

FEDERAL REGISTER

Vol. 76 Tuesday,

No. 75 April 19, 2011

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 433

Medicaid Program; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 433

[CMS-2346-F]

RIN 0938-AQ53

Medicaid Program; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities

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

ACTION: Final rule.

SUMMARY: This final rule will revise Medicaid regulations for Mechanized Claims Processing and Information Retrieval Systems. We are also modifying our regulations so that the enhanced Federal financial participation (FFP) is available for design, development and installation or enhancement of eligibility determination systems until December 31, 2015. This final rule also imposes certain defined standards and conditions in terms of timeliness, accuracy, efficiency, and integrity for mechanized claims processing and information retrieval systems in order to receive enhanced FFP.

DATES: *Effective Date:* These regulations are effective on April 19, 2011.

FOR FURTHER INFORMATION CONTACT: Richard Friedman, (410) 786–4451.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Current State of the Medicaid Management Information System (MMIS)

A Medicaid management information system (MMIS) is a mechanized system of claims processing and information retrieval used in State Medicaid programs under title XIX of the Social Security Act (the Act). The system is used to process Medicaid claims from providers and to retrieve and produce utilization data and management information about medical care and services furnished to Medicaid recipients. The system also is potentially eligible to receive enhanced administrative funding from the Federal government under section 1903(a)(3) of the Act. Specifically, section 1903(a)(3)(A)(i) of the Act provides that Federal financial participation (FFP) is available at 90 percent of expenditures for the design, development, or installation of mechanized claims processing and information retrieval

systems as the "Secretary determines are likely to provide more efficient, economical and effective administration of the plan and to be compatible with the claims processing and information retrieval systems utilized in the administration of title XVIII [Medicare]." In addition, section 1903(a)(3)(B) of the Act provides for the availability of FFP at 75 percent of expenditures attributable to operating the "systems * * * of the type described in [section 1903(a)(3)] subparagraph (A)(i)," which are approved by the Secretary and meet certain other requirements (including requirements relating to explanations of benefits). For purposes of this final rule, we refer to 90 percent and 75 percent FFP as "enhanced" FFP since it is greater than the 50 percent FFP available for most Medicaid administrative expenses. In addition, section 1903(r) of the Act places conditions on a State's ability to receive Federal funding for automated data systems in the administration of the State plan.

To receive an enhanced match, the Secretary must find that the mechanized claims and information retrieval system is adequate to provide more efficient, economical, and effective administration of the State plan. The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted on March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111– 152, enacted on March 30, 2010) (collectively referred to as the Affordable Care Act) also made additional changes to the requirements within section 1903(r) of the Act relating to the reporting of data to the Secretary; guidance on these requirements will be issued in a separate rulemaking document. Our Federal regulations concerning mechanized claims processing and information retrieval systems are at 42 CFR part 433, subpart C. A State that chooses to develop, enhance, or replace its required system or subsystems must first submit for approval an Advanced Planning Document (APD). The general Health and Human Services (HHS) requirements for approval of APDs are found at 45 CFR part 95, subpart F.

B. Availability of Enhanced FFP for Automated Eligibility Systems

Historically, Medicaid eligibility for many applicants and recipients was determined by an agency other than the State Medicaid agency. Under section 1902(a)(10)(A)(i) of the Act, States were required to provide Medicaid to recipients under the Aid to Families with Dependent Children (AFDC)

program, as well as recipients of the Supplemental Security Income (SSI) program. In these cases, eligibility determinations were derived from the cash welfare-assistance determination. As a result, States that maintained a Medicaid eligibility determination system usually integrated these systems into the public welfare systems. In the October 13, 1989 Federal Register (54 FR 41966, effective November 13, 1989), we published a final rule excluding eligibility determination systems from the enhanced funding that was available under section 1903(a)(3) of the Act, reasoning that the close interrelationship between these cash assistance programs and Medicaid eligibility rendered such enhanced assistance redundant and unnecessary (54 FR 41966 through 41974). As a result, we revised the definition of mechanized claims processing and information retrieval systems to exclude eligibility determination systems.

We also indicated in the 1989 final rule that to receive any FFP for Medicaid purposes for an eligibility determination system after November 13, 1989, a State must submit an APD for funding in accordance with the requirements of 45 CFR Part 95, Subpart F. If we approved the APD, the State agency would receive 50 percent FFP for administrative costs under section 1903(a)(7) of the Act for the system's design, development, and installation,

and operation.

C. Changes in Medicaid Eligibility Policies

Since we issued the October 13, 1989 final rule, a series of statutory changes have dramatically affected eligibility for Medicaid and how Medicaid eligibility is determined. Among other things, new eligibility coverage groups were created and expanded, and in 1996, Medicaid eligibility was "de-linked" from the receipt of cash assistance when the AFDC program was replaced by the Temporary Assistance to Needy Families (Pub. L. 104-193, enacted on August 22, 1996) (TANF) program created by the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) (Pub. L. 104-193, enacted on August 22, 1996).

With the passage of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA), States were required to coordinate eligibility for and enrollment in Medicaid with the new Children's Health Insurance Program (CHIP) to ensure enrollment of children in the appropriate program. With passage of the "Express Lane Eligibility" provisions in section 203 of the Children's Health

Insurance Program Reauthorization Act of 2009 (Pub. L. 111–3) (CHIPRA), States were provided with the option, and are encouraged, to coordinate and expedite eligibility for children in Medicaid and CHIP by using findings regarding income and other eligibility criteria made by other agencies, such as the Supplemental Nutrition Assistance Program (SNAP), as the basis for Medicaid and CHIP eligibility adjudications.

With the passage of the Affordable Care Act, we expect that changes to Medicaid eligibility policies and business processes need to be adopted. States will need to apply new rules to adjudicate eligibility for the program; enroll millions of newly eligible individuals through multiple channels; renew eligibility for existing enrollees; operate seamlessly with newly authorized Health Insurance Exchanges (see section 1311 of the Affordable Care Act) whether run by the State or the U.S. Department of Health and Human Services (HHS) if the State chooses not to operate a State Exchange (hereafter referred to as "Exchanges"); participate in a system to verify information from applicants electronically; incorporate a streamlined application used to apply for multiple sources of coverage and health insurance assistance; and produce notices and communications to applicants and beneficiaries concerning the process, outcomes, and their rights to dispute or appeal. We further anticipate, following consultation with States and other stakeholders, additional standard Federal requirements for more timely and detailed reporting of eligibility and enrollment status statistics, including breakdowns by eligibility group, demographic characteristics, enrollment in managed care plans, and participation in waiver programs.

System transformations will be needed in most States to accomplish these changes. These systems transformations should be undertaken in full partnership with Exchanges in order to meet coverage goals, minimize duplication, ensure effective reuse of infrastructure and applications, produce seamless enrollment for consumers, and ensure accuracy of program placements (see sections 1413 and 2201 of the Affordable Care Act). Extensive coordination and collaboration will be required between Exchanges and Medicaid, including on oversight and evaluation of the interoperability of the Exchange and Medicaid systems. In addition, States may consider how to coordinate systems changes with the eligibility determination systems used for other health and human services

programs, such as SNAP, because a large share of individuals who are eligible for Medicaid also are eligible for other programs as well.

II. Provisions of the Proposed Regulations

In the November 8, 2010 Federal Register (75 FR 68583), we published a proposed rule that revised the Medicaid regulations for Mechanized Claims Processing and Information Retrieval Systems. Specifically, we proposed to amend the definition of Mechanized Claims Processing and Information Retrieval Systems to include mechanized eligibility determination systems, which would include the enrollment and eligibility reporting activities associated with such systems. We also proposed that the enhanced FFP would be available for design, development and installation or enhancement of eligibility determination systems until December 31, 2015.

III. Analysis of and Responses to Public Comments

We received 40 timely comments on the November 8, 2010 proposed rule (75 FR 68583 through 68595).

Commenters expressed general support for the policies outlined in the proposed rule. Specifically, commenters agreed that providing enhanced matching funds for Medicaid eligibility systems is appropriate and necessary. Commenters expressed almost universal agreement that this enhanced match is critical to support State efforts to modernize their eligibility systems, and will allow States to bring these systems into the 21st Century so that they can provide cost-effective, accurate, reliable, and beneficiary-friendly assessments of eligibility for the Medicaid program. In light of the substantial changes made by the Affordable Care Act, commenters agreed that it is more important than ever to ensure that eligibility determination systems are designed and operated using the most up-to-date technological and business process solutions. With States expected to enroll millions of newly eligible individuals into Medicaid and to ensure seamless coordination with the new Exchanges, it is essential that States have modern and cost-effective eligibility systems that will accurately enroll eligible individuals, without unnecessarily cumbersome processes or delays. Commenters also believed that such initial investments would ultimately lower ongoing maintenance and operational expenses, driving savings for both States and the Federal government.

Commenters also noted that HHS had released additional documents at approximately the same time as the November 8, 2010 proposed rule, which reinforced our strategic direction and received their support. Specifically, commenters acknowledged the joint guidance released by CMS and the Office of Consumer Information and Insurance Oversight (now CMS' Center for Consumer Information and Insurance Oversight (CCIIO)) entitled, "Exchange/Medicaid Information Technology Guidance, version 1.0," and the Funding Opportunity Announcement for Cooperative Agreements to Support Early Innovator Grants for Exchanges. Commenters indicated that they greatly appreciated the foresight of CMS and CCIIO, and are supportive of the guidance providing direction towards a service-oriented IT infrastructure based on interoperable systems and that they fully support the concept of a collaborative IT development approach among States, CMS and CCIIO.

A summary of additional major issues and our responses follow. Since many of the comments were general in nature and not specific to any particular regulatory provision, we have identified the comments by nine categories:

- Requests for enhanced Federal funding.
- Requests for additional guidance.
- Public feedback and suggestions related to the seven standards and conditions.
- Public feedback and suggestions related to the APD process.
- Issues related to the transition period for compliance.
- Comments regarding CMS' strategy for monitoring and oversight, including performance reviews.
- Issues related to partial systems improvements or modernizations.
- Specific issues by regulatory provision.
- Issues related to the Regulatory Impact Analysis including the cost estimates, and information collection.

A. Requests for Enhanced Federal Funding

Comment: Numerous commenters requested that the enhanced FFP for design, development, and installation or enhancement of eligibility determination systems be extended beyond the December 31, 2015 deadline. Commenters indicated that new and significant enhancements may be needed beyond December 31, 2015, particularly in order to affect future legislative changes to Medicaid eligibility or to keep pace with technological innovations. The

commenters noted that State budgets continue to be in a state of crisis and State revenues may not fully recover until 2016 or later; consequently, the Federal government must take responsibility for ensuring adequate funding of the program infrastructure to ensure compliance by January 1, 2014. Commenters recommended several different options in this regard. Some commenters indicated that CMS should consider that the requirement apply to funds allocated rather than expended. Other commenters believed that CMS could allow for the possibility of a continued enhanced match beyond the deadline in specified circumstances (many outside the control of State governments), such as new Federal requirements or major advances in computer technology. Other exception categories suggested by commenters included unforeseen issues in implementation and/or new opportunities for interoperability with other health and human services programs. Other commenters indicated that CMS should extend funding if States have approved APDs on or before December 31, 2015 and the project has not been completed or if States are planning to leverage improvements from other State Medicaid eligibility systems. The commenters further indicate that they are concerned that they will be unable to receive legislative approval to begin their project, develop an APD, receive Federal approval, and then complete work on the project while meeting the standards and conditions before the enhanced FFP ends on December 31, 2015. Still other commenters believed the date should be changed to coincide with the end of the Federal fiscal year 2015 and 2016, so that enhanced funding would expire September 30, 2016. One commenter suggests that the deadline should be interpreted to apply to costs for projects receiving enhanced funding and obligated by that date rather than expended by December 31, 2015. One commenter expressed concern that a requirement for States to maintain existing eligibility processes for pregnant women and children until September 30, 2019 will mean States have to maintain dual eligibility systems during this time period. At the end of 2019, the IT systems will need to be updated to remove this function and that enhanced funding should be extended for States to make changes to eligibility systems when this requirement ends.

Response: We appreciate the significant number of comments we received on this aspect of our proposed

rule and the view of commenters that we should eliminate, extend, or modify the deadline for expiration of the enhanced match for eligibility systems. Nonetheless, while we appreciate the opinions of commenters, we continue to believe that the deadline we established in the proposed rule is appropriate and proper. We believe it is within our authority to determine that by a certain date, additional investments in eligibility determination systems will no longer continue to result in "more" efficient, effective or economical administration of the State Plan, as required by section 1903(a)(3)(A)(i) of the Act. Further, we continue to believe that December 31, 2015 is a reasonable and proper end-point for when investments cease to result in acceptable increases in efficiency, economy, or effectiveness. Our reason is threefold: First, changes imposed by the Affordable Care Act will require immediate attention and commitment to new technologies for eligibility and enrollment systems. Second, once appropriate systems are deployed to support the coverage expansions and other eligibility changes required by the Affordable Care Act, we anticipate significant efficiencies in both application maintenance and business operations. Third, the additional 2 years we provided to States after the Medicaid expansion goes into effect allows ample time for States to refine and enhance the capability of the systems, and to capitalize on the efficiencies of these investments.

We articulated in the proposed rule that additional investments are unlikely to yield similar rates of improvement and a regular administrative match should be sufficient for efficient and effective administration of State Medicaid programs. We anticipate that the improved underlying infrastructure supporting both Medicaid and Exchanges will be strongly leveraged in support of a State's person-centric outreach, eligibility and enrollment activities across the health and human services spectrum.

With respect to the request made by some commenters to establish an exceptions process, we believe this is already sufficiently provided for through our extension of enhanced FFP for an additional 2 years beyond the date for operation of the Exchanges. We are concerned that broadening or codifying exceptions to the deadline in the way suggested by the commenters would effectively render the deadline moot for many purposes and projects.

The September 30, 2019 date noted by one commenter is the end-date for maintenance of effort (MOE) provisions

for children (not pregnant women). Because of these MOE provisions, States must not have more restrictive "eligibility standards, methodologies, or procedures" for children than those in effect on March 23, 2010. The MOE requirement does not mean that States must maintain identical standards, methodologies or procedures as those in effect on March 23, 2010, and it does not mean that the same IT system or IT system processes be used. Rather, the MOE requires that the eligibility standards, methods, and procedures be no more restrictive than those in effect on March 23, 2010.

We are not certain of what the commenter is concerned about in terms of States' needing to maintain dual eligibility processes, but we assume he or she may be concerned about the interaction of the MOE requirements and the requirement under section 2002 of the Affordable Care Act. The conversion to a MAGI-equivalent income standard required under section 2002 of the Affordable Care Act is designed in the statute to ensure that individuals who meet the eligibility requirements in effect as of March 23, 2010 do not lose eligibility as a result of the shift to MAGI. Guidance will be provided by the Secretary regarding how States can accomplish the required conversion, and once the new MAGIequivalent income standard has been determined, the MOE requirements will be applied to such converted standard, using the MAGI methodologies to determine an individual's income, as required under the Affordable Care Act. Therefore, the MOE requirements will not require operating dual eligibility systems.

After consideration of the public comments received, we are maintaining the December 31, 2015 deadline in our regulations for eligibility determination systems.

Comment: One commenter requested that CMS consider interpreting the deadline of December 31, 2015 for projects receiving enhanced Federal funding to requiring the funds be obligated by that date rather than expended.

Response: We indicated in the proposed rule (75 FR 68589) that States would need to incur costs for goods and services furnished no later than December 31, 2015 to receive 90 percent FFP for design, development, installation, or enhancement of an eligibility system. For further clarification, this means that States must ensure that goods and services (for example, eligibility and enrollment modules, applications, systems, etc.) are provided to States no later than close of

business December 31, 2015. Thus, for example, if an amount has been obligated by December 31, 2015, but the good or service has not yet been furnished by that date, then such expenditure would not be eligible for enhanced FFP.

As a result of this comment, we are adding language to the regulations text to clarify this point.

Comment: Numerous commenters asked whether enhanced funding is available for subsystems that interface with and/or are part of the eligibility process since such subsystems will require modifications to meet the requirements of the Affordable Care Act. Additionally, commenters sought enhanced FFP for projects that meet Medicaid Information Technology Architecture (MITA) guidance, yet still may need to integrate with legacy systems, with the understanding that, where feasible, open rules and specifications developed for programs will be used to read, insert, or update data into systems that currently do not have the functionality of being interoperable. The commenters agreed that APDs would need to be put in place and approved to modernize the legacy systems/subsystems.

Response: We agree that enhanced funding can be available for subsystems that meet the standards and conditions outlined in this final rule. However, to the extent that such subsystems are reliant on or tied to a larger legacy system or suite of systems that introduce performance risk or ongoing costs to the operation of the subsystem, we may find that the system as a whole is not meeting the standards and conditions of this final rule and decline to approve enhanced match on that basis. It is our desire to acknowledge that subsystem modernization may be an entirely appropriate pathway to a high performing Medicaid program, while at the same time not binding ourselves to approve enhanced match for minor components of a large, fragmented legacy system that has little chance of delivering to expected business results. CMS will review APDs and make determinations regarding such subsystems, and to the extent that such subsystems meet with the standards and conditions outlined in this final rule and States can document that there is no performance risk or ongoing unnecessary costs, as a result of the subsystem being a part of larger legacy system, CMS will make determinations regarding enhanced funding accordingly.

Comment: Several commenters want to ensure that enhanced FFP is available to States that are not completely MITA

compliant, but rather to States that can demonstrate efficiencies are being achieved, redundancy is being decreased/eliminated, and system integration is being realized through application programming interfaces (API). States could demonstrate that APIs, in which a particular set of rules and specifications for services and resources have been developed by one software program that can be accessed and used by another software program implementing the API, can be used and serve as an interface between different software programs and facilitating their interaction, and thus, leading to efficiencies. Commenters added that with an approved APD reasonable and measureable milestones of system compliance can be demonstrated.

Response: Enhanced FFP is available for those systems that comply with the standards and conditions of this final rule. Aligning to, and advancing increasingly, in MITA maturity for business, architecture, and data is one of the standards and conditions that must be met. We did not use the term "MITA compliant" in our proposed rule because MITA maturity is by definition, a matter of degree. We agree that achieving increasing levels and degrees of MITA maturity is likely to happen in stages. Recognizing this, we will be requiring a MITA roadmap that delineates how the proposed system enhancements for eligibility and enrollment functions will fit into the States' greater MITA framework. Such requirement will align with our expectations to see States continuing to make measurable progress in implementing their MITA roadmaps. We believe it is critical to build on and accelerate the modernization we have collectively begun under MITA, so that States achieve the final vision of MITA and have a comprehensive framework with which to meet the technical and business demands required by an environment that will increasingly rely on health information technology and the electronic exchange of healthcare information to improve health outcomes and lower program costs.

Comment: One commenter requested clarification as to whether enhanced FFP will be available where a project has some components that meet the standards and guidelines required for enhanced FFP, but may include other components that do not.

Response: We believe it is entirely appropriate to accomplish system modernization through phasing. In cases such as the one raised by the commenter, the changes being made to various system components will need to be reviewed through submission of an APD and review. We will need to ensure

that component-based development is on a path toward an entire system or subsystem coming into compliance with the standards and conditions of this final rule. We would expect that if the components that do not meet the standards and conditions are essentially preventing the entire system or subsystem from meeting the standards and conditions, then the State would have a plan for updating such components, even if all components are not updated at the same time. For example, we do not expect that we would offer enhanced FFP for improvements to just the reporting aspect of the traditional, legacy eligibility system, if the State does not have a plan for bringing this entire legacy system into compliance with the standards and conditions. In addition, to receive enhanced FFP, States may not ignore any single standard or condition regardless of the level or breadth of their compliance with the remaining standards, although if a State is weaker or more at risk with certain standards or conditions, the State should include a roadmap in their APD demonstrating how they intend to come into compliance. We intend to carefully track progress against approved roadmaps when determining if system updates continue to meet the standards and conditions for enhanced match.

Comment: One commenter suggests that CMS clarify that enhanced funding is also available for "traditional" eligibility determinations, such as those made on behalf of medically needy clients, buy-in, elderly, disabled, long-term care and home and community-based individuals.

Response: To the extent that eligibility systems meet all requirements, standards, and conditions contained in this final rule, States will be eligible for enhanced FFP, and such enhanced funding is not dependent upon the eligibility group using the system.

Comment: One commenter recommended that CMS clarify that enhanced funding is available for personnel costs, as well as the costs of physical systems. Specifically, the commenter notes that Federal regulations at § 432.50(b) provide for enhanced funding at 75 percent for the costs of staff "engaged directly in the operation of mechanized claims processing and information retrieval systems" and for enhanced funding at 90 percent for staff costs related to the design, development, and installation of these systems. FFP is provided at 50 percent for the costs of training personnel when new systems are developed.

Response: We did not propose amendments to the regulations at § 432.50(b); thus, enhanced funding is available for staff time spent on mechanized eligibility determination systems in the same manner that they apply to all mechanized claims processing and information retrieval systems, since mechanized eligibility determination systems are now considered to be part of such systems, assuming the requirements of this section are met.

Comment: One commenter asked that we extend the enhanced funding to encompass the testing of the effectiveness of the eligibility systems, including testing beneficiary experience such as allowing States to receive reimbursement for conducting focus groups with community-based workers and/or beneficiaries who rely on the system to apply for and renew Medicaid coverage.

Response: Again, to the extent these costs would be reimbursable under § 432.50(b), they would be eligible for reimbursement under this rule as well (assuming all standards and conditions are met). States would need to ensure that the expenditures are tied to the mechanized eligibility determination system and follow all procedures for seeking approval.

Comment: Several commenters requested that CMS require States to pass enhanced match through to counties. The commenters stated that CMS should ensure that if a State requires counties to contribute to the non-Federal share of Medicaid and Medicaid administrative costs, and that receives enhanced FFP; the State should be required to share the enhanced FFP in proportion to the counties' contribution. The commenters stated that this requirement would reflect the clear Congressional intent as expressed in the enhanced Federal Medical Assistance Percentage (FMAP) requirements for certain States in section 5001(g)(2) of the American Recovery and Reinvestment Act (Pub. L. 111-5, enacted on February 17, 2009) and strengthened by section 10201(c)(6) of the Affordable Care Act.

Response: The commenters cite section 10201(c)(6) of the Affordable Care Act, which added section 1905(cc) to the Act. Under this provision, a State may not be eligible for certain increased FMAPs associated with health care reform and disaster recovery if the State requires that political subdivisions pay a greater percentage of the non-Federal share * * * than the respective percentages that would have been required by the State under the State plan under this title, State law, or both,

as in effect on December 31, 2009." Since the level of Federal funding available for the costs of the eligibility and enrollment determination systems under this final rule will increase and the level of the non-Federal share specific to such expenditures will decrease, there could be an effect on the level of required political subdivision contributions that would be subject to this limitation. We already issued guidance on how the political subdivision contribution limitations under section 1905(cc) apply in an SMD letter issued November, 9, 2010 (see http://www.cms.gov/smdl/downloads/ SMD10023.pdf). Rather than reiterate what is already in that guidance, we refer States and counties to such guidance. States and counties may also work with CMS to determine whether any required contributions by political subdivisions toward the non-federal share of these expenditures would be in compliance with political subdivision contribution provision.

Comment: One commenter urged

CMS to encourage States to consider in establishing actuarially sound Medicaid managed care rates, the additional systems-related investments by Medicaid health plans that are likely to be needed to interface with new State systems.

Response: We believe this commenter is asking about managed care rates, and not the proposal we issued with regard to mechanized claims processing and information retrieval systems, and when they will be eligible for enhanced FFP. As our proposed rule did not address Medicaid managed care rates, we believe this comment is outside the scope of the proposed rule.

Comment: One commenter asked for clarification on whether the addition of eligibility determination and enrollment systems is limited to stand-alone systems administered directly by the single State Medicaid Agency. The commenter indicates that some State eligibility systems are a joint venture with the HHS and the United States Department of Agriculture and are used to determine eligibility for financial assistance programs in addition to medical assistance programs.

Response: The enhanced funding can apply to "stand alone" systems or "integrated eligibility" systems, assuming they meet the standards and conditions specified in this final rule. Many States are considering ways to coordinate Medicaid, CHIP and Exchange eligibility with other health and human services programs. However, we will only provide enhanced funding for the portion of the costs that can be directly attributed to Medicaid

eligibility and enrollment functions. We also direct the commenter to the discussion on cost-allocation in OMB Circular A-87 (http:// www.whitehouse.gov/omb/ circulars a087 2004) specifying appropriate allocation of costs when the system includes various benefiting programs.

Comment: Other commenters have asked whether the enhanced funding can be used to support updating and completing the MITA assessment and roadmap, and performance

measurement.

Response: We agree with the commenters that it is appropriate to request enhanced funding for updating the MITA assessment and the roadmap, since one of the standards and conditions listed in § 433.112 speaks directly to MITA maturity. Enhanced funding is available assuming that updates are related to the standards and conditions and the State's plan for meeting them. We are making no further additions to the rule in response to this

Comment: Some commenters believed the timeframes related to the enhanced funding for the development of eligibility solutions seems to be extremely aggressive. Many of the activities related to the planning, design, development, and deployment of eligibility solutions will be new activities for both State and vendor staff. States will need to consider how they will integrate and leverage eligibility solutions into their Health Insurance Exchanges, their integrated human services eligibility solutions, their MMIS, and other points of intersection. Just the planning phase leading up to an approved APD and FFP release could easily consume more than a year. The commenters suggested that CMS should consider lengthening the timeframes for the completion of these efforts related to eligibility components.

Response: We recognize that the timelines for developing new eligibility systems, and for submitting and approving new APDs, must be greatly accelerated from historical and traditional experiences and approaches in order to meet the timelines in the Affordable Care Act and to take advantage of enhanced match prior to December 31, 2015. We emphasize that we expect to operate efficiently in processing APDs and work collaboratively with States to implement these changes, and we expect States to operate quite differently in how they pursue new development, share and reuse assets, and take advantage of "lightweight" applications and new

technologies to meet these needs. We

noted in our proposed rule that dramatic systems transformations would be necessary and while the timeframes may appear aggressive to some, the Department is committed to providing leadership, technical assistance, and financial support to produce the IT infrastructure necessary to accomplish the tasks required by the Affordable Care Act according to the timelines specified in the law. We note that the Affordable Care Act requires that States be able to enroll the newly eligible individuals and coordinate with Health Insurance Exchanges by January 1 of 2014. Thus, our timeline accounts for this statutory deadline, while still maintaining a period of two years (through December 31, 2015) to account for potential delays or unforeseen obstacles in developing new or improved eligibility determination systems.

We are making no further revisions to the rule as a result of this comment.

B. Requests for Additional Guidance

Comment: One commenter requested that CMS produce and make available to the States a project planning template illustrating key entry points to major phases of the projects

phases of the projects.

Response: We will be providing a whole series of artifacts and supporting tools, documentation, diagrams to States as part of our technical assistance, collaboration, and governance. We will consider the usefulness of a template for project planning as we develop and publish these materials.

Comment: Several commenters requested additional guidance on the IT enterprise

Response: We will issue additional Guidance for Exchange and Medicaid Information Technology Systems (IT guidance). We issued IT guidance version 1.0 on November 30, 2010, and expect to issue, expand and renew that guidance over time. These guidance documents will help States with the business rules necessary to design, develop, and implement State eligibility systems that can meet the requirements of the Affordable Care Act.

Comment: Several commenters inquired about future guidance on MITA, the MITA alignment process, and whether the process for certifying and/or validating MITA alignment will be detailed in the final rule.

Response: We have provided continued guidance and artifacts associated with MITA since the MITA Initiative began. We will continue to provide that guidance and related toolsets and details. We will consider a number of elements in reviewing states' alignment with MITA and increasing

MITA maturity, including States' self-assessments and MITA roadmaps.

Comment: Several commenters inquired about the "modular, flexible approach to systems development" and increasing MITA alignment requirements, as well as whether such requirements apply to all MMISs or only eligibility determination systems. The commenters believed that to promote the feasibility of a "modular, flexible approach to systems development" of Medicaid systems, CMS should continue to fund and aggressively develop necessary interfaces and technical standards that are required to facilitate MMIS interoperability.

Response: As stated in the above responses, we intend to issue a series of tools for States to use in ensuring the facilitation of interoperability. It should be noted that the requirements of this final rule apply to all MMISs, not just eligibility determination systems (which will now be considered part of the MMIS). We are making no further additions to the rule as a result of this comment.

Comment: Several commenters urged CMS to develop stronger Federal guidelines for enrollment and renewal procedures to accompany new eligibility systems, including guidance on acceptable data matches creating safe harbors for data sources used in electronic income verification, to allow States to move to paperless income verification with confidence that they comply with quality and accuracy standards. In developing additional requirements, the commenters urged CMS to ensure that Medicaid's application, renewal and verification procedures are no more paperwork intensive or burdensome than those for Exchange tax credit applicants.

Response: We agree with the commenters that simplification and streamlining of the consumer experience are expected outcomes of the Affordable Care Act. However, business process and policy requirements for determining eligibility are outside the scope of this regulation and will be addressed in separate rulemaking. As discussed later in the response to comments concerning performance measures, we will also publish measures concerning expected business outcomes in separate notices. We are making no further additions to this section of the final rule.

Comment: Some commenters requested reforms and clarifications regarding cost allocation principles.

Response: Our proposed rule did not contain any proposals to alter cost allocation principles, and we believe it is prudent that CMS and the States

continue to follow the cost allocation principles outlined by OMB in Circular A–87. As stated in the proposed rule, for integrated eligibility systems, assuming those systems meet the standards and conditions outlined in the final rule, only the costs associated with Medicaid eligibility and enrollment functions will be eligible for the enhanced funding and funding for Exchange activities is fully Federally funded through January 1, 2015. We discussed cost allocation and the principles of cost allocation in guidance that was released on November 2010; that is, the IT guidance version 1.0 and in the Funding Opportunity Announcement for the Early Innovator Grants. States can access the OMB Circular A-87 at http://www.whitehouse.gov/omb/ circulars a087 2004.

Comment: Several commenters asked for guidance on commercial off-the-shelf (COTS) software products, and indicated that such products are often modular, reusable, sharable, leveraged, and aligned with MITA. Commenters also stated that enhanced FFP should be available for COTS initial licensing and implementation service costs as well as ongoing software licensing and maintenance costs. Commenters also questioned why there is no language confirming established protections for COTS pre-existing intellectual property (IP) and newly developed IP used in eligibility modernization initiatives.

Response: We are not dictating specific solutions to States as they undertake their technology projects, as long as the standards and conditions of this final rule are met and we expect to work with States in an effort to share, reuse, and leverage other State solutions. For COTS products, we have a longstanding rule that the State must own any software that is designed, developed, installed or improved with 90 percent FFP (see § 433.112(b)(5)). In other words, software that is developed with public funds must be owned by the public and as a "public product" is available to be shared with other States. COTS-based solutions may still receive a 75 percent enhanced funding (that is, for licensing and implementation services costs), if they are related to the MMIS (including the eligibility determination system) and meet all the requirements of this final rule. In addition, current rules protecting intellectual property (such as copyright and/or patent laws) would simply apply in the way that they already do apply to intellectual property. Nothing in this final rule is attempting to alter those rules.

Comment: Several commenters asked that we define the terms "modular",

"modules", "models", and "successful models." Commenters indicated they are unclear about whether a model is equivalent to an architecture, reference model, process design, etc. for a given customer or class of customers and consistent with MITA architecture framework, process and planning guidelines, and maturity model.

Response: We believe it is important to frame our response in terms of the IT Guidance jointly issued by CMS and CCIIO. This guidance outlined a set of expectations and principles for sharing solutions and approaches between both Medicaid and the Exchanges. Consequently, we believe it is imperative for States and vendors to view all IT activities much more broadly than a single physical implementation of a set of technical capabilities.

'Modular" means reducing the complexity of a larger problem by breaking it down into small well defined pieces. For example, MITA business architecture reduced the complexity of the Medicaid program into eight high-level business areas. Each business area is further broken down/decomposed into smaller and manageable business processes. These business processes can be described as "modules". System components can also perform tasks in a similar fashion. "Modularity", if done right, accomplishes re-usability, maintainability, and reliability. The term also underscores our strong desire for States and the vendor community to develop "lighter-weight" and "loosely-coupled" approaches to the design of health care systems, including, but not limited to eligibility determination and enrollment functions.

In the MITA initiative, we have urged States to focus on designing sets of overarching and reusable functions that traditionally might have been included within one particular application and that would have been specific to that particular application, but that now could be used, in a consistent manner, by multiple applications used by the State. Additionally, we want to emphasize that the rules for processing data should be written in such a way as to be available to more than just one application. For example, whether it is a Web service querying for a response, or an Extract Transformation and Load (ETL) set of tools to move data from a database to an external interface, the rules that are invoked are the same, thus ensuring the underlying data maintains its inherent ability to consistently transform to the same information.

'Reference Models" focus on classification and conceptual structure. Typically, a Technical Reference Model,

for example, consists of infrastructure and business applications that interface with a number of operating and network services through a variety of specific applications such as graphics and imaging, data management, data interchange, user interface, transaction processing, security and system/ network management.

"Reference Architecture" is about proven solutions and best practices, typically without being vendor/platform specific. Typically arrayed in different tiers (access client tier, middle tier and data tier, for example), a technical reference architecture includes a client browser and an XML appliance to allow for access, a presentation layer using a portal with HTML and an application/ Web server, business services applications, enterprise information integration, and operational data storage facility typically through a data base with data exploration capabilities sometimes arrayed via data marts.

We believe MITA 2.0 addresses all of the defined terms. We also urge readers interested in these and related topics to familiarize themselves with the MITA Framework, look for additional guidance in the various iterations of the IT Guidance, and contact CMS staff for additional clarifications related to

specific circumstances.

Comment: Other commenters requested that the term "eligibility determination system" be defined. The term should indicate that eligibility determination system includes the technology interfaces for program applicants and beneficiaries, such as Web sites that include on-line applications and other Web features that allow individuals to use eligibility estimators, to report changes, to renew eligibility, or to seek information about their case status. Likewise, "eligibility determination system" should be defined to include computer generated notices and data.

Response: Our final rule considers systems that process claims for eligibility to be part of mechanized claims processing and information retrieval systems. Thus, to the extent that a function is part of processing the claim for eligibility, we believe it could be eligible for enhanced FFP under this final rule. We believe building an online application would likely be part of the system that processes claims and applications for eligibility. Additionally, we can envision how all of the components identified by the commenters will be part of an eligibility determination system, but we would need to understand more fully how such components are integrated into a system that processes claims for eligibility.

States will explain in their APDs how the various components are part of the mechanized claims processing and information retrieval system and will meet with our standards and conditions.

We are making no further additions to this section of the final rule.

Comment: One commenter indicated that it would be helpful if CMS provided additional leadership and technical assistance in further standardizing data semantics and information nomenclature across the eligibility function.

Response: We agree with the commenter and look forward to working in close partnership with States, Exchanges, and the Office of the National Coordinator for Health Information Technology, and the HIT Policy and Standards Committees on this activity. We intend to enforce industry standards as they develop in order to promote interoperability, improve reliability of outputs and outcomes, and reduce development costs.

Comment: A few commenters spoke of the importance of ensuring that county governments act as full partners in the planning, design, oversight and operations of necessary Medicaid eligibility system transformations. To ensure that counties are poised to best assist Medicaid applicants and recipients, the commenters suggested that the Secretary develop model systems and deploy the necessary resources for implementation including technical assistance and support for capital investment.

Response: We agree with the commenter that States, Tribal organizations, County governments, and Federal government agencies should work together to ensure effective interoperability and to develop model systems, as well as to deploy the necessary resources for implementation including technical assistance and support for capital investment. We recognize the historical contribution made by counties to making eligibility determinations in most States. We look to States to determine how best to deploy and optimize assets within the State to accomplish the purpose and requirements of the Affordable Care Act.

Comment: Several commenters believe that, to support the one application concept and streamlined eligibility determinations for Medicaid and related programs (including CHIP, TANF, Food Stamps, and WIC), CMS should work with other Federal agencies to obtain agreement to allow sharing of data across those related

programs.

Response: Our standard and condition regarding data exchange requires seamlessness with the Exchanges and also requires that States allow for interoperability with other health and human services programs. We also note that our standards and conditions require compliance with the standards and protocols adopted by the Secretary under sections 1104 and 1561 of the Affordable Care Act. We expect that such standards and protocols will promote reuse and data exchange.

Comment: One commenter believes that to support timely processing of eligibility, CMS should work with other Federal agencies that interface with State Medicaid agencies to allow a single point for correction of client data errors, including birthdates and erroneously posted death dates.

Response: We believe this comment addresses the actual program instructions and policy requirements for eligibility systems, and not the information technology solutions that will be needed for the systems themselves. Our requirements regarding these matters will be established in separate rulemaking.

Comment: One commenter requested that CMS offer strong guidance to the States on privacy and confidentiality issues that need to be observed in the new State systems.

Response: We agree that confidentiality and privacy are critical to protecting beneficiaries and providers. The final rule includes as a standard that systems ensure alignment with the HIPAA privacy, security and transaction standards.

Comment: One commenter indicates that we should issue guidance more definitively discussing the standards developed in response to section 1561 of the Affordable Care Act. The commenter noted that while section 1561 the Affordable Care Act is an outstanding source of ideas and information, section 1561 the Affordable Care Act standards appear to stop short of creating specific, concrete requirements.

Response: Section 1561 the
Affordable Care Act requires HHS, in
consultation with the Health
Information Technology (HIT) Policy
Committee and the HIT Standards
Committee, to develop interoperable
and secure standards and protocols that
facilitate electronic enrollment of
individuals in Federal and State health
and human services programs. The HIT
Policy and Standards Committees
approved initial recommendations, and
in September 2010, the Secretary
adopted these recommendations. The
recommendations include initial

standards and protocols that encourage adoption of modern electronic systems and processes that allow a consumer to seamlessly obtain and maintain the full range of available health coverage and other human services benefits.

The HIT Policy and Standards Committees recommendations are available at http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3161. We wish to note that one of the seven standards and conditions specifically requires States to ensure alignment with, and incorporation of, industry standards and specifies several national standards including standards and protocols adopted by the Secretary under section 1561 of the Affordable Care Act.

Comment: Another commenter suggested that we make all guidance documents, including the State Medicaid manual readily available.

Response: We agree. We are currently working to gather all applicable guidance documents on the CMS Web site. Guidance documents are already posted to several web sites, including the proposed rule (see regulations.gov), the IT guidance version 1.0, (see http://www.hhs.gov/ociio/regulations/ joint cms ociio guidance.pdf), Overview on the MITA framework, (see http://www.cms.gov/ MedicaidInfoTechArch), and Overview of the MMIS (see http://www.cms.gov/ MMIS). Please note that Chapter 11 of the State Medicaid Manual can be accessed electronically at http:// www.cms.gov/Manuals/PBM/ itemdetail.asp?filterType= none&filterByDID=-99&sortByDID=1& sortOrder=ascending& itemID=CMS021927.

In summary, we are making no revisions to regulation text as a result of these comments.

Comment: Several commenters suggested that CMS provide educational materials to ensure consumers get individualized assistance and have their questions answered to assure enrollment in Medicaid and the Exchanges.

Response: We believe this comment addresses the actual program instructions and policy requirements for eligibility systems, and not the information technology solutions that will be needed for the systems themselves. Our requirements regarding these matters will be established in separate rulemaking.

Comment: Commenters also requested that CMS issue "Frequently Asked Questions," establishing a direct contact line for assistance, make available a complete contact list of all of the States and their designated person/

representatives, and develop a Webpage/module to the existing Web site that will use this information and any ongoing data exchange information for the State. Commenters further recommended that CMS Regional Offices be fully trained and educated on the regulations and standards.

Response: We will consider these recommendations as we begin implementation of this final rule. We expect to provide numerous venues for sharing of information, including conferences, information posted to the CMS.gov Web site, letters, program memoranda, and training materials. The final rule and additional IT guidance will provide information regarding funding standards and conditions. We expect to release additional guidance on performance matrices. We are currently exploring several approaches to expedite the APD process and will be providing guidance on this process soon after publication of this final rule.

Additionally, we have recently awarded seven cooperative agreements to help a group of "Early Innovator" States design and implement the IT infrastructure needed to operate Exchanges. We expect to share information among these Innovator States and, as Exchanges are being developed, we expect to share information from these Innovator States with other States as well through the use of the CMS.gov Web site, conferences, and face-to-face meetings.

C. Public Feedback and Suggestions Related to the Seven Standard and Conditions

Comment: Several commenters requested clarification on the standards and conditions, and questioned how progress would be measured. Specifically, several commenters were concerned about our reference at § 433.112(b)(13) to "promoting sharing, leverage, and reuse of Medicaid technologies and systems within and among States." Commenters requested that CMS define "promoting" and specify how States will be required to leverage this information between States. Further, the commenters questioned when CMS will provide States with information regarding "promising State systems that can be leveraged and used by other States." They also questioned how these "promising State systems" will be identified. The commenters noted that it will be important for CMS to provide sufficient time for States to leverage promising systems and qualify for enhanced FFP to fund the development of those Medicaid eligibility systems. Other commenters expressed concern

that to meet the standards and conditions required for the Medicaid eligibility system to qualify for the enhanced funding, significant systems changes will be necessary to integrate Medicaid/CHIP eligibility and develop a single client identifier for all Medicaid and CHIP members to establish seamless coordination for eligibility and enrollment. Some commenters requested that CMS provide clarity on the criteria CMS will use to assess how States have demonstrated compliance with these standards and conditions including what documentation States will be expected to provide.

Several commenters questioned the phrase "seamless coordination." That is, § 433.112(b)(16) requires seamless Medicaid coordination and integration between Medicaid eligibility systems and the Exchange, allowing for interoperability with the Exchanges, and other health information systems. The required interoperability would involve the exchange of eligibility and enrollment status to the health information system, however, the rule did not specify the health information being exchanged among the eligibility and enrollment systems. The commenters believed it would be important for CMS to provide additional guidance on the type of data to be exchanged between eligibility and enrollment systems and other health information systems; thus, the commenters requested a definition of "seamless coordination." Additionally, the commenters requested that CMS provide clarity around whether other programs, such as the Supplemental Nutrition Assistance Program and the Temporary Assistance for Needy Families Program, are considered part of CMS' vision for "seamless coordination" and whether enhanced Medicaid funds would be used to make related changes to eligibility systems for these programs as well.

One commenter suggested that we add stronger language to the list of standards and conditions in § 433.112(b) consistent with the preamble language included in the proposed rule regarding the emphasis on the customer experience. Specifically, the commenter stated CMS references the goal of creating an ecosystem designed to deliver person- and citizen-centric services and benefits. The commenter requested similar language be added in regulations text.

Numerous commenters were supportive of our proposed standards and conditions. Specifically, several commenters have indicated they welcome our efforts to identify "promising State systems" that can be

leveraged and used by other States. Commenters indicated that they support our perspective that State eligibility and enrollment systems must be conceived of as contributing to a "system of systems." To achieve interconnected, functional systems in time to implement the Affordable Care Act, States must leverage existing systems to the greatest extent possible and successfully connect across silos. Commenters further stated that CMS should develop a repository or method of sharing information and support the development of reference applications. Additionally, commenters stated CMS should establish a means for communication between agencies at the Federal level in a manner that can be replicated at the State level. The commenters also stated that CMS should also provide support to those States that choose to "phase in" some of the changes, to ensure that they can proceed while also receiving enhanced funds. Additionally, the commenters requested that CMS should consider the MITA governance model for disseminating more detailed specifications for the standards and conditions; that is, the MITA governance model which includes the Business, Information, and Technical Review Boards, organized to support the MITA model for review, approval, and

adoption of national standards. Response: All of these comments are specific to § 433.112 and § 433.116 in which we have required that to receive enhanced funding for development, design, installation or enhancement of mechanized claims processing and information retrieval systems and operation of such systems, the standards and conditions specified in § 433.112(b)(10) through (16) must be met. The standards and conditions are prescriptive in nature; we did, however, recognize that for State systems to meet these standards and conditions, it would be necessary to provide additional guidance that clearly articulates our criteria for meeting these standards and conditions, the performance measures that we will use to ensure that State systems are complying with these standards and conditions, and the collaboration efforts we will take with CCIIO and other human services programs.

As mentioned previously, we released several guidance materials last year including the proposed rule and the IT guidance version 1.0, and we are committed to releasing additional guidance in the near future which will detail our criteria for ensuring compliance with the standards and conditions. States should consider that we will be interested in partnering with

them to ensure that they are making progress and meeting measurable goals. We consider that States may progress in several phases and ensure compliance by meeting goals along the way. Some examples that States may wish to consider in meeting the standards and conditions would be (1) That States should supply roadmaps for major improvements in current systems based on "as/is" MITA assessments and demonstrate how they will increase in MITA maturity by at least one maturity level; (2) States should identify how they plan to achieve full MITA maturity and in what timeframe; (3) States should ensure that their business architecture conforms to concept of operation and business process models distributed by CMS for specific business functions, or identify divergences to CMS; and (4) States should use a business rules engine which is maintained and operated separate from transactional programming language, which allow for modification and updates on an emergency as well as a regularly scheduled (at least quarterly) change control process.

Additionally, we will be releasing IT guidance version 2.0 soon and we will be releasing future versions of IT guidance, as the January 1, 2014 deadline approaches. We will also be issuing guidance surrounding APDs. We continue to work with the Early Innovator grant awardees to ensure that State "early innovator" systems will meet the goal of seamless coordination with the Exchange. Furthermore, we continue to provide technical assistance and support to States through several vehicles including CMS State calls, State workgroups, and conferences. We will convene an annual MMIS

conference in which States can share their experiences and provide feedback and request assistance regarding issues surrounding the implementation of the Affordable Care Act. We have committed to providing leadership and technical assistance in not only developing national standards and conditions but in ensuring systems transformation will provide that the goals of the Affordable Care Act goals can be met. That is, with systems transformation, States can meet coverage goals, minimize duplication, ensure effective reuse of infrastructure and applications, produce seamlessness for consumers, and ensure accuracy of program placements.

In terms of our plans for use of the MITA governance model which includes the Business, Information, and Technical Review Boards, organized to support the MITA model for review, approval and adoption of national

standards, it should be noted that the standards and conditions were developed considering many perspectives; that is, the Office of the National Coordinator's standards for enrollment, the HIPAA standards for privacy and security, the Office of Civil Right's views on the Rehabilitation Act and other accessibility standards, other Federal government agencies, States and other stakeholders.

Comment: Several commenters requested that we promote transparency and provide opportunities for beneficiary input since the proposed § 433.112(b)(14) would require effective communications with providers, beneficiaries, and the public. The commenters believed that States should be required to consult with beneficiaries, advocates, provider groups, including safety net providers such as Federally Qualified Health Centers, and public workers as they plan their new or improved eligibility systems; to make public copies of the business rules used to determine the decisions on eligibility that will be made by their new systems; and to gather data directly from beneficiaries on their experiences with eligibility determinations (for example, via fieldtested procedures such as focus groups or meetings with beneficiaries or lowincome advocates) on a periodic basis. Additionally, commenters believed that States must demonstrate that their modernized eligibility systems produce communications with beneficiaries (regardless of whether they are distributed through the mail, on-line, or through other alternative means) that are appropriate for their literacy level and consider the needs of people with disabilities. Commenters believed that policies regarding notices help ensure user-friendly notices which should include involvement of stakeholders, such as beneficiaries. Similarly, the commenters believed that CMS should actively solicit and include data on beneficiaries' perspectives when it conducts its periodic reviews of State's eligibility systems. Lastly, commenters believed that this standard and condition will be difficult to measure, and therefore, should include definable

Response: We believe it is wise for States to consult with their stakeholders as they implement the Affordable Care Act, and in developing business process models and technology roadmaps. While we do not intend to set Federal requirements regarding consultation in this rule and specific to this activity, we do note that other eligibility policy rulemaking may address this issue. One of our standards and conditions

specifically states the expectation that business rules should be maintained in human readable form; we agree with the recommendations of the HIT Policy and Standards Committees considering the requirements of section 1561 of the Affordable Care Act that such business rules should be submitted and maintained in a common repository, and are designing approaches to support that activity. These rules will be available to the public to the fullest extent possible and practicable, and we urge States to make their business rules public on the same basis. As for the request that we define the metrics that will be used in periodic reviews of State systems, such metrics will be published in a subsequent notice or notices. We will consider the suggestion to add beneficiary feedback and user experience in these measures.

Comment: One commenter questioned if the standards and conditions for Medicaid eligibility systems apply also to MMISs and claims adjudication and whether States have to meet the standards and conditions for MMISs to collect the enhanced FFP.

Response: Yes, under our proposed and final regulations, a State's entire MMIS (including its eligibility determination system) will be required to comply with all of the standards and conditions outlined in § 433.112. Please see our proposed rule (75 FR 68585) where we clarify that we were proposing standards and conditions that would apply to both "traditional claims processing systems, as well as eligibility systems to be eligible for the enhanced match."

We are making no further additions to this section of the final rule.

Comment: Several commenters requested that CMS ensure eligibility systems comply with all civil rights laws and provide beneficiaries with the opportunity to secure information in a culturally and linguistically appropriate manner. Commenters requested that CMS ensure that the experiences of people with disabilities are considered when CMS conducts its periodic reviews of the system. In addition, commenters believed that CMS should more clearly delineate that eligibility systems must be in compliance with all civil rights protections based on race, color, and national origin and be designed in a culturally and linguistically appropriate manner. Some commenters expressed concern regarding eligible children in immigrant families and individuals with limited English proficiency and the difficulties they experience in communicating with public assistance caseworkers and in navigating the Medicaid application

process in general. Commenters suggested that new systems and/or modifications to current systems address these needs. Additionally, commenters suggest that the eligibility systems qualifying for the enhanced match should be in compliance with Title VI of the Civil Rights Act of 1964, section 1557 of the Affordable Care Act, and all related rules, regulations and guidance, including the Department of Justice's policy document, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient

Response: While we believe the majority of these comments address determinations of eligibility, but are not specifically addressed to the actual systems technical requirements that are the subject of our proposed and final rules, we wish to clarify that we are requiring that States meet the standards and conditions outlined in § 433.112 and that one of the standards and conditions relates to effective communication with beneficiaries. States should consider that State systems should provide a 21st Century customer experience for all individuals and should provide for person-centric outreach, eligibility, and enrollment. In terms of determining eligibility, we are happy to work with States regarding assistance to individuals with limited English proficiency in the context of the Department's "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" ("Revised HHS LEP Guidance") accessible at: http://www.hhs.gov/ocr/ civilrights/resources/specialtopics/lep/ policyguidancedocument.html. Additionally, we note that section 201(b) of the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111-3, enacted on February 4, 2009) (CHIPRA), added section 1903(a)(2)(E) to the Act to provide increased Federal funding for translation and/or interpretation services provided in connection with the enrollment of, retention of, and use of services by children of families where English is not their primary language. Further, we note that our current regulation at 45 CFR 95.633 holds that State agencies that acquire automated data processing equipment and services are subject to nondiscrimination requirements in 45 CFR parts 90, 84 and 80 (nondiscrimination on the basis of age; disability; and national origin, race or color, respectively). Federal guidance

issued on September 21, 2000 by the Office of Civil Rights and the U.S. Department of Agriculture, Administration for Children and Families and the Health Care Financing Administration (as CMS was formerly known) "Policy Guidance Regarding Inquiries into Citizenship, Immigration Status and Social Security Numbers in State Applications for Medicaid, State Children's Health Insurance program (SCHIP), Temporary Assistance for Needy Families (TANF), and Food Stamp Benefits" ("Tri-Agency Guidance") also discusses application practices involving the citizen/legal immigrant children of immigrant parents, where questions asked of nonapplicant parents may deter the eligible children from enjoying equal participation in and access to the Medicaid program, thereby potentially violating prohibitions on national origin discrimination in Title VI of the Civil Rights Act). (See http://www.hhs.gov/ ocr/civilrights/resources/specialtopics/ tanf/triagencyletter.html). We also will continue to consider the Institute of Medicine's, 2009 report, "Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement," for collecting race, ethnicity, and language. Finally, we expect to address section 1557 of the Affordable Care Act in separate rulemaking.

Comment: One commenter suggested that, in considering the standard and condition supporting accurate and timely processing and adjudications/ eligibility determinations and effective communications with providers, beneficiaries, and the public, CMS should require States to adopt and implement translated notices and taglines in their eligibility systems to ensure effective communication with limited English proficient applicants and enrollees.

Response: We will consider this suggestion as we develop further technical guidance and additional rulemaking. We agree that such practices are worthy of consideration in development activities.

Comment: Other commenters expressed concerns regarding current barriers that immigrant families face when applying for public assistance benefits. Some of the barriers identified include the following: Requests for Social Security numbers in the application for non-applicants (that is, undocumented parents that wish to apply on behalf of their United States citizen children), requirements for income verification that nontraditional workers cannot access; and lack of translated forms and interpretive

services for individuals with limited English proficiency. Commenters wanted CMS to consider the "Tri-Agency Guidance," discussed in the responses above and require that eligibility determination systems should ensure that individuals can seek all of the benefits for which they or their family members may be eligible without providing unnecessary information.

Response: These comments address program and policy requirements, and will be addressed in separate rulemaking.

Comment: One commenter wanted CMS to require that State systems determine eligibility for low-income, lawfully present immigrants who are income eligible for Medicaid but whose immigration status makes them ineligible for Federal Medicaid. Specifically, since these individuals would not be eligible for Federal Medicaid but may be eligible for tax credits and Exchange coverage, their applications should be delivered to the Exchange without requiring a new application be submitted, while also providing the applicant clear notice of the status of their application and eligibility.

Response: These comments address program and policy requirements, and will be addressed in separate rulemaking. However, we wish to clarify that one standard and condition that must be met to receive enhanced match is seamless coordination and integration with the Exchange.

Comment: One commenter requested that CMS require that eligibility determination systems demonstrate how they will comply with sections 1411(e) and (g) of the Affordable Care Act. Section 1411(e) of the Affordable Care Act provides that certain procedures governing verification of eligibility in the Medicaid program, including its due process protections, apply to the Exchange. Section 1411(g) of the Affordable Care Act prohibits unnecessary questions during the application process and limits the use of information provided to the Exchange.

Response: These comments address program and policy requirements and will be addressed in separate rulemaking.

Comment: One commenter suggested that CMS prohibit States from delegating responsibility to private entities for administering on-line Medicaid eligibility systems without the State accepting the legal responsibility for the system.

Response: These comments address program and policy requirements, and will be addressed in separate rulemaking.

Comment: A commenter suggested that CMS oversee providing periodic notice to Medicaid beneficiaries for their individual use of medical services, similar to an explanation of benefits (EOB). The commenter believed this would alert Medicaid beneficiaries of fraud, provide treatment history, and could help with redeterminations.

Response: While we appreciate the commenter's proposal, such provisions are beyond the scope of the regulation of the final rule. As such, we are making no changes in response to the comment.

Comment: The commenters believed that the requirements for timely and accurate processing of claims and adjudications should take into account what is known about the major factors that contribute to system performance, such as system architecture, capacity, and usability by workers. Commenters recommended that decision logic and coding used by eligibility systems be publicly available, and States should be required to have a process for identifying errors and promptly correcting them. Further, the commenters believed that systems should be capable of producing audit trails of decisions.

Response: We agree with the commenter. We expect to address these issues when we issue performance metrics in a separate notice.

Comment: Several commenters agreed with our requirements that the eligibility determination system produce performance data and reports that contribute to program, evaluation, continuous improvement, and transparency and accountability. The commenters suggested that we further specify the minimum data and performance reports that the system must generate and provide the specifications for these reports and that we should aim for basic program and performance data that is comparable across States and that addresses fundamental program objectives and compliance with key requirements. Commenters believed this information should be posted to Web sites on a regular and timely basis.

Response: We agree with the commenters' suggestions, and further clarify the applicability of this standard to all MMISs and not just eligibility systems. While the regulation establishes standards and conditions for transaction data, reports and performance information, additional specifications will be addressed in future subregulatory IT guidance continuously as the January 1, 2014 deadline approaches.

Comment: Some commenters stated that the proposed regulatory changes

did not address the needs of Medicare beneficiaries for seamless enrollment to Medicaid, Medicare Savings Programs (MSPs), and Part D low income subsidy (LIS) support older people and people with disabilities.

Response: Because the regulatory changes addressed availability of enhanced Federal funding for Medicaid eligibility and enrollment functions and necessary standards, specific provisions impacting enrollment of Medicare recipients was outside the scope of these changes. We would like to note that the newly established Federal Coordinated Health Care Office within CMS, under section 2602 of the Affordable Care Act, will be addressing administrative and regulatory barriers between the Medicare and Medicaid programs in order to better serve this population and it is our belief that improvements in Medicaid eligibility systems will benefit many populations including individuals that are dually eligible for Medicaid and Medicare.

Comment: Several commenters noted that the systems should be built in a manner that allows for the effective expansion to other populations.

Response: We agree that systems should be built to allow for expansion and leverage, and indeed note that many of the standards and conditions (such as separation of business rules, service-oriented architecture, MITA, etc.) will effectively enable such downstream activities and extensions.

Comment: Several commenters believed that CMS standards and conditions should not be the only factor in considering enhanced FFP. For example, commenters believed that Federal leadership, technical assistance, and sub-regulatory guidance should focus on outcomes, as well as the standards and conditions.

Response: We concur that Federal (and State) leadership, technical assistance and subregulatory guidance needs to increasingly focus on outcomes. One of the standards and conditions is that systems effectively support and contribute to intended business results. We expect to publish proposed performance measures to help assess compliance with this condition and standard.

Comment: Commenters stated that the standard and condition regarding use of a modular, flexible approach to systems development and the separation of business rules from core programming available in human and machine readable formats do not address the maintainability, quality or governance process for changes to the rule sets which they believe have a much greater effect on quality and timeliness than the

particular syntax structure of the rules source code.

Response: While we do not believe this particular standard and condition will solve all of these challenges, we believe it will significantly reduce maintenance costs and provide added systems flexibility in an environment that is continually evolving. Use of a modular, flexible approach to systems development and the separation of business rules from core programming will allow States to make changes more quickly and efficiently than the situation in place today for most States. We did not attempt to tackle the governance process as we believe that, while very important, the relationship between systems performance and governance can be accommodated using different approaches depending upon the specific conditions within the States.

Comment: Several commenters recommended that the separation of business rules from core programming should recommend the use of commercially available business rules engines as opposed to custom or one-of-a-kind implementation of rules processing techniques.

Response: One of our standards and conditions focuses on reuse and leveragability. This encourages and even demands consideration of existing solutions, including proprietary and open source solutions, solutions in place at other States, or solutions already in place within a State, before embarking on ground up custom development. We believe this standard and condition adequately ensures that States give due attention and consideration to these options without dictating specific solutions.

Comment: Several commenters requested that CMS provide additional guidance on the business rules and specifically requested that since every State will have to meet the business rules requirement, it might be more efficient for CMS to develop a repository of business rules along the lines of the recommendations transmitted to HHS (recommendation 3.2) by the HIT Policy and Standards Committees. States could then adopt and adapt the rules to their own systems.

Response: We agree with the commenters that we should provide additional guidance on the business rules. As mentioned, we will continue to provide leadership, technical assistance, and guidance with an eye toward the January 1, 2014 date for required operation of the Exchanges and Medicaid expansion. We have also provided that States should consider other documents that articulate the

Department's strategy such as the IT guidance 1.0, Guidance for Exchange and Medicaid Information Technology Systems, and continue to consider such guidance in meeting the requirements of this final rule. As the commenters stated, the HIT Policy and Standards Committees' recommendations should be considered when developing systems that comply with the standard and condition regarding ensuring alignment with, and incorporation of, industry standards: HIPAA security, privacy, and transaction standards; accessibility standards under section 508 of the Rehabilitation Act and compliance with Federal civil rights laws; and standards adopted by Secretary under sections 1104 and 1561 of the Affordable Care Act. Our final rules will require that systems include usability features or functions that accommodate the needs of persons with disabilities, including those who use assistive technology. As noted in the IT guidance issued November 30, 2010, State enrollment and eligibility systems already are subject to the program accessibility provisions of section 504 of the Rehabilitation Act, which include an obligation to provide individuals with disabilities an equal and effective opportunity to benefit from or participate in a program, including those offered through electronic and information technology. The Department noted in that guidance that a State's Web sites, interactive kiosks, and other information systems addressed by section 508 Standards would be viewed as being in compliance with section 504 if such technologies meet the 508 standards. The Department also encouraged States to follow either the 508 guidelines or guidelines that provider greater accessibility to individuals with disabilities, and noted that States could consult the latest Section 508 guidelines issued by the US Access Board or W3C's Web Content Accessibility Guidelines (WCAG) 2.0 (see http://www.accessboard.gov/sec508/guide/index.htm). Therefore, we believe that as a result of complying with section 504, many States will already be in or moving toward compliance with the accessibility standards we have included in this final rule.

Lastly, we will be developing a repository of business rules; however, we wish to clarify that it may take some time to populate. Considering the deadlines imposed by the Affordable Care Act, we realize a repository of business rules may be helpful to some States and not others depending upon a given State's IT configuration at the time

it is in need of such rules. We are also considering the possibility of the development of model rules, in a collaborative project with States.

Comment: One commenter requested further clarification for the standards and conditions listed in § 433.112(b)(2) that require that the system meet the requirements of Part 11 of the State Medicaid Manual, and § 433.112(b)(12) that require that ensuring alignment with, and incorporation of, industry standards: HIPAA security, privacy, and transaction standards; accessibility standards under section 508 of the Rehabilitation Act and compliance with Federal civil rights laws; and standards adopted by Secretary under sections 1104 and 1561 of the Affordable Care Act. The commenter questioned how CMS will measure compliance with these requirements and if States are found to be out of compliance with this requirement in one area such as a small part of the conversion to ICD-10 coding or revision of the 5010 transaction standards, will States risk losing all enhanced FFP.

Response: States are required to meet all conditions for their mechanized claims processing and information retrieval system described in Title XIX of the Act in order to receive FFP. We have the authority to withhold enhanced FFP (or potentially all FFP) for issues of noncompliance with the conditions listed in Title XIX of the Act. It is not our intention to withhold FFP for a frivolous or insubstantial reason. We will give States the opportunity to correct any failures that might endanger FFP. However, a States' continued or persistent failure to adopt industry standards in a timely and compliant way would, in fact, place enhanced FFP at risk. We note that we have outlined a transition period for State MMIS systems to come into compliance that allows for up to 38 months of transition while, at the same time, still ensuring that State systems move expeditiously towards improvement and advanced technology (see our discussion below in section III.E. regarding the transition period).

D. Public Feedback and Suggestions Related to the APD Process

Comment: Several commenters suggested that the APD process and the Federal organizations responsible for its administration will likely be taxed in an unprecedented way by the volume of work spurred by the implementation of the Health Information Technology for Economic and Clinical Health Act and the Affordable Care Act. The commenters noted that even when applied to projects supporting a single

program with a fairly limited set of requirements, the many moving parts in the APD process can work more slowly than anticipated and lead to unforeseen outcomes. Consequently, the commenters suggested that the APD process be reformed. Commenters suggested that CMS make the APD process more transparent and that making the large history of APD documents and outcomes available to other States would promote increased collaboration. Other commenters agreed and indicate that with many States submitting APDs for both eligibility and MMIS systems within the same window of time, the APD approval process will put increased pressure on both State and Federal agencies to meet deadlines. The commenters urged CMS to provide an APD template and to examine ways to expedite the APD process to make sure it can support the critical timeframe and urged CMS to consult with States and the vendor community to identify options to ensure timely approval of APDs. Additionally, commenters recommended that CMS consider the waiver option in 45 CFR 95.627 as a method to streamline the enhanced funding approval process during this time limited availability of enhanced funds. This could allow States to submit alternative approaches to hasten implementation of needed systems changes.

Response: On October 28, 2010, HHS released a final rule (75 FR 66319) that introduced a new concept of "high risk" APDs that specified software development as a "high risk" trigger. Additionally, the period for Federal review currently identified in 45 CFR 95.611(d) allows up to 60 days for APD approval, disapproval, or requests for information.

We realize it will be important to conduct APD reviews quickly so as not to delay the projects the States are pursuing. As we are issuing this rule, we are also preparing additional guidance for APDs, and for the governance and collaboration process we will use to work with States to minimize project risk, optimize outcomes, and to ensure successful compliance with the seven standards and conditions added by this final rule. In response to the commenters' suggestions to make APDs more transparent and public, we agree. We are evaluating how, and in what form, to make APDs available as they are submitted.

E. Issues Related to the Transition Period for Compliance

Comment: One commenter proposed that the regulation not be retroactive to initiatives with an APD already.

Response: While not directly suggested here, we believe it is important to clarify that enhanced funding is currently not available for eligibility initiatives that have already been approved by CMS. However, we have provided that States currently receiving enhanced FFP for MMIS have a period of transition to come into compliance with the standards and conditions outlined in this rule. Specifically, for new MMIS development (new APDs requesting 90 percent FFP for design, development, installation, and enhancement), we provide for no transition period. For MMIS development already underway (approved APDs providing 90 percent enhanced FFP), we proposed a 12month transition period (beginning with the effective date of this final rule) in which to submit an updated Implementation APD (IAPD) detailing how systems would be modified to meet the required conditions and standards. For maintenance and operations of MMIS currently receiving 75 percent FFP, we proposed a 36-month transition period in which to submit an IAPD with plans to upgrade or modify systems to meet the required conditions and standards. Since we are providing that this final rule is effective upon publication, we are revising the transition periods by 2 months (to 14 and 38 months, respectively).

For new MMIS development (new APDs requesting 90 percent FFP for design, development, installation, and enhancement), we will continue to provide for no transition period. For MMIS development already underway (approved APDs providing 90 percent enhanced FFP), we provide for a 14month transition period (beginning with the effective date of this final rule) in which to submit an updated Implementation APD (IAPD) detailing how systems would be modified to meet the required conditions and standards. For maintenance and operations of MMIS currently receiving 75 percent FFP, we provide for a 38-month transition period (beginning with the effective date of this final rule) in which to submit an IAPD with plans to upgrade or modify systems to meet the required conditions and standards.

Additionally, we have discussed a period of transition to come into compliance with the standards and conditions outlined in this rule for eligibility systems as well. Specifically, for eligibility systems (currently receiving 50 percent for development and maintenance and operations), we are providing for no transition period for new requests for enhanced funding for eligibility systems. States with eligibility systems currently under development (approved APDs providing 50 percent FFP) can update their APDs to reflect how they would comply with these standards and conditions in order to begin receiving 90 percent FFP. Similarly, eligibility systems currently receiving 50 percent FFP for State expenditures would need to comply with our final standards and conditions to receive a 75-percent FFP.

We are making no change to the transition period for eligibility determination systems.

Comment: One commenter questioned whether CMS will impose additional deadlines on States following the submission of an IAPD requesting funding and specifying the plans for updating MMISs within the 36 month (now 38 month) transition period.

Response: In the context of this regulation, any more standards and conditions (in addition to the 7 finalized in this rule) would be subject to notice and public comment. Consequently, States would have an opportunity to provide CMS with feedback.

Comment: One commenter stated strong objections to the transition period for existing development projects and established MMIS applications for the submission of an IAPD to achieve CMS' proposed new MMIS standards. The commenter believed that this time limitation is extremely burdensome to States at a time when resources are already strapped. The commenter believed the development of an IAPD will require a planning period and this will be occurring at the same time that States are overhauling their eligibility and determination systems. Further, the commenter believed that States are already struggling to meet the HIPAA 5010 and the ICD-10 mandates. The State staff, contractors, and vendors conducting the work on these mandates are the same ones who would be involved in the planning necessary to submit an IAPD and they would be the same ones implementing the changes to the MMIS. The commenter believed the rule requires adherence to standards that don't exist and from the State's perspective the MMIS requirements represent an unfunded mandate. The commenter expressed concern that the requirement to "hurry up and meet" the new standards and conditions will turn current MMISs into "lame duck" systems. The commenter noted that with all States required to undertake

major eligibility systems projects, implement 5010 and ICD-10, and already facing impossible budget constraints, now is not the time to mandate onerous new requirements that in many cases require replacement of perfectly workable MMIS systems.

Response: In the January 16, 2009 Federal Register, HHS published two final rules: The ASC X12 Version 5010, NCPDP Version D.0, NCPDP Version 3.0 (74 FR 3296) and the ICD-10 code sets (74 FR 3328) were published by HHS on January 16, 2009 in 2 separate final rules. These rules are available at www.regulations.gov. In NCPDP Version D.0, NCPDP Version 3.0, HHS adopted ASC X12 Version 5010 and NCPDP Version D.0 for the HIPAA transactions that currently require the use of the ASC X12 Version 4010/4010A and NCPDP Version 5.1 standards. In that rule, HHS also adopts a new standard for Medicaid subrogation for pharmacy claims transactions, known as NCPDP Version 3.0. For Version 5010 and Version D.0, the compliance date for all covered entities is January 1, 2012. This gives the industry enough time to test the standards internally, to ensure that systems have been appropriately updated, and then to test between trading partners before the compliance date. The compliance date for the Medicaid subrogation standard is also January 1, 2012, except for small health plans, which have until January 1, 2013 to come into compliance.

In ICD-10 code sets final rule, HHS modified the standard medical data code sets for coding diagnoses and inpatient hospital procedures by concurrently adopting the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedural Coding System (ICD-10-PCS) for inpatient hospital procedure coding. These new code sets replace the current International Classification, 9th Revision, Clinical Modification, Volumes 1 and 2 and the International Classification, 9th Revision, Clinical Modification, Volume 3 for diagnosis and procedure codes respectively. The implementation date for ICD-10-CM and ICD-10-PCS is October 1, 2013 for all covered entities. Thus, we believe there has been ample time and ample guidance to States so that they can move towards compliance with these requirements.

We disagree that the new standards and conditions and the timeframe for meeting them represent an "unfunded mandate." We are not imposing any mandate on the State, but rather are creating standards which States will need to meet if they wish to receive an enhanced 90 or 75 percent FFP rate under the Act. States that do not wish to come up to these standards would continue to be eligible for a 50 percent FFP.

Additionally, in considering the deadlines outlined in the Affordable Care Act for operation of the Exchanges and the requirement that Exchanges also determine Medicaid eligibility, we believe, and States have agreed, that the procurement process for projects of the size and scope required to meet the challenges of the Affordable Care Act can take several months to complete. Thus, we considered these challenges and determined it necessary to provide flexibility by instituting a transition period and by providing additional financial support, additional IT guidance, Federal technical assistance, and leadership so that States can design systems that can meet the requirements of the Affordable Care Act.

Comment: One commenter questioned whether MMIS upgrades and modifications (as envisioned by a States IAPD) may be phased in over a period of years, so that by a certain end-date, the MMIS is fully compliant, or whether our final rule would require that the IAPD provide that the MMIS actually meet all standards and conditions by the end of the transition period.

Response: We believe the commenter is referring to the 36-month (now 38month) transition period that applies to current MMISs receiving 75 percent FFP for maintenance and operations. For this purpose, States will have up to 38 months to submit an IAPD. This transition period ensures that new systems receiving Federal funding are eventually designed in a manner that results in the most efficient use of technology. In reviewing APDs, we will be considering individual State factors such as budget, schedule and risk, and we will be evaluating the State's proposed timeline and pathway in an effort to ensure full compliance with the

F. Comments Regarding CMS' Strategy for Monitoring and Oversight, Including Performance Reviews

standards and conditions at the earliest

opportunity.

Comment: One commenter asked CMS to elaborate on how frequently the agency will perform periodic reviews—such as would reviews occur every 6 months, every year, or less frequently.

Response: We are not, at this time, creating specific deadlines for the periodic reviews. As mentioned earlier, large systems transformations will be needed in order to accomplish the

requirements outlined in the Affordable Care Act. As such, we plan to work with States, and as systems are designed and developed, we will be conducting reviews on a continuous basis keeping in mind the January 1, 2014 and December 31, 2015 deadlines. We are making no further revisions to the rule as a result of this comment.

Comment: A few commenters supported "the back-end review" of MMIS solutions, including certification and on-going performance monitoring. Many commenters requested to see more explicit details regarding oversight, frequency of reporting, record layout, and the specific performance metrics CMS will use to ensure ongoing successful performance. Other commenters suggested a "modernized" approach to the performance of these activities. Rather than basing the processes on the 30-year old traditional review of output, the commenters suggested focusing on whether "the implementation achieves the business goals that the funding was supposed to accomplish." The commenters believed that aligning these reviews to the goals set forth in the approved planning documents will result in solutions that more closely align with program objectives and will result in substantial reductions in burdens for both State and CMS staff.

Additionally, the commenters requested clarification on whether CMS is considering adopting a modular certification process in order to complement and align with the modular system development process.

Response: We appreciate the support for conducting periodic reviews of MMISs. Our performance measures will tie directly to the standards and conditions that are being issued in this final rule, and will be communicated to States through subsequent documents. We intend to publish performance metrics in a Federal Register notice, and then allow a period for public comments. The performance results of States and systems will be the primary driver of the periodicity and intensity of any CMS reviews. We also intend to focus reviews on whole systems, modules or components, based on those

Comment: Many commenters asked that CMS outline the expected timeframe for setting up the performance measures. Commenters believed that the timeframe could potentially impact the timeline for planning, design, and implementation of system enhancements for compliance. The commenters proposed an alignment of standards for ongoing review with standards used to evaluate States'

eligibility for enhanced funding, to ensure that proposed systems modifications lead to achieving standards established for ongoing monitoring.

Response: As stated above, we intend to publish performance metrics in subsequent notices, with a request for comments. We will consult with States and others prior to publishing metrics. To guide States in their development activities, we will issue a series of documents in concert with or shortly after publication of this rule, including IT Guidance 2.0, sub-regulatory guidance on complying with the seven standards and conditions, and instructions and protocols for APD submission and review. MITA 3.0 guidance will follow later this year. We emphasize to States that we expect to see a highly iterative and fluid approach to business process development, blueprinting, specifications, and development as we approach implementation of the coverage expansions and eligibility simplifications within the Affordable Care Act. We will give strong recognition of the iterative and collaborative approach and we intend to support Affordable Care Act implementation as we enforce the standards and conditions in this rule.

G. Issues Related to Partial Systems Improvements or Modernizations

Comment: One commenter recommended that the requirement for tracking ongoing progress should be eliminated for enhancement(s) made to address a specific requirement. These may be reviewed for compliance, once after implementation of enhancement, and subsequently any time changes are made that would impact the initial enhancement.

Response: We disagree with the commenter. To receive enhanced funding, State systems must meet with the standards and conditions outlined in this rule. We expect that a key outcome of our technology investments is a much higher degree of interaction and interoperability in order to maximize value and minimize burden and costs on providers, beneficiaries, and States. Additionally, we wish to ensure that enhanced FFP is approved only when infrastructure and application projects maximize the extent to which they utilize current technology development and deployment practices and produce reliable business outputs and outcomes. Further, MITA principles also require ongoing improvement—such that the system continues to meet certain milestones. Thus, States making

enhancements to address a specific requirement would, in accordance with MITA principles, have to continue to look to industry standards to ensure that the enhancement is evolving along with such standards. Tracking ongoing progress is critical to success.

H. Specific Issues by Regulatory Provision

Comment: One commenter noted that CMS has removed the authority in § 433.110(a)(2)(iii) and § 433.130 to provide for waivers of conditions of approval, conditions of re-approval, and FFP reductions in certain circumstances. The commenter expressed concern that removal of the current waiver flexibility to take into account State-specific circumstances will increase the potential for loss of enhanced Federal match with catastrophic budget impact to States.

Response: We agree with the commenter that language in sections 433.110(a)(2)(iii) and 433.130 is removed. These sections implemented section 1903(r) of the Act which requires reductions in FFP due to a State under section 1903(a) of the Act if a State fails to meet certain deadlines for operating a mechanized claims processing and information retrieval systems or if the system fails to meet certain conditions of approval or reapproval. We determined it is necessary to delete the waiver authority in § 433.110(a)(2)(iii) and § 433.130 since it is redundant and we noted in the preamble of the proposed rule to make conforming changes to 42 CFR part 433, subpart C in an effort to remove redundancy. We have, however, retained the authority in § 433.131 which provides for waivers of an FFP reduction in certain circumstances if the State is unable to comply with the conditions of approval or of reapproval.

Comment: One commenter requests that we clarify whether the intent of striking § 433.111(b)(3) includes deleting approved enhancements to mechanized systems, including claims processing and information retrieval systems, rather than merely removing the exclusion for eligibility determination systems.

Response: To clarify the striking of § 433.111(b)(3), we intended to specifically remove the language indicating that eligibility determination systems are not part of mechanized claims processing and information retrieval systems. However, in doing so, we realized that some may question our removal of the language in § 433.111(b)(3) relating to enhancements; and since we agree with the commenter that enhancements are

necessary to ensure that technology continues to improve, we are revising the regulation text in this final rule to include this language relating to enhancements.

Comment: One commenter remarked that in § 433.112, we have linked paragraph (a) with paragraph (c) thus creating, in the commenter's view, the elimination of the current opportunity for enhanced FFP at 90 percent for MMIS development and enhancements. The commenter believed that we have failed to recognize the true status of States' claims processing systems and future evolution.

Response: We disagree with the commenter. While States will continue to have an opportunity to receive enhanced FFP at 90 percent for most MMIS development and enhancements, assuming such systems meet the regulatory standards and conditions, § 433.112(c) simply indicates the more limited rule for eligibility determination systems that funding at enhanced rates will not be available for the design, development, installation or enhancement of such State eligibility determination systems after December 31, 2015. However, this deadline applies only to the eligibility component of MMIS, not the entire MMÍS.

Comment: One commenter is concerned that we have not clearly defined the regulatory requirements specified in § 433.112(b)(10), (11), and (13) through (16) and that these regulatory requirements lack explicit and nationally-recognized standards for measuring achievement.

Response: In proposing the 7 standards and conditions that States must meet in order to receive enhanced funding, we included information as to the importance of each of the standards and conditions. In addition, in some cases, we provided examples of how we will ensure that State systems meet the standards and conditions. For example, for the standard and condition that speaks to promoting sharing, leverage, and reuse of Medicaid technologies and systems within and among States, we specified that we would examine APDs to ensure that States make appropriate use and reuse of components and technologies available off the shelf or with minimal customization to maximize return on investment and minimize project risk. Further, we indicated in the proposed rule that we intend to issue further interpretations regarding each standard. In our preamble, we also provided an example of measurement; that is; we indicated that we would measure how a system meets requirements for providing

notices to beneficiaries, claims, and applications and renewals, proper determinations, and experience with appeals, interoperability with Exchanges, as well as traditional systems standards such as availability and down time. Thus, while we have provided detailed information regarding the standards and conditions, we also recognize that future interpretations will be forthcoming. We intend to ensure that any such interpretations, as well as performance metrics, are developed with input from the State agencies. As stated above, for performance measures, we will publish such measures in a Federal Register notice and provide for a period of comment.

Comment: One commenter requested that we reinstate the stepped down reduction in FFP that was outlined in § 433.113 prior to our proposed rule and eliminate the 25 percent reduction proposed in § 433.119 should there be a decertification action.

Response: We do not believe we have the authority to provide for the stepped down reductions in FFP as previously outlined in § 433.113. The specific authority to provide such stepped down reductions that previously existed in section 1903(r) of the Act was repealed by section 4753 of BBA. However, as explained elsewhere in preamble, we do have the authority to, on the basis of our review, determine that a system is no longer leading to more effective, efficient, or economical operation of the State plan, under section 1903(a)(3) of the Act, and therefore, to remove the enhanced FFP.

Comment: One commenter asks CMS to reconsider the proposed limit on the opportunity for enhanced funding at 75 percent for eligibility determination systems operation to only those systems approved prior to December 31, 2015. The commenter believed that the new standards and conditions listed in § 433.112 coupled with the typical timeframes for design, development, and implementation make it unlikely that the majority of States will achieve approval by the specified date.

Response: We disagree with the commenter. As stated elsewhere in this preamble, the Affordable Care Act requires that eligibility changes be in place by January 1, 2014, and we have already provided an additional 2 years beyond that date for States to meet the standards and conditions for enhanced funding for design, development, or installation.

Comment: One commenter requested that CMS reinstate the criteria previously listed in § 433.120(b) indicating that any reductions in FFP would be tied to a reasoned

determination that a system is failing to meet certification requirements in a significant manner.

Response: First, we are clarifying that any deficiencies found as the result of future reviews would be subject to a period of corrective action before making a determination that enhanced FFP would be discontinued.

Additionally, while we will be issuing future guidance regarding the specific performance review measurements, we do agree that it is likely that enhanced FFP would only be discontinued in situations where the system is failing to meet the standards and conditions in a significant manner.

I. Issues Related to the Regulatory Impact Analysis, Including the Cost Estimates, and Information Collection

Comment: One commenter stated that CMS underestimated States' eligibility system replacement costs. The commenter pointed out that the impact analysis assumes that new systems, on average, would cost \$50 million over 3 years for each State and that assumption includes design, development, and implementation. The commenter indicated that one State's plan to modernize/replace their Medicaid Eligibility System cost a total of \$200 million over the course of 4 years.

Response: In the Regulatory Impact Analysis of the proposed rule, we outlined the uncertainty surrounding the assumptions and associated cost estimates relating to the expenditures for the necessary technology, innovation, and implementation requirements. This uncertainty not only included recognizing the difficulty surrounding the extent of the necessary technology advancements, but how these changes would affect State systems. We concluded that time, money, resources, and considerable effort would be necessary for States to make changes to their current technology. Our estimates also accounted for the additional uncertainty surrounding the rate of adoption for States to make necessary changes in the proposed rule. As a result of the uncertainty in our assumptions surrounding State behavior, including adoption rates and the associated costs for implementing new systems within the timeframe assessed, we presented our concluding aggregate cost estimates within a 25 percent lower and upper range. This allowed us to reflect a larger cost estimate range, so that both States throughout the lower to higher bands of expenditures may be reflected.

In further substantiating the initial estimates, our experience regarding State costs for eligibility systems is based on considerably larger integrated systems involving SNAP and ACF programs, of which Medicaid typically has a 30 to 45 percent share based on how States choose to allocate costs. Thus, we recognize that total system costs may be higher than the \$50 million (total computable Medicaid costs) originally estimated, but the specific Medicaid share of those costs reflects a portion of the total; that is, on average \$50 million (total computable). The focus of our estimates for this rule is strictly Medicaid costs and not total system costs. Furthermore, we recognize larger States may have higher costs, while smaller States may experience lower costs. The \$50 million estimate is our best effort to estimate the midpoint for the Medicaid-only costs, with the estimated majority of States experiencing costs somewhere within the 25 percent lower to upper cost range provided in the regulatory impact analysis. As a result, we are not making revisions to the Regulatory Impact Analysis or associated cost estimates as a result of this comment.

Comment: One commenter noted that we indicate there are no additional information collection requirements; however, the commenter questioned the evolving certification requirements and asked if this means that additional information collection will be necessary.

Response: We considered that additional data may be necessary in terms of the performance measurements and compliance with our standards and conditions. However, we believe this process will be part and parcel to the APD process; that is, we believe that States will submit information to us as part of the APDs. We indicated in our proposed rule that States already submit to us for review and approval APDs for funding for automated data processing in accordance with Federal regulations at 45 CFR Part 95, Subpart F. However, we agree with the commenter that any new APDs for Medicaid systems that perform eligibility and enrollment functions will need to address the requirements of this final rule. Consequently, we developed an expedited APD checklist specific to the purposes of this rule and submitted to OMB for review and approval the burden associated with the information collection.

IV. Provisions of the Final Regulations

After consideration of the comments reviewed and further analysis of specific issues, with a few modifications, we are adopting the provisions of the November 8, 2010 proposed rule as final.

Specifically, we are finalizing the following provisions:

A. Medicaid Eligibility Determinations

In § 433.112, we have revised the definitions such that Medicaid eligibility determinations will be considered "claims" of eligibility and Medicaid eligibility determination systems are potentially eligible for the enhanced 90 and 75 percent FFP under section 1903(a)(3) of the Act. This final policy will apply only upon the effective date of this final rule. Additionally, enhanced FFP does not eliminate the responsibility of States to ensure compliance with cost allocation principles outlined in OMB Circular A–87.

Further, enhanced FFP at the 90 percent rate for design, development, installation, or enhancement of eligibility determination systems will be available for State expenditures only through calendar year (CY) 2015, even if work on approved APDs continues after 2015. Enhanced FFP at the 75 percent rate to maintain and operate systems that previously qualified for 90 percent FFP will be available after 2015 if those systems continue to meet the requirements specified in this final rule.

Additionally, enhanced funding at 75 percent to maintain and operate systems meeting the standards and conditions is available prior to December 31, 2015, (but after the effective date of any final rule), in recognition of the fact that some States may have already invested in improvements that will allow systems to qualify without the need for additional enhanced development, design, installation or enhancement funding. For any State receiving enhanced FFP at 90 percent or 75 percent prior to December 31, 2015, systems must continue to meet the requirements, standards and conditions specified in this rule in order to continue receiving 75 percent enhanced funding after December 31, 2015.

We are limiting the timeframe for which enhanced 90 percent FFP is available for design, development, installation or enhancement of automated eligibility systems because we view the changes made by the Affordable Care Act for the new eligibility rules in Medicaid as requiring an immediate, substantial commitment to, and investment in, technologies. In order words, we expect that changes to State systems will be completed with the start of the new Affordable Care Act provisions and support the operation of Exchanges on January 1, 2014. However, we realize that States may need to make additional changes to State systems to provide for additional functionality in

support of Medicaid eligibility rule modifications. Thus, we are providing for an additional 2 years of 90 percent enhanced FFP so that States' systems would have additional time to ensure the peak performance of their systems.

States would need to incur costs for goods and services furnished no later than December 31, 2015 to receive 90 percent FFP for the design, development, installation or enhancement of an eligibility determination system. This would mean that if an amount has been obligated by December 31, 2015, but the good or service has not yet been furnished by that date, then such expenditure would not be eligible for enhanced FFP. Further, we are limiting the availability of 75 percent enhanced funding for maintenance and operations to those eligibility determination systems that have complied with the standards and conditions in this rule by December 31,

B. Standards and Conditions for Receiving Enhanced Funding

Under sections 1903(a)(3)(A)(i) and 1903(a)(3)(B) of the Act, we are delineating standards and conditions that must be met by States in order for their Medicaid technology investments (including traditional claims processing systems, as well as eligibility systems) to be eligible for the enhanced match. These authorities provide that the enhanced FFP of 90 percent is not available unless the Secretary determines that a system is "likely to provide more efficient, economical, and effective administration of the plan" as described in section 1903(a)(3)(A)(i) of the Act. Similarly, section 1903(a)(3)(B) of the Act specifies that enhanced FFP of 75 percent is not available for maintenance or operations unless the system is "of the type described in subparagraph (A)(i)" and is approved by the Secretary.

We define MITA at § 433.111(c) and we build on the work of MITA by codifying that enhanced FFP (either at the 90 percent rate for design, development, installation or enhancement; or at the 75 percent rate for maintenance and operations) is only available when certain standards and conditions are met. Specifically, we articulate a set of standards and conditions that States must commit to in order to receive enhanced FFP:

• Use of a modular, flexible approach to systems development, including the use of open interfaces and exposed application programming interfaces; the separation of business rules from core programming; and the availability of business rules in both human and machine readable formats.

- Align to and advance increasingly in MITA maturity for business, architecture, and data.
- Ensure alignment with, and incorporation of, industry standards: the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security, privacy and transaction standards; accessibility standards established under section 508 of the Rehabilitation Act, or standards that provide greater accessibility for individuals with disabilities, and compliance with Federal civil rights laws; standards adopted by the Secretary under section 1104 of the Affordable Care Act; and standards and protocols adopted by the Secretary under section 1561 of the Affordable Care Act.
- Promote sharing, leverage, and reuse of Medicaid technologies and systems within and among States.
- Support accurate and timely processing of claims (including claims of eligibility), adjudications, and effective communications with providers, beneficiaries, and the public.
- Produce transaction data, reports, and performance information that would contribute to program evaluation, continuous improvement in business operations, and transparency and accountability.
- Ensure seamless coordination and integration with the Exchange (whether run by the State or Federal government), and allow interoperability with health information exchanges, public health agencies, human services programs, and community organizations providing outreach and enrollment assistance services.

To ensure that States have an opportunity to come into compliance with these requirements, the States currently receiving enhanced FFP for MMIS will have a period of transition to come into compliance with the standards and conditions listed above. Under our schedule, the following transition periods will apply:

- For new MMIS development (new APDs requesting 90 percent FFP for design, development, installation, and enhancement): No transition period.
- For MMIS development already underway (approved APDs providing 90 percent enhanced FFP): 14-month transition period (beginning with the effective date of this final rule) in which to submit an updated Implementation APD (IAPD) detailing how systems will be modified to meet the required conditions and standards.
- For maintenance and operations of MMIS currently receiving 75 percent

- FFP: 38-month transition period (beginning with the effective date of this final rule) in which to submit an IAPD with plans to upgrade or modify systems to meet the required conditions and standards.
- Eligibility systems (currently receiving 50 percent for development and maintenance and operations): Because eligibility systems are not currently receiving enhanced funding, there is no transition period and no need for a transition period for new requests for enhanced funding for eligibility systems. Any APDs requesting enhanced funding for eligibility systems funding following the effective date of this regulation will have to meet the standards and conditions above. States with eligibility systems currently under development (approved APDs providing 50 percent FFP) can update their APDs to reflect how they will comply with these standards and conditions in order to begin receiving 90 percent FFP. Similarly, eligibility systems currently receiving 50 percent FFP for State expenditures will need to comply with our final standards and conditions to receive a 75-percent FFP.

Our standards and conditions will be enforced through both front-end and back-end review processes. Front-end review will entail APD review and prior approval processes where States apply for enhanced match before entering into IT investment projects. Back-end reviews will entail certifications of the systems capabilities, as well as ongoing performance monitoring.

C. Reviews and Performance Monitoring of MMISs

In this final rule, we are also reinstituting periodic performance reviews of MMISs (including eligibility determination systems receiving enhanced funding). Our reviews will focus on performance measures we set to determine whether States are meeting the standards and conditions in this final rule. For example, we will measure how a system meets requirements for providing notices to beneficiaries, claims and applications intake and acceptance, efficient timely and accurate processing of claims, applications and renewals, proper determinations, and experience with appeals, interoperability with Exchanges, as well as traditional systems standards such as availability and down time. We expect to see such data automatically generated by the systems in which we invest, with standards and conditions established in consultation with States and

stakeholders, and based on industry experience.

Additionally, we will evaluate systems based upon their interoperability with other Federal and State health programs. Thus, in operating their systems, States will need to ensure that they consult documents articulating the Department's strategy on interoperability, such as the Guidance for Exchange and Medicaid Information Technology Systems.

Any failures or deficiencies will be the basis for investigation and opportunity for corrective action before making a determination that enhanced FFP will be discontinued.

To reflect the passage of the BBA, we have modified § 433.119 through § 433.121 to eliminate any reference to Systems Performance Reviews (SPRs) but, more importantly, to reflect the requirements for performance monitoring and review.

D. Partial Systems Improvements or Modernizations

As discussed in response to comment, as well as in the proposed rule, in referring to "system" or "technology," we recognize that States will likely use a system of systems in support of MMIS functions. States submitting partial system updates will need to submit and have an approved roadmap for achieving full compliance with the standards and conditions in the regulation. We will track progress against an approved roadmap when determining if system updates meet the standards and conditions for the enhanced match. For enhancements intended to satisfy a specific requirement or to address a compliance issue, for example, ICD-10 or implementation of the National Correct Coding Initiative, our final policy is that States making enhancements to address a specific requirement would have to continue to make improvements and continue to look to industry standards to ensure that the enhancement is evolving along with such standards.

E. Changes to Federal Regulations at 42 CFR Part 433 Subpart C—Mechanized Claims Processing and Information Retrieval Systems

We are deleting § 433.113 (referencing the need to have mechanized claims processing and information retrieval systems by a certain deadline, or face reduced Federal Medicaid funds as a consequence) and § 433.130 (referencing waiver provisions for qualifying States with a certain 1976 population and expenditures). We have also deleted various cross-references to these provisions.

We have also made conforming amendments to various provisions in part 433, subpart C to conform to our final policy that eligibility determination systems may now be considered part of mechanized claims processing and information retrieval systems. We have eliminated the statement in the current § 433.111(b)(3) that "Eligibility determination systems are not part of mechanized claims processing and information retrieval systems or enhancements to those systems." In response to comments we have reinserted language in § 433.111(b)(3) to include information regarding approved enhancements to mechanized systems, including claims processing and information retrieval systems. We have also eliminated the provision at § 433.112(c), which currently states that "eligibility determination systems are not part of mechanized claims processing and information retrieval systems and are not eligible for 75 percent FFP under this Subpart. These systems are also not eligible for 90 percent FFP for any APD approved after November 13, 1989." We have replaced this with language making clear that 90 percent FFP for the design, development, installation, or enhancement of an eligibility determination system is available only before December 31, 2015, even if work on an approved APD continues after 2015. In this final rule, we also are amending the regulation to make clear that States will need to incur costs for goods and services furnished no later than December 31, 2015 to receive 90 percent FFP for the design, development, installation, or enhancement of an eligibility determination system. We are also codifying in this final rule that FFP at 75 percent is not available for eligibility determination systems that do not meet the standards and conditions by December 31, 2015.

States will be required to supply information and demonstrate consideration of the standards and conditions to CMS for review and approval and as part of the APD before we will grant approval of enhanced funding. We will scrutinize all investments and will decline to approve enhanced funding (resulting in 50 percent FFP) that do not demonstrate careful consideration and application of these standards and conditions.

V. Waiver of Delay in Effective Date

Section 553(d) of the Administrative Procedure Act (APA) (5 U.S.C. 553(d)) ordinarily requires a 30-day delay in the effective date of final rules after the date of their publication. In addition, the

Congressional Review Act at 5 U.S.C. 801, requires a major rule to take effect no earlier than 60 days after the date the rule is published in the Federal Register. Both the 30- and 60-day delays in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 8 U.S.C. 808(2).

We find that it is both unnecessary and contrary to the public interest to delay the effective date of this final rule. This rule is altering the definition of a mechanized claims processing and information retrieval system, such that the definition will now include automated eligibility determination systems. As a result, enhanced Federal funding should be available to States that seek to alter their systems, or that have already altered their systems, in a manner that meets all of our

requirements.

We believe it is in the public interest to immediately ensure the availability of such enhanced funding, so that States are able to begin the process of altering their systems as soon as possible. States will be required to have systems in place that comply with the Affordable Care Act by the beginning of 2014, and the sooner States are able to start relying on Federal funding to begin modernizing their systems, the more likely they will be able to meet these deadlines. In addition, at least a few States already have systems that would comply with all of our standards and conditions. Therefore, an immediate effective date would allow such States to receive funding immediately to support such modernization efforts. For these reasons, it would be contrary to the public interest to delay the availability of enhanced funding.

In addition, given that States will have a period of time to come into compliance with the terms and conditions we have promulgated in this final rule, it is unnecessary to delay an effective date, as an immediate effective date will not require any State to immediately alter its systems. Rather, for eligibility determination systems, the rule simply conditions enhanced funding on States being in compliance with the terms and conditions of this final rule—but there is no immediate requirement that systems change. For current MMISs already receiving enhanced funding, the rule does impose new terms and conditions to continue the receipt of such enhanced funding, but a transition period is built in to allow States time to comply and this transition period has been extended by

2 months to account for the immediate effective date in this final rule.

For the above reasons, we find good cause, based on both public interest, and lack of necessity for a delayed effective date, to waive both the 30- and 60-day delayed effective dates and to make this rule effective upon publication.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

The changes specified in this final rule impose new reporting, recordkeeping or disclosure requirements for submission of APDs. Initially, we indicated that States already submit to us for review and approval APDs for funding for automated data processing in accordance with Federal regulations at 45 CFR Part 95, Subpart F. We noted, however, in section III.I. of this final rule that we received one comment on the burden associated with this final rule. As a result of review of this comment and the development of a new expedited ADP checklist specific to the purposes of this final rule, we are seeking emergency review and approval from OMB in order for the expedited APD checklist to be available to States at the time this rule becomes effective. In addition, we are soliciting public comments on the information collections and associated burden contained in this final rule.

An Expedited Eligibility and Enrollment (E&E)—APD checklist (CMS-10385; OMB number 0938-NEW) has been developed for States that participate in Early Innovator grants or Establishment grants to complete and submit to CMS for review and prior approval in order to receive enhanced

federal funding for Medicaid Information Technology (IT) system(s) projects related to eligibility and enrollment functions.

Specifically, this checklist:

- (1) Guides States in obtaining prior approval to secure 90 percent Federal financial participation (FFP) for the design, development, implementation (DDI), and/or enhancements of a system(s); and 75 percent FFP for maintenance and operations [42 CFR § 433 Subpart C].
- (2) Contains Seven Standards & Conditions that the State's APD must meet.
- (3) Contains Federal requirements for both Planning and Implementation

activities of an APD [45 CFR part 95 subpart F (Revised October 28, 2010)].

(4) Streamlines the process for States by requiring fewer documents, as well as potentially shortening the review timeframe for CMS, and if applicable, other Agencies, of system projects related to the Affordable Care Act. Although Federal Regulations allow up to 60 days for APD approvals, our goal is to provide an approval within 30 business days upon receipt.

We estimate that there are 56 State Medicaid programs (including the District of Columbia and 5 territories) and that it will take approximately 5 hours for each State program to complete the APD template with the requested information which in aggregate will take 280 total hours to complete one checklist, and 840 total hours to complete the anticipated average response of 3 per Medicaid program. We reviewed 2009 National Labor Statistics and speculate that the job role of Management Analyst (13-1111) with a mean hourly wage estimate rate of \$40.70 would be completing the data for the template. Based on these estimates, the total cost to complete the APD template would be \$2,279.20 (15 hours \times hourly rate of 40.70 = 610.50 \times 56 programs = \$34,188.00). We acknowledge that there are uncertainties regarding these burden estimates.

ESTIMATED ANNUAL REPORTING BURDEN REPORTING [States]

	Section	Estimated number of respondents	Frequency of responses	Average number of annual responses	Average burden per response (hours)	Annual burden hours
States that participate in Early Innovator grants or Establishment grants complete expedited checklist.	42 CFR Part 433 Subpart C and 45 CFR Part 95 Sub- part F.	56	3	168	5	840
Total		56	3	168	5	840

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access our Web site at http://www.cms.gov/
PaperworkReductionActof1995/PRAL/ list.asp#TopOfPage or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410–786–1326.

In commenting on the information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by June 20, 2011:

- 1. Electronically. You may submit your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.
- 2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500

Security Boulevard, Baltimore, Maryland 21244–1850.

VII. Regulatory Impact Analysis

A. Statement of Need

This regulation is important, since with the passage of the Affordable Care Act, we expect that changes to eligibility policies and business processes will need to be adopted. System transformations will be needed in most States to apply new rules to adjudicate eligibility for the program; enroll millions of newly eligible individuals through multiple channels; renew eligibility for existing enrollees; operate seamlessly with newly authorized Health Insurance Exchanges ("Exchanges"); participate in a system to verify information from applicants electronically; incorporate a streamlined application used to apply for multiple sources of coverage and financial assistance; and produce notices and communications to applicants and beneficiaries concerning the process, outcomes, and their rights to dispute or appeal.

We wish to ensure that a key outcome of our technology investments is a much higher degree of interaction and interoperability in order to maximize value and minimize burden and costs

on providers, beneficiaries, and States. Thus, we are committed to providing 90 percent FFP for design, development, and installation of eligibility determination systems through CY 2015 or 75 percent FFP for maintenance and operations of such systems that meet the new regulatory requirements. We have provided that States must commit to a set of standards and conditions to receive the enhanced FFP. This enhanced FFP reduces the financial burden on States to 10 percent of the costs compared to the 50 percent financial burden currently in place and ensures that States utilize current technology development and deployment practices and produce reliable business outputs and outcomes.

B. Overall Impact

The estimated costs of the Federalshare for Medicaid administration have been reflected in the FY 2012 President's Budget.

We have examined the impact of this final rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980; Pub. L. 96–354) (RFA), section 1102(b)

of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 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 Orders 12866 and 13563 direct 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year). This final rule is anticipated to have an annual effect on the economy of \$100 million or more, making it an economically significant rule under the Executive Order 12866 and hence a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of this final rule.

States will continue to receive the traditional 50 percent FFP for reasonable administrative expenditures for designing, developing, installing, or enhancing the Medicaid portion of their integrated eligibility determination systems. Similarly, States will continue to receive 50 percent FFP for expenditures associated with the maintenance and operation of such systems.

This final rule, however, addresses the impact related to enhanced FFP for mechanized claims processing and information retrieval systems, including those that perform eligibility determination and enrollment activities, as well as the Medicaid portion of integrated eligibility determination systems that the Secretary determines are likely to provide more efficient, economical, and effective administration of the State plan.

In projecting the impact to the Federal government and State Medicaid agencies, we considered how the standards and conditions on MMIS and the availability of enhanced match for State eligibility systems through CY 2015 will impact State investments over the 10-year period of 2011 through 2020. As discussed in section VI.C of this final rule, we considered the expected costs to the Federal government of providing the enhanced match rate, changes in State investments

due to the application of standards and conditions on MMIS (including eligibility systems), and possible savings as a result of the use of more modern, reusable, and efficient technologies.

C. Potential Savings

We considered a number of ways in which application of the standards and conditions, including increased use of MITA, could result in savings; however, as no States have yet reached MITA maturity, it is difficult to predict the savings that may accrue over any certain timeframe. These areas include the following:

(1) Modular technology solutions: As States, or groups of States, will begin to develop "modular" technology solutions, these solutions will be used by others through a "plug and play" approach, in which pieces of a new MMIS will not need to be reinvented from scratch every time, but rather, could be incorporated into the MMIS framework. We assume that savings associated with reusable technology could be achieved in both the development and operation of new systems. We expect that States will dispense with the need to engage in significant requirements analyses and the need to pay for new modules to be built when there are successful models around the country that they can draw down from a "technology bank" maintained by the Federal or State governments.

(2) Increased use of industry standards and open source technologies: While HIPAA administrative transaction standards have existed for 5 to 7 years, use of more specific industry standards to build new systems will allow such systems to exchange information seamlessly—a major goal of the Affordable Care Act, and one that is the explicit purpose of the standards work envisioned within section 1561 of the Act. We also believe that more open source technology will encourage the development of software solutions that address the needs of a variety of diverse activities—such as eligibility, member enrollment, and pharmacy analysis of drug claims. Software that is sufficiently flexible to meet different needs and perform different functions could result in cost savings, as States are able to use the systems without making major adaptations to them.

(3) Maintenance and operations: As States take up the changes in this final rule, the maintenance/operation costs of new systems should decrease. Less maintenance should be required than that necessary to reengineer special, highly customized systems every time

there is a new regulatory or legal requirement.

(4) Reengineering business processes, more Web-based solutions, service-oriented architecture (SOA): Savings are likely to result from the modular design and operation of systems, combined with use of standardized business processes, as States are compelled to rethink and streamline processes as a result of greater reliance on technology.

D. Calculation of MMIS Costs

MMIS costs are estimated at approximately \$10.0 billion over the 5-year budget window and \$23.0 billion over the 10-year budget window. These costs represent only the Federal share.

To calculate the impact of the regulation on MMIS costs, we assumed that new systems on average will cost \$150 million over 3 years for each State (\$50 million total cost per year, or \$45 million Federal costs at 90 percent FFP per year). We have identified that ten States have sophisticated systems that are very close to meeting the implemented regulation standards. As a result, we assumed the remaining 41 States will have approved APDs in place to replace or update their MMIS between FY 2011 and FY 2013 to comply with the new regulation standards and conditions.

We assumed that the States modernizing earlier in the cycle will see increased development, design, and installation costs, whereas States moving later will see increased development, design, and installation savings as they are able to take advantage of efficiencies gained by the early adopter States. Specifically, for those States that update or build new systems in FY 2011 and FY 2012, we assumed a 10 percent annual cost increase to new MMIS systems for design, development, and installation. For those States that build new systems in FY 2013 and FY 2014, we assumed a 5 percent annual savings to new MMIS systems for design, development, and installation. While it is difficult to predict State behavior, we believe all States will comply with the standards and conditions in this regulation to receive the 90 percent FFP, and have assumed that for the purpose of these estimates.

For maintenance, we assumed those States that have implemented the new regulation requirements would see a 20 percent annual savings, and for operations, we assumed those States that have implemented the new regulation requirements would see a 5 percent annual savings.

Based on these assumptions, we estimate the net Federal budgetary

impact on baseline MMIS costs from FY 2011 through 2015 of implementing the new regulation is approximately \$1.1 billion, and the net Federal budgetary impact from FY 2011 through 2020 is approximately \$557 million in savings.

E. Calculation of Eligibility Systems

For eligibility systems, we applied the same methodology we used to calculate net Federal costs to MMIS under the new regulation.

To meet the requirements of the Affordable Care Act, States would have to build new systems or modernize existing systems. Most States will add new functionalities to interface with the Exchanges and implement new adaptability standards and conditions (such as incorporation of new mandated eligibility categories). We assume baseline costs for development, design, and installation at 50 percent FFP for all States are approximately \$815 million from FY 2011 through 2015 and \$1.1 billion from FY 2011 through 2020. Eligibility systems costs for maintenance and operations at 50 percent for all States are approximately \$1.2 billion from FY 2011 through 2015 and \$2.7 billion from FY 2011 through 2020. These costs represent only the Federal share.

To calculate the impact of the implemented regulation, we assumed that new systems on average will cost \$50 million over 3 years for each State (\$16.7 million total cost per year, or \$15 million Federal costs at 90 percent FFP per year). We assumed that 25 States will replace their eligibility systems in FY 2011 through CY 2015. We assumed no States will build new systems past FY 2014 (beyond what is assumed in the baseline) due to the timing of the start of major coverage provisions in the Affordable Care Act, the length of time needed to build new systems (approximately 3 years), and the enhanced match ending after CY 2015. For maintenance, we assumed States that have implemented new systems meeting the required standards and conditions will see a 20 percent annual savings, and for operations, we assumed those States that have implemented the new systems would see a 5 percent annual savings. These assumptions are consistent with our approach for savings under MMIS in the regulation.

The net Federal cost impact from FY 2011 through 2015 of implementing our

regulation on eligibility systems is approximately \$2.2 billion, and the net Federal cost from FY 2011 through 2020 is \$2.9 billion. These costs represent only the Federal share.

F. Total Net Cost Impact

Combining the impact of the regulation, the total net Federal cost impact is approximately \$3.3 billion for FY 2011 through 2015 and approximately \$2.3 billion for FY 2011 through 2020. We see lower costs over the 10-year budget window due to the increased savings to MMIS over time.

Aligned with these Federal net costs, States will see a corresponding decrease in their net State share due to the enhanced Federal match for eligibility systems they will receive through CY 2015 and the benefits accrued to their systems by putting in place the set of standards and conditions articulated in our regulation. Combining the impact of the regulation, the total net State budget impact is approximately \$792.5 million in savings for FY 2011 through 2015 and approximately \$1.9 billion in savings from for FY 2011 through 2020. Similar to the Federal budget impact, we expect to see higher savings achieved by States over the 10-year budget window due to the increased savings to MMIS over time.

The projections in this analysis are subject to considerable uncertainty, as they reflect projected costs based on technology and innovation. While we believe that advancements in technology will likely have an impact on States' systems, it is difficult to predict with certainty how significant the technology advancements may be and how they would affect State systems. For example, we have worked for many years developing the MITA maturity model. We believe that States should adopt the MITA framework as the basis for all MMIS replacements and major system upgrades related to the MMIS, and while we are requiring that States move to a MITA framework in order to receive enhanced funding, to date there are no States that have reached full MITA maturity. Consequently, having no States at full MITA maturity indicates that it takes time, money, and considerable effort for States to make changes to their current

technology. Additional uncertainty exists because

we are unsure of the rate of adoption for

States to make the changes in this final

rule. The enhanced FFP is available for approximately 5 years, from CY 2011 through CY 2015, and States could upgrade or replace their systems at any point within the 5-year period. Further, States may simply choose to make moderate changes to existing systems, and even with the 90 and 75 percent enhanced FFP, such moderate changes could be less costly overall for States than replacing their systems.

Additional uncertainty exists about the rate of State adoption since some States may consider the costs needed to move to a more advanced system to be too high to undertake such a project. Similarly, States may decide not to make changes due to implementation of performance requirements and the performance reviews.

We acknowledge that there are uncertainties regarding our assumptions, including State behavior, and the associated cost estimates with respect to States implementing new systems within the timeframe assessed. However, we have offered our estimates with a 25 percent upper and lower range to capture such uncertainty in actual implementation outcomes. Due to a number of uncertainties in our assumptions, we believe a range of estimates better represents the net cost impact of this regulation. Tables 1 and 2 represent a 25 percent range for these aggregate net costs to the Federal and State government, respectively. It is important to point out that we believe that systems transformation is necessary to meet the vision of the Affordable Care Act and consequently, these costs are necessary and will provide for efficient systems that in the end will provide for more efficient and effective administration of the State plan. The separate impacts to MMIS and eligibility systems are summarized below.

TABLE 1—NET FEDERAL COST IMPACT OF REGULATION [Dollars in millions] *

	FY 2011–2020
MMIS (excluding eligibility) Eligibility Systems	(417.4)–(695.7) 2,154.6–3,591.0
Total	1,737.2–2,895.3

^{*} Numbers in parentheses represent savings to the Federal government.

TABLE 1.1—NET FEDERAL COST IMPACT OF REGULATION BY FISCAL YEAR [Dollars in millions]*

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2011– 2020
MMIS (excluding Eligibility) Eligibility Systems	231.1 328.9	469.4 436.7	435.6 634.6	54.3 469.3	(83.0) 337.4	(322.6) 127.9	(329.0) 130.5	(333.1) 133.1	(337.4) 135.8	(341.8) 138.5	(556.6) 2,872.8
Total	560.0	906.1	1,070.2	523.6	254.4	(194.7)	(198.5)	(200.0)	(201.6)	(203.3)	2,316.2

^{*} Numbers in parentheses represent savings to the Federal government.

FY 2011-2020

(170.6)-(284.4)

TABLE 2—NET STATE COST IMPACT OF REGULATION

[Dollars in Millions]*

MMIS (excluding eli-

gibility)

[Dollars in	Millionsj^
	FY 2011–2020
Fligibility Systems	(1.255.4)–(2.092.3)

TABLE 2—NET STATE COST IMPACT

OF REGULATION—Continued

TABLE 2—NET STATE COST IMPACT
OF REGULATION—Continued

[Dollars in Millions]*

	FY 2011–2020
Total	(1,426.0)–(2,376.7)

^{*}Numbers in parentheses represent savings to State governments.

TABLE 2.1—NET STATE COST IMPACT OF REGULATION BY FISCAL YEAR [Dollars in millions]*

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2011–2020
MMIS (excluding eligibility) Eligibility Systems	25.7 (285.6)	52.2 (276.7)	48.4 (258.0)	1.3 (139.9)	(24.1) 64.3	(61.6) (149.5)	(65.2) (152.5)	(66.6) (155.5)	(68.0) (158.6)	(69.5) (161.8)	(227.5) (1,673.8)
Total	(259.9)	(224.6)	(209.6)	(138.6)	40.2	(211.1)	(217.7)	(222.1)	(226.6)	(231.3)	(1,901.3)

^{*} Numbers in parentheses represent savings to State governments.

G. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires agencies to prepare a Regulatory Flexibility Analysis to describe and analyze the impact of final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the healthcare sector. Small Business Administration size standards define a small entity as one with between \$7 million and \$34 million in annual revenues. For the purposes of the RFA, essentially all non-profit organizations are considered small entities, regardless of size. Individuals and States are not included in the definition of a small

Since this rule will affect States, which are not considered small entities, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, we have not prepared a regulatory flexibility analysis.

Additionally, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operation 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 small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial amount of small rural hospitals. There is no negative impact on the program or on small businesses.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year of \$100 million in 1995 dollars (updated annually for inflation), by State, local, or tribal governments, in the aggregate, or by the private sector. In 2011, that threshold is approximately \$136 million. This final rule does not mandate expenditures by the State governments, local governments, tribal governments, in the aggregate, or the private sector, of \$136 million. This rule provides that States can receive enhanced FFP if States ensure that the mechanized claims processing and information retrieval systems (MMIS) including, for a limited time, those that perform eligibility determination and enrollment activities, as well as the

Medicaid portion of integrated eligibility determination systems, meet with certain conditions including migrating to the MITA framework and meet certain performance requirements. This is a voluntary activity; that is, States can continue to receive the traditional 50 percent FFP match rate for reasonable administrative expenditures for the design, development, or enhancement and maintenance and operations to the Medicaid portion of integrated eligibility determination systems to make eligibility determinations for Title XIX of the Act. This final rule imposes no substantial mandates on States. The State role in determining Medicaid eligibility is dependent upon the population type; specifically, some populations such as the elderly, blind, and disabled are typically determined by the Medicaid State agency whereas other population types may have their Medicaid eligibility determined by cashassistance programs. Mechanized claims processing and information retrieval systems, including those that perform eligibility determination and enrollment activities and the Medicaid portion of integrated eligibility determination systems, at a minimum, will need to be updated. However, providing 90 percent FFP for design, development, and

installation or 75 percent FFP for maintenance and operations of such systems reduces the financial burden on States to 10 percent of the costs compared to the 50 percent financial burden currently in place. Specifically, while this entails certain procedural responsibilities, these activities do not involve substantial State expense; providing 90 percent and 75 percent FFP reduces the total State outlay.

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. We wish to note again that this is a voluntary activity and as such this regulation does not mandate any direct costs on State or local governments. Consequently, the requirements of Executive Order 13132 are not applicable.

H. Alternatives Considered

We considered that an alternative to our final rule could be that we not provide enhanced match for a limited time for State systems builds and not provide Federal standards and conditions. In fact, States could continue to receive the traditional 50 percent FFP for reasonable administrative expenditures for designing, developing, installing, or enhancing Medicaid eligibility determination systems. Similarly, States could continue to receive 50 percent FFP for expenditures associated with the maintenance and operation of such systems.

However, States must continue to meet the requirements of Federal legislation. Since the Affordable Care Act significantly alters Medicaid eligibility and requires coordination with the Exchanges, it is imperative that States have the resources and systems to be able to meet this challenge. Therefore, we believe that if States were left to develop eligibility systems without Federal standards and conditions and without the benefit of enhanced match, States systems may not comport with our ultimate goal; that is, that design, development, implementation, and operation of IT and systems projects are in support of the Affordable Care Act.

I. Accounting Statement

As required by OMB Circular A–4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table 3, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this rule. This table provides our best estimate of the net costs decrease in Medicaid payments as a result of the changes presented in this rule.

TABLE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED NET COSTS, FROM FY 2011 TO FY 2020 [In \$millions]

	Transfers								
Category	Year dollar	Units disco	Davied envered						
	2010	7%	3%	Period covered					
Annualized Monetized Transfers	Primary Estimate Low Estimate High Estimate	\$311.31 233.48 389.14	\$266.55 199.91 333.19	FYs 2011–2020 FYs 2011–2020 FYs 2011–2020					
From	Federal Government to State								
Annualized Monetized Transfers	Primary Estimate Low Estimate High Estimate	-\$189.87 -142.40 -237.34	-\$189.82 -142.36 -237.28	FYs 2011–2020 FYs 2011–2020 FYs 2011–2020					
From	State Governments to System V								

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

List of Subjects in 42 CFR Part 433

Administrative practice and procedure, Child support Claims, Grant programs—health, Medicaid, 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 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 continues to read as follows:

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

Subpart C—Mechanized Claims Processing and Information Retrieval Systems

■ 2. Section 433.110 is amended by revising paragraph (a)(2) to read as follows:

§ 433.110 Basis, purpose, and applicability.

(a) * * *

(2) Section 1903(r) of the Act, which imposes certain standards and conditions on mechanized claims processing and information retrieval systems (including eligibility determination systems) in order for these systems to be eligible for Federal funding under section 1903(a) of the Act.

* * * * *

■ 3. Section 433.111 is amended by—

- A. Revising paragraph (b)(3).
- B. Adding paragraph (c).

 The revision and addition read as follows:

§ 433.111 Definitions.

* * * * *

(b) * * *

- (3) Approved enhancements to the system.
- (c) "Medicaid Information Technology Architecture (MITA)" is defined at § 495.302 of this chapter.
- 4. Section 433.112 is amending by—
 A. Revising paragraphs (a), (b)(2), an
- A. Revising paragraphs (a), (b)(2), and (c).
- B. Amending paragraph (b)(7) by removing the reference "45 CFR 74.171" and adding in its place, the reference "45 CFR 74.27(a)".
- C. Adding paragraphs (b)(10) through (b)(16).

The revisions and additions read as

§ 433.112 FFP for design, development. installation or enhancement of mechanized claims processing and information retrieval systems.

- (a) Subject to paragraph (c) of this section, FFP is available at the 90 percent rate in State expenditures for the design, development, installation, or enhancement of a mechanized claims processing and information retrieval system only if the APD is approved by CMS prior to the State's expenditure of funds for these purposes.
 - (b) * * *
- (2) The system meets the system requirements, standards and conditions, and performance standards in Part 11 of the State Medicaid Manual, as periodically amended.

- (10) Use a modular, flexible approach to systems development, including the use of open interfaces and exposed application programming interfaces; the separation of business rules from core programming, available in both human and machine readable formats.
- (11) Align to, and advance increasingly, in MITA maturity for business, architecture, and data.
- (12) Ensure alignment with, and incorporation of, industry standards: The HIPAA privacy, security and transaction standards; accessibility standards established under section 508 of the Rehabilitation Act, or standards that provide greater accessibility for individuals with disabilities, and compliance with Federal civil rights laws; standards adopted by the Secretary under section 1104 of the Affordable Care Act; and standards and protocols adopted by the Secretary under section 1561 of the Affordable Care Act.
- (13) Promote sharing, leverage, and reuse of Medicaid technologies and systems within and among States.
- (14) Support accurate and timely processing and adjudications/eligibility determinations and effective communications with providers, beneficiaries, and the public.
- (15) Produce transaction data, reports, and performance information that would contribute to program evaluation, continuous improvement in business operations, and transparency and accountability.
- (16) Ensure seamless coordination and integration with the Exchange, and allow interoperability with health information exchanges, public health agencies, human services programs, and community organizations providing

- outreach and enrollment assistance services.
- (c) FFP is available at 90 percent of a State's expenditures for the design, development, installation, or enhancement of an eligibility determination system that meets the requirements of this subpart and only for costs incurred for goods and services provided on or after April 19, 2011 and on or before December 31, 2015.

§ 433.113 [Removed]

- **■** 5. Section 433.113 is removed.
- 6. Section 433.114 is amended by—
- A. Amending paragraph (a) by removing the reference "(h)" and by adding in its place the reference "(i)".
- B. Revising paragraph (b). The revision reads as follows:

§ 433.114 Procedures for obtaining initial approval; notice of decision.

- (b) If CMS disapproves the system, the notice will include all of the following information:
- (1) The findings of fact upon which the determination was made.
- (2) The procedures for appeal of the determination in the context of a reconsideration of the resulting disallowance to the Departmental Appeals Board.
- 7. Section 433.116 is amended by —
- A. Amending paragraph (a) by removing the phrase "Subject to 42 CFR 433.113(c)," and by adding in its place "Subject to paragraph (j) of this section,".
- B. Amending paragraph (b) by removing the reference "(h)" and by adding in its place the reference "(i)".
- C. Adding new paragraphs (i) and (j). The additions read as follows:

§ 433.116 FFP for operation of mechanized claims processing and information retrieval systems.

(i) The standards and conditions of § 433.112(b)(10) through (b)(16) of this subpart must be met.

(j) Beginning and no earlier than, April 19, 2011, FFP is available at 75 percent of a State's expenditures for the operation of an eligibility determination system that meets the requirements of this subpart. FFP at 75 percent is not available for eligibility determination systems that do not meet the standards and conditions by December 31, 2015.

§ 433.117 [Amended]

■ 8. Section 433.117 is amended by— ■ A. Amending paragraph (a) by removing the phrase "all conditions" and adding in its place the phrase "all standards and conditions".

- B. Amending paragraph (c)(2) by removing the reference "(h)" and adding in its place the reference "(j)".
- 9. Section 433.119 is amended by revising paragraphs (a) and (c) to read as follows:

§ 433.119 Conditions for reapproval; notice of decision.

- (a) CMS periodically reviews each system operation initially approved under § 433.114 of this subpart and reapproves it for FFP at 75 percent of expenditures if the following standards and conditions are met:
- (1) The system meets the requirements of § 433.112(b)(1), (3), (4), (7) through (16) of this subpart.
- (2) The system meets the conditions of § 433.116 (d) through (j).
- (3) The system meets the standards, conditions, and performance standards for reapproval and the system requirements in part 11 of the State Medicaid Manual as periodically amended.
- (4) A State system must meet all of the requirements of this subpart within the appropriate period CMS determines should apply as required by § 433.123(b) of this subpart.

(c) After performing the review under paragraph (a) of this section, CMS will issue to the Medicaid agency a written notice informing the agency whether the system is reapproved or disapproved. If the system is disapproved, the notice will include the following information:

(1) CMS's decision to reduce FFP for system operations from 75 percent to 50 percent of expenditures, beginning with the first day of the first calendar quarter after CMS issues the written notice to

(2) The findings of fact upon which the determination was made.

- (3) A statement that State claims in excess of the reduced FFP rate will be disallowed and that any such disallowance will be appealable to the Departmental Appeals Board.
- 10. Section 433.120 is amended by revising paragraph (b) to read as follows:

§ 433.120 Procedures for reduction of FFP after reapproval review.

(b) CMS will reduce FFP in expenditures for system operations from 75 percent to 50 percent.

■ 11. Section 433.121 is amended by revising paragraph (a) to read as follows:

§ 433.121 Reconsideration of the decision to reduce FFP after reapproval review.

(a) The State Medicaid agency may appeal (to the Departmental Appeals Board under 45 CFR Part 16) a

disallowance concerning a reduction in FFP claimed for system operations caused by a disapproval of the State's system.

* * * * *

§ 433.130 [Removed]

- \blacksquare 12. Section 433.130 is removed.
- 13. Section 433.131 is amended by adding a new paragraph (c) to read as follows:

§ 433.131 Waiver for noncompliance with conditions of approval and reapproval.

* * * * * *

(c) Waiver of deadline. In no case will CMS waive the December 31, 2015 deadlines referenced in § 433.112(c) and § 433.116(j).

Authority: Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program. Dated: March 16, 2011.

Donald M. Berwick,

 $Administrator, Centers \ for \ Medicare \ \mathcal{E}$ $Medicaid \ Services.$

Approved: April 12, 2011.

Kathleen Sebelius,

 $Secretary, Department\ of\ Health\ and\ Human\ Services.$

[FR Doc. 2011–9340 Filed 4–14–11; 11:15 am]

BILLING CODE 4120-01-P