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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 95

Centers for Medicare & Medicaid Services

42 CFR Part 433

[CMS-2392-P]

RIN 0938-AS53

Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems

(90/10)

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would extend enhanced funding for Medicaid eligibility systems as part of a state's mechanized claims processing system, and would update conditions and standards for such systems, including adding to and updating current Medicaid Management Information Systems (MMIS) conditions and standards. These changes would allow states to improve customer service and support the dynamic nature of Medicaid eligibility, enrollment, and delivery systems.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: In commenting, please refer to file code CMS-2392-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2392-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2392-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.
4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:
 - a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,
Washington, DC 20201

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

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-0265 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT:

Victoria Guarisco (410) 786-0265, for issues related to administrative questions.

Carrie Feher (410) 786-8905, for issues related to regulatory impact questions.

Denise G. Osborn-Harrison (410) 786-1661 or Martin Rice (410) 786-2417, for general questions.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period

are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

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

I. Executive Summary

A. Purpose

This proposed rule would revise the regulatory definition of Medicaid mechanized claims processing and information retrieval systems to include Medicaid eligibility and enrollment (E&E) systems, which would have the consequence of making available for E&E systems the enhanced federal financial participation (FFP) specified in section 1903(a)(3) of the Social Security Act (the Act) on an ongoing basis. Enhanced FFP will be available, under certain circumstances, for costs of such systems at a 90 percent federal matching rate for design and development activities, and at a 75 percent federal matching rate for maintenance and operations activities. In addition to lifting the time limit that currently applies to the inclusion of E&E systems in the definition of mechanized claims processing and information retrieval systems, we are proposing changes to the standards and conditions applicable to such systems in order to access enhanced funding. We are also soliciting comment on new approaches to systems development, acquisition approvals and formal certification. Specifically, we are proposing new

definitions for “Commercial Off the Shelf (COTS) software”, “open source,” “proprietary,” “shared services,” and “MMIS Module.”

B. Summary of the Major Provisions

We are proposing changes to §§433.110, 433.111, 433.112, 433.116, 433.119, and 433.120. These changes provide for the 90 percent enhanced FFP for design, development and implementation activities for E&E systems to continue on an ongoing basis. The proposed changes would allow the states to complete fully modernized E&E systems and will support the dynamics of national Medicaid enrollment and delivery system needs. The changes will also set forth additional criteria for the submission, review and approval of Advance Planning Documents (APDs).

In addition, we are proposing changes to provisions within 45 CFR part 95, subpart F, §95.611. These changes align all Medicaid IT requirements with existing policy for Medicaid Management Information Systems (MMIS) pertaining to prior approvals when states release acquisition solicitation documents or execute contracts above a certain threshold amounts. In addition we propose to amend §95.611(a)(2) by removing the reference to 45 CFR 1355.52.

C. Summary of Costs and Benefits

Provision Description	Total Costs	Total Benefits
42 CFR part 433	The federal net costs from FY 2016 through 2025 of implementing the proposed regulation on eligibility systems is approximately \$3 billion. This includes approximately \$5.1 billion in increased federal costs for system design and development, offset by lower anticipated maintenance and operations costs. These costs represent only the federal share. These figures were derived from states' actual system development and maintenance costs as the foundation for projected costs.	We project lower costs over the 10-year budget window due to the increased savings to operating one E&E system and eliminating legacy systems. The costs shift from mostly 90 percent FFP for design, development, and installation to 75 percent FFP for maintenance and operations over time. (federal share only).
42 CFR part 433	The state net costs from FY 2016 through 2025 of implementing the proposed regulation on eligibility systems is approximately -\$1.1 billion. This includes approximately \$572 million in state costs for system design and development, offset by lower anticipated maintenance and operations costs. These costs represent only the state share.	We project savings for states over the 10-year budget window due to moving away from operating two or more systems, and replacing legacy systems.
45 CFR part 95, subpart F: §95.611	This is an administrative change with no associated costs.	This administrative change is expected to result in nominal savings from increased efficiency.

*See section VI. of this proposed rule for the underlying assumptions in support of these totals and further explanation.

II. Background

A. Legislative History and Statutory Authority

Section 1903(a)(3)(A)(i) of the Act provides for federal financial participation (FFP) at the rate of 90 percent for state expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems as the Secretary of the Department of Health and Human Services (the Secretary) determines are likely to provide more efficient, economical and effective administration of the state plan. In addition, section 1903(a)(3)(B) provides for federal financial participation (FFP) at the rate of 75 percent for state expenditures for maintenance and operation of such systems.

In a final rule published October 13, 1989, at 54 FR 41966, CMS revised the definition of a mechanized claims processing and information retrieval system at 42 CFR 433.111(b) to provide that eligibility determination systems would not be considered part of mechanized claims processing and information retrieval systems or enhancements to those systems. As a result, CMS also indicated at 42 CFR 433.112(c) that the enhanced FFP for mechanized claims processing and information retrieval systems in accordance with section 1903(a)(3) of the Act would not be available for eligibility determination systems.

We published a final rule entitled the “Federal Funding for Medicaid Eligibility Determination and Enrollment Activities” on April 19, 2011 (76 FR 21949-21975) that temporarily reversed the 1989 rule. We explained that this reversal was in response to changes made by the Affordable Care Act that required sweeping changes in Medicaid eligibility and enrollment systems and removed certain linkages between Medicaid eligibility determinations and eligibility determinations made by other federal-state programs, as well as changes in Medicaid eligibility and business processes that have occurred since our 1989 final rule to integrate eligibility and claims processing systems. The reversal was temporary to address the immediate need for eligibility system redesign to coordinate with the overall claims processing and reporting systems. Specifically, in the April 19, 2011 final rule (75 FR 21950), we included eligibility determination systems in the definition of mechanized claims processing and

information retrieval systems in §433.111(b)(3)(B). We also provided that the enhanced FFP would be available at the 90 percent rate for design, development, installation or enhancement of eligibility and enrollment systems and at the 75 percent rate for maintenance and operations of such systems, to the extent that the eligibility and enrollment systems were developed on or after April 19, 2011, operational by December 31, 2015, and met all standards for such systems. Under that rule, the 90 percent enhanced matching rate for system development is available through calendar year (CY) 2015 for state expenditures on eligibility and enrollment systems that meet specific standards and conditions, and the 75 percent match for maintenance and operations is available for systems that meet specific standards and conditions before the end of calendar year 2015, as long as those systems are in operation.

In the April 19, 2011 (75 FR 21950) regulation, under the authority of sections 1903(a)(3)(A)(i) and 1903(a)(3)(B) of the Act, we codified the conditions at 42 CFR 433.112(b) that must be met by the states for Medicaid technology investments including traditional claims processing systems, as well as eligibility systems, to be eligible for the enhanced funding match. We also issued sub-regulatory guidance: “Medicaid IT Supplement Version 1.0” in April 2011 that outlined in greater detail the seven standards and conditions for enhanced funding.

As explained in more detail below, we are proposing to make permanent the inclusion of eligibility and enrollment systems in the definition of mechanized claims processing and information retrieval systems, and to consequently extend the availability of enhanced FFP. We propose to define a state Medicaid eligibility and enrollment system as the system of software and hardware used to process applications, renewals and updates from Medicaid applicants and beneficiaries. In part, this proposed change reflects a new understanding of the complexity of the required eligibility and enrollment system redesign, and a new appreciation of the need for eligibility and enrollment systems to operate as an integral part of the mechanized claims

processing and information retrieval systems using a standard Medicaid information technology architecture.

We previously expected that fundamental changes to state systems would be completed well before December 31, 2015. It is now clear that additional improvements would benefit states and the federal government. It is also clear that such systems are integral to the operation of the state's overall mechanized claims processing and information retrieval systems and must be designed and operated as a coordinated part of such systems. Without recognition as an integral part of such systems, and without ongoing enhanced federal funding, state Medicaid eligibility and enrollment systems are likely to become out of date and would not be able to coordinate with, and further the purposes of, the overall mechanized claims processing and information retrieval systems.

B. Program Affected

Since 2011, CMS has worked with the states on the design, development and implementation of modernized Medicaid and CHIP eligibility and enrollment systems, supported by the enhanced FFP, to achieve the technical functionality necessary for the implementation of the new eligibility and renewal policies on January 1, 2014. In December 2012, we identified critical success factors in order for the states to demonstrate operational readiness, including: ability to accept a single, streamlined application; ability to convert existing state income standards to modified adjusted gross income (MAGI); ability to convey state-specific eligibility rules to the Federally-Facilitated Marketplace (FFM), as applicable; ability to process applications based on modified adjusted gross income (MAGI) rules; ability to accept and send application files (accounts) to and from the Marketplace; ability to respond to inquiries from the Marketplace on current Medicaid or CHIP coverage; and, ability to verify eligibility based upon electronic data sources (the Federal Data Services Hub or an approved alternative).

The states are in varying stages of completion of their E&E system functionality, with

work still ahead to maximize automation, streamline processes, and to migrate non-MAGI Medicaid programs into the new system. In addition, the majority of the states are engaged in system integration with human services programs, further increasing efficiencies and improving the consumer experience for those seeking benefits or services from programs in addition to Medicaid.

III. Provisions of the Proposed Regulations

The proposed regulatory changes in this proposed rule would permanently recognize Medicaid and CHIP eligibility and enrollment systems as an integral part of Medicaid mechanized claims processing and information retrieval systems, and would remove the time limits on the availability of enhanced rates of FFP for qualifying systems.

In addition, we are proposing to strengthen the standards and conditions for qualifying systems. Our purpose in the April 19, 2011 final rule (75 FR 21950) for moving to the standards and conditions-based approach to approving federal funding was intended to foster strong collaboration with the states, streamline the business process between the states and CMS by reducing unnecessary paperwork, and focus attention on the key elements of success for modern systems development and deployment. With the proposed on-going access to enhanced funding for eligibility systems, and in recognition of refinements needed to the standards and conditions that pertain to MMIS and eligibility and enrollment systems, we are proposing new criteria and modifying the existing standards and conditions required for the states to access the enhanced funding and provide greater accountability for the system investment.

These changes will permit states additional time to complete their full system modernization and retire their outdated “legacy” systems. In addition, these changes will promote an integrated, enterprise approach to Medicaid information technology. An enterprise approach involves the identification of functionality that can be shared across multiple programs, systems and subsystems. For example, a master person index or provider directory can be built

once for multiple uses within the larger Medicaid enterprise. We anticipate that this approach will help drive down potentially redundant IT costs.

Criteria will be set forth stating requirements for APDs and review of the same such as; for both MMIS and E&E systems, the state must identify in an APD its own key personnel (by type and time commitment) assigned to the project to ensure that sufficient state capacity is there to support a successful project outcome. We are proposing that for both MMIS and E&E systems, the state must meet the industry standards and conditions already in place.

We are proposing that states will need to, for both MMIS and E&E systems, develop mitigation plans for all major milestones and functionality that will contain strategies to mitigate the failure to achieve compliance with applicable requirements. For eligibility systems, the state must have delivered acceptable MAGI-based system functionality as demonstrated by performance testing and results based on critical success factors, with limited mitigations and workarounds.

Where applicable, we have proposed additional conditions that align to the best practices outlined in the new U.S. Digital Service Playbook (<https://playbook.cio.gov/>), such as the role of open source development. Other Playbook ideas will be included in sub-regulatory guidance regarding how CMS expects states to implement their Medicaid IT projects.

A. Proposed Amendments to 42 CFR Part 433

We propose to amend §433.110 by removing paragraphs (a)(2)(ii) and (iii) and paragraph (b). Previously, regulations at §433.119 indicated that we would review at least once every 3 years each system operation initially approved under §433.114 and, based on the results of the review, reapprove it for FFP at 75 percent of expenditures if certain standards and conditions were met. The final rule published April 19, 2011 (75 FR 21905) eliminated the requirement for the scheduled triennial review. Through a drafting error in the final rule published on April 19, 2011 (75 FR 21950), the reference to the scheduled triennial performance reviews at 42 CFR

433.110(a)(2)(ii) and (iii) was not deleted as intended, and we are proposing to delete the references here. The Secretary retains authority to perform periodic reviews of systems receiving enhanced FFP to ensure that these systems continue to meet the requirements of section 1903(a)(3) of the Act and that they continue to provide efficient, economical, and effective administration of the plan.

We are also proposing a technical correction to amend §433.110 by removing the reference to 45 CFR part 74, and replacing the reference with 45 CFR part 92. This proposed change is necessary because 45 CFR part 74 was supplanted by 45 CFR part 92 in September of 2003. Therefore, reference made to 45 CFR part 74 should have been removed at that time.

We are proposing to amend 42 CFR 433.111 to revise the definition of “mechanized claims processing and information retrieval system”, and provide new definitions for “Commercial Off the Shelf (COTS) software”, “open source”, “proprietary”, “shared services,” and “MMIS Module”. We are proposing to amend 42 CFR 433.112(c) to provide for the 90 percent enhanced FFP for design, development and implementation activities to continue on an on-going basis. Making enhanced E&E system funding available on an on-going basis, as is the case with the 90 percent match for the MMIS systems, would allow the states to complete fully modernized systems and avoid the situation where its ability to serve consumers well is limited by outdated systems. Enhanced funding will also support the dynamic and on-going nature of national Medicaid eligibility, enrollment, delivery system, and program integrity needs. Continued enhanced funding will support the retirement of remaining legacy systems, eliminating ongoing expense for maintaining these outdated systems. It will also achieve additional staffing and technology efficiencies over time by allowing for a more phased and iterative approach to systems development and improvement.

Our 2011 final rule limited the availability of 75 percent enhanced funding for maintenance and operations to those eligibility and enrollment systems that have complied with

the standards and conditions in that rule by December 31, 2015. Given our proposed modifications to 42 CFR part 433, subpart C, on-going successful performance, based upon CMS regulatory and sub-regulatory guidance, is a requisite for on-going receipt of the 75 percent FFP for operations and maintenance, including for any eligibility workers

(<http://www.medicaid.gov/State-Resource-Center/FAQ-Medicaid-and-CHIP-Affordable-Care-Act-Implementation/Downloads/FAQs-by-Topic-75-25-Eligibility-Systems.pdf>). We intend to work with the states to do regular automated validation of accurate processing and system operations and performance.

B. Technical Changes to 42 CFR Part 433, Subpart C-Mechanized Claims Processing and Information Retrieval Systems

We are authorized under the Act to approve enhanced federal funding for the design, development, and installation and operation and maintenance of such mechanized claims processing and information retrieval systems that are likely to provide more efficient, economical, and effective administration of the Medicaid program and to be compatible with the claims processing and information retrieval systems utilized in the administration of the Medicare program.

We implement this authority in part under regulations at 42 CFR part 433, subpart C. This regulation provides the primary technical and funding requirements and parameters for developing and operating the state MMIS and the state Medicaid eligibility and enrollment systems.

We intend to amend §433.116, which details how MMIS are initially approved and certified in order to be eligible for the 75 percent FFP for operations. Specifically, we propose that given the modular design approach required by our 2011 regulation, certification should also be available for MMIS modules, rather than only when the entire MMIS system is completed and operational. We have promulgated regulatory guidance at §433.112(b) that MMIS development

be modular. The states are accordingly taking a phased approach, with the procurement of a module or modules occurring at different times.

We believe in the reusability of existing or shared components so in the case that technology products exist that can be used for MMIS or E&E, we want to encourage that by allowing FFP for the developmental costs of integrating existing or shared components as part of the MMIS or E&E systems. We clarify that, while E&E system investments must be approved beforehand in order to be eligible for the enhanced FFP, the MMIS system certification requirements are not applicable at this time.

We will provide a series of artifacts, supporting tools, documentation and diagrams to the states as part of our technical assistance, monitoring and governance of MMIS systems design and development. It is also our intent to work with the states as systems are designed and developed on a continuous basis so that issues and solutions are identified and addressed prior to the certification stage.

We invite comment on our intention to move to a modular certification process for MMIS, based upon the Medicaid Information Technology Architecture (MITA) business processes <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/Medicaid-Information-Technology-Architecture-MITA.html> in order to seek an optimal balance in the use of open source and proprietary commercial off-the-shelf (COTS) software solutions, to further promote reuse, to expand the availability of open source solutions, and to encourage the use of shared services. Modular MMIS certification would allow the states to access the 75 percent FFP for maintenance and operations of the certified module(s) prior to having completed their total MMIS system replacement.

We are also seeking comment on the advantages and disadvantages of certifying MMIS modules, versus whole systems. We believe that certifying MMIS modules will remove the barrier to entry for many small IT solution vendors, increase the availability of certified modules

in the market for the states to choose from, and create an incentive for the states to take a modular approach both in IT architecture and in procurement strategy. We are soliciting comments on the opportunities that a modular MMIS certification process may create as well as the challenges that might arise, including defining a finite list of MMIS modules to ensure the appropriate combinations of certification criteria are established.

We also are seeking comments on a model where vendors propose modules for CMS certification prior to the state installation, unrelated to the question of the state's enhanced match rate for maintenance and operations. We would issue sub-regulatory guidance on how MMIS modules would be defined and how a modular certification process would be implemented.

With regard to all Medicaid IT, we are also seeking comments on how to achieve an effective and efficient balance when approving enhanced FFP for the acquisition of open source and proprietary COTS software and information technology solutions provided in the Medicaid information technology marketplace. 42 USC 1396b(a)(3)(A), which provides 90 percent FFP for the "design, development, or installation of such mechanized claims processing and information retrieval systems" could be interpreted to include use of COTS where that solution would be the more economical and efficient approach. CMS is proposing this approach, acknowledging that it would necessitate an exemption of COTS software (see proposed definition) from 45 CFR 95.617(b) to protect intellectual property. We are seeking comment on the inclusion of COTS software in DDI to further encourage the states to opt for COTS and Software-as-a-Service option, currently matched at 75 percent, rather than ground-up development approaches, which are duplicative and have a potentially much larger total cost over the span of the project. Commenters should take into consideration the costs and benefits to the Medicaid program of any proposed open source or proprietary COTS software solutions, as well as the technological benefits, including requirements for meeting the standards and conditions. Commenters are encouraged to recommend innovative ways to maximize CMS' and

the states' ability to share and reuse IT solutions while at the same time ensuring that there are appropriate incentives in the marketplace to provide the best quality and value in IT solutions and services to enhance operation of Medicaid programs nationwide.

Although we would like to encourage the use of COTS software solutions, we are proposing to clarify that states should only claim for the minimum necessary development costs to install and implement COTS. We are seeking to discourage the extra costs of unnecessary customization of COTS software solutions. Thus, we propose to explicitly provide in §433.112(c)(2) that development costs at the enhanced match rate would only include the minimum necessary to install the COTS software and ensure that other state systems coordinate with the COTS software solution.

Currently, regulations at 45 CFR 95.617(b) provide that the federal government shall have a royalty-free, nonexclusive and irrevocable license to reproduce, publish or otherwise use and to authorize others to use for federal government purposes, software, modifications and documentation that are developed with federal support. We are also seeking comment on requiring that states affirmatively document and make available such software to ensure that others may use it. Commenters should note the infrastructure and resources that would be needed at the state and federal levels to support such a requirement in an effective manner. Commenters should also consider whether public disclosure of some types of Medicaid software systems might compromise enforcement of Medicaid requirements by announcing review strategies.

Consistent with these requirements, and to encourage broader use and reuse of federally funded software, we are also proposing at §433.112(b)(20) and (21) that software developed with the 90 percent federal match be adequately documented so that it can be operated by contractors and other users, and that states consider strategies to minimize the costs and difficulty of operating the software using alternate hardware or operating systems.

We conduct periodic reviews of the states' MMIS and E&E system functionality and operations. Current regulations at §433.120 allow for reduction of FFP for system operations from 75 percent to 50 percent if the system fails to meet any or all of the standards and conditions. We are proposing to allow for the FFP reduction to be tailored where appropriate to specific operational expenditures related to the subpar system component rather than only being able to apply it across all operational expenditures. For example, we might reduce the FFP for operational expenditures for a particular sub-system, but not for the whole system. It is conceivable that the FFP reduction could be applied to an increasing percentage of operational expenditures over time as the impact of the system non-compliance grows. We have an established escalation process that includes notice and state appeal rights. We are also proposing to revise current regulations that require the disallowance to be for a minimum of four quarters so that there is no defined timeframe. Furthermore, we propose to remove the restriction on the FFP reduction occurring at least four quarters after the system was initially approved. When providing comments, the states should refer to the definitions found in §433.111 as they are provided to assist in formulating ideas and suggestions.

C. Proposed Changes to 45 CFR Part 95-General Administration – Grant Programs, Subpart F

In the final rule titled “State Systems Advance Planning Document (APD) Process”, (75 FR 66319, October 28, 2010), §95.611 was modified to include an acquisition threshold for prior approval of the state costs at the regular matching rate but noted that equipment or services at the enhanced matching rate necessitated prior approval regardless of the cost. We propose to amend §95.611 to align all Medicaid IT requirements with existing policy for MMIS regarding prior approvals, such that what is currently acceptable for regular match would be acceptable for enhanced match as well. We propose that if there is already an approved APD, prior approval will be required in order for the state to release acquisition solicitation documents or execute contracts when the contract is anticipated to or will exceed \$500,000. For all Medicaid IT

acquisition documents, an exemption from prior federal approval shall be assumed in the approval of an APD provided that: The acquisition summary provides sufficient detail to base an exemption request; the acquisition does not deviate from the terms of the exemption; and, the acquisition is not the initial acquisition for a high risk activity, such as software application development. All acquisitions, must comply with the federal provisions contained in §95.610(c)(1)(viii) and, (c)(2)(vi) or, submit an Acquisition Checklist for prior approval.

For noncompetitive acquisitions, including contract amendments, when the resulting contract is anticipated to exceed \$1,000,000, the state will be required to submit a sole source justification in addition to the acquisition document. The sole source justification can be provided as part of the APD.

If the state does not opt for an exemption or submittal of an Acquisition Checklist for the contract, prior to the execution, the state will be required to submit the contract when it is anticipated to exceed the following thresholds, unless specifically exempted by CMS: Software application development—\$6,000,000 or more (competitive) and \$1,000,000 or more (noncompetitive); Hardware and Commercial Off-the-Shelf (COTS) software—\$20,000,000 or more (competitive) and \$1,000,000 or more (noncompetitive); Operations and Software Maintenance acquisitions combined with hardware, COTS or software application development—the thresholds stated in §95.611(b)(1)(v)(A) and (B) apply.

For contract amendments within the scope of the base contract, unless specifically exempted by the Department, prior to execution of the contract amendment involving contract cost increases which cumulatively exceed 20 percent of the base contract cost.

In addition, we propose to amend §95.611(a)(2) by removing the reference to 45 CFR 1355.52. This paragraph provides prior approval requirements when states plan to acquire ADP equipment or services with FFP at an enhanced matching rate for the title IV-D, IV-E, and XIX programs, regardless of acquisition costs. We propose to delete the reference to the title IV-E

regulation, §1355.52 because enhanced funding for information systems supporting the title IV-E program expired in 1997.

IV. Collection of Information Requirements

This proposed rule does not contain any new or revised reporting, recordkeeping, or third-party disclosure requirements. Consequently, the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) and its implementing regulations (5 CFR part 1320) do not apply.

V. Response to Comments

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

VI. Regulatory Impact Analysis

A. Statement of Need

Experience with the Affordable Care Act implementation has shown that Medicaid eligibility policies and business processes benefit from continued updating and strengthening. System transformations are needed 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 the Health Insurance Marketplaces (“Marketplaces”); 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 our technology investments result in a high degree of interaction

and interoperability in order to maximize value and minimize burden and costs on providers and beneficiaries. Thus, we are committed to providing ongoing 90 percent FFP for design, development, and installation or 75 percent FFP for maintenance and operations of such systems. We have provided that states must commit to a set of standards and conditions in order 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 continue to utilize current technology development and deployment practices and produce reliable business outputs and outcomes.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), 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). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) (Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants,

user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

1. While it is difficult to predict state behavior, we believe all states will comply with the standards and conditions proposed in this regulation to receive the 90 percent FFP, and have assumed that for the purpose of these estimates.

In order to meet the requirements of the Affordable Care Act, states, the District of Columbia and the U.S. Territories must build new eligibility and enrollment (E&E) systems or modernize existing E&E systems. Most states have added new functionalities to interface with the Marketplaces and implemented new adaptability standards and conditions (such as incorporation of mandated eligibility categories).

There are currently 9 states that have relatively new E&E systems and do not need replacement of whole systems, but are instead making modular improvements and upgrades. We believe that most states have not had sufficient time to complete the total system replacement for both MAGI and non-MAGI eligibility functionality. We assume that an additional 28 states will quickly move forward to retire their legacy E&E systems with ongoing 90 percent FFP for design and development. Based on previous spending trends, we assume that those 9 states with new systems account for 15 percent of E&E spending and the 28 states that we anticipate retiring their legacy E&E systems account for 55 percent of E&E spending. We believe that by

eliminating 28 legacy systems, we reduce M&O costs by maintaining only one E&E system per state. Eventually, we assume that all states will replace their current E&E legacy system(s) using ongoing 90 percent FFP. To calculate the impact of the regulation, we assumed that new E&E systems on average would cost \$50 million over 3 years for each state (\$15 million federal costs at 90 percent FFP per year).

States will see a decrease in their net state share due to the enhanced federal match for eligibility systems and states will also realize benefits by putting in place the set of standards and conditions articulated in this proposed regulation.

The state net costs from FY 2016 through 2025 of implementing the proposed regulation on eligibility systems is approximately -\$1.1 billion. This includes approximately \$572 million in state costs for system design and development, offset by lower anticipated maintenance and operations costs. These costs represent only the state share.

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 by moving away from operating two or more systems, and replacing legacy systems.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities.

Since this rule would primarily affect states, which are not considered small entities, the Secretary has determined that this proposed rule would not be likely to have a significant economic impact on a substantial number of small entities. Therefore, we have not prepared a regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside

of a metropolitan statistical area and has fewer than 100 beds. This rule will not have a significant impact on hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately \$144 million. This rule does not mandate expenditures by the state governments, local governments, tribal governments, or the private sector. This rule provides that states can receive enhanced FFP if states ensure that the 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, meet with certain conditions including migrating to the MITA framework and meeting certain performance requirements. This is a voluntary activity and the rule imposes no substantial mandates on states.

2. The federal net costs from FY 2016 through 2025 of implementing the proposed regulation on eligibility systems is approximately \$3 billion. This includes approximately \$5.1 billion in increased federal costs for system design and development, offset by lower anticipated maintenance and operations costs. These costs represent only the federal share.

We see lower costs over the 10-year budget window due to the increased savings to operating one E&E system and eliminating legacy systems. The costs shift from mostly 90 percent FFP for design, development, and installation to 75 percent FFP for maintenance and operations over time.

Uncertainty exists because we are unsure of the rate of adoption for states to make the changes in this proposed rule.

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:

(a) Modular technology solutions: As states, or groups of states, would begin to develop “modular” technology solutions, these solutions could be used by others through a “plug and play” approach, in which pieces of a new MMIS would 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.

(b) Increased use of industry standards and open source technologies: While HIPAA administrative transaction standards have existed for 8 to 10 years, use of more specific industry standards to build new systems would allow such systems to exchange information seamlessly. We also believe that more open source technology would 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.

(c) Maintenance and operations: As states continue to implement changes, the maintenance and 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.

(d) 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 being compelled to

rethink and streamline processes as a result of greater reliance on technology.

There are uncertainties regarding our assumptions, including state behavior, and the associated cost estimates with respect to states implementing new systems. However, we have based our assumptions on data on states' previous behavior, spending and advance planning documents over the last 4 years. 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 provide for efficient systems that in the end would provide for more efficient and effective administration of the state plan.

D. Alternatives Considered

We considered as an alternative to our proposed rule to not continue to provide enhanced match for state eligibility systems builds after December 2015, and to not update federal standards and conditions for Medicaid IT development. We also considered an extension for a 2 or 3 year timeline but deduced that it was both insufficient for states to effectively transition out of their legacy systems and to complete human services integration in the new shared eligibility system. Furthermore, this assumes that all significant policy changes that trigger the need for IT updates were limited to those in the Affordable Care Act, however systems reforms are an ongoing facet of eligibility policy with an accompanying ongoing financial burden. A limited extension would also ignore that states that already modernized and did not replace their systems starting in 2011 will eventually need to do so in order to maintain system integrity and modernity sometime after a two or three year extension. Absent an ongoing extension, states would receive the traditional 50 percent FFP for reasonable administrative expenditures for designing, developing, installing, or enhancing Medicaid eligibility determination systems. Similarly, states would receive 50 percent FFP for expenditures associated with the maintenance and operation of such systems. However, states would have to continue to meet the requirements of federal legislation. Since the Affordable Care Act significantly alters Medicaid eligibility, we believe

that treating eligibility and enrollment systems as an integral part of mechanized claims processing system and information retrieval systems is consistent with the federal statute. This would have the effect of continuing the higher federal matching rate, which would provide states additional resources to meet this challenge. In addition, the federal guidance in the form of clearer federal standards and conditions would facilitate the design, development, implementation, and operation of IT and systems projects that fully support the Medicaid program, including the new responsibilities under the Affordable Care Act. Supporting the transformation of Medicaid eligibility and enrollment systems through these enhanced funding and clearer federal guidelines will also reduce duplication of systems and overall system costs.

E. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement. We have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this rule. Tables 1 through 5 provides our best estimate of the net costs as a result of the changes presented in this rule.

TABLE 1: FEDERAL NET COSTS

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$million/year)	444.3	2016	7%	2016 - 2025
	363.6	2016	3%	2016 - 2025

TABLE 2: FEDERAL NET COSTS BY FISCAL YEAR
(in Millions)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016-2025
E&E Systems-DDI	1,788	2,192	333	277	184	143	89	47	44	44	5,141
E&E Systems-M&O	(19)	(19)	(95)	(120)	(165)	(298)	(325)	(344)	(360)	(367)	(2112)
Total	1,769	2,173	238	157	19	(155)	(236)	(298)	(315)	(323)	3029

* Numbers in parentheses represent savings to the federal government.

TABLE 3: STATE NET COSTS

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$million/year)	-81.2	2016	7%	2016 - 2025
	-99.1	2016	3%	2016 - 2025

TABLE 4: STATE NET COSTS BY FISCAL YEAR (in Millions)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016-2025
E&E Systems-DDI	199	244	37	31	20	16	10	5	5	5	572
E&E Systems-M&O	(19)	(19)	(95)	(120)	(165)	(213)	(240)	(263)	(280)	(286)	(1700)
Total	180	225	(58)	(89)	(145)	(197)	(230)	(258)	(275)	(281)	(1128)

* Numbers in parentheses represent savings to State Governments.

**Table 5. ESTIMATED NET PRESENT VALUE OF FEDERAL COSTS, FY 2016-2025
(in millions of dollars)**

	Discount Rate	
	7%	3%
Federal Costs NPV	\$3,120.6	\$3,101.8
State Costs NPV	-\$570.7	-\$845.5

F. Conclusion

We considered a number of ways in which application of the standards and conditions, including increased use of MITA, could result in savings. We see increased investments in DDI somewhat offset by lower costs over the 10-year budget window due to the increased savings to operating one E&E system and eliminating legacy systems. The costs shift from mostly 90 percent FFP for design, development, and installation to 75 percent FFP for maintenance and operations over time.

The federal net costs from FY 2016 through 2025 of implementing the proposed regulation on eligibility systems is approximately \$3 billion. This includes approximately \$5.1 billion in increased federal costs for system design and development, offset by lower anticipated maintenance and operations costs. The state net costs from FY 2016 through 2025 of implementing the proposed regulation on eligibility systems is approximately -\$1.1 billion. This includes approximately \$572 million in state costs for system design and development, offset by lower anticipated maintenance and operations costs.

There are uncertainties regarding our assumptions, including state behavior, and the associated cost estimates with respect to states implementing new systems. However, we have based our assumptions on data on states' previous behavior, spending and advance planning documents over the last 4 years. 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 would provide for efficient systems that in the end would provide

for more efficient and effective administration of the state plan.

The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis. The reason to refer to other portions of the preamble is that they include sections, such as the statutory authority and purpose that are required but are not normally included in the impact analysis section.

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

List of Subjects**42 CFR Part 433**

Administrative practice and procedure, Child support claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

45 CFR Part 95

Claims, Computer technology, Grant programs-health, Grant programs-social programs, Reporting and recordkeeping requirements, Social security.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 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: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

§433.110 [Amended]

2. In §433.110--

a. Amend paragraph (a)(1) by removing the reference “45 CFR part 74” and adding in its place “45 CFR part 92.”

b. Remove paragraphs (a)(2)(ii) and (iii).

c. Remove and reserve paragraph (b).

3. Section 433.111 is amended by revising paragraph (b) and adding paragraphs (d) through (h) to read as follows:

§433.111 Definitions.

* * * * *

(b) “Mechanized claims processing and information retrieval system”, or “system” means the system of software and hardware used to process claims for medical assistance and to retrieve and produce service utilization and management information required by the Medicaid single state agency and Federal government for program administration and audit purposes.

(1) The system consists of--

(i) Required subsystems specified by the Secretary.

(ii) Required changes to the system or required subsystem that are specified by the Secretary.

(iii) Approved enhancements to the system or subsystem.

(2) A “Mechanized claims processing and information retrieval system” may include

(i) An eligibility and enrollment system, or “E&E system”, used to process initial claims (applications) from Medicaid or CHIP applicants and beneficiaries for eligibility for enrollment in the Medicaid or CHIP programs, as well as change in circumstance updates and renewals; and/or

(ii) A claims system, or MMIS, used to process claims for Medicaid payment from providers of medical care and services furnished to beneficiaries under the medical assistance program.

* * * * *

(d) “Open source” means software that can be used freely, changed, and shared (in modified or unmodified form) by anyone. Open source software is distributed under Open Source Initiative-approved licenses that comply with an open source framework that allows for free redistribution, provision of the source code, allowance for modifications and derived works, free and open distribution of licenses without restrictions and licenses that are technology-neutral.

(e) “Proprietary” means closed source software licensed under exclusive legal right of the copyright holder with the intent that the licensee is given the right to use the software only under certain conditions, and restricted from other uses, such as modification, sharing, studying, redistribution, or reverse engineering.

(f) “Shared Services” means the provision of a service by one part of an organization or group where that service had previously been found in more than one part of the organization or group. Thus the funding and resourcing of the service is shared and the providing department effectively becomes an internal service provider.

(g) “MMIS Module” refers to a group of MMIS business processes that can be implemented through a collection of IT functionality.

(h) “Commercial Off the Shelf (COTS) software” refers to specialized software designed for specific applications that is available for sale or lease to other users in the commercial marketplace, and that can be used with little or no modification. COTS software does not include software developed specifically for public assistance programs.

4. Section 433.112 is amended by revising paragraphs (b) introductory text, (b)(12), (b)(16), and (c); and, adding paragraphs (b)(17) through (b)(22) to read as follows:

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

* * * * *

(b) CMS will approve the E&E or claims system described in an APD if certain conditions are met. The conditions that a system, whether a claims or E&E system, must meet are:

* * * * *

(12) The agency ensures alignment with, and incorporation of, industry standards adopted by the Office of the National Coordinator for Health IT in accordance with 45 CFR part 170, subpart B: 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.

* * * * *

(16) The system supports seamless coordination and integration with the Marketplace, the Federal Data Services Hub, and allows interoperability with health information exchanges, public health agencies, human services programs, and community organizations providing outreach and enrollment assistance services as applicable.

(17) For eligibility and enrollment systems, the State must have delivered acceptable MAGI-based system functionality, demonstrated by performance testing and results based on critical success factors, with limited mitigations and workarounds.

(18) The State must submit plans that contain strategies for reducing the operational consequences of failure to meet applicable requirements for all major milestones and functionality.

(19) The agency, in writing through the APD, must identify key personnel by type and time commitment assigned to each project.

(20) Systems and MMIS modules developed, installed or improved with 90 percent match must include documentation of components and procedures such that the systems could be operated by a variety of contractors or other users.

(21) For software systems and MMIS modules developed, installed or improved with 90 percent match, the State must consider strategies to minimize the costs and difficulty of operating the software on alternate hardware or operating systems.

(22) Other conditions as required by the Secretary.

(c) (1) FFP is available at 90 percent of a state's expenditures for the design, development, installation or enhancement of an eligibility and enrollment system that meets the requirements of this subpart and only for costs incurred for goods and services provided on or after April 19, 2011.

(2) Design, development, installation or enhancement costs include costs to procure commercial off-the-shelf (COTS) software, but should only include the minimum necessary costs to analyze the suitability of COTS software, install and integrate the COTS software, and modify non-COTS software to ensure coordination of operations. The nature and extent of such costs must be expressly described in the approved APD.

5. Section 433.116 is amended by revising paragraphs (b) and (c) to read as follows:

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

* * * * *

(b) CMS will approve enhanced FFP for system operations if the conditions specified in paragraphs (c) through (i) of this section are met.

(c) The conditions of §433.112(b)(1) through (22) must be met at the time of approval.

* * * * *

6. Section 433.119 is amended by revising paragraph (a)(1) to read as follows:

§433.119 Conditions for reapproval; notice of decision

(a) * * *

(1) The system meets the requirements of §433.112(b)(1), (3), (4), and (7) through (22).

* * * * *

7. Section 433.120 is revised to read as follows:

§433.120 Procedures for reduction of FFP after reapproval review.

(a) If CMS determines after the reapproval review that the system no longer meets the conditions for reapproval in §433.119, CMS will reduce FFP for certain expenditures for system operations.

(b) CMS will reduce FFP from 75 percent to 50 percent for expenditures related to the operations of non-compliant functionality or system components.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 95 as set forth below:

PART 95--GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE, MEDICAL ASSISTANCE AND STATE CHILDREN'S HEALTH INSURANCE PROGRAMS)

8. The authority citation for part 95 continues to read as follows:

Authority: 5 U.S.C 301, 42 U.S.C. 622(b), 629b(a), 652(a), 652(d), 654A, 671(a), 1302, and 1396a(a).

9. Section 95.611 is amended by revising paragraph (a)(2) to read as follows:

§95.611 Prior approval conditions.

(a) * * *

(2) A State shall obtain prior approval from the Department which is reflected in a record, as specified in paragraph (b) of this section, when the State plans to acquire ADP equipment or services with proposed FFP at the enhanced matching rate subject to one of the following:

(i) If authorized by 45 CFR 205.35 and 45 CFR part 307, regardless of the acquisition cost.

(ii) If authorized by 42 CFR part 433, subpart C, if the contract is anticipated to or will exceed \$500,000.

* * * * *

Dated: March 11, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: March 27, 2015.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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