vi. Number of unit(s) error

The incorrect number of units was billed for a particular procedure/service, National Drug Code (NDC) units, or revenue code. This does not include claims where the provider billed for less than the allowable amount, as provided for in written State policy.

vii. Medically unnecessary service

The service was medically unnecessary based upon the documentation of the patient's condition in the medical record in accordance with written State policies and procedures related to medical necessity.

viii. Policy violation

A policy is in place regarding the service or procedure performed and medical review indicates that the service or procedure is not in agreement with the documented policy.

ix. Administrative/other medical review error

A payment error was determined by the medical review but does not fit into one of the other medical review error categories, including State-specific noncovered services.

c. Eligibility errors (State errors)

i. Not eligible

An individual beneficiary or family is receiving benefits under the program but does not meet the State's categorical and financial criteria in the first 30 days of eligibility being verified using the State's documented policy and procedures.

ii. Eligible with ineligible services

An individual beneficiary or family meets the State's categorical and financial criteria for receipt of benefits under the Medicaid or CHIP program but was not eligible to receive particular services in accordance with the State's documented policies and procedures.

iii. Undetermined

The case record lacks or contains insufficient documentation, in accordance with the State's documented policies and procedures, to make a definitive review decision for eligibility or ineligibility.

iv. Liability overstated

The beneficiary overpaid toward an assigned liability amount or cost of institutional care and the State paid too little.

v. Liability understated

Beneficiary underpaid toward an assigned liability amount or cost of institutional care and the State paid too much.

vi. Managed care error 1

Ineligible for managed care—Upon verification of residency and program eligibility, the beneficiary is enrolled in managed care but is not eligible for managed care.

vii. Managed care error 2

Eligible for managed care but improperly enrolled—Beneficiary is eligible for both the program and for managed care but not enrolled in the correct managed care plan as of the month eligibility is being verified.

viii. Improper denial

An application for program benefits was denied by the State for not meeting a categorical and/or financial eligibility requirement but upon review is found to be eligible for the tested category or a different category under the program in accordance with the State's documented policies and procedures.

ix. Improper termination

Based on a completed redetermination, the State determines an existing beneficiary no longer meets the program's categorical and/or financial eligibility requirements and is terminated but upon review is found to still be eligible for the tested category or a different category under the program in accordance with the State's documented policies and procedures.

2. Definitions

We proposed to add the following definitions for "provider error" and "State error" to § 431.958.

Provider error includes, but is not limited to, an improper payment made due to lack of or insufficient documentation, incorrect coding, improper billing (for example, unbundling, incorrect number of units), a payment that is in error due to lack of medical necessity, or evidence that the service was not provided in compliance with documented State or Federal policy.

State error includes, but is not limited to the following:

• A payment that is in error due to incorrect processing (for example, duplicate of an earlier payment, payment for a non-covered service, payment for an ineligible beneficiary).

• Incorrect payment amount (for example, incorrect fee schedule or capitation rate applied, incorrect thirdparty liability applied).

• A payment error resulting from services being provided to an individual who—

++ Was ineligible when authorized or when he or she received services;

++ Was eligible for the program but was ineligible for certain services he or she received;

++ Had not met applicable beneficiary liability requirements when authorized eligible or overpaid toward actual liability; or

++ Had a lack of or insufficient documentation to make a definitive eligibility review decision for the tested category or a different category under the program in accordance with the State's documented policies and procedures.

To avoid any confusion that may have been caused by listing some types of provider and State errors in the definitions of "provider error" and "State error," while at the same time listing overlapping errors in §431.960, "types of payment errors," we are revising §431.958 and §431.960 to clarify the relationship between provider errors, State errors, and types of payment errors. These revisions do not modify the substance of our proposed rule. Accordingly, we are adding § 431.960(b)(3) to specify that data processing errors include, but are not limited to, payment for duplicate items, payment for non-covered services, payment for FFS claims for managed care services, payment for services that should have been paid by a third party but were inappropriately paid by Medicaid or CHIP, pricing errors, logic edit errors, data entry errors, managed

care rate cell errors, and managed care payment errors.

¹ We are adding § 431.960(c)(3) to specify that medical review errors include, but are not limited to, lack of documentation, insufficient documentation, procedure coding errors, diagnosis coding errors, unbundling, number of unit errors, medically unnecessary services, policy violations, and administrative errors.

We are also revising 431.960(d)(1), to specify that eligibility errors include, but are not limited to, benefits being provided to ineligible beneficiaries, benefits provided to eligible beneficiaries but for ineligible services, cases where the case record lacks or contains insufficient documentation to determine eligibility, cases where the beneficiary's liability is understated, cases where the beneficiary's liability is overstated, cases where the beneficiary received managed care benefits but is ineligible for managed care, cases where the beneficiary is eligible for managed care but is improperly enrolled in the correct managed care plan, improper denials of eligibility, and improper termination of eligibility.

The error criteria listed under § 431.960, "types of payment errors," can be generally categorized into provider errors and State errors. Therefore, we are revising the definitions of "provider errors" and State errors" in § 431.958 to reference the errors as provided in § 431.960.

We received the following comments regarding our proposed revisions to the error criteria.

Comment: Several commenters stated that "no documentation" errors are not errors, that they are actually undetermined, and should not be included as errors for purposes of error rate calculation. In addition, the commenters requested that error rates reported by CMS include breakouts to show errors attributed to data processing versus medical review.

Response: We disagree with the comments that "no documentation" errors are not errors. We consider cases in which no documentation is received to be errors based on Medicaid statute and OMB guidance. Providers are required to support their claims for payment, when requested, with records and documentation demonstrating the medical context and medical necessity of the service or good provided. It is only through the assessment of this documentation that the claim can be reviewed for its accuracy. In the PERM program, when providers fail to respond to a request for documentation, or the documentation provided is insufficient to support the validity of medical

service or good provided, the claim is counted as an error in payment. Title XIX, section 1902(a)(27)(A) of the Act, requires providers to maintain documentation necessary to fully disclose the extent of the services provided to Medicaid and CHIP beneficiaries, and authorizes the individual State or the Secretary of Health and Human Services to request that that documentation from the provider to support the claim for payment:

A State plan for medical assistance must * * * provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency or the Secretary with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request. (42 U.S.C. 1396a(a)(27)).

Section 2107(b)(1) of the Act requires States to collect data, maintain records, and furnish reports that the Secretary determines necessary to monitor the administration, compliance and evaluation of the CHIP program. Section 2107(b)(3) of the Act requires the State to afford the Secretary access to any records or information relating to the CHIP program for purposes of review or audit.

In addition, OMB's guidance on implementing the IPIA specifies that, "* * when an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment must also be considered an error." (OMB M–06–23, Appendix C to OMB Circular A–123, August 10, 2006). For these reasons, we will continue to consider claims for which no documentation is received as errors for purposes of error rate calculation and recoveries.

We do agree that it is important to provide as much information as possible about the different types of errors comprising the overall error rate. Therefore, we will continue to provide States with more detail on the number of errors and dollars in error by error type, aggregated nationally and by State in reports following the measurement cycle for corrective action purposes. In addition, we will continue to publish our error rate report on our Web site at http://www.cms.gov/PERM. This report contains detailed breakouts of the error rates including errors found during the medical review, errors found in the data processing review, and eligibility review errors. Finally, starting with the FY 2010 cycle, we intend to perform additional analysis on the error rate data, including categorizing errors by service type and error type as recommended by the Office of Inspector General (OIG). We intend to publish the results in the annual PERM report and also incorporate the findings into the corrective action reports provided to States.

Comment: Some commenters suggested that the proposed rule does not amend the administrative criteria into State and provider errors as required by the CHIPRA. Additionally, some commenters questioned what would be done with the definitions and requested that two State error rates be provided to States-the State error rate and the provider error rate.

Response: The IPIA requires Federal agencies to measure "improper payments" and does not distinguish between different types of improper payments (for example, unintentional errors vs. fraud) or different types of errors (for example, State-caused errors vs. provider-caused errors). The CHIPRA requires CMS to define the criteria for State and provider errors but does not exclude either from the error rate. Therefore, for purposes of calculating the error rate, any error found (whether State-caused or provider-caused) must be included.

The PERM criteria for the three types of errors are described in § 431.960(a) through (d). More specific criteria will be, to a certain extent, State-specific depending on local policies. We will consider publishing more details on the process for reviewing payments and determining errors in a program manual. We do not intend to use the definitions to calculate a separate State and provider error rate at the national level; we believe the overall benefit of classifying errors as "State" and "provider" will be seen in the corrective action phase of PERM. For this reason, we are adopting the commenter's recommendation, and will provide individual States with three State error rates for corrective action purposes—a State error rate, a provider error rate, and an overall program error rate which combines the State and provider error rates into one. The official error rates recognized by CMS will continue to be the overall error rates which take into account all errors found during the PERM review.

Comment: Some commenters asked that the timeframe for providers to submit documentation should be extended from the current 60 days to 90 days, which was allowed in earlier versions of the PERM regulations.

Response: Based on an analysis of data from the past three PERM measurement cycles, providers generally submit documentation well in advance of the 60 days allowed. In FY 2007, the average number of days providers took to respond to a request for documentation was 35; in FY 2008, the average was 32 days; and in FY 2009, the average number of days has been 32 thus far. In addition, PERM accepts late documentation in certain instances and recommends that States encourage providers to submit documentation to the PERM contractor even if it is late. However, in view of the commenters' concerns, as well as to be consistent with the Comprehensive Error Rate Testing (CERT) program which measures the Medicare FFS error rate, we are extending the timeframe for documentation submission from 60 days to 75 days, or the final cut-off date for error rate calculation purposes (generally July 15th of the second year of a measurement cycle), whichever occurs first.

In cases where the PERM contractor receives no documentation from the provider once 75 days has passed since the initial request, the PERM contractor will consider the case to be a no documentation error. The PERM contractor will consider any documentation received after the 75th day "late documentation". If the PERM contractor receives late documentation prior to the documentation cut-off date for error rate calculation and reporting purposes (generally the second July 15 of a measurement cycle), they will review the records and, if justified, revise the error finding. Claims that complete the review process are included in the report. Claims for which the PERM contractor receives no documentation are counted as no documentation errors. Additionally, in accordance with established PERM process, if we determine that the documentation submitted by the provider is insufficient to make a determination about whether or not the claim should have been paid, we will request additional documentation from the provider. Providers have 14 calendar days to submit the additional documentation to CMS. We maintain that this policy will allow providers sufficient time to submit required documentation.

We revised §431.970(b) to reflect the timeframes described previously.

Comment: A commenter questioned the data processing error category "FFS claim for a managed care service", stating that the procedure followed by CMS with regard to this criterion should be to ensure that MMIS system edits related to the types of services to deny are working properly, rather than comparing FFS claims to encounter data.

Response: Under PERM, we not only need to check that edits used to deny claims are working properly, but also need to ensure that all claims paid in the sample are paid correctly. When conducting a managed care review, we do not compare FFS claims to encounter data, but rather check for program, recipient and provider eligibility. We also determine if the beneficiary was enrolled or should have been enrolled in managed care. If a FFS claim was paid for a managed care recipient, we also have to determine whether the FFS claim was for a service carved out of the managed care contract or whether the claim was paid because the beneficiary was still in a FFS window prior to enrollment.

Comment: One commenter stated that their State policy does not allow a provider to bill for higher codes or units of service than what was provided; however, it does not preclude the provider from billing for a lesser code or fewer units of service than was provided. The commenter recommended that a payment error not be automatically assessed whenever lesser codes or fewer units of service are billed.

Response: In 2007, we established a policy in guidance (the Review Contractor's medical review manual), which, for PERM purposes, allows for under-billing for number of units-type claims by providers. Under that policy, these cases are not automatically determined errors. For wrong procedure code errors, wrong diagnosis code errors, or DRG errors, we identify those instances where a provider billed using an incorrect procedure code based on the medical record documentation and we request repricing by the State. It is up to the State to determine (in accordance with their written policies and payment schedules) under repricing and/or difference resolution if the original payment was correct or if the use of the corrected procedure code/ diagnosis code/DRG resulted in wrong claim payment. States are required to reprice the claim by providing the correct payment that should have been made for the correct code identified during the medical review.

We are clarifying that the term "number of unit(s) error" excludes underpayment errors that occur when a provider bills for a lesser code or fewer units of service than was provided, as provided for in written State policy.

Comment: We received a comment about situations in which payment may not correspond with the pricing schedule. The commenter stated that their State's policies support reimbursement based on the lesser of the provider charge amount or the fee schedule. The commenter stated it is inappropriate to assess an error if the payment for service does not correspond with the pricing schedule on file and in effect for the date of service and recommends that errors not be assessed based solely on payment corresponding to the fee schedule.

Response: We do not assess errors solely based on payment/fee schedules. We inquire about each State's payment policies at orientation meetings and in data processing questionnaires. We document each State's policies regarding whether any types of claims are paid when the billed amount is less than that allowed by the State's fee schedules. If it is the State's policy to pay the allowed amount up to the amount billed by the provider then we would not consider the claim an error. Decisions about errors are based on each State's policies.

Comment: We received comments regarding third-party liability (TPL) errors determined during the data processing review. One commenter stated that the procedure followed by CMS with regard to this criterion should be to ensure that MMIS TPL system edits are working properly, rather than verifying the amount paid by the other insurer. Another commenter stated that both State policies and Federal regulations support methodologies to seek reimbursement of a claim if TPL is discovered after the claim was paid. The commenter recommends not assessing an error based on TPL discovered after the claim was paid.

Response: We ascertain whether the TPL edits are working appropriately. However, if TPL should have been applied to the claim and was not, then we would need to know the amount paid by the liable third party in order to determine how much of the payment was in error. Even when edits are working appropriately, human intervention often allows a claim to pay even though the system suspended the payment.

¹ We make our determination based on what information was known or should have been known at the time of payment. For instance, if TPL was indicated on a paper claim but that information was not entered into the MMIS and the full claim was paid by Medicaid, it would be determined as an error.

Comment: Regarding the process for determining medical necessity, one commenter questioned whether or not

the PERM review is based solely on InterOual Criteria, as some States not only utilize InterQual Criteria but also a utilization review that includes a nurse and physician review in certain instances for determination of medical necessity. The commenter stated that through this process, the physician may override the nurse's finding based on experience and clinical judgment. The commenter recommended that physician findings for inpatient hospital stays not be overridden by CMS for States that utilize medical experts to augment their determination of medical necessity.

Response: The purpose of the PERM review is to conduct an independent review of the sampled claims to identify improper payments. During the PERM medical review orientation conducted with each State prior to the beginning of the medical review process, the Statespecific criteria and guidelines used to determine medical necessity are requested as States use various methods (for example, Milliman's, InterQual, the Quality Improvement Organization (QIOs)). Our contractor takes into consideration the medical necessity criteria used by the individual State for screening purposes, and, if a medical necessity error is identified, the record is reviewed by a second level reviewer with greater expertise than the first reviewer. Where there are comorbidities or complications documented in the record, clinical review judgment is applied before any error is reported to the State. In no case does clinical review judgment override statutory, regulatory, ruling, or policy provisions. All documentation and policy requirements are met before clinical review judgment applies.

For example, if the State uses InterQual Criteria to determine medical necessity, our contractor screens the medical record using InterQual Criteria at the first level of review. When an improper payment is identified, the case is referred to a second level review for verification that the InterQual Criteria are applied accurately and that State policy, rulings, statute and Federal statute, regulatory, ruling, and policy provisions are applied with accuracy. Clinical review judgment is applied only if needed after all other review is completed. It may be needed when the medical decision requires clinical judgment based on the patient's condition, co-morbidities or complications documented in the medical record submitted. If an error is found and the State disagrees with the finding, the State has the opportunity to request difference resolution with the contractor. For errors disputed by the

State, the difference resolution review is conducted by review supervisors or managers and if the medical necessity error is upheld, the record is reviewed by a review panel consisting of review managers, directors and a board certified physician. During the difference resolution process, the State can provide to the PERM contractor any relevant utilization review findings that will be given full consideration when the claim is re-reviewed and a final determination is made.

Comment: Several commenters requested that we reconsider the 60-day adjustment period policy at §431.970(a)(8), which requires that, for claims reviews, States submit adjustments within 60 days of the adjudication dates for the original claims or line items with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items. Commenters stated that the State timeframe for allowing adjustments is often greater than 60 days, in some case up to 12 months. Some commenters noted that this policy has resulted in inappropriate errors when States have adjusted after 60 days.

Response: While we understand the commenters' concerns and have carefully reconsidered this requirement, we are not modifying the adjustment rule in regulation at this time. The purpose of the rule is to maintain consistency across States in the time they have to submit adjustments, as well as to ensure that the measurement is completed on time. As States have varying timeframes in which claims are adjusted, we cannot extend the timeframe in a manner that would accommodate all States' practices. The 60-day timeframe allows for claims adjustments while maintaining a timeline that also allows for completing the reviews and computing and reporting the error rates in time for inclusion in the Agency Financial Report (AFR). If we extend the timeframe to a point beyond 60 days, we cannot be assured that the error rate measurement process will be completed in time to report the error rate.

However, if an error is cited and it would not have been in error had the adjustment been considered, the State may document in writing to CMS on what Form CMS–64 or Form CMS–21 report this claim's adjustment was included on. In these instances, the State will not be required to return the FFP to CMS.

Eligibility Errors

Comment: One commenter requested clarification for what constitutes an

eligibility improper payment if an error must affect payment to be an improper payment.

Response: An improper payment for eligibility is cited when the services received by the beneficiary in the sample month were improperly paid based on the State's documented policies and procedures, in whole or in part, due to the ineligibility of the beneficiary, the beneficiary receiving uncovered services, the beneficiary being eligible for the program but ineligible for the services he or she received, an eligibility review decision that cannot be completed, the beneficiary's liability being understated or overstated, or the beneficiary being improperly enrolled in the correct managed care plan. Eligibility errors will not result in improper payments if no services were received in the sample month or, based on State findings, services were not received in error. Accordingly, we proposed to specify in the new §431.960 that the dollars paid in error due to the eligibility error is the measure of the payment error.

Comment: A few commenters requested CMS clarify how Liability Overstated and Liability Understated errors should be computed.

Response: Liability Overstated and Liability Understated are error categories addressed in the eligibility instructions found at http:// www.cms.gov/PERM. The States should verify that any liability, co-payment, or premium amounts were calculated correctly to determine if State and Federal dollars were paid correctly. The PERM reviews only apply State and Federal dollars to the amounts of improper payments. Beneficiary dollars are not inclusive to the payment error rate. Based on State feedback during a cycle, we have introduced other situations that could result in these types of errors and have added it to the definitions of these errors in the eligibility instructions.

Comment: A commenter requested that we increase the tolerance level for cost share liability error to more than \$25 to factor in caseload growth and inflation over the past 30 years.

Response: While we understand that other quality control programs have adopted a threshold for certain components of the measurement, PERM is subject to IPIA requirements and there is no allowance for a minimum dollar in error threshold. Therefore, we are not implementing this recommendation.

Undetermined Eligibility Errors

Comment: A commenter requested clarification on the newly designated

§ 431.980(e)(1)(vii)(A), which states the following: "If eligibility or ineligibility cannot be verified, cite a case as undetermined." The commenter asked if the text applies to all eligibility elements or just the client's selfdeclared or self-certified eligibility elements only.

Response: The requirements are the same for all elements of the review. We have provided the information for cases cited as undetermined in two places: First, we are redesignating § 431.980(e)(1)(viii) as § 431.980(vii)(A) to clarify that the new (e)(1)(vi) of this section specifically relates to review of self-declaration and second, paragraph (e)(1)(ix)(B) of this section relates to all elements of the eligibility review.

Comment: Several comments received were in reference to cases where the sampled beneficiary is incarcerated, and therefore, cannot cooperate in the eligibility review conducted, often resulting in a finding of "undetermined." It was recommended that CMS add a provision to the regulation that in instances where a sampled beneficiary is incarcerated, the State should be allowed to drop and replace this case. Another commenter references MEQC and dropping cases in which the sampled beneficiary does not cooperate. Additional commenters also cited the existence of a threshold in other quality control programs, such as the measurement for the Supplemental Nutrition Assistance Program, to allow for a certain percentage of cases that cannot be completed and recommended that a threshold be developed.

Response: The purpose of the "undetermined" review findings is to address cases such as those described by the commenter where the eligibility review cannot be completed and/or eligibility cannot be verified for the PERM review. Therefore, we are not adopting this recommendation.

Beneficiary cooperation is not required to complete the PERM review and other reasonable evidence may be used to verify eligibility if the beneficiary cannot be contacted.

Furthermore, the charge of PERM is to calculate a statistically valid error rate, which is a different outcome than the goals of other quality control programs that might employ a threshold. Dropping cases that cannot be determined lessens the validity of the State error rate and introduces risk to not meeting IPIA precision requirements. Dropping cases would also introduce bias into the error rate measurement in that universe totals cannot be adjusted to account for what percentage of the universe, which is used to weight the sample each month, is comprised of undetermined cases.

Comment: Several commenters recommend that "undetermined" cases be excluded from the eligibility payment error rate. The commenter states that not all "undetermined" cases represent dollars in error.

Response: "Undetermined" cases must not be excluded as payment errors as they are cases in which there is insufficient documentation to verify whether, or not, payments made on behalf of the sampled case were appropriately paid. Under OMB's IPIA guidance, such cases must be included as errors. However, as we proposed, we will allow States to have their Statespecific error rates calculated with undetermined cases included as errors, and with undetermined cases excluded as errors. We will also post this information with the final State-specific program and component error rates on the medical review contractor's tracking Web site.

Comment: A few commenters expressed concern about excluding undetermined cases from State-specific error rates, but including them in the national payment error rate. Although a positive step, the commenters would rather exclude undetermined cases completely.

Response: Under the OMB guidance, undetermined cases must be included in the national error rate. Therefore, we cannot exclude those cases completely. After some consideration, operationally there is no way that we can exclude undetermined cases from State errors but include them in the national error rate. The number and amount of undetermined cases will still be weighted according to States' sizes and may still be associated with each State. CMS' official error rate for Medicaid and/or CHIP includes undetermined cases as errors, the States' error rates for future operations must be the Statespecific error rate with undetermined cases included as errors.

As a result, we are removing the proposed § 431.960(f)(2) that excludes undetermined cases from State specific error rates.

Comment: One commenter asked whether or not a missing eligibility case record would be considered an improper payment as this would constitute insufficient or lack of documentation and whether or not an electronic case record could be used if a physical case record cannot be obtained.

Response: For eligibility, a missing case record could be classified as a technical error and does not affect the eligibility of a sampled beneficiary. An

eligibility review must still be completed for this case using other reasonable evidence. Furthermore, we define case record at § 431.958 as either a hardcopy or electronic file that contains information on a beneficiary regarding program eligibility.

Comment: One commenter suggests that we exclude undetermined cases from the error counts and that if CMS is concerned about States placing cases in the undetermined category to avoid citing them as errors it should hire a Federal contractor to conduct re-reviews to ensure the accuracy and integrity of States' findings.

Response: We appreciate the recommendation for procuring a contractor to complete re-reviews of States' eligibility findings. We continue to consider this recommendation as a possibility in future operations.

C. Self-Declaration for Eligibility Reviews

Section 601(c)(2) of the CHIPRA requires that the payment error rate determined for a State shall not take into account payment errors resulting from the State's verification of an applicant's self-declaration or selfcertification of eligibility for, and the correct amount of, medical assistance or child health assistance, if the State process for verifying an applicant's selfdeclaration or self-certification satisfies the requirements for such process. We have interpreted the CHIPRA to mean that CMS must revise its eligibility review procedures to be consistent with State self-declaration policies, to the extent they conform to Federal requirements for self-declaration.

Currently, States are required to review the case record and independently verify eligibility criteria where evidence is missing, or outdated and likely to change, or otherwise as needed. We proposed that an applicant's self-declaration statement for Medicaid or CHIP would be acceptable verification for eligibility where State policy allows for selfdeclaration, so long as the following requirements are met. The selfdeclaration statement must be:

• Present in the record;

• Not outdated (more than 12 months old);

• In a valid, State approved format; and

• Consistent with other facts in the case record.

Additionally, we proposed that if the above requirements are not met, a State may verify eligibility through a new self-declaration statement if permitted under State law or policy, and, if a new self-declaration cannot be obtained, the

State may verify eligibility using third party sources, for example, documentation listed in section 7269 of the State Medicaid Manual. We proposed that if none of these efforts to verify the self-declaration are successful, then the case should be cited as "Undetermined." We proposed that these undetermined cases would not be included in the State-specific payment error rate. However, we proposed to specify in the new §431.960 that these errors be tracked nationally by including these Undetermined cases in the national program payment error rates.

We proposed to modify § 431.980 to provide these review requirements for self-declaration in accordance with States' documented policies and procedures. We also proposed to modify the PERM eligibility instructions, found at *http://www.cms.gov/perm/ downloads/*

PERM_Eligibility_Review_Guidance.pdf. These instructions, which clarify and provide additional guidance in implementing the regulations, reflect the new review procedures for selfdeclaration.

We received the following comments regarding our proposed revisions to the Self-Declaration for Eligibility Reviews.

Comment: One commenter recommended that we clarify the regulation to say that States do not have to obtain a new self-declaration statement for the PERM review and that the existing statement meets the necessary review criteria.

Response: The regulation will allow a self-declaration that is present in the case record to be used to verify eligibility for the PERM reviews if it meets the requirements of § 431.980(e)(1)(vi). If it does not meet these requirements, States may obtain a new self-declaration statement, or verify the applicant's eligibility using third party sources, including applicable caseworker notes, information obtained by the PERM reviewer, and documentation listed in section 7269 of the State Medicaid Manual.

Comment: One commenter recommended that we clarify that statements obtained online or over the telephone as part of an initial application or redetermination are acceptable as self-declaration for the PERM review.

Response: For the PERM review, these statements qualify as acceptable selfdeclaration if they meet the requirements of 431.980(e)(1)(vi). If the self-declaration from the most recent case action in the case record does not meet these requirements, the eligibility of the applicant must be verified in accordance with the requirements of § 431.980(e)(1)(vii) and the State's documented policies and procedures.

Comment: A commenter believes that verifying household composition that is self-declared, as required by the eligibility review instructions, is difficult to verify and many times not questionable.

Response: We agree with the commenter that verifying household composition is difficult and will revise the eligibility review guidance to say that self-declaration for PERM is an acceptable form of verification for the PERM review, including household composition, as long as the self-declared information meets the criteria of § 431.980(e)(1)(vi).

Comment: Several commenters requested clarification for what is acceptable self-declaration for the PERM review.

Response: After considering comments, we will consider revising the eligibility review guidance for verifying self-declaration statements for the PERM review. The guidance will include acceptable forms of self-declaration to include information taken over the telephone, or information obtained by the PERM reviewer, case worker notes, information accessed from other beneficiary records (for example, the Supplemental Nutrition Assistance Program), as well as the current guidance for obtaining a new selfdeclaration statement in a Stateapproved format.

Comment: One commenter recommended that we reissue eligibility review guidance consistent with the provisions of the new regulation. Another commenter suggested that we clarify that the PERM eligibility reviews should be conducted consistent with State eligibility policies and procedures.

Response: We plan to release new eligibility review guidance based on the provisions of the new regulation, as well as feedback received from States from prior cycles. The purpose of the eligibility review is to verify the eligibility of sampled cases using State eligibility policies and criteria in effect in the review month (so long as the policies and criteria comply with the State plan or if the plan is silent, Federal laws and regulations).

Comment: One commenter agreed with our proposed change to allow States additional opportunities to reduce the number of undetermined cases by verifying eligibility using third party sources if a new self-declaration statement cannot be obtained.

Response: Although some commenters interpret this as a new policy, this is not a change from current

policy. The eligibility review guidance states that other reasonable evidence can be used to verify eligibility. We will add to this regulation and will consider further clarifying in the eligibility review instructions that States may use other reasonable evidence to verify eligibility if a self-declaration statement in the case record does not meet the requirements of § 431.980(e)(1)(vi) and a new self-declaration statement cannot be obtained.

Comment: Several commenters wanted to know the rationale behind determining two different error rates based on whether or not undetermined cases are due to self-declaration or other reasons. The commenters question the purpose of including any undetermined cases in the national error rate if they are to be excluded from the Statespecific error rates.

Response: Although we proposed to exclude undetermined cases from Statespecific error rates and only include them in the national error rate, we have discovered that there is no true way to exclude undetermined cases and not associate them with each State. State error rates will continue to be calculated with and without the undetermined cases. Also, the self-declaration review procedures are being revised to reduce the number of undetermined cases based on conflicts between PERM review procedures and State and Federal policy.

Comment: Several commenters are concerned that the proposed rule contradicts both State self-declaration policies and the eligibility review procedures from previous years and puts CMS at risk of not being compliant with the CHIPRA legislation and of calculating inconsistent error rates from year to year.

Response: We agree with the concern that the proposed rule contradicts State self-declaration policies and are revising our self-declaration policy to ensure that it is not contradictory to States' selfdeclaration policies and procedures. The self-declaration statement for the PERM review must be in a valid, Stateapproved format.

Also, all changes we are making to the eligibility review procedures comply with the CHIPRA and implement process improvements recommended by States that have participated in the measurements. The goal of PERM is to have a consistent measurement process. We believe that the new self-declaration regulations provide for a consistent measurement process while at the same time providing CMS with flexibility to take into consideration different State's self-declaration policies. We will be revising our eligibility review procedures in guidance to ensure that we obtain more accurate eligibility error findings based on current practices for State Medicaid and CHIP eligibility determinations.

Comment: A commenter recommended clarification in the regulation that certain eligibility criteria are not always considered outdated if verified correctly, but are older than 12 months, for example, citizenship or alien status, birth date, and social security number.

Response: We agree that there may be certain eligibility criteria like those identified by the commenter that are not likely to change, and therefore, are not always considered outdated if verified correctly, but are older than 12 months. Section 431.980(e)(1)(iv) provides that States must independently verify information that is missing, outdated and likely to change, or otherwise as needed, to verify eligibility. We will add in guidance that in addition to verifying outdated information more than 12 months old, information that is not required to be verified every 12 months (citizenship is never outdated if verified correctly) does not have to be re-verified for the PERM review.

Birth date and social security number are examples of eligibility criteria that are unlikely to change and the rules on outdated information do not apply. We will consider making the necessary clarifications in guidance that some eligibility criteria are unlikely to change or are not required to be verified every 12 months. We will also consider the commenter's suggestion to add alien status as a criterion to be verified when we issue new eligibility review instructions.

It should also be noted that for the PERM review, if applicable verification is present in the record, meets the State's documented policies and procedures, and is current (for example, a paystub to verify income for the State's last action on the case) no further verification is required.

Comment: Several commenters believe that PERM's requirement for a new self-declaration statement results in an increase of undetermined cases and undermines simplification efforts for eligibility determinations promoted by the CHIPRA legislation.

Response: The CHIPRA gives the Secretary authority to promulgate regulations governing the State process for verifying an applicant's selfdeclaration. In accordance with this authority, we have determined that a new self-declaration statement is only required if one does not exist in the case record, or, if one does exist in the case record, it is outdated; the self-

declaration statement is not in a valid State approved format; or the selfdeclaration statement is inconsistent with other facts in the case record. Therefore, we do not believe that a new self-declaration statement from the sampled beneficiary, when required, will result in an increase of undetermined cases. Additionally, we are adding to the regulation that if the last case action occurred for the sampled case more than 12 months prior to the sample month, the selfdeclaration statement must either be verified or a new one requested. We are also adding to the self-declaration criteria in regulation that the selfdeclared information must originate from the last action on a case in which that last action was no more than 12 months prior to the sample month. We are making this addition to the regulation because all eligibility criteria that are likely to change must be verified as of the sample month for the PERM review. States may use other reasonable evidence, including information from other beneficiary records, before contacting the beneficiary for verification or a new selfdeclaration statement. Further, conflicting information can be resolved by the PERM reviewer through other reasonable evidence, and an eligibility review decision can be made based on the most accurate information received. Additionally, we believe the selfdeclaration validation requirements, including that of a new self-declaration, conform to the CHIPRA and are reasonable methods of verifying eligibility based on self-declarations.

We would also like to clarify that PERM reviewers do not make eligibility determinations, but review cases to verify eligibility. We will change the section heading at § 431.980(e) from Eligibility Review Determinations to Eligibility Review Decisions.

Comment: A commenter suggests suspending counting undetermined cases as errors until the measurement to review Express Lane Eligibility is developed since both are products of the effort to simplify eligibility processes, that is, self-declaration and Express Lane Eligibility.

Response: We are unable to suspend how we measure undetermined cases. Children enrolled in Medicaid or CHIP through the Express Lane Eligibility option are excluded from MEQC and PERM reviews per the CHIPRA. PERM will continue to review all other cases not enrolled via Express Lane Eligibility. When issuing future guidance, we will consider how Express Lane Eligibility determinations interact with PERM. *Comment:* A commenter requested clarification on whether or not citizenship can be verified through selfdeclaration.

Response: States must document citizenship based on the Medicaid and CHIP regulations and the applicable documentation must be present in the case record to be verified for PERM. Our intent is not to use PERM guidelines to change current citizenship verification requirements. If citizenship has been documented correctly, new verification of citizenship (due to verification being more than 12 months old) is not required because citizenship is not likely to change.

Comment: A commenter requested clarification on prior communications from CMS to the State regarding whether or not a new self-declaration statement was required for States with continuous eligibility policies, in which a recipient is eligible at application or redetermination and is eligible for 12 months, regardless of changes in income.

Response: Previously in guidance a new self-declaration statement was always required for continuous eligibility cases in which a child is determined eligible at application or redetermination and remains eligible for the length of the continuous eligibility period specified by the State in its State plan (no longer than 12 months), regardless of any changes in circumstances, for example, income. States needed to verify the information on the self-declaration statement concerning applicant's eligibility at the time of the last case action, which was either the initial application for eligibility or the State's most recent redetermination of the applicant's eligibility.

Under the new regulations, a new self-declaration statement is only required when it does not meet the requirements of § 431.980(d)(1)(vi).

Comment: A commenter suggested we revise the proposed § 431.960(d)(3) to state, "A State eligibility error does not result from the State's verification of an applicant's self-declaration or selfcertification of eligibility for, and correct amount of, medical assistance or child health assistance, if the State process for verifying an applicant's selfdeclaration or self-certification satisfies the requirements in Federal law, Secretary guidance, or if applicable, Secretary approval."

Response: We agree and are revising § 431.960(d)(3) accordingly. We believe this revision appropriately describes the self-declaration verification requirements.

Comment: One commenter believes that the ability to exclude unwanted cases (for example, a case belongs in a different stratum than the one in which it was sampled) and to drop unreviewable cases, such as cases where the client does not respond to requests for information, is essential to ensuring that error rates reflect meaningful definitive conclusions. The commenter stated that to include sampling mistakes and undetermined findings in the error rates contaminates corrective actions derived from those error rates. The commenter also noted that CMS Regional Office staff in the past has conducted Federal re-reviews for MEQC and reviewed cases dropped from the MEQC reviews to deter and eliminate abuse and that this practice should be resumed.

Response: States are allowed to drop cases that were sampled by mistake. These cases are not included in the error rate. However, undetermined cases are included in the error rate due to the inability to determine if services paid on behalf of a beneficiary were properly paid. We appreciate the commenter's suggestion to re-implement Federal rereviews for MEQC, and, although the majority of States conduct pilot reviews and are under section 1115 waivers and therefore exempt from several of the "traditional" MEQC provisions, we will consider this and other options for future operations.

Eligibility Review Procedures

Comment: A commenter noted that the proposed rule should clarify if States only look at information available at the time of client application/ eligibility review/last action processing vs. information discovered during the IPIA review that was being withheld by the client.

Response: We disagree with this clarification. The eligibility review requirements tell the agency that it must review the documentation in the case record, and independently verify eligibility criteria where information is missing, outdated and likely to change, or otherwise as needed. If there is inconsistent information in the case record, the PERM reviewer is responsible for resolving any inconsistencies by using case record documentation or other reasonable evidence.

Comment: One commenter recommended clarifying the timeframe for submitting eligibility reports as written in the eligibility guidelines. The commenter noted that the language indicates that 100 percent of case review findings must be completed within 150 days and payment review findings within 210 days. However, the commenter stated that in practice CMS allowed States to submit and adjust a report beyond these timeframes in previous cycles, as long as findings were complete by July 1. The commenter recommended that the guidance should be revised to indicate that these timeframes are for "initial" reporting.

Response: We appreciate the commenter's concern and we will consider this recommendation when we revise our guidance.

Comment: One commenter requested that we add language to the regulations to allow States to impose Medicaid and CHIP sanctions for noncompliance with PERM eligibility reviews.

Response: A client's noncompliance with a PERM review is not specified as a reason in Federal statute or regulation for denial or termination of Medicaid or CHIP participation or benefits or for imposition of sanctions. There is no authority under Federal statute or regulation that allows a State to treat a beneficiary's cooperation or lack of cooperation with PERM reviews as a condition of eligibility for Medicaid or CHIP. The appropriate action for cases where a client does not cooperate in any audit process is to send the case back to the responsible agency for an official redetermination.

D. Difference Resolution and Appeals Process

Section 601(c)(1)(B) of the CHIPRA requires CMS to include in the new final rule for PERM a clearly defined process for appealing error determinations by review contractors or State agency and personnel responsible for the development, direction, implementation, and evaluation of eligibility reviews and associated activities.

1. Medical and Data Processing Review

The October 5, 2005 IFC established the difference resolution process, which is codified at § 431.998. Medical reviews and data processing reviews for FFS and managed care payments are conducted by an independent Federal contractor. States supply relevant policies but do not participate in the review; States are notified of all error findings. The difference resolution process is the mechanism by which a State may try to resolve with the Federal contractor differences in the Federal contractor's error findings; the State may appeal to CMS if it cannot resolve the difference in findings with the Federal contractor.

In accordance with the CHIPRA, we proposed a timeline associated with the difference resolution and CMS appeals processes. We also proposed to revise the heading of § 431.998 to read, "Difference resolution and appeal process," which more accurately describes the regulation.

We proposed to revise §431.998 to explain that the State may file, in writing, a request with the Federal contractor to resolve differences in the Federal contractor's findings based on medical or data processing reviews of FFS and managed care claims in Medicaid or CHIP within 10 business days after the disposition report of claims review findings is posted on the contractor's Web site. Additionally, the State may appeal to CMS for a final resolution within 5 business days from the date the contractor's finding as a result of the difference resolution is posted on its Web site.

In addition to establishing the timeline for the difference resolution and appeal processes, we proposed to eliminate the dollar threshold for engaging in the CMS appeals process. Section 431.998 currently provides that States may apply to the Federal contractor to resolve differences in findings and may appeal to CMS for final resolution for any claims in which the State and Federal contractor cannot resolve the difference in findings, as long as the difference in findings is in the amount of \$100 or more. We established the \$100 threshold in order to prevent *de minimis* disputes and to ensure that appeals to CMS were substantial enough to warrant reconsideration. We were also concerned that a large volume of smalldollar appeals would prevent the States from receiving timely decisions on their appeals.

¹ Information from the FY 2006 and FY 2007 PERM cycles on the number of total claims (including those with errors less than \$100) submitted to the Federal contractor for difference resolution and on the number appealed to CMS for final resolution suggests that the volume of appeals will not substantially increase if CMS allows appeals of errors of less than \$100. Because all errors regardless of their dollar amount ultimately contribute to a State's error rate and hence the national error rate, we proposed to remove the \$100 threshold set forth in § 431.998(b)(1).

2. Eligibility

As stated in the current PERM regulations at § 431.974(a)(2), personnel responsible for PERM eligibility sampling and review "must be functionally and physically separate from the State agencies and personnel that are responsible for Medicaid and CHIP policy and operations, including eligibility determinations." The intent of this provision was to ensure the independence of the review in order to achieve an unbiased error rate. We provided further clarification in the preamble of the August 2007 final rule, indicating that the agency responsible for PERM could be under the same umbrella agency that oversees policy, operations and determinations but the two agencies cannot report to the same supervisor.

In the preamble to the proposed rule, we further clarified that qualified staff with knowledge of State eligibility policies may be used to conduct the eligibility reviews, but the staff that is chosen must be independent from the staff that oversees policy and operations.

We would further like to clarify that we consider staff to be independent if they temporarily work on PERM eligibility reviews even though they usually work under eligibility policy and operations, so long as the staff does not discuss PERM eligibility reviews with the staff that oversees policy and operations during the time the staff is working on PERM eligibility reviews.

Furthermore, the PERM eligibility instructions ask States to provide assurance that the agency or contracting entity responsible for the PERM eligibility reviews ("Agency") is independent of the State Medicaid or CHIP agency responsible for eligibility determination and enrollment. The State is responsible for ensuring the integrity of the PERM eligibility reviews, but we do not preclude the agency from sharing or reporting the PERM eligibility review findings to the State Medicaid or CHIP agencies.

Provided that agency independence could cause a difference in findings between the agency and the State Medicaid and CHIP agencies, we proposed that appeals for eligibility review findings should be conducted in accordance with the State's appeal process, as eligibility reviews are conducted at the State level.

In consideration of States that may not have a State appeals process in place, we proposed to make State findings available to each respective State's Medicaid and CHIP agencies for the period between the final monthly payment findings submission and eligibility error rate calculation, for example, April 15th through June 15th after the fiscal year being measured or according to the eligibility timeline. We proposed facilitating documentation exchange between the State Medicaid or CHIP agency and the agency conducting the PERM eligibility reviews to resolve differences. If any eligibility appeals issues involve Federal policy, States can appeal to CMS for resolution. If our decision causes an erroneous payment finding to be made, any resulting recoveries will be governed by § 431.1002.

We proposed that the State Medicaid or CHIP agencies may document their differences in writing to the agency for consideration. If resolutions of differences occur during the PERM cycle, eligibility findings can be updated to reflect the resolution. If differences are not resolved by the deadline for eligibility findings to be submitted to CMS (July 1), the documentation of the difference can be submitted to CMS for consideration no sooner than 60 days and no later than 90 days after the deadline for eligibility findings.

We also solicited comments on other ways that we can implement an eligibility appeals process for which we can provide consistent oversight.

We received the following comments regarding our proposed revisions to the Difference Resolution and Appeals Process.

Fee-for-Service and Managed Care Appeals Process

Comment: Several commenters requested that the timeline for a State to request difference resolution with the review contractor be extended. Many commenters suggested extending the timeframe from 10 business days to 15 business days, while others requested an extension to 20 business days. In addition, the commenters asked that the timeframe to request an appeal to CMS be extended from 5 business days. The majority of commenters suggested allowing 10 business days to request an appeal, while others suggested 15 business days.

Response: We agree that more time to file a difference resolution and appeal would be beneficial for States, and are adopting the recommendation to allow States 20 business days to request a difference resolution and 10 business days to request an appeal to CMS. We are revising the language at § 431.998 accordingly.

Eligibility Appeals Process

Comment: A few commenters believe that a new process would have to be developed to implement an eligibility review appeals process and that this will create a workload that will impact the timely submission of monthly findings when errors are identified.

Response: States may develop an appeals process if one does not exist at the State level. States do not have to implement a new process for eligibility appeals if there is already a process in place or no error findings are in dispute. The agency should submit all findings according to the deadlines and have until the designated deadline after the fiscal year being measured to resubmit findings based on the State level appeals process.

Comment: One commenter endorses the proposed eligibility appeals process but cautions CMS that it must ensure consistency during the resolution process if its assistance is needed by States.

Response: We appreciate the comment. In addition to CMS intervention for Federal policy issues, we are considering developing guidance for a standard process for States to exchange documentation to ensure consistency between States. As this is a new policy, changes to the procedure may need to be updated to best meet the needs of States. Any procedural changes will be communicated to States as necessary.

Comment: Some commenters needed clarification on who renders a final decision on eligibility appeal findings.

Response: If States have a functioning appeals process at the State level, this must be used to resolve eligibility issues of State policy. The purpose for allowing for an existing State level appeals process to be used to resolve differences on eligibility review findings is to have a third party settle disputed review decisions between the agency and the State Medicaid and CHIP agencies. Review findings would be revised or unchanged based on the findings of the third party and not the agency or State Medicaid or CHIP agency. States must use an appeals process at the State level to resolve State-level policy issues. If the State does not have a State level appeals process in place (for example, an appeals process set up to dispute MEQC findings could be used for PERM purposes) documentation exchange can take place between the two parties, with CMS as facilitator and based on new information or policy clarifications provided by the policy branch. The agency will make a final review decision. The agency's final review decision may be appealed to CMS for consideration no sooner than 60 days and no later than 90 days after the final deadline for eligibility findings. If any eligibility appeals issues involve Federal policy, States can appeal directly to CMS for resolution. CMS' decisions will be final.

E. Harmonization of Medicaid Eligibility Quality Control (MEQC) and PERM Programs

1. Options for Applying PERM and MEQC Data

Section 601(e)(2) of the CHIPRA requires that, once this final rule is effective for all States, States will be given the option to elect, for purposes of determining the erroneous excess payments for medical assistance ratio applicable to the State for a fiscal year under section 1903(u) of the Act, to substitute data resulting from the application of the PERM requirements to the State for data obtained from the application of the MEQC requirements to the State with respect to a fiscal year. We had proposed that this substitution option would not be effective until 6 months after the final rule is in effect based on the CHIPRA's requirement under section 601(b) that there shall be no calculation or publication of any national or State specific CHIP error rate until 6 months after the final rule is effective. However, because the MEQC program does not measure all CHIP eligibility errors, we believe that a more accurate interpretation of the CHIPRA is to not require the 6-month delay. Nevertheless, because section 601(e)(2) permits the PERM data substitution for MEOC data only after the final rule is in effect, States will not have this substitution option until after the final rule is effective.

We considered several interpretations of the CHIPRA requirements that would allow States the option to substitute PERM data for MEQC data for purposes of the MEQC reviews, but would also retain two separate, independent processes (MEQC and PERM), which are governed by separate statutes and regulations. As PERM is required to meet specific statistical precision requirements and the MEQC error rate is not, we do not believe it is feasible to incorporate the PERM error rate into a State's overall MEQC error rate. Therefore, we proposed to interpret "data" as the sample, eligibility review findings, and payment findings as measured under MEOC or PERM. We also proposed to calculate separate rates for each program.

We proposed to amend § 431.806 and § 431.812 of the MEQC regulations. These proposed amendments would provide for the State's option in its PERM year to use their samples, eligibility findings, and payment findings as measured using PERM sampling and review requirements to meet their MEQC review requirement. After further consideration, we are adding the exception that PERM cases cited as undetermined errors may be dropped from the MEQC error rate calculation so long as the reasons for the dropped cases are in accordance with section 7230 of the State Medicaid Manual. The PERM data and results will be used to meet the statutory and regulatory ("traditional") MEQC requirements. All provisions for "traditional" MEQC will apply, including the 3 percent national standard and disallowance provisions.

We proposed that States that choose to substitute PERM data for MEQC data, would still have two eligibility error rates calculated—one for MEQC using MEQC measurement requirements and one for PERM using PERM requirements. We proposed to revise § 431.806 of the MEQC regulations to require that a State plan be amended for States opting to use PERM for MEQC in a State's PERM cycle.

We proposed to amend § 431.812 of the MEQC regulation to provide that States substituting PERM data for MEQC data must use a sampling plan that meets the requirements of § 431.978 of the PERM regulation and perform active case reviews in accordance with § 431.980 of the PERM regulation.

We proposed that States with CHIP stand alone programs will only have the option to substitute PERM Medicaid data to meet MEQC requirements under § 431.812(a) through (e) since CHIP stand alone programs are not reviewed under MEQC.

We also proposed that States with Medicaid and Title XXI Medicaid expansion programs may use Medicaid and CHIP PERM reviews to meet the MEQC requirements described under § 431.812(a) through (e), as both Medicaid and Title XXI Medicaid expansion programs are reviewed under MEQC. States with Title XXI Medicaid expansion programs must combine their Medicaid and CHIP PERM findings to calculate one MEQC error rate. The data must be kept separate for purposes of calculating the PERM error rates.

In addition, we proposed that States with combination CHIP programs, in which a portion of their CHIP cases are under a stand-alone program and a portion of their CHIP cases are under a Title XXI Medicaid expansion program, may use the PERM Medicaid eligibility reviews and the portion of the PERM CHIP eligibility reviews under Title XXI Medicaid expansion programs to meet their MEQC requirement. The Federal contractor will combine the CHIP case findings under the Title XXI Medicaid expansion program and CHIP stand alone findings to calculate one PERM CHIP error rate. The Title XXI Medicaid expansion portion of the PERM data

must be included with the Medicaid PERM data to calculate the MEQC error rate.

Section 601(e)(3) of the CHIPRA provides that for purposes of satisfying the requirements of the PERM regulation relating to Medicaid eligibility reviews, a State may elect to substitute data obtained through MEQC reviews conducted in accordance with section 1903(u) of the Act for data required for purposes of PERM requirements, but only if the State MEQC reviews are based on a broad, representative sample of Medicaid applicants or enrollees in the States. The CHIPRA's general effective date of April 1, 2009 applies to this provision. Therefore, as of April 1, 2009, States have the option to substitute MEQC data for PERM data so long as the MEQC reviews are based on a broad, representative sample of Medicaid applicants or enrollees in the States.

We considered several interpretations of the CHIPRA requirements that would allow States the option to substitute MEQC data for PERM data for purposes of the PERM reviews, but would also retain two separate, independent processes (MEQC and PERM), which are governed by separate statutes and regulations. As PERM is required to meet specific statistical precision requirements and the MEQC error rate is not, we do not believe it is feasible to incorporate the MEQC error rate into a State's PERM error rate. Therefore, we proposed to interpret "data" as the sample, eligibility review findings, and payment findings as measured under MÉQC or PERM. We will calculate separate rates for each program. States operating under MEQC waivers and pilot programs cannot use this option because the CHIPRA only permits substitution of MEQC data for PERM reviews where the MEQC review is conducted under section 1903(u) of the Act, and the MEQC waivers and pilot programs are not conducted under the requirements of section 1903(u) of the Act. Additionally, the CHIPRA only permits substitution of MEQC data if the reviews are based on a "broad, representative sample" of Medicaid applicants and beneficiaries. MEQC section 1115 waivers and pilot programs are special studies or conducted on focused populations of Medicaid beneficiaries and are not considered a representative sample of all Medicaid beneficiaries.

We proposed to interpret "broad, representative sample of Medicaid applicants or enrollees" to mean that States must develop the MEQC universe according to requirements at § 431.814 in order to consider the option to use

one program's findings to meet the requirements for the other. Under § 431.814, States must sample from a universe of all Medicaid and Title XXI Medicaid expansion beneficiaries (except for the exclusions provided in §431.814(c)(4)). States operating MEQC pilots or waivers will need to continue operating PERM separately from MEQC. Additionally, we proposed that the MEQC samples must meet the PERM confidence and precision requirements. We are clarifying here that this means that the MEQC sample size may need to be adjusted to meet the PERM confidence and precision requirements if the State elects to substitute MEQC data for PERM data.

We proposed that States with CHIP stand alone programs only have the option to substitute Medicaid MEQC data to meet the PERM Medicaid eligibility review requirement, as CHIP stand alone is not reviewed under the MEQC review.

We also proposed that States with Title XXI Medicaid expansion programs may use their MEQC reviews described in § 431.812(a) through (e) to meet both the PERM Medicaid and CHIP eligibility review requirements, as both Medicaid and Title XXI Medicaid expansion are reviewed under MEQC. Title XXI Medicaid expansion data must be separated from the MEQC Medicaid data to calculate a PERM CHIP error rate.

We also proposed that States with combination programs in which a portion of their CHIP cases are under a stand-alone program and a portion of their CHIP cases are under a Title XXI Medicaid expansion program may use the MEQC reviews described under §431.812(a) through (e) to meet the PERM Medicaid eligibility review requirement and the portion of the PERM CHIP eligibility review requirement under Title XXI Medicaid expansion. However, the stand alone portion of the CHIP universe must remain separate and either stratified or not stratified, as described in §431.978(d)(3), as CHIP stand alone is not measured under the MEQC program. The Federal contractor, who we proposed will calculate State eligibility error rates, will combine the Title XXI Medicaid expansion and CHIP stand alone findings to calculate one PERM CHIP error rate.

In addition, we proposed to amend § 431.980 to allow for States in their PERM year the option to use their MEQC samples, eligibility findings, and payment findings to meet their PERM eligibility review requirement. We proposed that MEQC reporting requirements to the CMS Regional Offices remain the same, including reporting the error findings for the two 6-month review periods, but States will also be required to comply with the PERM eligibility reporting deadlines by posting error findings to the PERM Error Rate Tracking (PERT) Web site or other electronic eligibility findings repository specified by CMS. We proposed that States that choose to substitute MEQC data for PERM data, will still have two eligibility error rates calculated—one for MEQC using MEQC measurement requirements and one for PERM using PERM requirements.

We also proposed that States that choose to substitute MEQC or PERM data should note that although two error rates are calculated, only the MEQC error rate will be subject to disallowances under section 1903(u) of the Act. PERM does not have a threshold for eligibility errors and any improper payments identified during the eligibility measurement are subject to recovery according to § 431.1002 of the regulations.

We proposed that if a State chooses to substitute PERM or MEQC data, the State may not dispute error findings or the eligibility error rate based on the possibility that findings would not have been in error had the other review methodology been used.

We solicited comments on the following alternative process for the substitution of MEQC and PERM data: States would select one annual sample that meets MEQC minimum sample requirements and PERM confidence and precision requirements. The State would conduct both an MEQC review and a PERM review on each applicable case. This would ensure a clear distinction between an MEQC error and a PERM eligibility error, and would be the basis for the MEQC error rate and the PERM eligibility error rate. We also solicited comments on other possible methods for substitution of data.

States that choose to substitute MEQC data may only claim the regular administrative matching rate for performing the MEQC procedures for Medicaid and Title XXI Medicaid expansion cases. The 90 percent PERM enhanced administrative matching rate will only be applicable to States conducting PERM reviews for CHIP cases.

2. Definition of a Case

Section 431.958 currently defines a case as an "individual beneficiary." States are required to sample and conduct eligibility and payment reviews for an individual beneficiary even if the State grants eligibility at the family level. However, sampling at the individual beneficiary level has proven to be difficult for States from a programming perspective.

Many States receive, review, and grant eligibility based on an application for an entire family, which could be for one person or multiple people. Dividing the family unit for PERM eligibility sampling has been difficult for States to achieve.

The MEQC regulation, at § 431.804, defines an active case, in pertinent part, as an "individual [beneficiary] or family." Changing the definition of a case for PERM eligibility to include both individual beneficiaries and families will support the harmonization process and reduce redundancies in the MEQC and PERM programs as required by section 601(e)(1) of the CHIPRA, by making it easier for States to utilize their new option of substituting PERM data for MEQC data, and vice versa.

Therefore, we proposed to revise the definition of a case in § 431.958 to mean an individual or family, at a State's option.

3. Error Rate Calculation: State Responsibility for Calculating Error Rates

Section 431.988 requires, as part of the PERM eligibility review process, for States to calculate and report case and payment error rates for active cases and case error rates for negative cases. As originally envisioned, States retained responsibility for sampling cases, conducting eligibility reviews, collecting payment information for errors, and calculating eligibility error rates. States were to report final eligibility error rates to CMS, which will forward the information to the Federal contractor for inclusion in the overall State and national error rates.

In practice, States have found it difficult to calculate the eligibility error rates. In most cases, States lack the necessary statistical or technical expertise to execute the error rate calculation formulas provided in the PERM eligibility instructions. During the FY 2007 cycle, the Federal contractor provided substantial technical assistance to the States to assist them in conducting these calculations including developing a spreadsheet that States could use to perform the required calculations. Several States requested that, rather than have the Federal contractor provide a spreadsheet that the States merely populate and return to CMS, the Federal contractor perform the required calculations.

Initially, we did not consider it feasible for the Federal contractor to conduct the PERM eligibility error rate calculations because the States conduct the reviews and maintain the case and payment error data. However, during FY 2007, we developed a centralized reporting system for monthly case and payment error data. The Federal contractor can access the centralized system to conduct the eligibility error rate calculations.

Given the difficulties States have experienced in calculating the PERM eligibility error rates and that there are now mechanisms and processes for the Federal contractor to calculate these error rates, we proposed to revise § 431.988(b)(1) and (b)(2) by replacing "rates" with "data" to read as follows: "The agency must report by July 1 following the review year, information as follows: (1) Case and payment error *data* for active cases; and (2) Case error *data* for negative cases."

We maintain that this approach will reduce the burden on the States, reduce redundancies in the MEQC and PERM programs, and more accurately reflect current practice, which is that the Federal contractor calculates the eligibility error rates used in the generation of the PERM error rate, as well as the State and national-level error rates. We will continue to require States to report data, including the total number of cases in the universe, to the centralized reporting system and will provide States with a spreadsheet or similar calculator that can be used to estimate their own eligibility error rates, but will not require States to submit these estimates to CMS.

We received the following comments regarding our proposed revisions to the harmonization of MEQC and PERM programs.

PERM & MEQC Data Substitution

Comment: One commenter requested clarification on the relationship between PERM and the claims processing assessment system (CPAS) in § 431.806.

Response: There is no direct relationship between PERM and CPAS. The end of redesignated paragraph (c) was changed from referring to "assessment that meets the requirements of § 431.830 through § 431.836 of this subpart" to "assessment that meets the requirements of § 431.836 of this subpart" by mistake and will be revised to show the original range "§ 431.830 through §431.836". Section 431.806 was revised to add paragraph (b), and redesignate paragraph (b) as (c). Paragraph (b) was added, which requires that a State's "State Plan provide a State Plan Amendment for States opting to use PERM for MEQC in a State's PERM cycle."

Comment: One commenter questioned whether the Medicaid eligibility

sampling plan would need to be submitted separately from the CHIP plan due to the PERM for Medicaid MEQC substitution.

Response: Section 431.978(a) of the regulation already requires States to submit separate Medicaid and CHIP sampling plans and States will need to continue to do so.

Comment: One commenter believes that harmonization does not reduce the burden on States that are required to generate PERM and MEQC eligibility review data by conducting a PERM and an MEQC review on each sampled case.

Response: We appreciate the comment regarding the proposed alternative substitution process. Based on public comments, we are finalizing that States would not be required to separately sample and review if substituting PERM for MEQC or vice versa. States substituting MEQC data for the PERM review will use MEQC review requirements. States substituting PERM data for the MEQC review use PERM review requirements. However, while MEQC allows cases to be dropped from review under certain circumstances, as discussed in the proposed rule, undetermined cases must be included in the PERM error rate. Accordingly, we are revising §431.980(f) to clarify that all MEQC cases must be included in the PERM error rate. States must either apply a PERM eligibility review findings to dropped MEQC cases, or cite the cases as an undetermined errors.

We intend to calculate two error rates. For the MEQC error rate measured using PERM data, we are using the lower limit of the confidence interval, that is typically used for MEQC and allowing drops for MEQC that are allowable in the MEQC manual. For the PERM error rate measured using MEQC data, we will use the midpoint estimate typically used for PERM and any MEQC drops will be considered part of the PERM error rate.

Comment: One commenter suggested that PERM precision requirements be used when sampling for eligibility under both the MEQC and PERM programs, and that traditional MEQC reviews should be conducted on each sampled case when substituting MEOC data for PERM. The commenter stated that this would produce an MEQC error rate using the lower limit and a PERM error rate using the midpoint. The commenter believes that corrective action plans would have more meaningful findings using MEQC review methodology. Another commenter stated that its State conducts traditional MEQC reviews and appreciates this proposal.

Response: We appreciate the alternatives that commenters provided for us to consider in the future as viable operational changes to reduce redundancies between the two programs. As discussed previously, we are finalizing that when substituting MEQC data for PERM data, the MEQC sample, MEQC eligibility review findings, and MEQC payment review findings, which must include any dropped cases and sufficient cases to meet the PERM precision requirements, will be used in calculating the PERM error rate. When substituting PERM data for MEQC data, the PERM sample, PERM eligibility review findings, and PERM payment review findings will be used in calculating the MEQC error rate. PERM cases cited as undetermined may be dropped from the MEQC error rate calculation so long as the reasons for the dropped cases are in accordance with section 7230 of the State Medicaid Manual.

Comment: One commenter believes that it was proposed that States with approved MEQC pilots have no options and must continue the pilots and also do PERM reviews.

Response: We do not agree. States with approved MEQC pilots have the option to return to a "traditional" MEQC review and substitute the MEQC data for PERM, or discontinue the MEQC pilot and use the PERM reviews to substitute the data for "traditional" MEQC.

Comment: Some commenters do not believe we are complying with the CHIPRA which clearly requires the harmonization of MEQC and PERM and that we should modify the rule to truly harmonize the two programs. Among the commenters' concerns are that PERM and MEQC continue to have differences in sample size, sampling methodologies (including stratification), review procedures, error rate calculations and other significant differences.

Response: We disagree with the commenter that we are not in compliance with the CHIPRA and the harmonization provisions. The substitution options do reduce redundancies as required by the CHIPRA in that only one sample will be drawn and one review process will be used, which is where many of the redundancies between PERM and MEQC lay. But the underlying statutory requirements keep us from changing other places where PERM and MEQC overlap, such as the error rate calculation. Two separate error rates, one for PERM and one for MEQC, must still be calculated. We appreciate the commenter's concerns and may address them in future rulemaking.

Comment: A few commenters do not believe that many States will opt to substitute data because substitution will require States to return to traditional MEQC reviews and leave them subject to disallowances that they otherwise would not have been subjected to, if they experience error rates over the 3 percent national standard. Commenters stated that at the same time States would be subject to PERM recoveries.

Response: We understand that States may not conduct traditional MEQC reviews for a variety of reasons. The intent of offering both options of substituting PERM or MEQC data is for States, at their option, to choose what is most beneficial for their State and to comply with the CHIPRA.

Comment: Some commenters believe that since pilot States and traditional MEQC States will be allowed to substitute PERM negative case reviews to meet the negative MEQC requirements for Medicaid, States may have a semblance of savings.

Response: The August 2007 PERM final rule made effective the option for States to use PERM negative case reviews to meet the negative MEQC requirement and some States have already realized these savings.

Comment: One commenter agrees with the stipulation that error findings and error rates cannot be disputed based upon any realization that the error findings would have been different or error rates would have been lower had the other programs' review methodology been used. The commenter stated that once an eligibility review methodology is selected, all rules pertinent to the selected eligibility review methodology must prevail.

Response: We appreciate this comment.

Comment: One commenter expresses that there are fundamental differences in the MEQC and PERM review methodology mostly centering on consideration of the administrative period. Simply substituting MEQC findings for PERM reporting purposes would yield potentially higher error rates for MEQC due to the exclusion of the administrative period under MEQC regulations.

Response: We agree that there are fundamental differences between PERM and MEQC, but if States choose to substitute MEQC data for the PERM data, the MEQC administrative period will be applied. States are not required to substitute data if there are concerns of a potentially higher error rate for either program.

Comment: One commenter stated that pilots are a valuable option to be able to focus on targeted error prone areas to

reduce errors and improve program administration. Another commenter disagrees with not allowing pilot MEQC States to use the pilot findings to meet PERM eligibility requirements. Both commenters agree that in order to reduce the duplication of effort and take advantage of the harmonization effort, States would have to give up the pilot option and revert back to traditional MEQC with the possibility of sanction liability. The commenters suggested that we consider allowing PERM data to be substituted for data used in MEQC pilots, and allow MEQC pilot data to be substituted for PERM data for purposes of meeting the PERM requirements.

Response: We do not agree with this recommendation. To comply with the IPIA, the PERM program must sample from the entire Title XIX and Title XXI eligibility case universe, subject to the enumerated regulatory exceptions. The universe of a MEQC pilot would not meet the broad PERM eligibility universe requirements because MEQC pilot programs have narrower eligibility universes that use focused reviews or special studies.

For the same reason, MEQC pilot programs do not meet the CHIPRA's requirement that MEQC data substituted for PERM data to meet the PERM requirements must be based on a broad, representative sample of all Medicaid beneficiaries.

Additionally, the CHIPRA only permits substitution of MEQC and PERM data where the MEQC review is conducted under section 1903(u) of the Act.

Definition of a Case

Comment: Some commenters expressed concern regarding our proposal to revise the definition of a PERM "case" from an "individual beneficiary" to an "individual beneficiary or family." Some commenters had concerns about the potential for increased workloads, noting that changing the PERM definition of "case" to an "individual beneficiary or family," would require changes to universe development programs and require more time to review a family rather than an individual. Other commenters questioned what a payment error would be comprised of if one family member were ineligible but not the others and whether the definition change would lead to more errors and a higher State and national error rate. Some commenters supported this definition change, noting that in their States eligibility is based on a family application and the revised definition

would simplify programming and review.

Response: This new definition parallels the definition of a case used in MEQC in support of PERM-MEQC harmonization. We are finalizing the definition of a case as proposed. However, we offer the following clarifications. For States where sampling at the individual beneficiary level is easier from a programming and/ or review perspective, no changes to a State's process need to be made. States that opt to sample at the family level will need to update their sampling plans accordingly. Some State programs have both individual and family applications and can choose to sample either at the individual beneficiary level or at the application level (that is, with a combination of both individuals and families in the universe).

The change in the definition of a case will not impact State error rates or the national error rate, as the case and payment error rates are weighted by the universe totals submitted by States. States that sample at the individual beneficiary level will continue to submit the total number of individual beneficiaries in the universe each month. States that opt to sample at the family level will submit the total number of families in the universe each month. States that have a mix of individual and family applications will submit the total number of applications in each sample month.

For family applications, if one individual in the family unit is identified as ineligible, then the case will be considered not eligible. However, the dollars in error will be identified as only those dollars associated with the individual in the family who is ineligible. We understand that this case review finding differs from MEQC, which would consider this case "eligible with an ineligible member." As the PERM eligibility review is focused on the eligibility decision rather than the beneficiary's eligibility at the time the case is sampled (for MEQC), we believe that it is appropriate to call a case "not eligible" for the purpose of calculating the case error rate.

Eligibility Stratification

Comment: We received numerous comments regarding eligibility stratification. Commenters identified multiple issues with programming and accuracy relating to aligning the eligibility universe with the appropriate PERM eligibility strata. Several commenters noted that the stratification process was burdensome on staff, financial, and IT resources. For some commenters, information on new

application and redetermination effective dates are located in a system outside of the State's eligibility system or, for other commenters, information required for stratification is not maintained in a manner that is consistent with the PERM eligibility strata definitions, increasing the programming effort required. Other commenters stated that stratification is unnecessary because all PERM eligibility reviews are completed as of the State's last action, effectively meaning that all cases are reviewed as new applications or redeterminations. Commenters recommended that CMS give States the option to stratify and also the option not to stratify, since there is no statistical significance to stratification and all States are reviewing cases as of the last case action. Commenters also observed that current stratification requirements greatly decrease the accuracy of the sample and require States to drop and replace numerous cases to ensure that the sample for each stratum is properly defined.

Response: Based on comments and a review of eligibility issues over the past several PERM cycles, we have reexamined the eligibility stratification requirements for PERM at § 431.978(d)(3), and will make stratification optional for States. Therefore, based on the commenter's concerns, we are modifying § 431.978 of the PERM regulations.

States will have the option to either maintain stratification (if the elimination of stratification would cause additional State burden) as currently required under § 431.978(d)(3), or sample from an unstratified universe. States will be required to report, for all sampled cases, whether the universe was stratified or not, whether the last action was a new application or a redetermination. We are modifying § 431.988 to reflect this requirement. States will continue to report the total number of cases in the case universe for each month (either the total universe number or the universe totals for each stratum, as appropriate). We have placed this requirement in regulatory text at § 431.988(a).

Eligibility Error Rate Calculation

Comment: One commenter questioned whether States that wished to continue calculating their own eligibility error rates would be given the methodology and means to do so.

Response: Yes, States may still calculate their own eligibility error rates. We expect some type of calculator and the error rate formulas to be available for States to use, as well as assistance from the statistical contractor to explain State specific error rates. However, it should be noted that the PERM contractor will calculate official error rates for the State.

F. Corrective Action Plans

Section 601(c)(1)(C) of the CHIPRA requires CMS to provide defined responsibilities and deadlines for States in implementing corrective action plans.

1. Corrective Action Plan Due Dates

We proposed to revise § 431.992 to provide that States would be required to submit to CMS and implement the corrective action plan for the fiscal year it was reviewed no later than 60 calendar days from the date the State's error rate is posted to the CMS Contractor's Web site. State error rates will be posted to the Web site no later than November 15 of each calendar year.

2. Types of Plans

In addition to measuring programs at risk for significant improper payments, the IPIA also requires a report on Federal agency actions taken to reduce improper payments. Since States administer Medicaid and CHIP and make payments for services rendered under these programs, it is necessary that States take corrective actions to reduce improper payments at the State level. We issued a State Health Official letter in October 2007 to all States detailing the corrective action process under PERM, which can be found on the CMS PERM Web site at http:// www.cms.gov/PERM/Downloads/ Corrective Action Plan.pdf.

The corrective action process is the means by which States take administrative actions to reduce errors which cause misspent Medicaid and CHIP dollars. The corrective action process involves analyzing findings from the PERM measurement, identifying root causes of errors and developing corrective actions designed to reduce major error causes, and trends in errors or other factors for purposes of reducing improper payments.

Development, implementation, and monitoring of the corrective action plan are the responsibility of the States. In order to develop an effective corrective action plan, States must perform data and program analysis, as well as plan, implement, monitor, and evaluate corrective actions. We proposed to revise § 431.992 to define States' responsibilities for these activities as explained below.

(1) Data Analysis—States must conduct data analysis such as reviewing clusters of errors, general error causes, characteristics, and frequency of errors that are associated with improper payments. Data analysis may sort the predominant payment errors and number of errors as follows:

• *Type*—general classification (for example, FFS, managed care, eligibility).

• *Element*—specific type of classification (for example, no documentation or insufficient documentation, duplicate claims, ineligible cases due to excess income).

• *Nature*—cause of error (for example, providers not submitting medical records, lack of systems edits, unreported changes in income that caused ineligibility). For the eligibility component, States must analyze both active and negative case errors and also causes for undetermined case findings.

(2) Program Analysis—States must review the findings of the data analysis to determine the specific programmatic causes to which errors are attributed (for example, a provider's lack of understanding of section 1902(a)(27) of the Act and §431.107 of the regulations requiring providers under their provider agreements, to submit information regarding payments and claims as requested by the Secretary, State agency, or both) and to identify root error causes. The States may need to analyze the agency's operational policies and procedures and identify those policies or procedures that contribute to errors, for example, policies that are unclear, or there is a lack of operational oversight at the local level.

(3) *Corrective Action Planning*—States must determine the corrective actions to be implemented that address the root error causes.

(4) Implementation and Monitoring— States must implement the corrective actions in accordance with an implementation schedule. States must develop an implementation schedule for each corrective action initiative and implement those actions. The implementation schedule must identify major tasks and key personnel responsible for each activity, and must include a timeline for each action including target implementation dates, milestones, and monitoring.

(5) *Evaluation*—States must evaluate the effectiveness of the corrective action by assessing improvements in operations, efficiencies, and the incidence of payment errors or number of errors. Subsequent corrective action plans that are submitted as a result of the State's next measurement must include updates on the following previous actions: (1) Effectiveness of implemented corrective actions using concrete data; (2) discontinued or ineffective actions, and actions not implemented and what actions were used as replacements; (3) findings on short-term corrective actions; and (4) the status of the long-term corrective actions.

In addition, we proposed that CMS would review and approve the corrective action plans submitted by States, and may request regular updates on the approved corrective actions. We solicited public comments on the timeline and process associated with this review and approval.

We received the following comments regarding our proposed revisions to the corrective action plans.

Comment: Several commenters stated that to submit and implement corrective action plans for the fiscal year under review no later than 60 days from the date the error is posted on the CMS contractor's Web site is too short of a timeframe for States to successfully review the error rate, and develop and submit a meaningful plan. Commenters recommended that States be given either a 90-day or 120-day submission and implementation deadline.

Response: We understand the States' concern regarding the need for adequate time to submit and implement a meaningful corrective action plan. Therefore, we will revise § 431.992 to require that States submit to CMS and implement the corrective action plan for the fiscal year it was reviewed no later than 90 calendar days from the date the State's error rate is posted to the CMS Contractor's Web site. Adopting the 90calendar day timeframe will still allow CMS to utilize the States' corrective action plans in the IPIA-required Error Rate Reduction Plan (ERRP) due to OMB annually. For example, if States submit their corrective action plan reports 90 days from the posting of the error rate on November 15th, reports will be due to us on February 15th, leaving us approximately 45 days to finalize the ERRP for submission to the Department.

Comment: Several comments received were on our proposal to review and approve the corrective action plans submitted by States as well as request regular updates on the approved corrective actions. Commenters stated that the States should have an equal role with CMS in reviewing and approving State corrective action plans. Commenters also stated that the proposed rule does not allow CMS approval time for the plan and that it is not clear if CMS would want States to implement a plan that CMS has not approved. Some commenters suggested that while the proposed rule indicates that States would submit and implement the corrective action plan at

the same time, it would be more prudent for feedback to be provided by CMS to assure the corrective action plan meets CMS guidelines prior to implementation. Additionally, some commenters believed that while it may be prudent for CMS to review and approve corrective action plans, the commenters are concerned that the level of reporting would prove draining on State staff and border on micromanaging. The commenters also stated that it is not reasonable to expect States to report at this level when there are no Federal funds to support the PERM project.

Response: Based on comments received, we are not adopting an approval process at this time. States should be able to move forward by the required deadline to submit and implement corrective actions plans within the specified timeframe. However, we will continue to provide guidelines and examples to aid in the development of the corrective action plan and will be available to provide States with technical assistance as needed or requested.

During prior measurement cycles, we have worked closely with the States as they develop their corrective action plans and States have demonstrated that they have the ability to submit a corrective action plan and implement corrective actions at the same time. We will consider commenters' recommendations concerning additional corrective action plan guidance when we publish the PERM manual.

Finally, in response to the comment regarding lack of funding to support the PERM project, we note that States are reimbursed at the applicable administrative Federal match under Medicaid and CHIP for PERM related activities. We also provide States significant technical assistance throughout the corrective action process including facilitating State-specific calls after error rate findings are released and hosting State forum calls which provide States the opportunity to share best practices.

Comment: Several commenters requested that a tolerance be established when overpayments are pennies and the State's error rate is low, it is not productive to develop a corrective action plan. Another commenter noted that States should be required to document corrective action plans only if there are material error rates or significant trends in types of errors. The commenter stated that in such instances, corrective action plans are needed to document necessary remedial action and/or process improvements. The commenter further stated that if errors are neither material, nor trendbased, corrective action plans do not produce meaningful results nor do they justify the administrative burden in completing them. The commenter felt that the corrective action plan documentation requirements are more intensive than necessary given the low error rate in some states. The commenter recommended that we establish an error rate threshold, perhaps of an error rate between 2 and 3 percent, below which States would not be required to complete a corrective action plan.

Response: We do not agree and, therefore, we will not exempt any State from submitting a corrective action plan regardless of their error rate. IPIA requires that we submit an ERRP to OMB annually and State corrective action plans are an integral part to this process. We plan to release a PERM manual which will provide States with additional information on how the ERRP incorporates the individual State corrective action plan reports such as trends in correction action processes across States. However, we expect that if most of the errors are from no documentation or undetermined cases, the State's corrective action plan will address how to correct that problem in future PERM reviews, rather than how to correct material problems in eligibility determinations and claims payments.

Comment: Several commenters said that the corrective action plan is too prescriptive and a burden on State resources. One commenter stated that it was onerous.

Response: Section 601(c)(1)(C)of the CHIPRA requires CMS to clearly define responsibilities and deadlines for States in implementing corrective action plans. We have considered the States' concern that the proposed rule is too prescriptive and a burden on State resources. For this reason, we have reevaluated the proposed regulatory text and made edits to condense and consolidate the regulatory text to only state the corrective action plan requirements. The proposed regulatory text contained suggestions on how to sort and analyze errors, and these have been removed. We will also consider the commenter's concerns when we publish the forthcoming PERM manual. Additionally, we have taken several steps to assist States with the CAP process, including providing States with a corrective action plan example during their corrective action plan orientation call with CMS and conducting all-State calls where States can share best practices.

Comment: Several commenters stated that in order for States to develop the level of analysis required in the proposed rules it would be necessary to utilize a model that can be detailed or abstract, complex or simple, accurate or misleading. The commenters stated that models of this type are used extensively in root cause analysis. The commenters explained that some models used are "causation" and "fish bone analysis" models, which are based on manipulability, probability and counterfactual logic. The commenter explained that these models are extremely complex and no single model can address all possible situations. The commenters recommended that if CMS is requiring the State to perform this level of analysis, additional guidance and recommendation must be provided in order to achieve conformity across all State corrective action plans. Another commenter stated that thorough data and program analysis is time intensive and a drain on staff resources and that the main difficulty with this comprehensive process being added to the Rule is that it does not give the States flexibility to tailor the extent of the program and system analysis based on staffing and other resources. Another commenter questioned whether CMS will share in the development of automated systems to provide necessary support to perform meaningful data analysis.

Response: We are not requiring that States use complex data analysis models. The corrective action plan requirement is to conduct data analysis, such as reviewing clusters of errors, general error causes, characteristics, and frequency of errors that are associated with improper payments as well as error causes associated with number of errors and States should determine the corrective actions to be implemented that address the root error causes. Using error prone profiles, trend analyses, causation, fish bone and other such analyses are at the State's discretion.

Comment: Several commenters expressed concern on the feasibility for States to measure updates of previous corrective actions utilizing "concrete data". Another commenter requested that CMS clarify the expectation for "concrete data".

Response: We believe that in order to determine whether a corrective action is successful, States may need to utilize additional State studies or other reports such as State assessment reports, internal audits and special studies which can demonstrate the progress of implemented corrective action processes. Progress can also be demonstrated through a State's next PERM measurement. However, we understand that the use of the word "concrete" is unclear. Therefore, we are revising \S 431.992(d)(1) to replace the term "concrete" with the term "objective data sources."

Comment: One commenter recommended CMS consider developing a baseline plan that all States could implement and States could add to or individualize as needed based on their PERM experience from their measurement.

Response: We believe that States should have some flexibility in developing their corrective action plans. However, we are available to assist States with the development of the corrective action plans and have already taken steps to provide States with additional information including an example corrective action plan and the all-State call on corrective action plans where States shared their experiences, challenges, and best practices.

Comment: Several commenters requested clarity on whether separate corrective action plans needed to be submitted for Medicaid and CHIP.

Response: If a State has been cited with errors under each of these programs, a corrective action plan would be expected for each, but could be substantively the same for both as appropriate. We are revising § 431.992(a) to require separate Medicaid and CHIP plans.

We received a number of comments on PERM-related issues that, while not included in regulatory text, are issues related to PERM policies and procedures. Below, we address these issues to provide further clarification to States as well as to share current initiatives CMS is engaging in order to improve the PERM measurement overall and ensure an accurate error rate measurement.

Claims

Comment: We received a number of comments and questions related to the work of our contractors. Some commenters questioned what quality assurance processes are in place to ensure that the work completed by PERM contractors is accurate. Other commenters questioned if contractors will be required to persistently attempt to secure information needed to complete review from providers. Commenters also questioned whether the contractor should request medical records on the same day for each State, quarter, and program to allow the States to more easily track provider compliance and monitor the due dates for documentation. Commenters also questioned if the contractor should

include the State claim ID on the record request sent to providers and on the status charts made available to States to allow States to more efficiently track progress and answer provider questions. The commenters questioned whether the review contractor's Web site should not only provide sampling unit disposition repots by program (that is, Medicaid and CHIP) but also be FFS and managed care, as that is how the States are required to provide the universe data. Finally, commenters questioned whether CMS and our contractors will consider allowing providers to submit medical records electronically, given our push to move toward electronic health records in order to: reduce the amount of hard copy material for both providers and the contract agency; speed up the process for submitting medical records; and further the intent of Federal and State paper work reduction rules and regulations.

Response: We appreciate the comments and will consider these operational issues. As appropriate, we will issue guidance to our contractors to make changes as necessary and practical. In utilizing the national contractor model, our goal is to operate a consistent measurement across States that minimizes State burden to the extent possible. We will review our internal quality control policies and the procedures of our contractors and communicate any changes with States accordingly.

Comment: We received several comments requesting enhanced FFP for Medicaid to match the enhanced FFP that the CHIPRA provides for CHIP.

Response: We are unable to adopt this recommendation. We do not have the statutory authority to provide enhanced FFP for Medicaid activities.

Comment: We received several comments related to the current measurement model and meeting IPIA requirements. Commenters stated that because IPIA requires a national error rate and not State-specific error rates, PERM should be a national measurement model where all States are measured each year by selecting a random sample of records from each State, which would decrease the sample size, incorporate PERM as an ongoing program integrity activity and reduce State burden.

Another commenter suggested CMS reconsider the multiple contractor model and allow States to conduct, in whole or in part, their own sampling, data processing reviews and medical reviews, similar to eligibility, to reduce the burden on the State to bring the Federal contractors up to speed. One commenter recommended that CMS allow States to establish their own protocol for eligibility and claims review by submitting to CMS plans that provide details on the State's universe development, sampling plans, and protocol for performing medical record collection, data processing reviews and medical reviews where States could optionally request assistance from CMS' contractors, as with the eligibility component of PERM.

Another commenter stated that given the high cost of conducting PERM versus the cost recoveries and efficiencies identified, CMS should consider allowing States that achieve a determined payment accuracy and can prove that they are not susceptible to overpayments to receive a waiver from CMS to discontinue measuring PERM.

One commenter stated that CMS should provide States information on how national error rates will be compared over time. Another commenter asked that CMS provide States additional information on the national erroneous payment level targets which are required by IPIA. Finally, a commenter recommended CMS allow more State engagement and involvement in meeting needs of IPIA and the target rate setting process.

Response: We do not believe a national sample is the best method to achieve IPIA compliance. The Medicaid and CHIP programs are State administered and, as such, we think it is necessary for States to participate and have State-level error rates calculated, as well as the national error rate. The current contractor model of PERM minimizes the cycles in which each State has to participate to once every 3 years, therefore reducing the burden on States to provide data each year. Furthermore, PERM is constructed in order to best achieve an unbiased statistically valid error rate by sampling each State once every 3 years for a total of 17 States each cycle, which, is meant to reduce the burden on States from participating each year. A statistically valid error rate that meets IPIA precision requirements is predicated on all 17 States in each cycle participating in the measurement. Allowing some States to "sit out" for a cycle would mean that a national error rate could not be calculated with the required precision.

We recognize that changes in how States operate their Medicaid programs and how the PERM program evolves can impact the State and national error rates from year to year. In the FY 2008 final PERM report, we calculated a weighted 2-year average based on the calculations in FY 2007 and FY 2008. (FY 2006 was not included because managed care, CHIP, and eligibility were not included in that cycle.)

We meet IPIA reporting requirements through the publication of the Department of Health and Human Services' annual Agency Financial Report. This report includes information on all IPIA required error rates for HHS governed programs, as well as corrective action plans and the required targets. The FY 2007, 2008, and 2009 reports are available at http://www.hhs.gov/afr/ index.html.

Finally, we are continually looking for ways to engage States on improving the PERM process. We appreciate the offers of assistance and will continue to work with States to meet the requirements of IPIA.

Comment: We received numerous comments inquiring as to the status of the FY 2009 CHIP measurement and requesting that we discontinue the CHIP measurement for this cycle. Commenters expressed concern over the difficulty that States would have if the measurement was restarted at this point. Commenters explained that if the CHIP measurement restarts, States will need to go back to cases that could have been acted on over a year ago, making the completion of the reviews more difficult, requiring additional State staff time and dollars, increasing the opportunity for undetermined cases and having a negative impact on the FY 2009 States' error rates compared to previous cycles. If we choose to continue with the FY 2009 Medicaid and CHIP measurements, commenters requested that we consider extending the original deadlines for completion and provide detailed guidance regarding how States are to proceed with the reviews, what the new timeline will be and what regulation guidance States should follow, particularly given that States have been conducting Medicaid and CHIP reviews up until the stopwork on CHIP based on the August 2007 regulation. The commenters also suggested that CMS take time to convene a State workgroup to address the PERM regulation, guidelines, and standards, as well as examine overlaps between PERM and other oversight programs in order to reduce the burden and duplication of effort on States.

Response: We understand State's concerns related to the multitude of issues related to restarting the CHIP measurement for FY 2009 and FY 2010. For this reason, we will not measure CHIP error rates for FY 2009 or FY 2010, and will instead begin the PERM review process for CHIP starting with the first fiscal year that begins after the date of the publication of this rule.

Due to IPIA requirements, we are proceeding with the Medicaid error rate reviews and calculations under existing rules, and will begin reviews according to the provisions of this final rule once it is effective.

We have also reconvened the PERM TAG and continue to hold cycle calls to keep States involved and updated as information becomes available.

Comment: We received several comments about State-specific issues related to PERM.

Response: We will work with these States directly to discuss their concerns and encourage States to contact us directly to discuss specific issues.

III. Provisions of the Final Regulations

With the exception of the following provisions, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

In § 431.806(b), we are revising this paragraph to state that State plans must provide for operating a Medicaid eligibility quality control program that is in accordance with § 431.978 through § 431.988.

In § 431.812(a)(2)(iv), we are adding individuals whose eligibility was determined under a State's option under section 1902(e)(13) of the Act to the list of those cases for which the agency is not required to conduct reviews.

In §431.812(f), we are revising this paragraph to state that the substitution of PERM data must be in accordance with §431.980 through §431.988 and that PERM undetermined cases may be dropped from the MEQC error rate calculation if the reasons for drops are acceptable reasons listed in the State Medicaid Manual.

In § 431.958, we are revising the proposed definition of "Provider error" and "State error". In addition, we are revising the definitions of "Active fraud investigation," "Agency," and "Case," as a result of issues raised by commenters.

In § 431.960, we are adding paragraph (b)(3) to the proposed provisions to include examples of data processing errors. In § 431.960(c)(3), we are adding a list of medical review error examples to the proposed provisions. In § 431.960(d), we are revising this paragraph in response to concerns raised by commenters. In § 431.960, we are removing paragraph (f)(2) from the proposed provisions.

In § 431.978(d)(3), we are revising the regulations text to provide states with the option of stratifying the eligibility universe.

In §431.980(d), we are amending the proposed provisions by adding this

paragraph to state that the agency must identify erroneous payments resulting from ineligibility for services or for the program as determined in accordance with the State's documented policies and procedures.

In § 431.980(e) (proposed as paragraph (d)), we are revising the heading of this paragraph from "eligibility review determination," to "eligibility review decision."

In § 431.980(f) we are adding a paragraph (2) to require MEQC samples to meet PERM confidence and precision requirements.

În § 431.980(f) we are adding a paragraph (3) to require States to include all MEQC cases in the PERM calculation.

In § 431.988(a), we are revising an eligibility reporting requirement for States to report the total number of cases in the eligibility universe.

In § 431.988(b)(3) for States that do not stratify the eligibility universe in accordance with § 431.978(d)(3) to report the last action on a case, either application or redetermination.

In § 431.992(a), after reviewing the public comments, we are amending the proposed provisions to not require CMS approval of the corrective action plan.

In § 431.992(b), we are amending the proposed provisions to remove all suggested steps in the corrective action process and only state the required elements for corrective action plans.

In § 431.992(c), we are revising the proposed language of "no later than 60 days" to read "no later than 90 days" as requested by the commenters.

In § 431.998(b), after reviewing public comments, we are revising the proposed timeframe for States to file a difference resolution with the contractor from 10 business days to 20 business days after the disposition report of claims review findings is posted on the contractor's Web site. Additionally, we are revising the proposed language of "filing the appeal within 5 business days" to read "filing the appeal within 10 business days" as requested by the commenters.

In § 431.998(c), we are adding an appeals process for the eligibility component in which State agencies can appeal eligibility review decisions to the agency conducting PERM eligibility reviews and file appeal requests for Federal eligibility policy to CMS.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60day 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.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Review Procedure (§ 431.812)

Section 431.812(a)(1) states that except as provided in paragraph (a)(2) of this section, the agency must review all active cases selected from the State agency's lists of cases authorized eligible for the review month, to determine if the cases were eligible for services during all or part of the month under review, and, if appropriate, whether the proper amount of recipient liability was computed. In §431.812, paragraph (f) states that a State in its PERM year may elect to substitute the random sample of selected cases, eligibility review findings, and payment review findings obtained through PERM reviews conducted in accordance with § 431.980 through § 431.988 of the regulations for data required in this section, where the only exclusions are those set forth in §431.978(d)(1) of this regulation. The burden associated with this requirement is the time and effort necessary to complete the review of active cases. The burden associated with this requirement is currently approved under OMB control number 0938-0147 with a December 31, 2012, expiration date.

States in their PERM year that elect to substitute PERM data to meet the requirements of § 431.812 would significantly reduce the burden associated with reviewing active cases for MEQC. The burden associated with the information collection requirements contained in § 431.812(f) is the time and effort necessary for a State to substitute the random sample of selected cases, eligibility review findings, and payment review findings obtained through PERM reviews conducted in accordance with § 431.980 through § 431.988. Currently, we believe 19 States (12 Medicaid States and 7 CHIP States) can elect the data substitution and comply with this requirement. We estimate that it would take each agency 10,055 hours to comply with the information collection requirements. In subsequent years, we expect that more States will elect to substitute data from section § 431.980 to meet this requirement so we are estimating the maximum burden for 34 States (17 Medicaid States and 17 CHIP States). The total burden associated with the requirements in § 431.812(f) is 341,870 hours.

Although the review burden would be significantly reduced, States would still be required to report PERM and MEQC findings separately. The additional burden is explained in the section below for § 431.980. We will submit a revised information collection request for 0938–0147 to account for the increased burden as a result of the requirements in § 431.812(f).

B. ICRs Regarding MEQC Sampling Plan and Procedures (§ 431.814)

Section 431.814 states that an agency must submit a basic MEQC sampling plan (or revisions to a current plan) that meets the requirements of this section to the appropriate CMS Regional Office for approval at least 60 days before the beginning of the review period in which it is to be implemented. The burden associated with this requirement is the time and effort necessary to draft and submit a new sampling plan or to draft and submit a revised sampling plan to the appropriate CMS Regional Office. While this requirement is subject to the PRA, it is currently approved under OMB control number 0938–0146 with a December 31, 2012, expiration date.

C. ICRs Regarding PERM Eligibility Sampling Plan and Procedures (§ 431.978)

In §431.978, the revisions to paragraph (a) discuss the requirements for sampling plan approval. Specifically, the revision to §431.978(a)(1) and (2) states that for each review year, the agency must submit a State-specific Medicaid or CHIP sampling plan (or revisions to a current plan) for both active and negative cases to CMS for approval by the August 1 before the review year and must receive approval of the plan before implementation. The revision to §431.978(b)(2) further explains that the agency must notify CMS that it would be using the same plan from the previous review year if the plan is unchanged.

Section 431.978(c)(3) sets a maximum sample size of 1,000 active and negative

cases, respectively in subsequent PERM review years after the base year. The burden associated with the requirements to review the maximum number of cases in the active and negative case sample sizes set forward in § 431.978(c) will be adjusted and submitted for OMB approval.

The burden associated with the information collection requirements contained in § 431.978(a) and (b) is the time and effort necessary for State agencies to draft and submit the aforementioned information to CMS. While this requirement is subject to the PRA, the associated burden is approved under OMB control number 0938–1012 with an April 30, 2013, expiration date.

D. ICRs Regarding Eligibility Review Procedures (§ 431.980)

Section 431.980(e) states that unless the State has elected to substitute MEQC data for PERM data under paragraph (f) of this section, the agency must complete the following. Specifically, §431.980(e)(iv) requires a State to examine the evidence in the case file that supports categorical and financial eligibility for the category of coverage in which the case is assigned, and independently verify information that is missing, older than 12 months and likely to change, or otherwise as needed, to verify eligibility. Section 431.980(e)(vi) states that the elements of eligibility in which State policy allows for self-declaration can be verified with a new self-declaration statement. Section 431.980(e)(vi) also contains the requirements for a self-declaration statement.

The burden associated with the requirements contained in § 431.980 is the time and effort necessary for a State agency to complete the aforementioned requirements. While this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938–1012.

Section 431.980(f)(1) allows for a State in its PERM year to elect to substitute the random sample of selected cases, eligibility review findings, and payment reviews findings obtained through MEQC reviews conducted in accordance with section 1903(u) of the Act to meet its PERM eligibility review requirement. MEQC dropped cases will be classified as undetermined in order to calculate the PERM error rate, unless the State attempts to complete these cases. The substitution of the MEQC data is allowed as long as the State MEQC reviews are based on a broad, representative sample of Medicaid applicants or enrollees in the State. In addition, as stated in §431.980(f)(2), the MEQC samples must also meet PERM confidence and precision requirements.

The burden associated with the information collection requirements contained in § 431.980(f) is the time and effort necessary for a State to collect, review, and submit the MEQC data as part of meeting its PERM eligibility review requirement. States that elect to substitute MEQC data to complete the requirements of §431.980 would significantly reduce the burden associated with reviewing active cases for PERM. Although the review burden would be eliminated, States would still be required to report PERM and MEQC findings separately. Currently we believe 19 States (12 Medicaid States and 7 CHIP States) can elect the data substitution and comply with this requirement. We estimate that it would take each agency 10,500 hours to comply with the information collection requirements. In subsequent years, we expect that more States will elect to substitute data from section § 431.812 to meet this requirement so we are estimating the maximum burden for 34 States (17 Medicaid States and 17 CHIP States). The total burden associated with the requirements in §431.980(f) is 357,000 hours.

We also propose adding additional burden as stated previously. States must report PERM and MEQC findings separately and will use an estimated 2 hours per required form to reformat PERM or MEQC data into the appropriate forms. We are adding an additional 98 hours for each State to reformat MEQC data into the appropriate PERM eligibility forms and 98 hours for each State to compile PERM eligibility data to submit on the appropriate MEQC forms. We will submit a revised information collection request for 0938-1012 to account for the increased burden as a result of the requirements in §431.980(f).

E. ICRs Regarding Corrective Action Plan (§ 431.992)

The revisions to §431.992(a) specify that State agencies must develop a corrective action plan to reduce improper payments in its Medicaid and CHIP programs based on its analysis of the error causes in the FFS, managed care, and eligibility components. In §431.992(c), we require States to submit to CMS and implement the corrective action plan for the fiscal year it was reviewed no later than 90 days from the date the State's error rate is posted to the CMS Contractor's Web site. As detailed in §431.992(c), States are required to implement corrective actions in accordance with their corrective action plans as submitted to

CMS. Section 431.992(b) details the required components of a corrective action plan.

The burden associated with the information collection requirements in

revisions to § 431.992 is the time and effort necessary for States to develop corrective action plans, submit the plans to CMS, and implement corrective actions as dictated by their corrective plans. While these requirements are subject to the PRA, the burden is approved under the OMB control numbers shown in Table 1.

TABLE 1—OMB CONTROL NUMBERS

Program component	OMB Control No.	Expiration date
Fee-for-Service	0938–0974	02/29/2012
Managed Care	0938–0994	11/30/2012
Eligibility	0938–1012	04/30/2013

F. ICRs Regarding Difference Resolution and Appeal Process (§ 431.998)

As described in § 431.998(a), a State may file, in writing, a request with the Federal contractor to resolve differences in the Federal contractor's findings based on medical or data processing reviews on FFS and managed care claims in Medicaid and CHIP within 20 business days after the disposition report of claims review findings is posted on the contractor's Web site. The written request must include a factual basis for filing the difference and it must provide the Federal contractor with valid evidence directly related to the error finding to support the State's position that the claim was properly paid.

Section 431.998(b) states that for a claim in which the State and the Federal contractor cannot resolve the difference in findings, the State may appeal to CMS for final resolution within 10 business days from the date the contractor's finding as a result of the difference resolution is posted on its Web site.

Section 431.998(c) states that for eligibility error determinations made by the agency with personnel functionally and physically separate from the State Medicaid and CHIP agencies and personnel that are responsible for Medicaid and CHIP policy and operations, the State may appeal error determinations by filing an appeal request with the appropriate State agency. If no appeals process is in place at the State level, differences in findings must be documented in writing and submitted directly to the agency responsible for the PERM eligibility review for their consideration, or differences in findings may be resolved through document exchange facilitated by CMS between the State agency appealing the error and the agency responsible for the PERM eligibility review. Any unresolved differences may be addressed by CMS between the final

month of payment data submission and error rate calculation. Any changes in error findings must be reported to CMS by the deadline for submitting final eligibility review findings. Any appeals of determinations based on interpretations of Federal policy may be referred to CMS.

The burden associated with the information collection requirements contained in § 431.998(a) through (c) is the time and effort necessary to draft and submit requests for difference resolution proceedings and determination appeals. We believe the burden associated with these requirements is exempt from the PRA under 5 CFR 1320.4. Information collected subsequent to an administrative action is not subject to the PRA.

G. OMB Control Number(s) for Reporting and Recordkeeping Burden

The burden is approved under the OMB control numbers stated in Table 2.

TABLE 2—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
§ 431.812	0938–0147	10	120	8	¹ 960
§431.814	0938–0146	10	20	24	480
§ 431.978	0938–1012	34	1,360	393.875	535,670
§ 431.980	0938–1012	34	1,360	393.875	¹ 535,670
§ 431.992	0938–0974	34	34	840	28,560
	0938–0994	36	² 18,000	1	23,400
	0938–1012	34	1,360	393.875	³ 535,670
Total					589,070

¹We are submitting a revision of the currently approved ICR for the information collection requirements in this section of the regulation. ²The currently approved number of responses is 23,400; however, the value is incorrect due to an arithmetic error. We have already submitted an 83–C Change Worksheet to OMB to correct the error.

³For the purpose of totaling the burden associated with the ICRs in this regulation, the annual burden associated with OMB control number 0938–1012 is counted only once.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258) 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). For the reasons discussed below, we have determined that this final rule is not a major rule.

1. Federal Contracting Cost Estimate

We have estimated that it will cost \$14.7 million annually for engaging Federal contractors to review FFS and managed care claims and calculate error rates in 34 State programs (17 States for Medicaid and 17 States for CHIP). We estimated these costs as follows:

In the August 31, 2007 final rule, we estimated the Federal cost for use of Federal contractors conducting the FFS and managed care measurements to be \$19.8 million annually. Due to more recent data acquired through our experience with Federal contractors in the FY 2007, FY 2008, and FY 2009 PERM cycles, we were able to produce a more accurate estimate by taking the average of Federal contracting costs for the three cycles and including anticipated future PERM cycle costs. The error rate measurements for 34 State programs (17 States for Medicaid and 17 States for CHIP) would cost approximately \$14,682,777 in Federal funds for the Federal contracting cost.

2. State Cost Estimate for Fee-for-Service and Managed Care Reviews

We estimated that total State cost for FFS and managed care reviews for 34 State programs is \$6.2 million (\$4,309,490 in Federal cost and \$1,846,924 in State cost). This cost estimate is based on the cost for States to prepare and submit claims universe information for both FFS and managed care payments, prepare and submit claims details and provider information for sampled records, submit State program policies and updates on a quarterly basis, cooperate with Federal contractors during data processing review, participate in the difference resolution and appeals process, and prepare and submit a corrective action plan for claims errors. These costs are estimated as follows:

We estimated that the annualized number of hours required to respond to requests for required claims information for FFS and managed care review for 34 State programs will be 112,200 hours (3,300 hours per State per program). At

the 2009 general schedule GS-12-01 rate of pay that includes fringe and overhead costs (\$54.87/hour), we calculated a cost of \$6,156,414 (\$4.309.490 in Federal cost and \$1,846,924 in State cost). This cost estimate includes the following estimated annualized hours: (1) Up to 1,800 hours required for States to develop and submit required claims and capitation payments information; (2) up to 500 hours for the collection and submission of policies; and (3) up to 1,000 hours for States to cooperate with CMS and the Federal contractors on other aspects of the claims review and corrective action process.

Therefore, the total annual estimate of the State cost for 34 State programs to submit information for FFS and managed care reviews and participate with CMS and Federal contractors is \$6,156,414 (\$4,309,490 in Federal cost and \$1,846,924 in State cost).

3. Cost Estimate for Eligibility Reviews

Beginning in FY 2007, States review eligibility in the same year they are selected for FFS and managed care reviews in Medicaid and CHIP. We estimated that total cost for eligibility review for 34 State programs is \$24,588,344 (\$17,211,841 in Federal cost and \$7,376,503 in State cost). This cost estimate is based on the cost for States to submit information to CMS and the cost for States to conduct eligibility reviews and report data to CMS. These costs are estimated as follows:

We estimated in the information collection section, that the annualized number of hours required to respond to requests for information for the eligibility review (for example, sampling plan, monthly sample lists, the eligibility corrective action report) for 34 State programs will be 108,800 hours (3,200 hours per State per program). At the 2009 general schedule GS-12-01 rate of pay that includes fringe and overhead costs (\$54.87/hour), we calculated a cost of \$5,969.856 (\$4,178,899 in Federal cost and \$1,790,957 in State cost). This cost estimate includes the following estimated annualized hours: (1) Up to 1,000 hours required for States to develop and submit a sampling plan; (2) up to 1,200 hours for States to submit 12 monthly sample lists detailing the cases selected for review; and (3) up to 1,000 hours for States to submit a corrective action plan for purposes of reducing the eligibility payment error rate. For the eligibility review and reporting of the findings, we estimated that each State would need to review an annual sample size of 504 active cases

to achieve a 3 percent margin of error at a 95 percent confidence interval level in the State-specific error rates. We also estimated that States would need to review 204 negative cases to produce a case error rate that met similar standards for statistical significance. We estimated that for 34 State programs the annualized number of hours required to complete the eligibility case reviews and report the eligibility-based error data to CMS would be 339,320 hours (9,980 hours per State, per program). At the 2009 general schedule GS-12-01 rate of pay that includes fringe and overhead costs (\$54.87/hour), we calculated a cost of \$18,618,488 (\$13,032,942 in Federal cost and \$5,585,547 in State cost).

Therefore, the total annual estimate of the cost for 34 State programs to submit information and to conduct the eligibility reviews and report the error data to CMS is \$24,588,344 (\$17,211,841 in Federal cost and \$7,376,503 in State cost). However, these cost and burden estimates must be revised based on the maximum eligibility sample sizes of 1,000 active and negative cases, respectively, set forth in § 431.978(c).

The CHIPRA requires CMS to provide States in their PERM year the option to use PERM data to meet the MEQC requirements described in section 1903(u) of the Act, and the option to use MEQC data described in § 431.812 to meet the PERM eligibility review requirement. While the intent is to reduce redundancies and cost burden between the two programs and their review requirements, States that substitute findings may incur more costs to implement changes to their PERM or MEQC sampling and review procedures.

4. Cost Estimate for Total PERM Costs

Based on our estimates of the costs for the FFS, managed care and eligibility reviews for both the Medicaid and CHIP programs at approximately \$45.4 million (\$36,204,108 in Federal cost and \$9,223,428 in State cost), this rule does not exceed the \$100 million or more in any 1 year criterion for a major rule, and a regulatory impact analysis is not required.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$34.5 million in any 1 year). Individuals and States are not included in the definition of a small entity.

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

In addition, the information should be readily available and the response should take minimal time and cost since the response would merely require gathering the documents and either copying and mailing them or sending them by facsimile. 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 CHIP and should not have a significant impact on the provider's operations. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds.

These entities may incur costs due to collecting and submitting medical records to the contractor to support medical reviews; but, like any other Medicaid or CHIP provider, we estimate these costs would not be outside the limit of usual and customary business

practices. Also, since the sample is randomly selected and only FFS claims are subject to medical review, we do not anticipate that a great number of small rural hospitals would be asked for an unreasonable number of medical records. As stated before, a State will be reviewed only once, per program, every 3 years and it is unlikely for a provider to be selected more than once per program to provide supporting documentation. Therefore, the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately \$133 million. This final rule does not impose costs on States to produce the error rates for FFS and managed care payments, but requires States and providers to submit claims information and medical records and cooperate with Federal contractors during the review so that error rates can be calculated.

Based on our estimates of State participation burden for both Medicaid and CHIP, for 34 States (17 States per Medicaid and 17 States for CHIP), we calculated that the annual burden for these States for the PERM program is approximately \$9,223,428 in State costs for both Medicaid and CHIP. The combined costs of both programs total approximately \$542,555 for each of the 17 States. Thus, we do not anticipate State costs to exceed \$133 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule requires States to prepare and submit claims universe information for both FFS and managed care payments, prepare and submit claims details and provider information for sampled records, submit State program policies and updates on a quarterly basis, cooperate with Federal contractors during data processing reviews, participate in the difference resolution and appeals process, and prepare and submit a corrective action plan for claims errors. We estimated that the burden to respond to requests for claims information for the FFS and managed care measurement for

Medicaid and CHIP for 34 State programs (17 States for Medicaid and 17 States for CHIP) will be \$6,156,414 (\$4,309,490 in Federal cost and \$1,846,924 in State cost).

This final rule also requires States selected for review to submit an eligibility sampling plan, monthly sample selection information, summary review findings, State error rate data, and other information in order for CMS to calculate the eligibility State-specific and national error rates. We estimated that the burden to conduct the eligibility measurement for Medicaid and CHIP for 34 State programs (17 States for Medicaid and 17 States for CHIP) will be approximately \$24,588,344 (\$17,211,841 in Federal cost and \$7,376,503 in State cost). As a result, we assert that this regulation will not have a substantial impact on State or local governments.

B. Anticipated Effects

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

C. Alternatives Considered

This final rule reflects changes required by the CHIPRA. Therefore, we considered only applying additional changes to the CHIP component of PERM (except in instances where the CHIPRA specifically requires the provision to apply to Medicaid and CHIP). However, in order to maintain a consistent measurement process for the Medicaid and CHIP programs, we did not choose this alternative. No other alternatives were considered since the modifications were required by Federal statute.

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 447

Accounting, Administrative practice and procedure, Drugs, Grant programshealth, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 457

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

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

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

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

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

Subpart P—Quality Control

■ 2. In § 431.636, amend the heading by removing the reference to "State Children's Health Insurance Program" an by inserting "Children's Health Insurance Program" in its place.

3. Section 431.806 is amended by— ■ A. Redesignating paragraph (b) as paragraph (c).

B. Adding new paragraph (b). The addition reads as follows:

§ 431.806 State plan requirements. *

* *

(b) Use of PERM data. A State plan must provide for operating a Medicaid eligibility quality control program that is in accordance with §431.978 through § 431.988 of this part to meet the requirements of §431.810 through § 431.822 of this subpart when a State is in their PERM year. * *

■ 4. Section 431.812 is amended by—

■ A. In paragraph (a)(2)(i), removing the ";" and adding a "." in its place and in paragraph(a)(2)(ii), removing the "; and" and adding a "." in its place.

■ B. Adding new paragraphs (a)(2)(iv) and (f).

The additions read as follows:

§431.812 Review procedures.

(a) * * *

(2) * * *

(iv) Individuals whose eligibility was determined under a State's option under section 1902(e)(13) of the Act.

(f) Substitution of PERM data.

(1) A State in its Payment Error Rate Measurement (PERM) year may elect to substitute the random sample of selected cases, eligibility review findings, and payment review findings obtained through PERM reviews conducted in accordance with § 431.978 through §431.988 of this part for data required in this section, if the only exclusions are those set forth in § 431.978(d)(1) of this part.

(2) PERM cases cited as undetermined may be dropped when calculating MEQC error rates if reasons for drops are acceptable reasons listed in the State Medicaid Manual.

■ 5. Section 431.814 is amended by revising paragraph (c)(4) to read as follows:

§431.814 Sampling plan and procedures.

* (c) * * *

(4) States must exclude from the MEQC universe all of the following:

(i) SSI beneficiaries whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act.

(ii) Individuals in foster care or receiving adoption assistance whose eligibility is determined under Title IV-E of the Act.

(iii) Individuals receiving Medicaid under programs that are 100 percent Federally-funded.

(iv) Individuals whose eligibility was determined under a State's option for Express Lane Eligibility under section 1902(e)(13) of the Act. * *

Subpart Q—Requirements for **Estimating Improper Payments in** Medicaid and CHIP

§431.950 [Amended]

■ 6. Amend § 431.950 by revising the reference to "State Children's Health Insurance Program" to read "Children's Health Insurance Program."

■ 7. Section § 431.954 is amended by revising paragraph (a) to read as follows:

§431.954 Basis and scope.

(a) Basis. The statutory bases for this subpart are as follows:

(1) 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.

(2) The Improper Payments Information Act of 2002 (Pub. L. 107-300), which requires Federal agencies to review and identify annually those programs and activities that may be susceptible to significant erroneous payments, estimate the amount of improper payments, report such estimates to the Congress, and submit a report on actions the agency is taking to reduce erroneous payments.

(3) Section 1902(a)(27)(B) of the Act requires States to require providers to agree to furnish the State Medicaid agencies and the Secretary with information regarding payments claimed by Medicaid providers for furnishing Medicaid services.

(4) Section 601 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111-3) which requires that the new PERM regulations include the following: Clearly defined criteria for errors for both States and providers; Clearly defined processes for appealing error determinations; clearly defined responsibilities and deadlines for States in implementing any corrective action plans; requirements for State verification of an applicant's selfdeclaration or self-certification of eligibility for, and correct amount of, medical assistance under Medicaid or child health assistance under CHIP; and State-specific sample sizes for application of the PERM requirements.

* * *

■ 8. Section 431.958 is amended by— ■ A. Revising the definitions of the terms "Active fraud investigation," "Agency," and "Case."

■ B. Adding definitions of the terms "Annual sample size," "Children's Health Insurance Program (CHIP)" "Provider error," and "State error" in alphabetical order.

■ C. Removing the definition of "State Children's Health Insurance Program (SCHIP)".

The additions and revisions read as follows:

§ 431.958 Definitions and use of terms. * *

Active fraud investigation means a beneficiary or a provider has been referred to the State Medicaid Fraud Control Unit or similar Federal or State investigative entity including a Federal oversight agency and the unit is currently actively pursuing an investigation to determine whether the beneficiary or the provider committed health care fraud. This definition applies to both the claims and eligibility review for PERM.

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

*

Annual sample size means the number of fee-for-service claims, managed care payments, or eligibility

*

cases necessary to meet precision requirements in a given PERM cycle.

Case means an individual beneficiary or family enrolled in Medicaid or CHIP or who has been denied enrollment or has been terminated from Medicaid or CHIP. The case as a sampling unit only applies to the eligibility component.

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

Provider error includes, but is not limited to, medical review errors as described in § 431.960(c) of this subpart, as determined in accordance with documented State or Federal policies or both.

State error includes, but is not limited to, data processing errors and eligibility errors as described in § 431.960(b) and (d) of this subpart, as determined in accordance with documented State or Federal policies or both.

■ 9. Section 431.960 is added to read as follows:

§ 431.960 Types of payment errors.

*

*

(a) *General rule.* State or provider errors identified for the Medicaid and CHIP improper payments measurement under the Improper Payments Information Act of 2002 must affect payment under applicable Federal policy or State policy or both.

(b) Data processing errors.

(1) A data processing error is an error resulting in an overpayment or underpayment that is determined from a review of the claim and other information available in the State's Medicaid Management Information System, related systems, or outside sources of provider verification.

(2) The difference in payment between what the State paid (as adjusted within improper payment measurement guidelines) and what the State should have paid, in accordance with the State's documented policies, is the dollar measure of the payment error.

(3) Data processing errors include, but are not limited to the following:

(i) Payment for duplicate items.

(ii) Payment for non-covered services.(iii) Payment for fee-for-service claims

for managed care services.

(iv) Payment for services that should have been paid by a third party but were inappropriately paid by Medicaid or CHIP.

- (v) Pricing errors.
- (vi) Logic edit errors.
- (vii) Data entry errors.

(viii) Managed care rate cell errors. (ix) Managed care payment errors.

(c) Medical review errors. (1) A medical review error is an error resulting in an overpayment or underpayment that is determined from a review of the provider's medical record or other documentation supporting the service(s) claimed, Code of Federal Regulations that are applicable to conditions of payment, the State's written policies, and a comparison between the documentation and written policies and the information presented on the claim.

(2) The difference in payment between what the State paid (as adjusted within improper payment measurement guidelines) and what the State should have paid, in accordance with 42 CFR 440 to 484.55 of the Code of Federal Regulations that are applicable to conditions of payment and the State's documented policies, is the dollar measure of the payment error.

(3) Medical review errors include, but are not limited to the following:

(i) Lack of documentation.

(ii) Insufficient documentation.

(iii) Procedure coding errors.

(iv) Diagnosis coding errors.

- (v) Unbundling.
- (vi) Number of unit errors.
- (vii) Medically unnecessary services.
- (viii) Policy violations.
- (ix) Administrative errors.
- (d) Eligibility errors.

(1) An eligibility error includes, but is not limited to, errors determined by applying Federal rules and the State's documented policies and procedures, resulting from services being provided to an individual who meets at least one of the following provisions:

(i) Was ineligible when authorized as eligible or when he or she received services.

(ii) Was eligible for the program but was ineligible for certain services he or she received.

(iii) Lacked or had insufficient documentation in his or her case record, in accordance with the State's documented policies and procedures, to make a definitive review decision of eligibility or ineligibility.

(iv) Overpaid the assigned liability due to the individual's liability being understated.

(v) Underpaid toward assigned liability due to the individual's liability being overstated.

(vi) Was ineligible for managed care but enrolled in managed care.

(vii) Was eligible for managed care but improperly enrolled in the incorrect managed care plan.

(2) The dollars paid in error due to the eligibility error is the measure of the payment error.

(3) A State eligibility error does not result from the State's verification of an applicant's self-declaration or selfcertification of eligibility for, and the correct amount of, medical assistance or child health assistance, if the State process for verifying an applicant's selfdeclaration or self-certification satisfies the requirements in Federal law, guidance, or if applicable, Secretary approval.

(4) Negative case errors are errors, based on the State's documented policies and procedures, resulting from either of the following:

(i) Applications for Medicaid or CHIP that are improperly denied by the State.

(ii) Existing cases that are improperly terminated from Medicaid or CHIP by the State.

(5) No payment errors are associated with negative cases.

(e) Errors for purposes of determining the national error rates. The Medicaid and CHIP national error rates include but are not limited to the errors described in paragraphs (b) through (d) of this section, with the exception of negative case errors described in paragraph (d)(4) of this section.

(f) Errors for purposes of determining the State error rates. The Medicaid and CHIP State error rates include but are not limited to, the errors described in paragraphs (b) through (d)(1)(vii) of this section, with the exception of negative case errors as described in paragraph (d)(4) of this section.

(g) *Error codes.* CMS may define different types of errors within the above categories for analysis and reporting purposes. Only dollars in error will factor into a State's PERM error rate.

10. Section 431.970 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 431.970 Information submission requirements.

(a) * * *

(1) Adjudicated fee-for-service (FFS) or managed care claims information or both, on a quarterly basis, from the review year;

* * * *

(b) Providers must submit information to the Secretary for, among other purposes estimating improper payments in Medicaid and CHIP, which include but are not limited to, Medicaid and CHIP beneficiary medical records within 75 calendar days of the date the request is made by CMS. If CMS determines that the documentation is insufficient, providers must respond to the request for additional documentation within 14 calendar days of the date the request is made by CMS. ■ 11. Section 431.972 is added to read as follows:

§431.972 Claims sampling procedures.

(a) *Claims universe*.

(1) The PERM claims universe includes payments that were originally paid (paid claims) and for which payment was requested but denied (denied claims) during the FFY, and for which there is FFP (or would have been if the claim had not been denied) through Title XIX (Medicaid) or Title XXI (CHIP).

(2) The State must establish controls to ensure FFS and managed care universes are accurate and complete, including comparing the FFS and managed care universes to the Form CMS–64 and Form CMS–21 as appropriate.

(b) *Sample size*. CMS estimates a State's annual sample size for claims review at the beginning of the PERM cycle.

(1) Precision and confidence levels. The annual sample size should be estimated to achieve a State-level error rate within a 3 percent precision level at 95 percent confidence interval for the claims component of the PERM program, unless the precision requirement is waived by CMS on its own initiative.

(2) Base year sample size. The annual sample size in a State's first PERM cycle (the "base year") is—

(i) Five hundred fee-for-service claims and 250 managed care payments drawn from the claims universe; or

(ii) If the claims universe of fee-forservice claims or managed care capitation payments from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(3) *Subsequent year sample size.* In PERM cycles following the base year:

(i) CMS considers the error rate from the State's previous PERM cycle to determine the State's annual sample size for the current PERM cycle.

(ii) The maximum sample size is 1,000 fee-for-service or managed care payments, respectively.

(iii) If a State measured in the FY 2007 or FY 2008 cycle elects to reject its State-specific CHIP PERM rate determined during those cycles, information from those cycles will not be used to calculate its annual sample size in subsequent PERM cycles and the State's annual sample size in its base year is 500 fee-for-service and 250 managed care payments.

■ 12. Section 431.978 is amended by-

■ A. Revising paragraphs (a), (b) and (c).

 B. Revising paragraphs (d)(1)(i), (d)(1)(ii), (d)(3), and (d)(4).
 The revisions read as follows:

§431.978 Eligibility sampling plan and procedures.

(a) *Plan approval.* For each review year, the agency must—

(1) Submit its Medicaid or CHIP sampling plan (or revisions to a current plan) for both active and negative cases to CMS for approval by the August 1 before the review year; and

(2) Have its sampling plan approved by CMS before the plan is implemented.

(b) *Maintain current plan.* The agency must do both of the following:

(1) Keep its plan current, for example, by making adjustments to the plan when necessary due to fluctuations in the universe.

(2) Review its plan each review year. If it is determined that the approved plan is—

(i) Unchanged from the previous review year, the agency must notify CMS that it is using the plan from the previous review year; or

(ii) Changed from the previous review year, the agency must submit a revised plan for CMS approval.

(c) Sample size.

(1) Precision and confidence levels. Annual sample size for eligibility reviews should be estimated to achieve within a 3 percent precision level at 95 percent confidence interval for the eligibility component of the program.

(2) Base year sample size. Annual sample size for each State's base year of PERM is—

(i) Five hundred four active cases and 204 negative cases drawn from the active and negative universes; or

(ii) If the active case universe or negative case universe of Medicaid or CHIP beneficiaries from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(3) Subsequent year sample size. In PERM cycles following the base year the annual sample size may increase or decrease based on the State's prior results of the previous cycle PERM error rate information. The State may provide information to CMS in the eligibility sampling plan due to CMS by the August 1 prior to the start of the review year to support the calculation of a reduced annual sample size for the next PERM cycle.

(i) CMS considers the error rate from the State's previous PERM cycle to determine the State's annual sample size for the current PERM cycle. (ii) The maximum sample size is 1,000 for the active cases and negative cases, respectively.

(iii) If the active case universe or negative case universe of Medicaid or CHIP beneficiaries from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(iv) If a State measured in the FY 2007 or FY 2008 cycle elects to reject its PERM CHIP rate as determined during those cycles, information from those cycles is not used to calculate the State's sample size in subsequent PERM cycles and the State's sample size in its base year is 504 active cases and 204 negative cases.

- (d) * * *
- (1) * * *

(i) *Medicaid*. (A) The Medicaid active universe consists of all active Medicaid cases funded through Title XIX for the sample month.

(B) The following types of cases are excluded from the Medicaid active universe:

(1) Cases for which the Social Security Administration, under section 1634 of the Act agreement with a State, determines Medicaid eligibility for Supplemental Security Income recipients.

(2) All foster care and adoption assistance cases under Title IV–E of the Act are excluded from the universe in all States.

(3) Cases under active fraud investigation.

(4) Cases in which eligibility was determined under section 1902(e)(13) of the Act for States' Express Lane Eligibility option.

(C) If the State cannot identify cases that meet the exclusion criteria specified in paragraph (d)(1)(i)(B) of this section before sample selection, the State must drop these cases from review if they are selected in the sample and are later determined to meet the exclusion criteria specified in paragraph (d)(1)(i)(B) of this section.

(ii) *CHIP*. (A) The CHIP active universe consists of all active case CHIP and Title XXI Medicaid expansion cases that are funded through Title XXI for the sample month.

(B) The following types of cases are excluded from the CHIP active universe:

(1) Cases under active fraud investigation.

(2) Cases in which eligibility was determined under section 2107(e)(1) of the Act for States' Express Lane Eligibility option.

(Č) If the State cannot identify cases that meet the exclusion criteria

specified in paragraph (d)(1)(ii)(B) of this section before sample selection, the State must drop these cases from review if it is later determined that the cases meet the exclusion criteria specified in paragraph (d)(1)(ii)(B) of this section.

(3) *Stratifying the universe.* States have the option to stratify the active case universe.

(i) Each month, the State may stratify the Medicaid and CHIP active case universe into three strata:

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

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

(C) All other cases.

(ii) States that do not stratify the universe will sample from the entire active case universe each month.

(4) *Sample selection*. Each month, an equal number of cases are selected for review from one of the following:

(i) Each stratum as described in paragraph (d)(3)(i) of this section.

(ii) The entire active case universe if opting not to stratify cases under

paragraph (d)(2)(ii) of this section. (iii) Otherwise provided for in the State's sampling plan approved by CMS.

■ 13. Section 431.980 is amended by—

■ A. Revising paragraph (d).

B. Adding paragraph (f).

The revision and addition read as

follows:

§431.980 Eligibility review procedures.

(d) Eligibility review decision.

(1) Active cases—Medicaid. Unless the State has selected to substitute MEQC data for PERM data under paragraph (f) of this section, the agency must complete all of the following:

(i) Review the cases specified at § 431.978(d)(3)(i)(A) and § 431.978(d)(3)(i)(B) of this subpart in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the review month and identify payments made on behalf of such beneficiary or family for services received in the first 30 days of eligibility.

(ii) For cases specified in § 431.978(d)(3)(i)(C) of this subpart, review the last action as follows:

(A) If the last action was not more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the last action and identify payments made on behalf of such beneficiary or family in the first 30 days of eligibility.

(B) If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the sample month and identify payments made on behalf of the beneficiary or family for services received in the sample month.

(iii) For cases in States that do not stratify the universe, as specified in § 431.978(d)(3)(ii) of this subpart, review the last action as follows:

(A) If the last action was no more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the last action and identify payments made on behalf of such beneficiary or family for services received in the sample month.

(B) If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria, and documented policies and procedures, as of the sample month and identify payments made on behalf of the beneficiary or family for services received in the sample month.

(C) Cases that are not stratified must have the last action identified as either falling under the criteria of § 431.978(d)(3)(i)(A) or § 431.978(d)(3)(i)(B) of this subpart after the sample is selected.

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

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

(vi) Elements of eligibility in which State policy allows for self-declaration or self-certification are considered to be verified with a self-declaration or selfcertification statement. The selfdeclaration or self-certification must be—

(A) Present in the record;(B) Not outdated (more than 12 months old);

(C) Originating from the last case action that was not more than 12 months prior to the sample month;

(D) In a valid, State-approved format; and

(E) Consistent with other facts in the case record.

(vii) If a self-declaration or selfcertification statement does not meet the provisions of paragraphs (e)(1)(vi)(A) through (D) of this section, eligibility may be verified through a new selfdeclaration or self-certification statement or other third party sources.

(A) If eligibility or ineligibility cannot be verified, cite a case as undetermined.

(ix) As a result of paragraphs (e)(1)(i) through (e)(1)(vii) of this section—

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

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

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

*

(f) Substitution of MEQC data. (1) A State in their PERM year may elect to substitute the random sample of selected cases, eligibility review findings, and payment review findings, as qualified by paragraphs (d)(2) and (d)(3) of this section, which are obtained through MEQC reviews conducted in accordance with section 1903(u) of the Act for data required in this section, as long as the State MEQC reviews meet the requirements of the MEQC Sampling Plan and Procedures at § 431.814 of this part, and if the only exclusions are those set forth in section 1902(e)(13) of the Act, §431.814(c)(4), and §431.978(d)(1) of this part.

(2) MEQC samples must also meet PERM confidence and precision requirements.

(3) MEQC cases that are dropped due to the acceptable reasons listed in the

State Medicaid Manual are included in the PERM error rate calculation.

14. Section 431.988 is amended by—
A. Revising paragraphs (a), (b)(1), and (b)(2).

■ B. Redesignating paragraphs (b)(3) and (b)(4) as paragraphs (b)(4) and (b)(5), respectively.

■ C. Adding new paragraph (b)(3).

The revisions and addition read as follows:

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

(a)(1) States must complete and report to CMS the findings, including total number of cases in the eligibility universe, the error causes for all case reviews listed on the monthly sample selection lists, including cases dropped from review due to active fraud investigations, and cases for which eligibility could not be determined.

(2) States must submit a summary report of the active case eligibility and payment review findings to CMS by July 1 following the review year.

(b) * *

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

(2) Case error data for negative cases.

(3) Identify the last action on a case, either application or redetermination for States that do not stratify the eligibility sample in accordance with § 431.978(d)(3)(i) of this subpart.

* * * * * *

■ 15. Section 431.992 is revised to read as follows:

§431.992 Corrective action plan.

(a) The State agency must develop a separate corrective action plan for Medicaid and CHIP, which is not required to be approved by CMS, designed to reduce improper payments in each program based on its analysis of the error causes in the FFS, managed care, and eligibility components.

(b) In developing a corrective action plan, the State must take the following actions:

(1) *Data analysis.* States must conduct data analysis such as reviewing clusters of errors, general error causes, characteristics, and frequency of errors that are associated with improper payments.

(2) *Program analysis.* States must review the findings of the data analysis to determine the specific programmatic causes to which errors are attributed (for example, provider lack of understanding of the requirement to provide documentation) and to identify root error causes.

(3) *Corrective action planning.* States must determine the corrective actions to

be implemented that address the root error causes.

(4) Implementation and monitoring.
(i) States must develop an implementation schedule for each corrective action initiative and implement those actions in accordance with the schedule.

(ii) The implementation schedule must identify all of the following:

(A) Major tasks.

(B) Key personnel responsible for each activity.

(C) A timeline for each action including target implementation dates, milestones, and monitoring.

(5) *Evaluation*. States must evaluate the effectiveness of the corrective action

by assessing all of the following: (i) Improvements in operations.

(ii) Efficiencies.

(iii) Number of errors.

(iv) Improper payments.

(c) The State agency must submit to CMS and implement the corrective action plan for the fiscal year it was reviewed no later than 90 calendar days after the date on which the State's Medicaid or CHIP error rates are posted on the CMS contractor's Web site.

(d) The State must submit to CMS a new corrective action plan for each subsequent error rate measurement that contains an update on the status of a previous corrective action plan. Items to address in the new corrective action plan include, but are not limited to the following:

(1) Effectiveness of implemented corrective actions, as assessed using objective data sources.

(2) Discontinued or ineffective actions, actions not implemented, and those actions, if any, that were substituted for such discontinued, ineffective, or abandoned actions.

(3) Findings on short-term corrective actions.

(4) The status of the long-term corrective actions.

■ 16. Section 431.998 is amended by—

- A. Revising the section heading.
- B. Revising paragraphs (a) and (b).

■ C. Redesignating paragraph (c) as (d).

D. Adding new paragraph (c).

The revisions and addition read as follows:

§ 431.998 Difference resolution and appeal process.

(a) The State may file, in writing, a request with the Federal contractor to resolve differences in the Federal contractor's findings based on medical or data processing reviews on FFS and managed care claims in Medicaid or CHIP within 20 business days after the disposition report of claims review findings is posted on the contractor's Web site. The State must complete all of the following:

(1) Have a factual basis for filing the difference.

(2) Provide the Federal contractor with valid evidence directly related to the error finding to support the State's position that the claim was properly paid.

(b) For a claim in which the State and the Federal contractor cannot resolve the difference in findings, the State may appeal to CMS for final resolution, filing the appeal within 10 business days from the date the contractor's finding as a result of the difference resolution is posted on the contractor's Web site. There is no minimum dollar threshold required to appeal a difference in findings.

(c) For eligibility error determinations made by the agency with personnel functionally and physically separate from the State Medicaid and CHIP agencies with personnel that are responsible for Medicaid and CHIP policy and operations, the State may appeal error determinations by filing an appeal request.

(1) *Filing an appeal request.* The State may—

(i) File its appeal request with the appropriate State agency or entity; or

(ii) If no appeals process is in place at the State level, differences in findings—

(A) Must be documented in writing and submitted directly to the agency responsible for the PERM eligibility review for its consideration;

(B) May be resolved through document exchange facilitated by CMS, whereby CMS will act as intermediary by receiving the written documentation supporting the State's appeal from the State agency and submitting that documentation to the agency responsible for the PERM eligibility review; or

(C) Any unresolved differences may be addressed by CMS between the final month of payment data submission and error rate calculation.

(2) After the filing of an appeals request. (i) Any changes in error findings must be reported to CMS by the deadline for submitting final eligibility review findings.

(ii) Any appeals of determinations based on interpretations of Federal policy may be referred to CMS.

(iii) CMS's eligibility error resolution decision is final.

(iv) If CMS's or the State-level appeal board's decision causes an erroneous payment finding to be made, if the final adjudicated claim is actually a payment error in accordance with documented State policies and procedures, any resulting recoveries are governed by § 431.1002 of this subchapter.

■ 17. In 42 CFR part 431, revise all references to "SCHIP" to read "CHIP".

PART 447—PAYMENTS FOR SERVICES

18. The authority citation for part 447 continues to read as follows:

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

§447.504 [Amended]

■ 19. In § 447.504, amend paragraph (g)(15) by removing the reference "State Children's Health Insurance Program (SCHIP)" and by adding the reference "Children's Health Insurance Program (CHIP)" in its place and amend paragraph (h)(23) by removing the reference "(SCHIP)" and by adding the reference "(CHIP)" in its place.

PART 457—ALLOTMENTS AND **GRANTS TO STATES**

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

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

■ 21. Section 457.10 is amended by— ■ A. Adding the definition of "Children's Health Insurance Program (CHIP)" in alphabetical order. ■ B. Removing the definition of "State Children's Health Insurance Program (SCHIP)".

The addition reads as follows:

§457.10 Definitions and use of terms. * * *

Children's Health Insurance Program (CHIP) means a program established and administered by a State, jointly funded with the Federal government, to provide child health assistance to uninsured. low-income children through a separate child health program, a Medicaid expansion program, or a combination program. *

■ 22. In 42 CFR part 457, revise all references to "SCHIP" to read "CHIP".

§457.10 [Amended]

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■ 23. In § 457.10, in the definition of "Applicant" remove the reference to "State Children's Health Insurance Program" and add the reference "Children's Health Insurance Program", in its place.

§457.301 [Amended]

■ 24. In § 457.301, paragraph (5) of the definition "Qualified entity" remove the reference to "State Children's Health Insurance Program" and add the reference "Children's Health Insurance Program", in its place.

§457.606 [Amended]

■ 25. In § 457.606 paragraph (b) remove the reference to "State's Children's Health Insurance Program" and add the reference "Children's Health Insurance Program" in its place.

§457.614 [Amended]

■ 26. In § 457.614 paragraph (b)(1) remove the reference to "State

Children's Health Insurance Program" and add the reference "Children's Health Insurance Program", in its place.

§457.618 [Amended]

■ 27. In § 457.618 in the section heading remove the reference to "State Children's Health Insurance Program" and add the reference "Children's Health Insurance Program", in its place.

§457.622 [Amended]

■ 28. In § 457.622 paragraph (e)(5) remove the reference to "State Children's Health Insurance Program" and add the reference "Children's Health Insurance Program", in its place.

§457.630 [Amended]

■ 29. In § 457.630 paragraphs (b) and (c)(1) remove the reference to "State Children's Health Insurance Program" and add the reference "Children's Health Insurance Program", in its place each time it appears.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Section 601 of the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111-3))

Dated: March 16, 2010.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 23, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010-18582 Filed 8-10-10; 8:45 am] BILLING CODE 4120-01-P