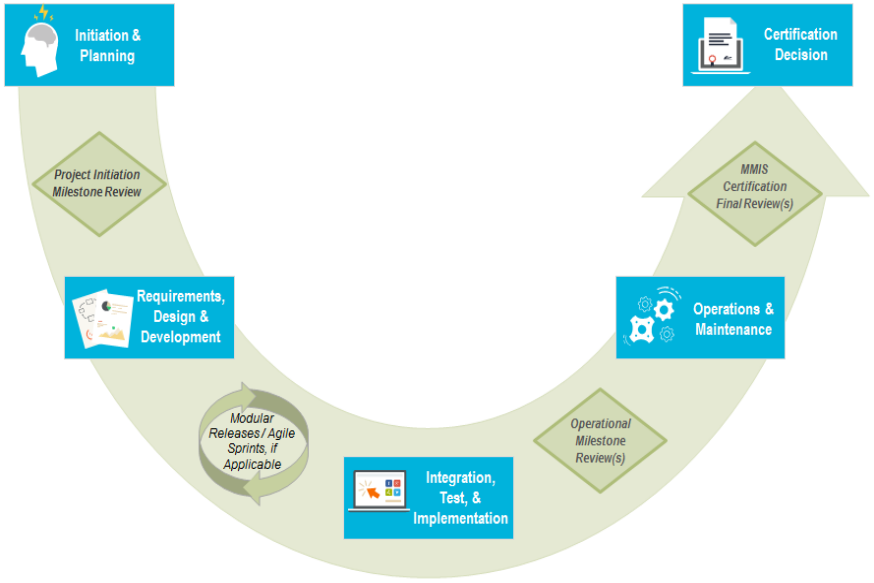
MEDICAID ENTERPRISE CERTIFICATION LIFE CYCLE

August 2018



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1 MMIS Certification Overview

1.1 Introduction

The Medicaid Enterprise Certification Toolkit ("toolkit") was developed by the Centers for Medicare & Medicaid Services (CMS) Center for Medicaid & Children's Health Insurance Program Services (CMCS) to respond to the many changes that have transformed the Medicaid Management Information System (MMIS). This toolkit provides a revised approach to Medicaid enterprise certifications to assist states as they work to modernize and improve MMIS.

The purpose of the toolkit is to provide a consistent, detailed process to certify an MMIS and to help states prepare for the federally required certification review of a state's MMIS. Use of the toolkit will help ensure that the new MMIS meets all federal requirements and satisfies the objectives described in the state's Advanced Planning Document (APD).

While the MMIS certification process formerly focused on the final, onsite certification visit at the end of a multi-year project, the certification process described in this toolkit is designed to assist states at every stage of the development process. The new Medicaid Enterprise Certification Life Cycle (MECL) works with the various approaches states may use in MMIS development—modular, agile, waterfall, etc.

The standards and conditions for Medicaid information technology (IT) require that states use a modular approach to systems development. In the final rule 80 FR 75817, CMS has defined an MMIS module as "a group of MMIS business processes that can be implemented through a collection of IT functionality." The new MECL supports modular development. The Federal Funds Participation (FFP) process (75 CFR 66319) allows funding for MMIS in modular increments, and CMS does certify modules.

CMS staff will use the material in this document as a standard for review that supersedes all previous certification protocol documents. State personnel and their consultants and contractors working on systems that are subject to CMS review, approval, and/or certification should also use the toolkit to plan their work.

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This document is maintained on Medicaid.gov.

1.2 Toolkit Organization

The Medicaid Enteprise Certification Toolkit (MECT) contains the following:

- A welcome document with toolkit release notes
- This Medicaid Enterprise Certification Life Cycle guidance document
- A separate certification life cycle workflow diagram with At-a-Glance sheets
- Medicaid Certification MMIS Checklists
- Independent verification and validation (IV&V) standard Request for Proposal (RFP)/contract language

- An MMIS IV&V Progress Report Template
- A Project Partnership Understanding (PPU) template
- A list of artifacts required for each type of review
- Uniform RFP Guide
- A MITA self-assessment scorecard
- An MMIS Concept of Operations (ConOps) template
- A mapping of the 2007 criteria to the current checklists
- A certification request letter template
- A map of MITA business areas to the checklist criteria
- A guide for preparing for a milestone review

Section 1 of this guidance document, MMIS Certification Overview, introduces MMIS Certification and how it addresses the diversity of development approaches taken by states, such as waterfall and agile methodologies, modular architectures, outsourcing of Medicaid services, and reuse of other states' MMIS components.

Section 2, Medicaid Enterprise Certification Roles, explains the entities involved in the life cycle and their responsibilities. Section 3, Medicaid Enterprise Certification Life Cycle, describes the process and milestone reviews by which CMS certifies a state's MMIS. Section 4, Medicaid Enterprise Certification Checklists, explains the CMS checklists used during certification milestone reviews. Section 5, Certification Milestone Reviews, explains the milestone review process and how to prepare. Section six provides reference materials. The toolkit appendices contain tools, templates, and checklists.

1.3 A Flexible Medicaid Enterprise Certification Life Cycle

The new certification process contains four life cycle phases and three types of certification milestone reviews. Figure 1 depicts these at a high level. Section 3 provides a detailed life cycle process workflow and an in-depth description of each process activity.

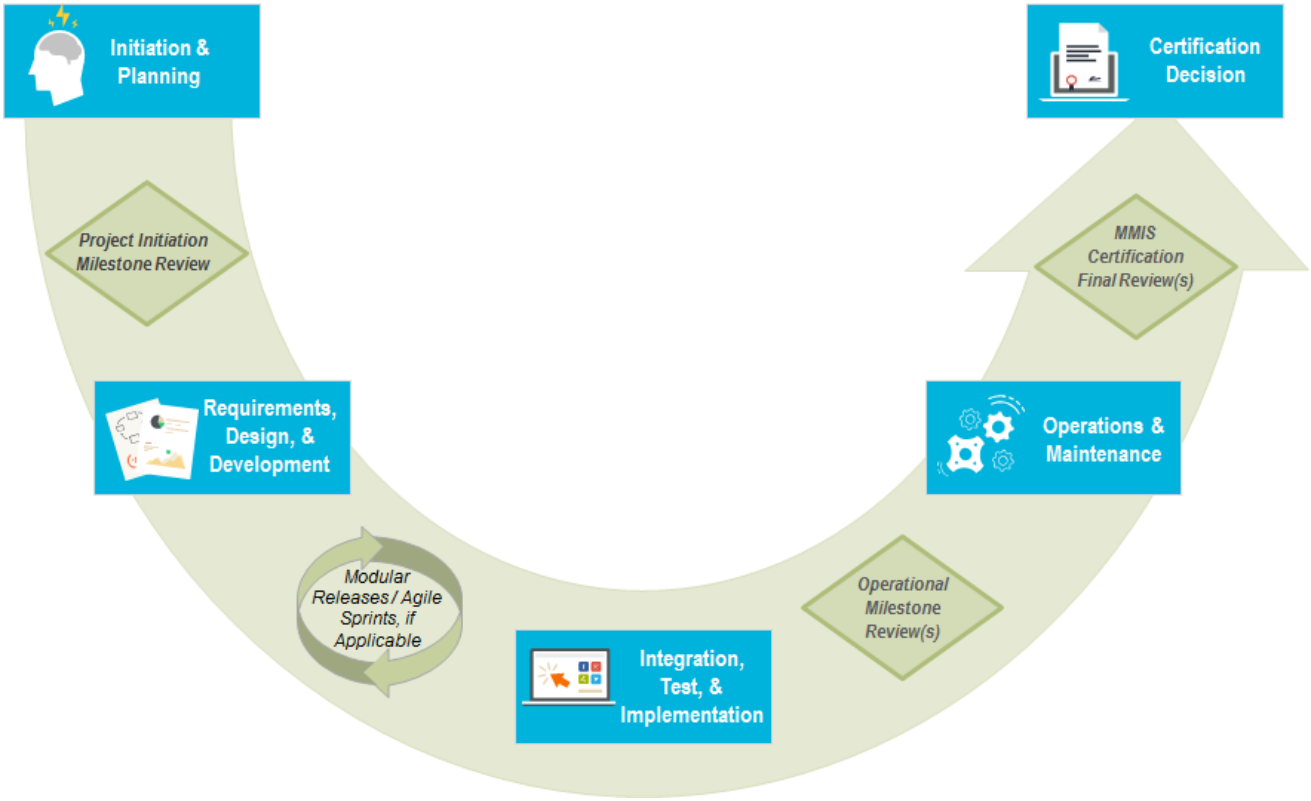

Figure 1. Medicaid Enterprise Certification Life Cycle Phases and Milestone Reviews

The MECL accommodates various approaches that states employ to update or upgrade their MMIS systems. The flexibility is manifest in four characteristics:

- MECL fits with a state's own system development life cycle (SDLC), whether that SDLC is agile-based, waterfall-based, or a hybrid of the two (see Figure 2 for two state examples).
- MECL accounts for states that choose to outsource some or all Medicaid functions.
- MECL can be used to certify and obtain FFP for MMIS modules (state developed, commercial off-the-shelf [COTS], or reuse modules), even when the modules are developed and deployed at different times.
- MECL allows CMS and the state to schedule each review to fit within the state SDLC schedule (see Section 1.4).

1.4 States' System Development Life Cycles

SDLC refers to the phased approach the state and its contractors use in planning, creating, testing, deploying, and maintaining the MMIS. CMS designed its certification life cycle to fit with waterfall, agile, and hybrid system development methodologies.

CMS certification reviews should not interrupt state SDLC reviews. Certification reviews are planned for key transitions in development efforts and should be an extension of state SDLC practices. CMS is flexible in scheduling MMIS certification reviews, and the state and CMS must work together to set the timing of the certification milestone reviews to be consistent with the state's own SDLC.

CMS expects that the state will manage its own SDLC, including conducting SDLC gate reviews where "go / no go" decisions are made to move the MMIS through the state's SDLC phases. CMS certification reviews serve a different purpose than SDLC gate reviews. SDLC gate reviews focus on development progress, while CMS certification reviews monitor compliance with CMS MMIS requirements. CMS does not participate in state SDLC reviews.

To avoid confusion between the two types of reviews—state SDLC gate reviews and CMS certification reviews—this toolkit refers to CMS certification reviews as "milestone reviews."

The toolkit and the MECL do not show state-level SDLC steps or gate reviews performed by the state and its IV&V contractor. Rather, the MECL sits atop the state's SDLC. The state's project management plan needs to explain how the state's SDLC and certification fit together. Figure 2 shows two examples of how actual states' SDLCs—one using a waterfall SDLC and one using agile—are compatible with the MECL.

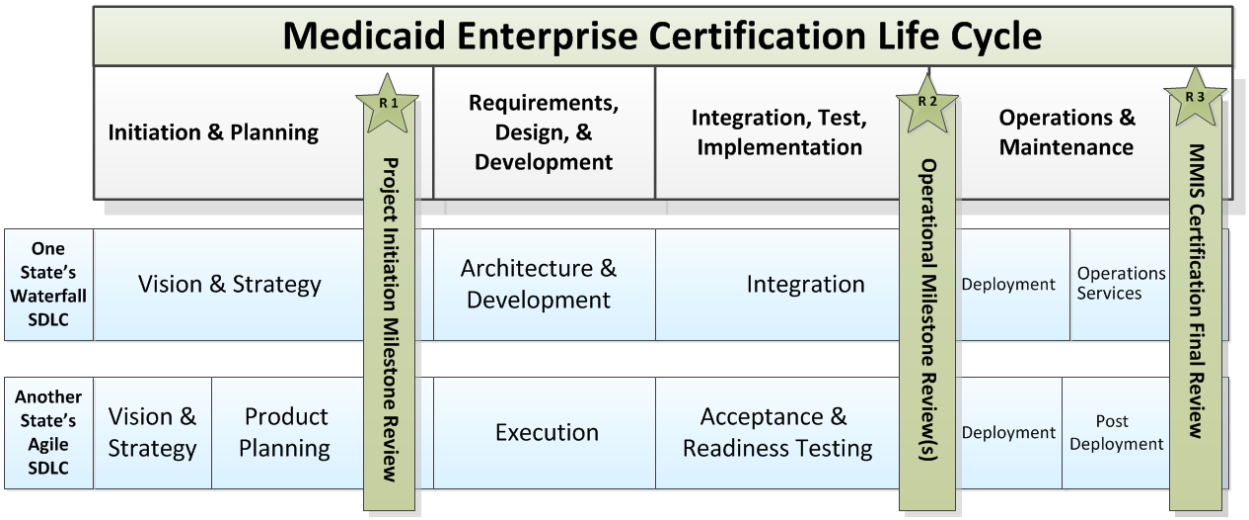

Figure 2. Examples of How MECL Fits atop States' SDLCs

1.5 Outsourcing Medicaid Services

The MECL is flexible to accommodate a state that contracts with a third party (such as an administrative-services organization) to perform Medicaid functions. The state has a choice of which certification checklist set to use for certification and can tailor the checklists to fit its outsourcing strategy. Tailoring of checklists is done in consultation with CMS, and CMS approves the tailored checklists. This consult happens in the very first step of the MECL so that together, the state and CMS can map the best path through the certification life cycle for the state.

1.6 Recommendations for Establishing a State Program Management Office

CMS has found that states with well-established project management offices (PMOs) are more likely to produce successful Medicaid systems. CMS expects a state to demonstrate project management planning activities during the planning and initiation phase of the MECL. The state manages the project plan, the budget, risk register, and risk plan; coordinates the work of various MMIS contractors; and ensures that the state's SDLC gate reviews are being conducted throughout the MMIS project. A PMO

can be helpful in serving as a central point for managing these activities. A PMO can also plan the logistics for MMIS certification milestone reviews, such as setting up teleconference lines, developing agendas for review sessions, reserving conference rooms, and facilitating reviews.

1.7 Recommendations for Having a Systems Integrator

A good systems integrator (SI) coordinates the merger of technical solutions, modules, and testing schedules, increasing the likelihood that the MMIS will securely achieve state goals and Medicaid requirements. The SI could be the state or a contractor.

As stated in State Medicaid Director (SMD) Letter #16-010, "states are encouraged to use an acquisition approach that limits the potential for conflict of interest an SI may have in choosing the modular solutions to be incorporated into the system. Such an approach could preclude the SI from bidding on functional modules, but still allow the SI to provide elements of the technical infrastructure such as the enterprise service bus, master data management, etc."

Please refer to the complete SMD letter on Medicaid.gov for additional details.

The SI typically:

- Ensures that all modules work together seamlessly and work securely with external systems.
- Ensures that overall security and privacy remain intact when various modules and components are integrated.
- Negotiates solutions to disagreements that may arise between development contractors who are developing or testing different MMIS components.
- Manages risks that may arise when schedule or technical slippage in one module(s) affects other modules.
- Cooperates with a state PMO and the IV&V contractor to give an accurate, honest reporting of the project status.

1.8 How the Certification Life Cycle Fits with the Advance Planning Document Process

A detailed description of how the APD process works is not within the scope of the MMIS toolkit. This section, however, briefly describes the intersection of APDs and the MECL.

An APD is a plan of action the state uses to request FFP for the costs of planning and implementing an MMIS. Specific types of APDs are used during the MECL:

- A planning advance planning document (PAPD), which is optional
- A planning advance planning document update (PAPDU)
- An implementation advance planning document (IAPD)
- An implementation advance planning document update (IAPDU)

The operational advance planning document (OAPD), used outside of the MECL, is for systems that have already been certified and are in operation.

APD preparation falls within the Planning and Initiation phase of the certification life cycle. The state sends its completed IAPD to the CMS Regional Office (RO) to begin the APD approval process. If needed, the CMS office has 60 days to send a letter with questions to the state. Once the state responds, the CMS RO has another 60 days to approve or disapprove the APD.

The MECL does not disrupt the APD process, but has been designed to mesh with it (see Section 3, Figure 3 for the MMIS certification life cycle workflow). Before the state submits its IAPD to the CMS RO, the IV&V contractor reviews the state planning documents, evaluating them against the MECL checklist criteria and critical success factors. The results are compiled into a progress report. The IV&V contractor sends a copy of this MMIS IV&V Progress Report to the state, to the CMS RO, and to the CMS certification email address (MES@cms.hhs.gov). This gives the state time to remedy gaps or issues before submitting the IAPD. The RO may also find the report helpful when preparing questions for the state.

The Project Initiation Milestone Review is held within 30 days of the IAPD submission. The milestone review does not alter the usual APD approval process; the APD approval process is still followed, with CMS and the state exchanging official letters within regulatory timeframes. The Project Initiation Milestone Review provides a forum for the state and CMS to discuss the state's plans, including the IAPD.

When an IAPD is approved, funds are typically released on a yearly basis, although the RO may decide to approve more or less than a year. This means that the RO usually reviews the IAPD annually to ensure that the budget in the original IAPD is still accurate before CMS releases the next round of funds. If enough time has passed that the original plans are out of date or plans have altered considerably (e.g., there is a contract protest, scope is changed, additional modules are included in a cohort, etc.), CMS may determine that another review is warranted.

Table 1 describes each APD and where it fits within the MECL.

Table 1. Types of APDs

APD Type	Name	Description	Overlap with Medicaid Enterprise Certification Life Cycle
PAPD	Planning Advance Planning Document	Used to request federal funds for planning the MMIS development.	At the beginning of the Planning and Initiation phase, before the state begins most planning. The PAPD is optional.
PAPDU	Planning Advance Planning Document Update	Used to update a previously approved PAPD.	If an update to a PAPD is necessary; needed PAPD updates usually occur during the Planning and Initiation phase. The RO reviews and approves, as usual.
IAPD	Implementation Advance Planning Document	Used to request federal funds for developing and implementing the MMIS. It should contain the overall development plan, including any staggered development and a breakout of costs associated with each module by federal fiscal year.	In the Planning and Initiation phase, the IAPD is submitted to the RO after the IV&V contractor has delivered its MMIS IV&V Progress Report and before the Project Initiation Milestone Review. The IAPD is a required document. Because funds are typically released on an annual basis, the RO reviews the IAPD each year to ensure the budget is still accurate before the next round of funding is released.
IAPDU	Implementation Advance Planning Document Update	Used to update a previously approved IAPD.	Updates to the IAPDU are most likely to occur during Design and Development or during the Integration, Test, and Implementation phase of the certification life cycle. IAPDUs are used during a long MMIS development project in which requirements and system designs have evolved. The RO must review and approve any IAPDU. If enough time has passed that the original plans are out of date or plans have altered considerably (e.g., there is a contract protest, scope is changed, additional modules are included in a cohort, etc.), CMS may determine that another review is warranted.
OAPD	Operations Advance Planning Document	Used to request funds for operating a certified MMIS.	The state submits OAPDs annually for certified systems that are already in operation. Therefore, OAPDs do not apply to the MECL; they are used after the system is certified.

1.9 Transitioning to the Certification Life Cycle

A state whose MMIS project began prior to the publication of MECT 2.0 (April 2016) needs to align its project schedule with the MECL in this toolkit. States must meet the legislative requirements embodied in the Medicaid Enterprise Certification Checklists, regardless of when the MMIS project began.

Legislation and CMS policies are expected to evolve over time. When legislation or policies change, CMS updates the Medicaid Enterprise Certification Checklists and makes them available to states.

A state encounters less difficulty adjusting to the new MECL when the MMIS project is at the beginning of its SDLC. To support the new certification process, states need to ensure that proper contracts are in place so that sufficient time and resources are available to conduct certification activities. The further along a state is in its SDLC, however, the more adjustment may be necessary to ensure compliance with the latest CMS certification requirements. A state that is very far along in its MMIS project may not be required to undergo every milestone review, with the exception of the final certification review. CMS works with states that are "in-flight" with their MMIS replacement efforts to ensure minimal disruption in project schedules and system development.

Several factors influence the complexity and amount of adjustment necessary to comply with changes in the new MMIS certification requirements. In the planning phase of the certification process, documents and artifacts are prepared to define the development approach and are used to estimate cost, schedule, and acquisition intentions. Most of this initial information is included in the PAPD and is updated and included in the IAPD. The system developers, state PMO, and IV&V contractors must continually monitor compliance with certification requirements to complete milestone reviews successfully.

State PMOs can meet with the RO at any time to discuss concerns about certification requirements. The more flexible or modular the system development approach, the less likely changes to meet certification requirements will incur excessive time and cost on the part of the state.

1.10 System Modularity and MMIS Certification

The standards and conditions for Medicaid IT require that states use a modular approach to systems development. The state may choose to stagger the development of its modules. The MECL supports such a staggered approach. In a case of staggered deployment, during the Initiation and Planning phase, the state explains its overall strategy in its project management plan, MITA documents, MMIS ConOps, and PAPD and IAPD documents.

CMS reviews these planning documents during the first certification milestone review (R1), the Project Initiation Milestone Review. Together, these documents should give CMS a clear understanding of the state's overall approach to modular development. The IAPD should include a breakout of anticipated costs by module and federal fiscal year.

The RO usually releases funds on a yearly basis (although the RO has discretion in this). Modules that are designed, developed, and deployed around the same time constitute a cohort of modules. States may send cohorts of modules through each of the milestone reviews independently of other module cohorts the state may be developing. A state may even send a single module through the certification life cycle. Once a module or cohort of modules has been certified, the state may begin collecting FFP for operations for those modules, even if the remaining MMIS modules are still under development.

If a state is planning only a few modules initially, it will send those modules through a Project Initiation Milestone Review before a development contract is awarded. If plans change (e.g., there is a contract protest, scope is altered, additional modules are added to a cohort, etc.), CMS may determine that another review is warranted. When the state plans additional modules, those too will undergo a Project Initiation Milestone Review. Therefore, a state using a staggered approach to development can have multiple Project Initiation Milestone Reviews, multiple Operational Milestone Reviews, and multiple MMIS Certification Final Reviews.

1.11 Reuse

CMS has established a Medicaid Enterprise System Reuse Repository, which is stored in the CMS Opportunity to Network and Engage (zONE) Community. States can collect, store, and share reusable artifacts for Medicaid programs of Health Information Technology, MMIS, and Eligibility and Enrollment. States should coordinate with their RO contact to gain access to the repository.

1.12 Critical Success Factors

The MECL incorporates critical success factors (CSFs) into the certification process. There are two types of CSFs—programmatic and functional. Programmatic CSFs identify activities the state PMO will need to perform in managing its MMIS project. They are found in the Programmatic Tab of the IV&V Progress Report Template, which the IV&V contractor fills out as part of the regular progress reports.

MMIS functional CSFs identify system capabilities required to support Medicaid agency functions and are included in the Medicaid Enterprise Certification checklists. Compliance with functional CSFs is tracked by the IV&V contractor using the checklists, which contain built-in mapping between the functional CSFs and certification criteria. CMS uses this mapping to determine a state's compliance with functional CSFs.

2 Medicaid Enterprise Certification Roles

Four main entities are involved in the MECL: the CMS Central Office (CO), the CMS RO, the state (including its PMO and contractors), and the IV&V contractor.

2.1 CMS Central Office

The CMS CO provides overall supervision for MMIS certifications. The CO attends pre-milestone review calls and certification milestone reviews, as needed. The CO approves all IV&V certification milestone review summary reports and issues MMIS / module(s) final certification decisions.

2.2 CMS Regional Office

The RO serves as a resource for the state throughout the certification life cycle and is the point of contact for the state regarding all matters concerning MMIS system development projects.

At the beginning of the life cycle, the RO reviews and approves draft IV&V RFPs and PAPDs and consults with the state once the MMIS ConOps is complete. As part of the CMS certification review team, the RO reviews the IV&V contractor's MMIS IV&V Progress Report, completes the CMS tab of the IV&V progress report and participates in the milestone reviews. The RO approves IAPDs and development contracts and stays abreast of the state's progress throughout the MMIS project. A state may consult with its RO at any time.

2.3 State

The state plans and manages the MMIS project. The state ensures that the IV&V contractor has access to evidence needed to prepare its MMIS IV&V Progress Report, tracks issues identified by the IV&V contractor, and manages them through resolution. The state plans MMIS certification milestone reviews in coordination with the CMS RO.

2.4 IV&V Contractor

The IV&V contractor represents the interests of CMS, and as such, provides an independent and unbiased perspective on the progress of MMIS development and the integrity and functionality of the system. CMS expects that the IV&V contractor will participate in state SDLC gate reviews and will inform CMS of significant risks or issues as the module(s) / system is planned, developed, and deployed. **To ensure independence, the IV&V contractor must not report to the same agency or department that oversees the Medicaid program**. (For example, the IV&V contract may be owned by the state's auditor's office or the state's department of treasury.) The IV&V contractor must not be the contractor performing software testing.

According to 45 CFR § 95.626 (b) and (c),

(b) Independent verification and validation efforts must be conducted by an entity that is independent from the state (unless the state receives an exception from the Department), and the entity selected must:

(1) Develop a project work plan. The plan must be provided directly to the Department at the same time it is given to the state.

(2) Review and make recommendations on both the management of the project, both state and vendor, and the technical aspects of the project. The IV&V provider must give the results of its analysis directly to the federal agencies that required the IV&V at the same time it reports to the state.

(3) Consult with all stakeholders and assess the user involvement and buy-in regarding system functionality and the system's ability to support program business needs.

(4) Conduct an analysis of past project performance sufficient to identify and make recommendations for improvement.

(5) Provide risk management assessment and capacity planning services.

(6) Develop performance metrics which allow tracking project completion against milestones set by the State.

(c) The acquisition document and contract for selecting the IV&V provider (or similar documents if IV&V services are provided by other state agencies) must include requirements regarding the experience and skills of the key personnel proposed for the IV&V analysis. The contract (or similar document if the IV&V services are provided by other state agencies) must specify by name the key personnel who actually will work on the project. The acquisition documents and contract for required IV&V services must be submitted to the Department for prior written approval.

CMS has developed standard IV&V language to be included in the state's IV&V RFP and contract (or contract modification, if a contract already exists) to ensure that the IV&V contract includes duties that CMS expects of the contractor. The standard language can be found in the toolkit appendices.

Throughout the certification life cycle, the IV&V contractor prepares the IV&V and programmatic tabs of the MMIS IV&V Progress Reports. For the report immediately preceding a milestone review, the contractor also completes the reviewer columns of the checklists. The IV&V contractor reviews project and technical progress against the state's baseline plans and against requirements in the Medicaid Enterprise Certification Checklists. The IV&V contractor delivers the MMIS IV&V Progress Reports, including draft reports, to CMS and to the state simultaneously.

The IV&V contractor should help the state ensure it is meeting certification requirements as part of normal business operations by offering advice and participating in state-level gate reviews. However, when it is time to start preparing for a milestone review (about six to eight weeks before the milestone review), independence must be maintained. Therefore, the IV&V contractor does not assist the state in generating checklist answers and evidence, nor does it store its draft adjudications where the state can access them. The guiding principle is that the state and CMS receive IV&V comments at the same time.

IV&V contracts entered after February 17, 2018 must comply with all IV&V requirements, per State Medicaid Director Letter #16-010 and regulation. RO analysts will verify with the states that the IV&V contracts are being modified where needed to meet the new requirements.

3 Medicaid Enterprise Certification Life Cycle

The MECL is composed of the following four phases:

- Initiation and Planning
- Requirements, Design, and Development
- Integration, Test, and Implementation
- Operations and Maintenance

Each phase has distinct activities that a state is expected to perform during MMIS certification. This chapter provides detailed explanations of each activity shown in the workflow diagram (Figure 3). An interactive version of the MECL is included in the toolkit as a separate document. That version also contains quick-reference At-a-Glance sheets for each activity.

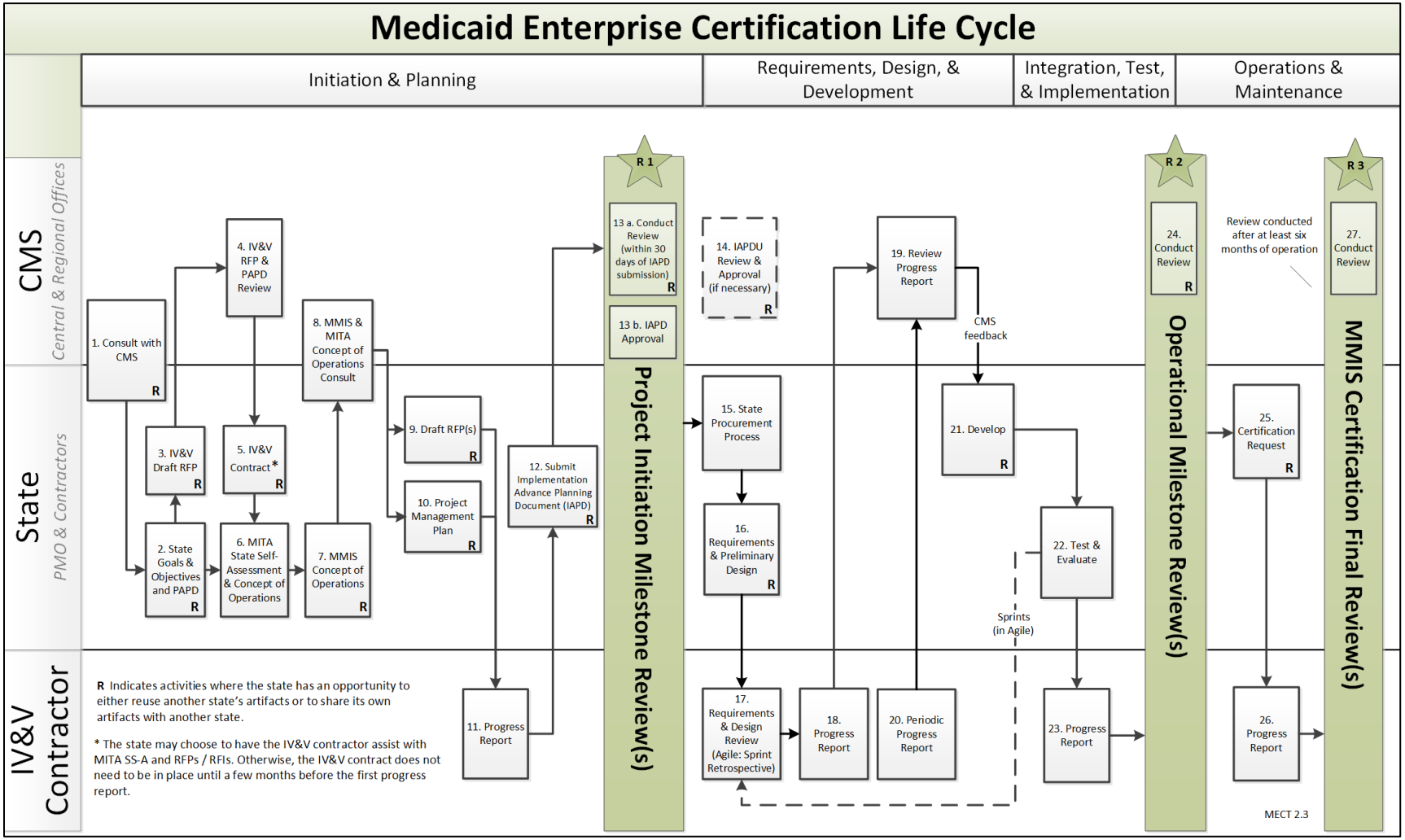

Figure 3. Medicaid Enterprise Certification Life Cycle

3.1 Initiation and Planning

Figure 4 shows the activities in the Initiation and Planning phase.

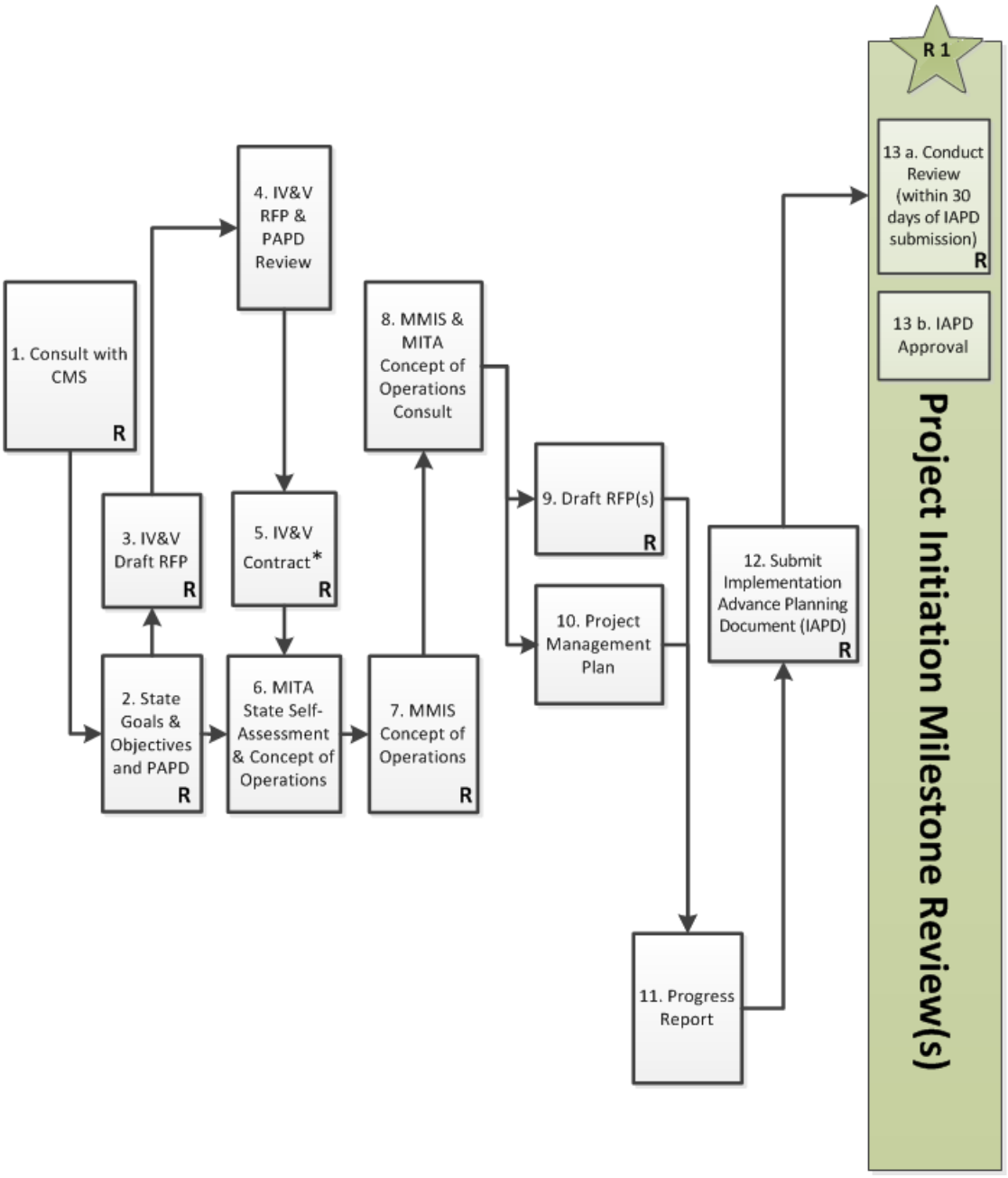

Figure 4. Initiation and Planning Phase

During the Initiation and Planning phase, the state performs the following actions:

- Consults with the CMS RO to explain its approach and asks questions about the life cycle
- Selects a certification checklist set for use throughout the certification life cycle

- Documents it goals and objectives for the new, upgraded, or replacement MMIS
- Submits a PAPD, if requesting planning funds from CMS
- Assesses itself against the MITA maturity model
- Contracts with an IV&V provider
- Prepares the MMIS ConOps (A courtesy template is provided in toolkit Appendix E.)
- Prepares an IAPD and draft RFP(s)
- Creates its project management plan, schedule, and risk register
- Cooperates with the IV&V contractor as the contractor prepares the MMIS IV&V Progress Report and the checklists review prior to the first milestone review
- Cooperates with the RO in its review and completion of the MMIS IV&V Progress Report
- Undergoes the first certification milestone review
- Is notified of whether the IAPD and RFP(s) have been approved by the CMS RO

3.1.1 Activity 1: Consult with CMS

Figure 5 shows the steps within the Consult with CMS activity. This activity includes:

- Opportunities for the CMS RO to understand the state's approach to MMIS enhancement / replacement
- Opportunities for the state to ask questions about the MECL at the onset of the project
- Agreement between the state and the RO on a preliminary "critical path" for the state's certification life cycle. This includes a high-level timeline for milestone reviews and frequency of MMIS IV&V Progress Reports that will fit with the state's project schedule.

In this activity, the CMS RO and the state agree to a frequency for the MMIS IV&V Progress Reports that the IV&V contractor will prepare throughout the project. MMIS IV&V Progress Reports must be submitted at least quarterly, but the state and CMS may deem it necessary to have more frequent reports. MMIS IV&V Progress Reports created in certification review preparation may be considered as one of the quarterly reports.

The MMIS Module Checklist Set is the default checklist set for certification. However, the state may use a customized set of checklist criteria (subject to RO approval) for unconventional releases or for funding requests for innovative MMIS approaches. If the state plans to have state-specific criteria in addition to those in the certification checklists, the state should talk to its RO as how best to incorporate those state-specific criteria into the checklists. Checklist sets are not to be switched in the middle of development. (If some situation warrants a change from the MMIS Module Checklist Set to the customized set, the state will need to discuss this with the RO.) Section 4 covers the checklists and how to use them.

The decisions made between the state and CMS are documented in the Project Partnership Understanding. Appendix H is a copy of the template. It can be updated whenever the CMS and the state find it necessary to alter plans. The state should send new or updated PPUs and related

correspondence to the RO and the CMS email box (MES@cms.hhs.gov), being sure to include "MMIS" in the subject line.

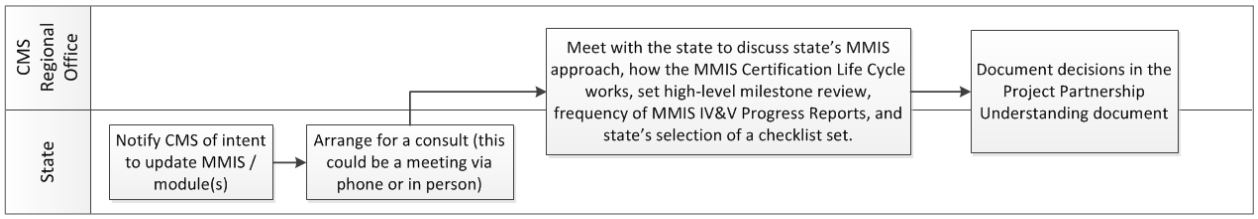

Figure 5. Activity 1: Consult with CMS

3.1.2 Activity 2: State Goals and Objectives and PAPD

Figure 6 shows the steps in Activity 2. The state agency considers its vision of the future and sets goals and objectives for the new MMIS. The state should use MITA business areas to guide its planning. The state submits a PAPD to the RO, if requesting FFP for MMIS planning. States are not required to submit a PAPD. The output of this activity is a documented set of state goals and objectives and a PAPD, if the state is using one. The state and RO follow the established APD processes during this activity. The details of the APD process are beyond the scope of the MECL.

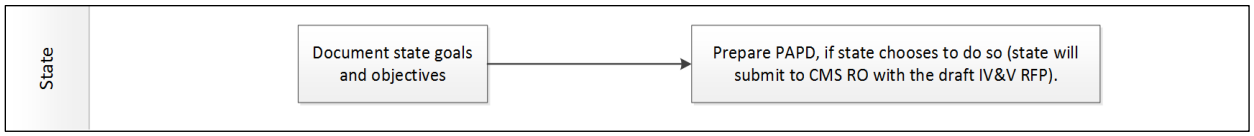

Figure 6. Activity 2: State Goals and Objectives & PAPD

3.1.3 Activity 3: IV&V Draft RFP

The state drafts an RFP for an IV&V contractor or drafts a modification to an existing contract, if necessary (Figure 7). The inputs to this activity are the state goals and objectives and the Medicaid Enterprise Certification Checklists; the output is a draft IV&V RFP.

CMS expects the state to include certain standard language in the RFP to ensure that the contractor:

- Is independent from the state agency that manages the MMIS project
- Does not perform software testing
- Reviews project management and technical designs (e.g. security, performance management, claims editing)
- Submits periodic MMIS IV&V Progress Reports (including drafts) to the CMS RO, the CMS email box, and the state simultaneously

Standard language for the state to copy into its IV&V draft RFP/contract can be found in Appendix C of the toolkit. The wording is to be used as written. The standard wording is not intended to provide exhaustive coverage of IV&V contract scope, but stipulates those activities that are the minimum required by CMS during planning, design, development, and implementation through certification. The state may add other duties. If the state is using an agile approach, the state is encouraged to add

language requiring the IV&V contractor to participate in sprint burn-downs. To maintain true independence, the IV&V contractor must not perform software testing of the system.

The state and CMS RO may need to discuss the frequency of MMIS IV&V Progress Reports prepared by the IV&V contractor. Reports should be frequent enough to give the RO a solid understanding of MMIS risks and progress, yet not so frequent as to add undue expense and burden on the state and on CMS. Reports must be submitted at least quarterly.

The standard RFP/contract language required by CMS does not cover activities that the state may require of the IV&V contractor during ongoing operations and maintenance (O&M). CMS, however, does expect the state to have an IV&V service provider for O&M. The state may choose to hire a different IV&V contractor for O&M or retain the one used during development. The IV&V role during O&M is outside the scope of this toolkit.

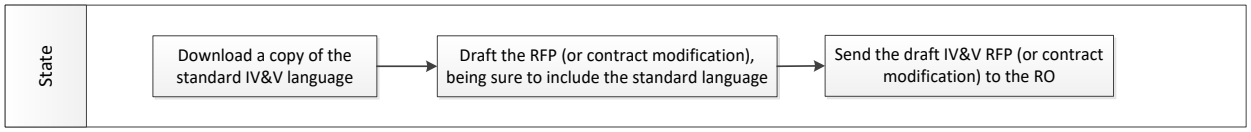

Figure 7. Activity 3: IV&V Draft RFP

3.1.4 Activity 4: IV&V RFP and PAPD Review

During Activity 4 (Figure 8), the RO will review the IV&V RFP to ensure that CMS's interests are represented by the contractor and that the scope of IV&V review is comprehensive. If the state is submitting a PAPD, it will send the draft IV&V RFP with the PAPD. The CMS RO will review both and provide feedback, if warranted.

The RO should check the frequency of MMIS IV&V Progress Reports required in the RFP. MMIS IV&V Progress Reports are needed before each milestone review and throughout the project, with a minimum of quarterly report submission. (A report prepared for a milestone review counts toward the quarterly report minimum.) MMIS IV&V Progress Reports should be frequent enough to give CMS a solid understanding of the risks and progress as the MMIS project proceeds, yet not so frequent as to add undue expense and burden on the state and on CMS. After the state makes any necessary corrections to the PAPD and the IV&V RFP, the RO will decide whether the IV&V RFP and the PAPD have been approved.

The standard IV&V RFP language and certification checklists are inputs to this activity. The outputs are RO decisions of approval or disapproval for the IV&V RFP and the PAPD.

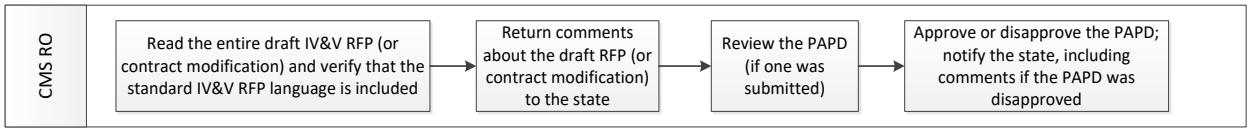

Figure 8. Activity 4: IV&V RFP and PAPD Review

3.1.5 Activity 5: IV&V Contract

The inputs for Activity 5 (Figure 9) are the state's acquisition policies and procedures, the certification checklists, and the IV&V RFP/contract standard language in toolkit Appendix C. The output of Activity 5 is a contract submitted to the RO for approval.

The state follows its procurement processes for issuing an IV&V contract, ensuring that the standard language is included in the contract. The state also must ensure that the contractor is qualified to perform reviews of business processes and IT service management processes and technical reviews of design, databases, applications, and security. The state sends the contract to the RO for approval.

Any changes to the IV&V contract that alter the scope of the contract must be reviewed and approved by the CMS RO. Once the state has contracted with an IV&V contractor, the state should conduct a kickoff meeting with the IV&V contractor to explain the state's goals, SDLC, module release plans, and the checklist set it selected.

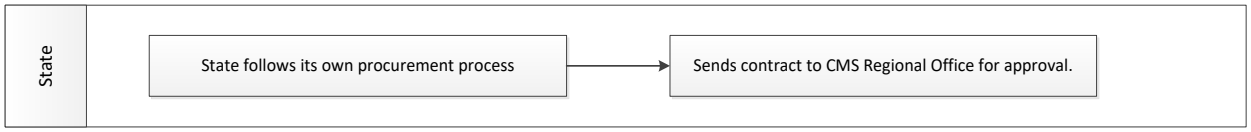

Figure 9. Activity 5: IV&V Contract

3.1.6 Activity 6: MITA State Self-Assessment

Per MITA 3.0, the state performs a MITA state self-assessment (MITA SS-A) and prepares its MITA ConOps. This is Activity 6 (Figure 10) in the MECL. The input for this activity is the latest MITA guidance, and the output is a set of MITA documents, particularly the MITA ConOps and the MITA SS-A. States may have their IV&V contractors perform the SS-A. CMS encourages states to use the eSS-A scorecard (Appendix F) for submitting the SS-A to CMS. The state is encouraged to consider reusing examples from other states and to share its artifacts with other states. The state may find it easier and more cost-effective to tailor elements of another state's SS-A than to start from scratch in preparing its own SS-A. States that use documents from other states can show that use as evidence of compliance with the leverage condition.

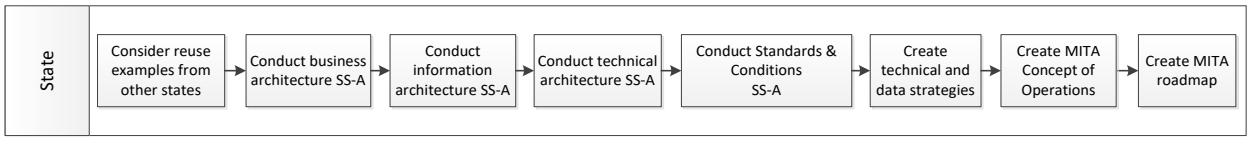

Figure 10. Activity 6: MITA State Self-Assessment

3.1.7 Activity 7: MMIS Concept of Operations

The state writes a technical MMIS ConOps in Activity 7 (Figure 11). The input for this activity is the state's technical concept for the MMIS solution. The output is an MMIS ConOps. The ConOps describes, at a high level, the technical solutions the state has selected and how those technical components will integrate internally and with external state and federal IT systems. The concept should explain how the state intends to apply the conditions of reuse and modularity. The state should be able to reuse much of

the ConOps language for its IAPD. The state may choose to use the MMIS ConOps template provided in Appendix E of the toolkit.

The state is encouraged to consider reusing examples from other states and to share its artifacts with other states. The state may find it easier and more cost-effective to tailor elements of another state's MMIS ConOps than to start from scratch in preparing its ConOps. States that use documents from other states can show that use as evidence of compliance with the leverage condition.

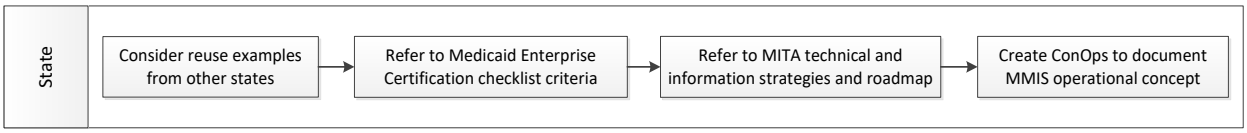

Figure 11. Activity 7: MMIS Concept of Operations

3.1.8 Activity 8: MITA and MMIS Certification Concept of Operations Consult

After the MMIS ConOps is developed, the state sends the document to the RO for review and consult. The CMS RO discusses the high-level design with the state to understand the scope of the work (and later, the funding request for it). CMS also identifies issues with the high-level operational design that may pose certification problems. Figure 12 shows the steps in this activity. The inputs to this activity are the state's MMIS ConOps and the MITA ConOps.

The MMIS ConOps consult is informal and usually uncomplicated. The state and RO decide how to conduct the consult—over the phone, through emails, in-person meeting, etc. The RO is welcome to use other CMS subject matter experts (SMEs) during the activity. The output is a revised MMIS ConOps and revised MITA ConOps, based on comments, if any, received from the RO.

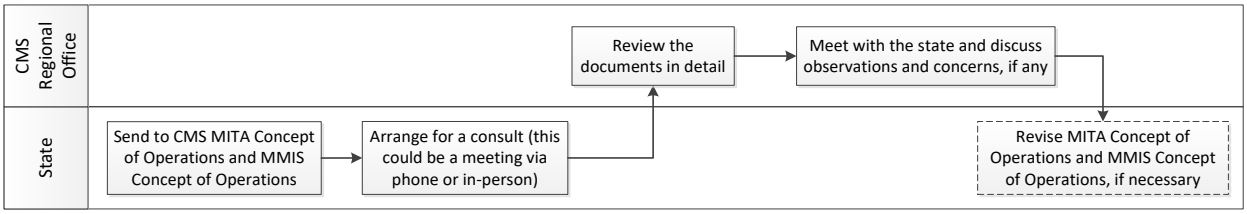

Figure 12. Activity 8: MITA and MMIS Concept of Operations Consult

3.1.9 Activity 9: Draft Request for Proposal

The state often contracts with one or more vendors to design, develop, test and install its MMIS. The state must ensure that MMIS requirements in the RFP map to its APD, its MITA roadmap, and the Medicaid Enterprise Certification Checklists. Figure 13 shows the steps in this activity. The inputs are the certification checklists, the MITA documents, and the MMIS ConOps; the output is one or more draft RFPs for system development.

CMS has discovered through experience that states that include certain provisions in their RFPs and contracts are more successful in system deployments. Wherever enforceable under state law, a state should include the following provisions:

- Defined goals and objectives

- Environment requirements (business, architecture, data), including reuse, interoperability, and modularity requirements
- Conditions tying compensation to meeting or exceeding defined goals (e.g., service level agreements)
- Reservation of right for the state to approve and/or remove subcontractors
- Requirement that contractors cooperate with other contractors (including the IV&V contractor) and facilitate progress

The state should also include language in the RFP and contract that requires contractors to abide by all the state's security and privacy policies.

According to 45 CFR Part 92, procurement that exceeds a certain threshold dollar amount needs to be approved by CMS. For MMIS, the draft RFP(s) are reviewed by the RO.

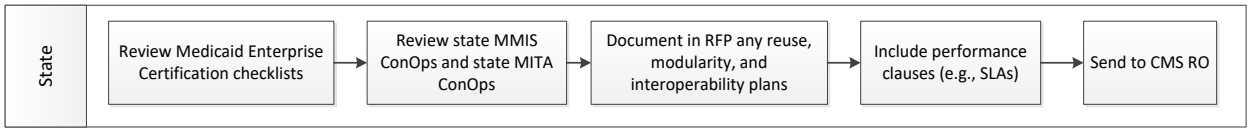

Figure 13. Activity 9: Draft Request for Proposal

3.1.10 Activity 10: Project Management Plan

The steps in Activity 10 are displayed in Figure 14. The inputs to the project management plan are the MITA and MMIS documentation developed to this point, and the outputs are a high-level milestone schedule, project management plan including budget, risk management plan, risk register, and SDLC.

If the state has not already established a PMO, the state could do so during this activity. The state performs the following actions:

- Writes or updates the project management plan
- Develops or updates the budget
- Develops the project schedule
- Documents the SDLC it will use to develop the MMIS and how the MECL fits atop that SDLC (see Figure 2 for examples)
- Creates a risk register (waterfall) or exception plan (agile)
- Ensures that all necessary artifacts are ready for the Project Initiation Milestone Review (see toolkit appendices for the list of artifacts)

The first version of the project schedule may only show high-level milestones broken out by quarter because, often, a project schedule is detailed only after a system's detailed requirements are determined. The schedule can contain more detail after the system requirements /user stories are defined.

The state is encouraged (not required) to consider examples of other states' documents. The state may find it easier and more cost-effective to tailor elements of another state's required documents than to

start from scratch. States that reuse documents from other states can show that use as evidence of compliance with the leverage condition.

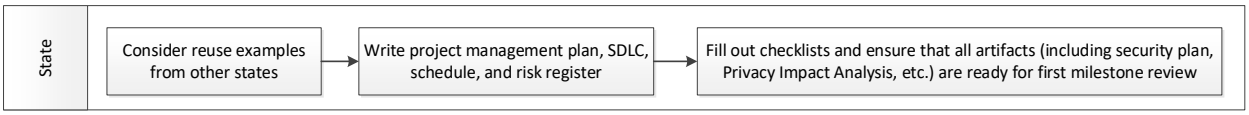

Figure 14. Activity 10: Project Management Plan

3.1.11 Activity 11: Progress Report

In preparation for the Project Initiation Milestone Review, the IV&V contractor prepares a MMIS IV&V Progress Report (Figure 15). The state fills out its portion of the checklists that apply to the modules undergoing the milestone review. The Technical Architecture (3), Information Architecture, and Standards and Conditions checklists must be used regardless of which module(s) is being reviewed. When the state completes its sections of its Medicaid Enterprise Certification Checklists, it stores the checklists and supporting evidence in its own repository.

The IV&V contractor then completes the reviewer sections of the checklists and completes the IV&V tabs of the MMIS IV&V Progress Report Template.[1] The completed checklists are appended to the report. Even if a state is using multiple development vendors, the IV&V contractor prepares only a single report that covers all modules undergoing review.

The IV&V contractor then submits the reports and checklists simultaneously to the state, to the CMS RO, and to the CMS certification email address (MES@cms.hhs.gov) being sure to include “MMIS” in the subject line, no later than two weeks prior to the milestone review. When the state receives the checklists from the IV&V contractor, it should save the IV&V-completed checklists in the state repository as new versions of the checklists. (The checklists should continue to be updated as new versions with subsequent progress reports.)

The IV&V contractor is not to send drafts of the report to the state unless it is also sending the same draft simultaneously to CMS. CMS uploads the completed checklists to its tracking database. The state may respond to issues identified in the MMIS IV&V Progress Report. CMS can insert comments in the CMS section of the report. CMS will review how the state is including security and privacy in the modules/system.

When preparing the MMIS IV&V Progress Report required before the Project Initiation Milestone Review, the IV&V contractor evaluates the following state documents for thoroughness, accuracy, and consistency:

- State goals and objectives
- MITA self-assessment / MITA roadmap

[1] It is recommended that the contractor use the MMIS IV&V Progress Report Template in Appendix D, as it contains all required information for this report. If the state or IV&V contractor desires to use a different format, it should discuss with CMS RO to ensure proper content and structure of the report.

- MITA ConOps
- MMIS ConOps
- Draft RFP(s)
- Privacy impact analysis
- State security policies and security plan
- Project management plan artifacts (budget, schedule, risk register/exception plan)

The MMIS IV&V Progress Report details what, if any, issues the state should address before CMS conducts the Project Initiation Milestone Review. The inputs to this activity are the certification checklists, supporting evidence, and documents, including project management artifacts, and the MMIS IV&V Progress Report Template. The outputs are an MMIS IV&V Progress Report and completed checklists, which are appended to the report. CMS reviews the MMIS IV&V Progress Report and the checklists, and completes the CMS section of the MMIS IV&V Progress Report.

If the contractor and state have identified particularly good examples of final versions of required documents, the state should consider sharing them with other states. Such documents need to be owned by the state and not contain sensitive or proprietary information. States that contribute documents to other states for reuse can show that contribution as evidence of compliance with the leverage condition.

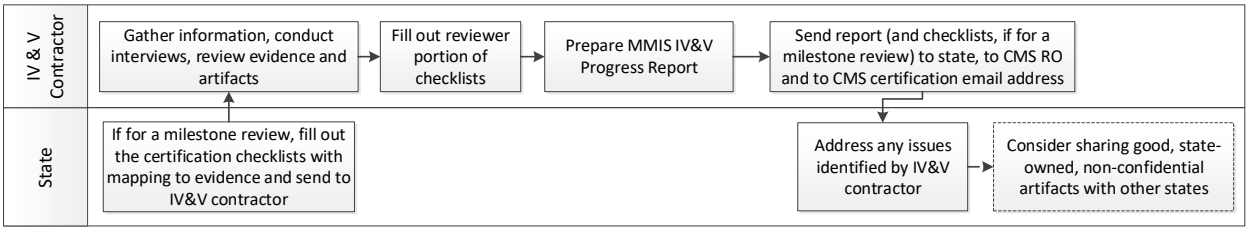

Figure 15. Activity 11: Progress Report

3.1.12 Activity 12: Submit Implementation Advance Planning Document

Activity 12 (Figure 16) represents IAPD submission. The inputs for IAPD submission are all the state's planning documents prepared to this point. The state follows the APD process specified in 45 CFR, Part 95.

The IAPD includes the following:

- Statement of need and objectives
- Requirements and alternatives analysis, including considering reuse consideration
- Project management plan
- Proposed project budget and cost distribution
- Statement of security/interface and disaster recovery requirements
- Assurances
- Compliance with standards and conditions for Medicaid IT

- MITA SS-A, as an attachment

The state sends the IAPD to the RO; the IAPD is the output of this activity. Submission of the IAPD starts the APD approval process, which can last as long as 120 days, but is usually concluded in much less time. The RO evaluates the business case presented in the IAPD, formally submits questions to the state, considers the answers received from the state, and issues a decision on approval.

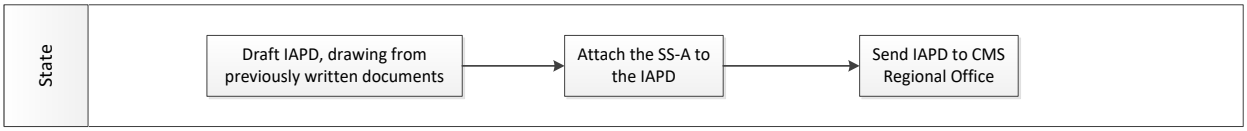

Figure 16. Activity 12: Submit IAPD

3.1.13 Activities 13 a and b: Project Initiation Milestone Review and IAPD Approval

The activity after the state addresses any issues identified in the MMIS IV&V Progress Report is the Project Initiation Milestone Review (Figure 17). The Project Initiation Milestone Review (R1) ensures that the state has documented goals and objectives, a solid MITA SS-A and roadmap, and a technical ConOps. In this review, CMS evaluates the state's business case, project management plan, and RFPs.

This first milestone review must be conducted within 30 days of the IAPD submission. If a state is planning only a few modules initially, it will send those modules through a Project Initiation Milestone Review. Subsequent cohorts of modules will have their own Project Initiation Milestone Reviews. If enough time has passed that the original plans are out of date or plans have altered considerably (e.g., there is a contract protest, scope is changed, additional modules are included in a cohort, etc.), CMS may determine that another review is warranted.

The entry criteria for the Project Initiation Milestone Review are that the state has made all required artifacts and evidence available to CMS and that the IV&V contractor has sent the progress report and completed checklists to the state, to the RO, and to the CMS certification email box (MES@cms.hhs.gov) with "MMIS" in the subject line, no later than two weeks prior to the milestone review. See Appendix L_Milestone Review Preparation Guide for details about the timeline and logistics of milestone reviews.

The inputs to the Project Initiation Milestone Review are the MMIS IV&V Progress Report, the IAPD, the draft RFP, and all other planning documents. (See toolkit Appendix B for a list of artifacts required for each milestone review.) CMS may choose to send test cases and scenarios to the state to be included as part of the milestone review. In such instances, the state would be expected to show how the module or SMA would process the test cases or scenarios. If CMS makes test cases part of the review, the RO analyst will provide further guidance to the state.

The outputs of the Project Initiation Milestone Review are an IAPD decision from the RO, an RFP decision from the RO, and the CMS portion of the MMIS IV&V Progress Report, including comments, if any, about the state's status.

States should talk to their RO analysts to gain access to the CMS repository for uploading milestone review evidence. Using the CMS repository is the preferred method of submitting materials, however, the state may also grant CMS direct access to the state's evidence repository. If that is not possible, the state may make other secure arrangements with CMS, such as using encrypted File Transfer Protocol

(FTP). It is critical to follow all Health Insurance Portability and Accountability Act (HIPAA) regulations when submitting evidence that contains personal health information (PHI) and personally identifiable information (PII). Using an unencrypted thumb drive or other forms of physical storage through shipping services, for example, would not be acceptable. If a state has questions, it should contact its RO.

The Project Initiation Milestone Review consists of CMS reviewing the progress report and checklists and supplying comments in the CMS section of the report. The CMS review team may or may not include comments in the checklists. The milestone review is concluded when CMS sends copies of the completed progress report to the state and to the IV&V contractor; no site visit is required.

There may be cases where CMS considers a more formal review to be appropriate and may schedule a teleconference or site visit for R1. In such cases, the RO will notify the state and will work with the state to schedule the review and arrange logistics.

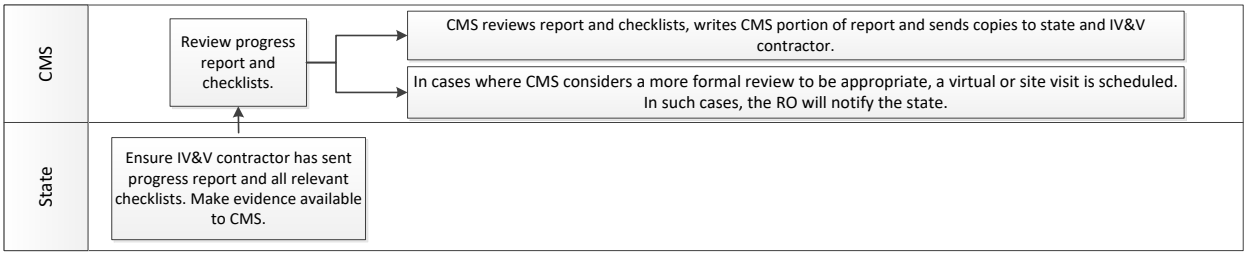

Figure 17. Activity 13a: Project Initiation Milestone Review

From the time the state submits its IAPD (Activity 12) through IAPD approval, the state and CMS RO follow the APD process (Figure 18). (A full description of the APD process is outside the scope of this toolkit.) IAPD approval is shown in the MECL to illustrate how the APD process is conducted concurrently with the MECL milestone review process. The state may proceed with the other certification workflow activities so long as the IAPD is approved. It does not need to wait until CMS updates the MMIS IV&V Progress Report.

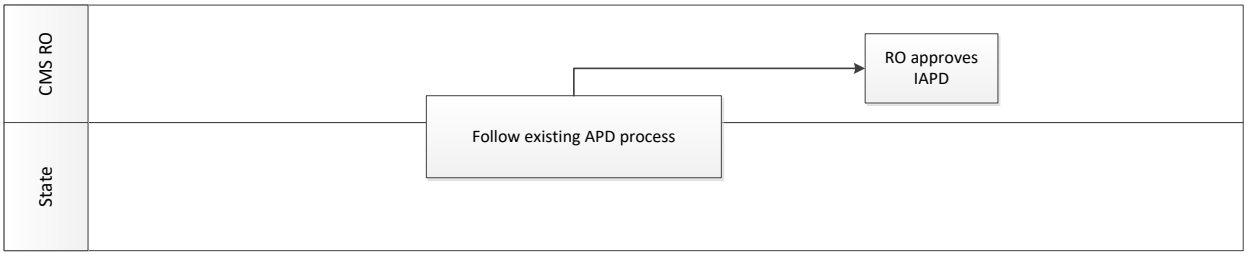

Figure 18. Activity 13b: IAPD Approval

3.2 Requirements, Design, and Development

Figure 19 shows the activities in the Requirements, Design, and Development phase.

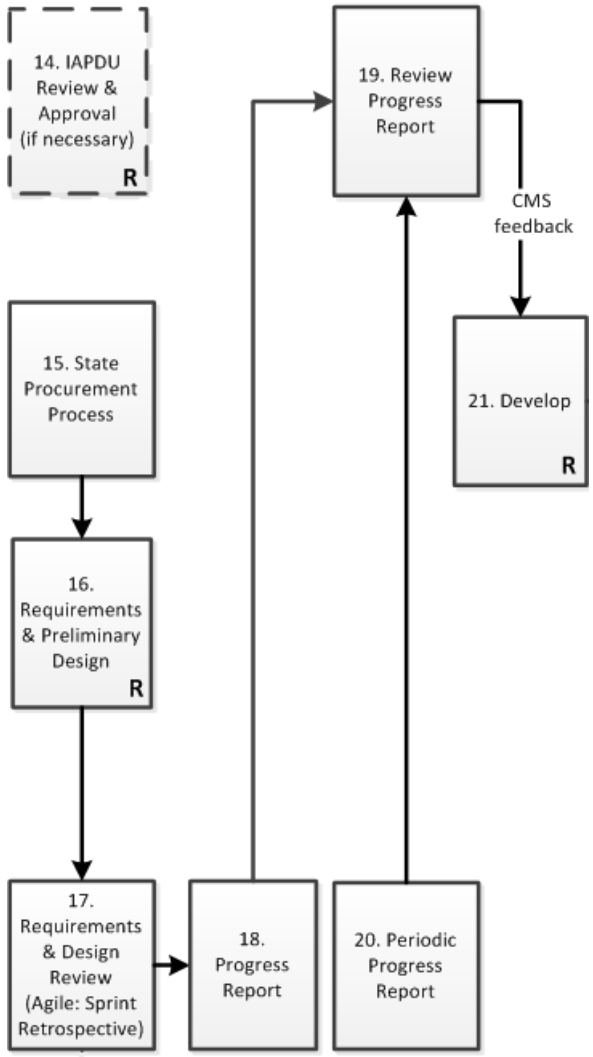

Figure 19. Requirements, Design, and Development Phase

During the Requirements, Design, and Development phase, the state performs the following actions:

- Documents system requirements
- Designs the system
- Undergoes an IV&V requirements and design review
- Documents test/validation plans
- Cooperates with the IV&V contractor as the periodic MMIS IV&V Progress Reports are prepared
- Develops the MMIS modules

States may employ a waterfall, agile, or hybrid development methodology. The IV&V contractor reviews the requirements and the designs and sends periodic IV&V progress reports to the CMS RO, the CMS email box (MES@cms.hhs.gov) and the state about the progress of the project.

3.2.1 Activity 14: IAPDU Review and Approval (if Necessary)

A state that has already cleared the Project Initiation Milestone Review and needs to update a previously approved IAPD does not need to go through another Project Initiation Milestone Review. The state would update its IAPD, along with any related RFPs, and send them to the RO to review and approve (Figure 20).

This activity also covers the case where the RO plans to release funds annually and needs to review a previously approved IAPD before releasing funds. Again, in annual IAPD review by the RO, the state will not undergo another Project Initiation Milestone Review.

The input to this activity is the updated IAPD (or a previously approved IAPD). The output is a decision from the RO regarding approval and a release of funds.

Figure 20. Activity 14: IAPDU Review and Approval (If Necessary)

3.2.2 Activity 15: State Procurement Process

The state follows its own procurement processes to enter into contracts with developers, testers, SIs, etc. The state sends the contracts to the RO for approval (Figure 21). The inputs are the state's procurement policies and procedures and the RFP. The output is a contract(s) submitted to the RO for approval.

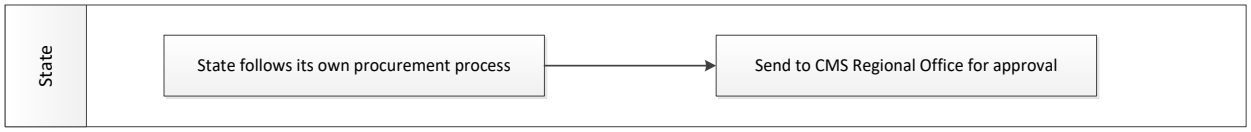

Figure 21. Activity 15: State Procurement Process

3.2.3 Activity 16: Requirements and Preliminary Design

If the state is developing a system (as opposed to purchasing a COTS product or outsourcing services), the state documents the system requirements, system design, and test plans (Figure 22). If the state is purchasing a COTS product, the state must produce an interface design document, including a description of Application Programming Interfaces (APIs). The state also must develop a test plan to verify that the system/module meets all CMS requirements and will operate seamlessly within the MMIS (e.g., host identity management, data updates). The toolkit Appendix B contains a list of artifacts required for each milestone review.

In an agile development, requirements may take the form of epics and user stories on note cards or in a software suite. Each user story is mapped to a test case for validating the code produced during sprints. Use case testing is developed in parallel with product development. Integration testing is crucial for MMIS success and must be included in test plans.

In traditional waterfall development, mapping between requirements and test cases is called a requirements traceability matrix (RTM). Agile approaches may not have a formal RTM, but regardless of the methodology used, mapping must contain requirements traceability and must detail requirements for the following categories:

- Business
- Data
- Capacity/performance
- Security/privacy/HIPAA compliance
- Usability
- Maintainability
- Interface
- 508 compliance

The inputs for this activity are the MITA technical strategies, MITA ConOps, MMIS ConOps, and the certification checklists, including CSFs. The output is a set of technical designs and requirements/use cases or user stories.

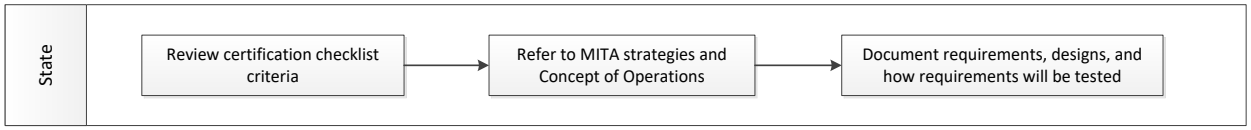

Figure 22. Activity 16: Requirements and Preliminary Design

All applicable criteria found in the Medicaid Enterprise Certification Checklists must be covered in the requirements, along with any state-specific requirements. The requirements and design typically change over the course of a large development and must be kept current.

CMS has seen the importance of states carefully managing requirements. In one large system implementation, the state lacked a unified, approved version of requirements. Different requirement versions were used for development of software, test cases, stakeholder expectations, and test data creation, and the system failed as a result.

3.2.4 Activity 17: Requirements and Design Review(s)/Sprint Retrospective

3.2.5 Activity 18: Progress Report

3.2.6 Activity 19: Review Progress Report

3.2.7 Activity 20: Periodic Progress Report

Activities 17, 18, 19, and 20 are covered together because they are closely related. Regarding Activity 17, the success of the MMIS project depends on the inclusion of all federal and state Medicaid systems requirements in the technical designs. CMS does not perform a formal milestone review of the detailed requirements and designs because states develop detailed designs at different times and in different ways, depending on their SDLC. CMS does require that the IV&V contractor use the Medicaid Enterprise Certification Checklists to review the requirements and design as they are developed. The IV&V contractor also needs to report to CMS any risks and gaps, using the periodic MMIS IV&V Progress Reports. The inputs for Activity 17 (Figure 23) are the ConOps documents and preliminary designs, requirements, and test plans. The output of Activities 17 and 18, together, is an MMIS IV&V Progress Report.

The IV&V contractor prepares progress reports at least quarterly (Activities 18 and 20) and throughout the MECL (Figure 24) on a schedule agreed on by the state and CMS during Activity 1. (The state and CMS may have agreed on a more frequent schedule of reporting during the Consult with CMS activity.) The IV&V contractor appends only the checklists for the modules that are undergoing a milestone review in the report that immediately precedes a milestone review.

Special occurrences of the MMIS IV&V Progress Reports can count toward the minimum of quarterly reports. Even if a state is using multiple development vendors, the IV&V contractor only prepares a single report that covers all modules undergoing planning, development, test, or implementation.

The MMIS IV&V Progress Reports are prepared immediately before a milestone review (Activities 11, 23, and 26) and after the preliminary requirements and designs have been created (Activity 18). The report generated after preliminary design development gives the CMS RO a chance to review the designs and notify the state of any issues early in development, when it is least costly and less time-consuming for the state to correct them.

The state should schedule the MMIS IV&V Progress Report after the preliminary requirements and design to fit its SDLC phase gates. For example, a state following a waterfall development may have a single design phase gate. That would be the most appropriate time for the IV&V contractor to perform its requirements and design review.

A state employing an agile approach will not likely have a design gate review. It may, instead, perform a series of sprint retrospectives, where the backlog is prioritized and designs are modified after each sprint. In such a case, the IV&V contractor may perform a requirements and design review at each sprint retrospective, during every other sprint retrospective, or at some other pre-agreed schedule. The requirements and design must have been thoroughly reviewed at least once by the IV&V contractor.

For the periodic MMIS IV&V Progress Reports, the IV&V contractor will review the following:

- System design document or, if the state is purchasing a COTS system, an interface design document
- Information system security assessment
- Test plan
- Test report/validated product reports
- Interface control document
- Database design
- Data conversion/data management plan
- Implementation plan
- Contingency/recovery plan
- Data use/exchange interconnection security project
- Project progress against plans
- MITA progress

For progress reports prepared in advance of a milestone review, the state fills out its portion of the checklists that apply to the modules undergoing the milestone review. The Technical Architecture (3), Information Architecture, and Standards and Conditions checklists must be used regardless of which module(s) is being reviewed. When the state completes its sections of its Medicaid Enterprise Certification Checklists, it stores the checklists and supporting evidence in its own repository.

The IV&V contractor then completes the reviewer sections of the checklists and completes the IV&V and Programmatic tabs of the MMIS IV&V Progress Report Template.[2] Even if a state is using multiple development vendors, the IV&V contractor prepares only a single report that covers all modules undergoing review.

The IV&V contractor submits the reports and checklists simultaneously to the state, to the CMS RO, and to the CMS certification email address (MES@cms.hhs.gov). When the state receives the checklists from the IV&V contractor, it should save the IV&V-completed checklists in the state repository as a new version of the checklists. (The checklists should continue to be updated as new versions with subsequent progress reports.)

The IV&V contractor is not to send drafts of the report to the state unless it is also sending the same draft simultaneously to CMS. The state may respond to issues identified in the MMIS IV&V Progress Report. State comments are appended to the report, but the report is not altered. CMS can insert comments in the appropriate section of the report. CMS will review the state is including security and privacy in the modules/system.

[2] It is recommended that the contractor use the MMIS IV&V Progress Report Template provided in Appendix D, as it contains all required information for this report. If the state or IV&V contractor desires to use a different format, the state should discuss with its RO to ensure proper content and structure of the report.

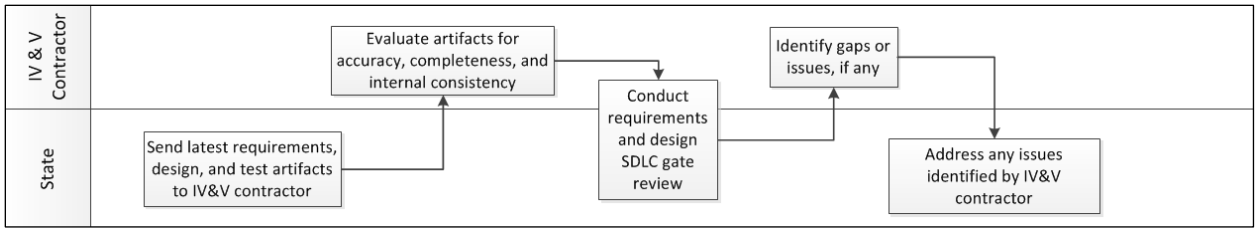

Figure 23. Activity 17: Requirements and Design Review

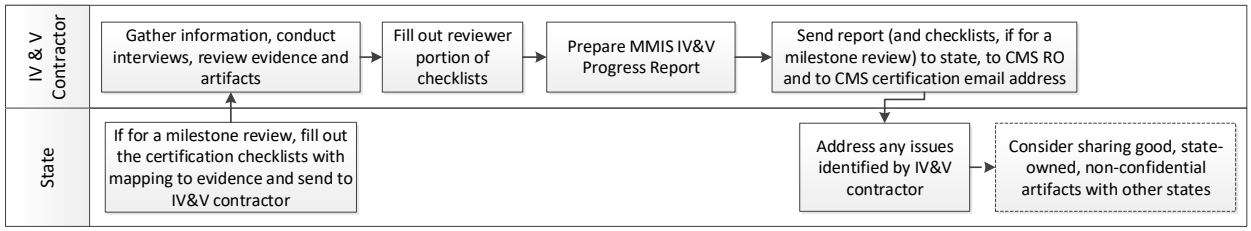

Figure 24. Activities 18 and 20: Progress Report

Once CMS reviews the MMIS IV&V Progress Report, it makes suggestions in the CMS section of the report, if any. The state should incorporate CMS suggestions into project plans, as appropriate. If CMS has made comments, it sends the final version of the IV&V Progress Report to the state and the IV&V contractor and the state stores it in the state's repository. Figure 25 shows the steps of Activity 19. The input is the MMIS IV&V Progress Report; the output is comments in the CMS section of the report, if CMS has comments.

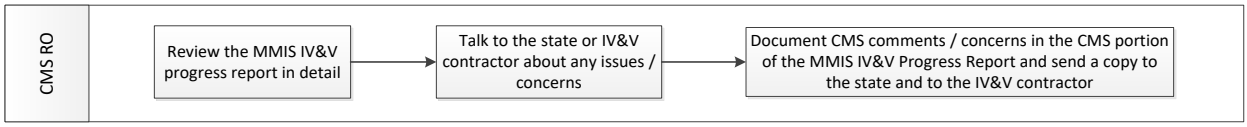

Figure 25. Activity 19: Review Progress Report

3.2.8 Activity 21: Develop

The state and its contractors develop the MMIS/modules according to their own SDLC processes.

3.3 Integration, Test, and Implementation

Figure 26 shows the activities in the Integration, Test, and Implementation phase.

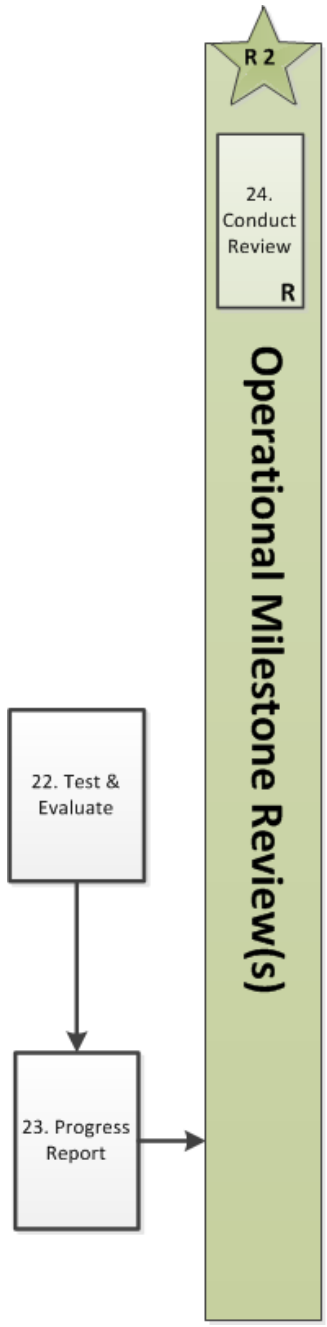

Figure 26. Integration, Test, and Implementation Phase

During the Integration, Test, and Implementation phase, the state performs the following actions:

- Integrates modules
- Tests the integrated system
- Cooperates with IV&V contractor as periodic MMIS IV&V Progress Reports are prepared
- Undergoes Operational Milestone Review(s)
- Deploys the system/newly developed modules into production

3.3.1 Activity 22: Test and Evaluate

The state and its contractors employ their own testing procedures to evaluate the functionality of the MMIS/modules against documented requirements or user stories (Figure 27). Testing includes generating reports of how documented requirements or user stories were tested, along with the test results or evidence of product acceptance by users. For agile approaches, use case testing is developed in parallel with product development. If the state is using an automated test suite, the entire set of test cases could be run on the production environment before the Operational Milestone Review(s). CMS encourages the use of automated testing and continuous integration, when possible.

The inputs for Activity 22 are working code and test plans/test cases. The output is documented test results or, in the case of agile development, product acceptance by the customer.

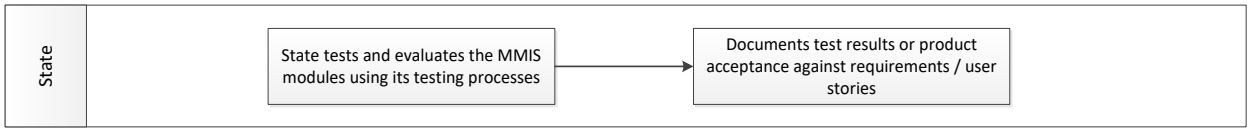

Figure 27. Activity 22: Test and Evaluate

3.3.2 Activity 23: Progress Report

During this activity (Figure 28), the IV&V contractor reviews the working modules/system and all artifacts required for the Operational Milestone Review (see the list of required artifacts in the toolkit appendices) and evaluates whether the modules are ready for the Operational Milestone Review.

If a state is using multiple development vendors and releasing several modules at the same time, the IV&V contractor prepares only a single report that covers all those modules.

The state completes the state section of the checklists and stores the checklists and supporting evidence in its own repository. The IV&V contractor then submits the reports and checklists simultaneously to the state, to the CMS RO, and to the CMS certification email address (MES@cms.hhs.gov) being sure to include “MMIS” in the subject line, no later than two weeks prior to the milestone review. The state should save the IV&V-completed checklists in its repository as a new version of the checklists. (The checklists should continue to be updated as new versions with subsequent progress reports.)

If the IV&V contractor sends drafts of the report to the state, it must also send the same draft simultaneously to the CMS RO. The progress report details what, if any, issues the state should address before Operational Milestone Review. As with all MMIS IV&V Certification Progress Reports, the state may respond, and those responses will be appended to the report.

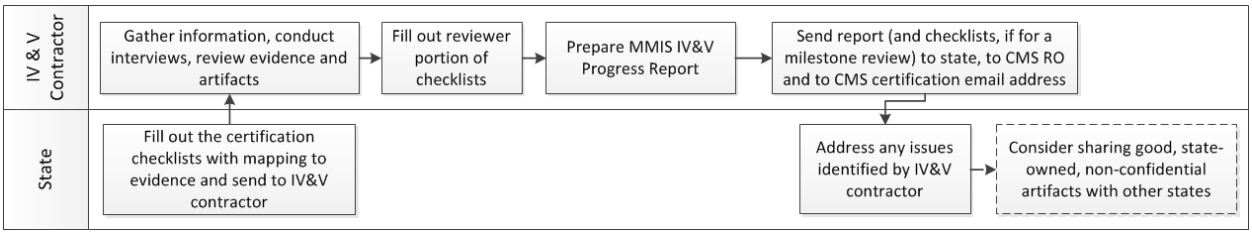

Figure 28. Activity 23: Progress Report

3.3.3 Activity 24: Operational Milestone Review

The entry criteria to this activity are that the state 1) has one or more MMIS modules ready for deployment, 2) no later than two weeks prior to the milestone review the IV&V contractor has submitted the MMIS IV&V Progress Report and checklists to the RO and to the CMS email box (MES@cms.hhs.gov), having included "MMIS" in the subject line, and 3) the state has made evidence available to CMS. CMS may choose to send test cases or scenarios to the state to be included as part of the milestone review. In such instances, the state would be expected to show how the module or SMA processed the test cases or scenarios. If CMS makes test cases part of the review, the RO analyst will provide further guidance to the state.

A state should talk to its RO analyst to gain access to the CMS repository for uploading milestone review evidence. Using the CMS repository is the preferred method of submitting materials, however, the state may also grant CMS direct access to the state's evidence repository. If that is not possible, the state may make other secure arrangements with CMS, such as using encrypted FTP. It is critical to follow all HIPAA regulations when submitting evidence that contains PHI and PII. Using an unencrypted thumb drive or other forms of physical storage through shipping services, for example, would not be acceptable. If a state has questions, it should contact its RO. During this review, CMS validates the functionality and security of the MMIS/modules before deployment. See Appendix L_Milestone Review Preparation Guide for details about the timeline and logistics of milestone reviews.

The Operational Milestone Review consists of the RO reviewing the progress report and checklists and supplying comments in the CMS section of the report. The CMS review team may or may not include comments in the checklists. That review is concluded when the RO sends copies of the completed progress report to the state and to the IV&V contractor—no site visit is generally required.

There may be cases where CMS considers a more formal review to be appropriate and may schedule a teleconference or site visit for R2. In such cases, the RO will notify the state and will work with the state to schedule the review and arrange logistics.

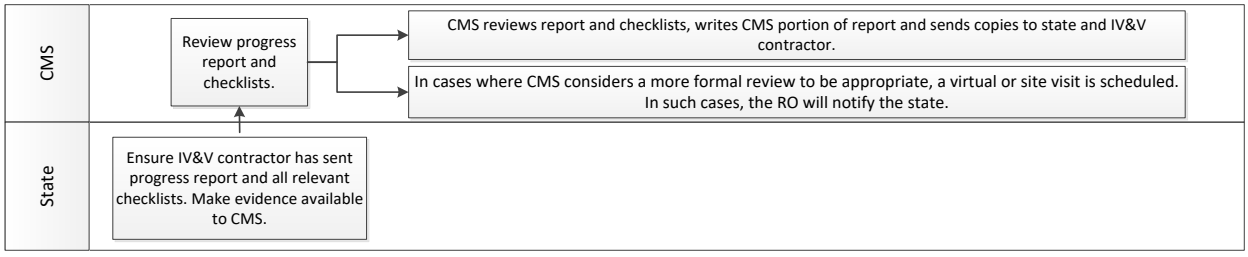

Figure 29. Activity 24: Operational Milestone Review(s)

3.4 Operations and Maintenance

Figure 30 shows the activities in the Operations and Maintenance phase.

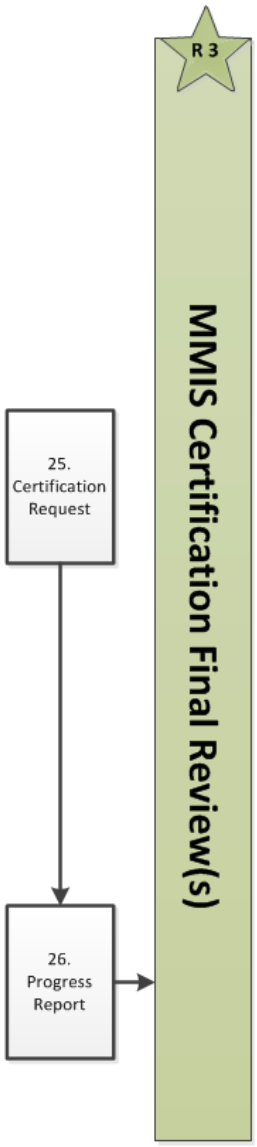

Figure 30. Operations and Maintenance Phase

During the Operations and Maintenance phase, the state performs the following actions:

- Operates the MMIS according to the state's processes and procedures
- Requests certification formally
- Undergoes the final certification review

3.4.1 Activity 25: Certification Request

The system or module must have been in operation for at least six months before certification can be granted. At least six weeks prior to a desired final milestone review date and often even earlier, the state discusses with CMS its desire to have a certification milestone review. This allows CMS and the state four to six weeks of planning (e.g., scheduling, assembling teams, etc.). CMS and the state will discuss the format and timing of the review, the state's evidence storage plans, and any legal agreements that need to be in place for sharing data with CMS. (See toolkit Appendix L_Milestone Review Preparation Guide for more details about milestone review timing and logistics.)

No later than two weeks prior to the target milestone review date, the state's Medicaid director or comparable state official sends a package of information to the CMS RO in preparation for the MMIS Certification Final Milestone Review. This package must include:

- A certification request letter (see Appendix J, MMIS Certification Request Letter Template)
- A proposed date for certification review (included in certification request letter)
- A copy of the state's acceptance letter addressed to the system developer, indicating that the system or module was accepted as fully operational at least six months prior to the requested certification review date

The certification request letter must include the following:

- The date the system/module(s) became fully operational
- Attestation that the state has made all documentation required for MMIS Certification Final Milestone Review available to CMS
- A copy of the state's letter to the MMIS contractor or state development team, accepting the system/modules(s)
- A proposed timeframe for the review
- A declaration that the state's MMIS / module(s) meets all requirements of law and regulation:
    - Meets the requirements of 42 CFR 433.117 for all periods for which the 75 percent FFP is being claimed
    - Is ready for CMS certification, based on the state's evaluation using the checklists in the toolkit
    - A copy of the latest New Medicaid Card Program Readiness Report has been provided to CMS
    - Generates up-to-date and accurate Transformed Medicaid Statistical Information System (T-MSIS) data
    - Routinely generates backups
    - Exercises appropriate privacy and security controls over the system in accordance with 45 CFR Part 164, P.L. 104-191, the HIPAA of 1996, and 1902(a)(7) of the Social Security Act, as further interpreted in regulations at 42 CFR 431.300 to 307

Additional declarations should be included, depending on the module for which certification is being requested:

- Issues Explanation of Benefits on a regular basis for all periods for which 75 percent FFP is being claimed, in accordance with the provisions of Section 10 of P.L. 95142, which amends section 1903(a)(3) of the Social Security Act (for modules that cover claims processing functions)
- Adjudicates claims and information required for payment of services in accordance with all provisions of 42 CFR 447 and the approved state Medicaid plan (for modules that cover claims processing and financial functions).

No fewer than two weeks before the certification milestone review, the IV&V contractor must send the MMIS IV&V Progress Report with completed checklists to the CMS RO, to the state, and to the CMS certification email box (MES@cms.hhs.gov), being sure to include "MMIS" in the subject line. Also, no fewer than two weeks before the certification milestone review, the state must grant CMS access to the checklist evidence. This evidence should include all artifacts required for the MMIS Final Certification Review (see Required Artifacts List in the toolkit appendices).

States should talk to their RO analysts to gain access to the CMS repository for uploading milestone review evidence. Using the CMS repository is the preferred method of submitting materials, however, the state may also grant CMS direct access to the state's evidence repository. If that is not possible, the state may make other secure arrangements with CMS, such as using encrypted FTP. Using an unencrypted thumb drive or other forms of physical storage through shipping services, for example, would not be acceptable. If a state has questions, it should contact CMS. Together, CMS and the state will set dates for the MMIS Certification Final Review.

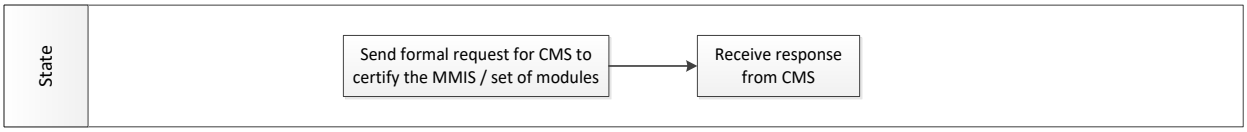

Figure 31. Activity 25: Certification Request

3.4.2 Activity 26: Progress Report

During this activity, the IV&V contractor reviews the working modules/system and all artifacts required for the MMIS Certification Final Review (see toolkit appendices) and evaluates whether the modules/system are ready for the MMIS Certification Final Review (Figure 32).

The state fills out its portion of the checklists that apply to the modules undergoing the milestone review. The Technical Architecture (3), Information Architecture (1), and Standards and Conditions for Medicaid IT (1) checklists must be used regardless of which module(s) is being reviewed. When the state completes its sections of its Medicaid Enterprise Certification Checklists, it stores the checklists and supporting evidence in its own repository.

The IV&V contractor then completes the reviewer sections of the checklists and completes the IV&V tabs of the MMIS IV&V Progress Report Template.[3] The completed checklists are appended to the report. Even if a state is using multiple development vendors, the IV&V contractor prepares only a single report that covers all modules undergoing review.

No later than two weeks prior to the milestone review, the IV&V contractor submits the report and checklists simultaneously to the state, to the CMS RO, and to the CMS certification email address (MES@cms.hhs.gov) being sure to include "MMIS" in the subject line. When the state receives the checklists from the IV&V contractor, it should save the IV&V-completed checklists in the state repository as a new version of the checklists.

The IV&V contractor is not to send drafts of the report to the state unless it is also sending the same draft simultaneously to CMS. CMS uploads the completed checklists to its tracking database. The state may respond to issues identified in the MMIS IV&V Progress Report. State comments are appended to the report, but the report is not altered. CMS will insert comments in the CMS section of the report after the milestone review is complete.

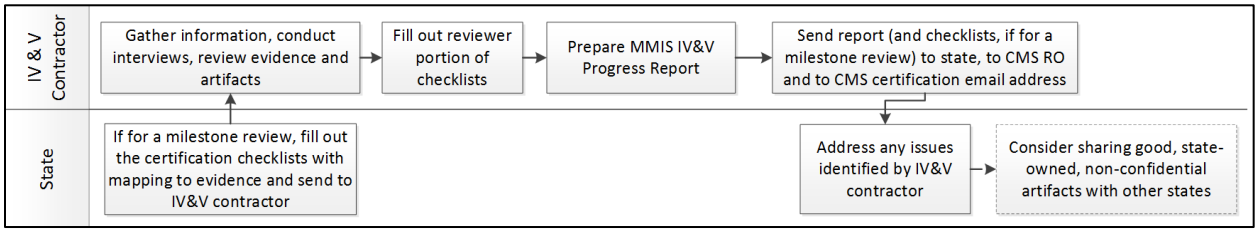

Figure 32. Activity 26: Progress Report

3.4.3 Activity 27: MMIS Certification Final Review

During Activity 27 (Figure 33), CMS evaluates the modules against CMS guidelines and federal regulations after the modules/system have operated for at least six months. The entry criteria to this activity are that the state has one or more working MMIS modules it has accepted from the vendors, the IV&V contractor has submitted the MMIS IV&V Progress Report and checklists, and the state has made evidence and required artifacts available to CMS.

This section gives a high-level summary of the MMIS Certification Final Review. For detailed information about how milestone reviews are conducted and how the state can prepare for them, see Appendix L_Milestone Review Preparation Guide.

States should talk to their RO analysts to gain access to the CMS repository for uploading milestone review evidence. Using the CMS repository is the preferred method of submitting materials, however, the state may also grant CMS direct access to the state's evidence repository. If that is not possible, the state may make other secure arrangements with CMS, such as using encrypted FTP. It is critical to follow all HIPAA regulations when submitting evidence that contains PHI and PII. Using an unencrypted thumb

[3] It is recommended that the contractor use the MMIS IV&V Progress Report Template provided in Appendix D, as it contains all required information for this report. If the state or IV&V contractor desires to use a different format, the state should discuss with its RO to ensure proper content and structure of the report.

drive or other forms of physical storage through shipping services, for example, would not be acceptable. If a state has questions, it should contact its RO.

During the review, CMS will verify that the criteria based on federal and state requirements are satisfied by reviewing the functionality of the modules/system in production. CMS will perform the verification by actual system interaction, review of documents, and interviews with state and, potentially, contractor staff. CMS may choose to send test cases or scenarios to the state to be included as part of the milestone review. In such instances, the state would be expected to show how the module or SMA processed the test cases or scenarios. If CMS makes test cases part of the review, the RO analyst will provide further guidance to the state.

The milestone review visit will conclude with a closeout or exit conference in which CMS summarizes the activities and observations made during the review. The decision to certify or not certify the state's system is deferred until CMS can analyze all information gathered during the review or submitted subsequently by the state.

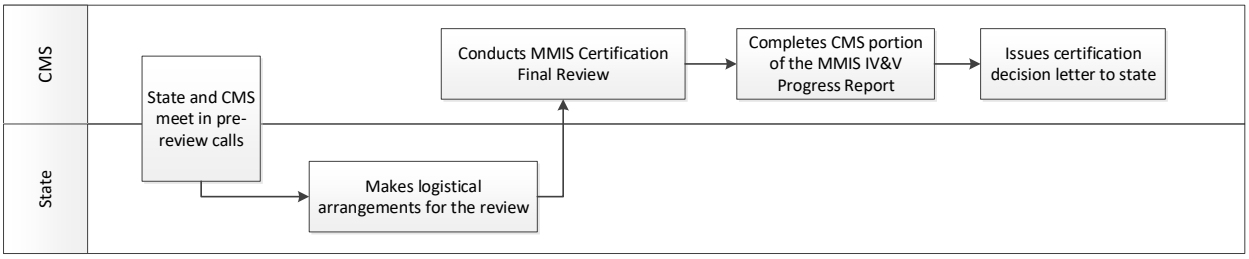

Figure 33. Activity 27: MMIS Final Certification Review(s)

On-site certification milestone reviews follow a pattern (Figure 34). See Appendix L_Milestone Review Preparation Guide for information about how virtual/on-site sessions are structured.

Two to six weeks prior to the certification milestone review, the IV&V contractor must send the MMIS IV&V Progress Report with completed checklists to the CMS RO, to the CMS certification email box (MES@cms.hhs.gov), and to the state. Also, no fewer than two weeks before the certification milestone review, the state must grant CMS access to the checklist evidence. This evidence should include all artifacts required for the MMIS Final Certification Review (see Required Artifacts List) along with a list of existing system defects by severity and priority.

After submission of the MMIS IV&V Progress Report, and at least two weeks before the milestone review, the state and CMS will have one or more pre-certification calls to plan the logistics and agenda of the review meetings. The state will give CMS access to the evidence and documentation. A milestone review kickoff meeting will be held for the state and CMS to introduce their respective team members.

The review meetings generally last from two to five days and are broken into sessions based on system functionality and/or checklist areas. The state arranges logistics for the MMIS Certification Final Review, such as scheduling rooms, granting CMS access to evidence, and setting up teleconference lines. CMS team members will be assigned to sessions based on their subject matter expertise. CMS may conduct the reviews entirely by web conferencing or may send a few members of the team to the state site while the remaining members join via phone.

Questions may come up during the milestone review for which the state may not have immediate answers. Generally, there are a few weeks following the review in which the state supplies any additional evidence requested by CMS. After all evidence has been reviewed, CMS fills out the CMS portion of the MMIS IV&V Progress Report and sends copies to the state and to the IV&V contractor. CMS will also send a certification decision letter signed by the technical director and regional administrator.

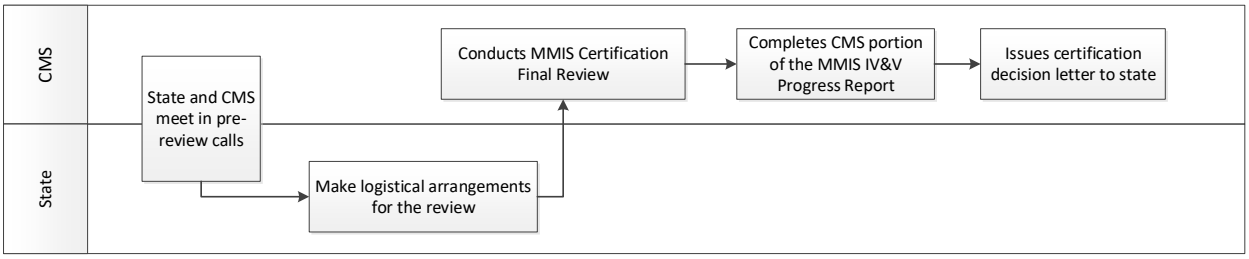

Figure 34. MMIS Certification Final Milestone Review

If certification and funding have been granted for a module or group of modules, but additional MMIS modules are still under development, the remaining MMIS modules must also go through final certification review to be funded.

Once all MMIS modules have been certified (either through a series of staggered final certification reviews or all at one time), the capabilities of the certified system will be used as the baseline for future MMIS updates.

4 Medicaid Enterprise Certification Checklists

The Medicaid Enterprise Certification Checklists have been updated to reflect current regulations, MITA architectures (business, information, and technical architectures), and the standards and conditions for Medicaid IT. Checklists are used throughout the certification life cycle and support a variety of state development approaches—modular, phased, agile, waterfall, etc.

4.1 Selecting a Checklist Set

During the first activity of the certification life cycle, together the state and the CMS RO select a set of checklists that the state will use throughout the MECL. The state can choose one of two checklist set options.

The custom set option allows a state to arrange all the existing checklist criteria into its own set of checklists. This option is available only for exceptional, non-traditional solutions in which a state takes an innovative approach to MMIS or in which the state is requesting funds for a non-traditional function that cannot be covered under the MMIS Module Checklist Set (for example, claims processing as a service). This checklist option requires approval by the CMS in two ways. First, CMS must approve the approach and secondly, CMS must approve the checklists the state generates. In most cases, states will use the default option, which is the MMIS Module Checklist Set.

Table 2 lists the checklists that make up the sets. Note that the Technical Architecture, Information Architecture, and the Standards and Conditions for Medicaid IT checklists are included in both checklist sets.

If the state plans to have state-specific criteria in addition to those found in the checklist sets, the state should talk to its RO about how best to incorporate those state-specific criteria into the checklists.

Table 2. Checklist Sets

MMIS Module Checklist Set	Customized Checklist Set
• Member Enrollment • FFS Claims & Adjudication • Pharmacy • Third Party Liability • Care Management • Program Integrity • Decision Support System • Reference Data Management • Provider Management • Registries • Information Architecture • Technical Architecture—Access and Delivery • Technical Architecture—Integration and Utility • Technical Architecture—Intermediary and Interface • Standards and Conditions for Medicaid IT	• Checklist determined by the state and approved by CMS • Information Architecture • Technical Architecture—Access and Delivery • Technical Architecture—Integration and Utility • Technical Architecture—Intermediary and Interface • Standards and Conditions for Medicaid IT

Before the first milestone review, the state downloads the zip file of its checklist set from Medicaid.gov, along with the Technical Architecture, Information Architecture, and the Standards and Conditions for Medicaid IT checklists (which are required every time, regardless of the modules being developed). The state fills out the checklists, and the IV&V contractor uses the checklists to complete its MMIS IV&V Progress Report. The IV&V contractor completes the reviewer section of the checklists, appends them to the MMIS IV&V Progress Report, and sends copies of the report simultaneously to the state, to the CMS RO, and to the CMS email address (MES@cms.hhs.gov), being sure to include “MMIS” in the subject line. The checklists are then uploaded to a tracking database maintained by CMS. This allows CMS to keep a running record of the MMIS certification progress throughout the certification life cycle. CMS runs a report from the database that shows which CSFs have not been met.

This process is repeated every time an MMIS IV&V Progress Report is prepared by the IV&V contractor. Figure 35 shows the checklists through the certification life cycle.

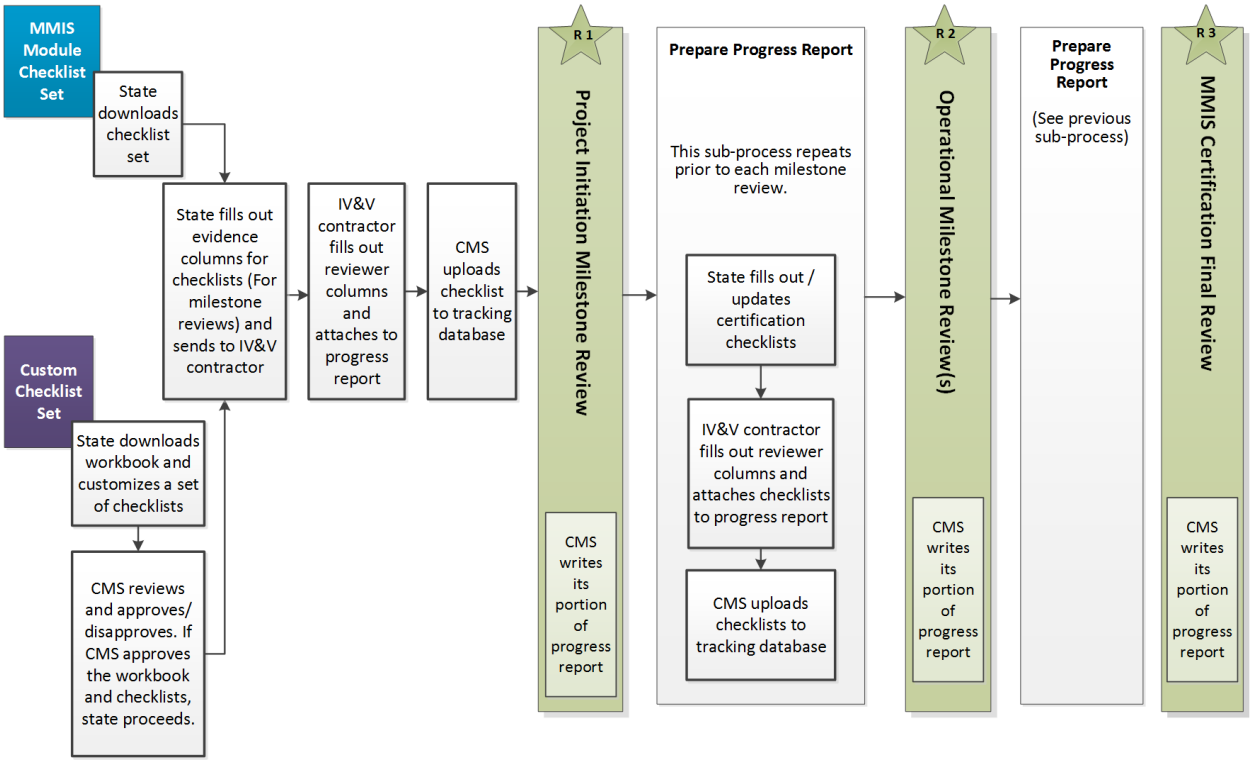

Figure 35. The Life of Checklists

4.2 Anatomy of a Checklist

Each checklist is an Excel workbook with tabs. One tab is a set of instructions (Figure 36), one tab is the checklist (Figure 37), one tab (Figure 38) is a list of MITA business areas. Some checklists include a guidance tab (Figure 39). The Pharmacy, Provider Management, Technical Architecture, Information Architecture, and the Standards and Conditions for Medicaid IT checklists each contain a guidance tab that explains the type of evidence that could be provided for each criterion.

Checklist: Information Architecture Checklist

Note: Some of these instructions are MMIS specific.

Checklist Instructions

A. General Information – What users need to know about the Checklists
B. State and IV&V Specific Instructions – The process of completing the Checklist by the state
C. Sample Criteria and Evidence – Sample evidence in each of the Milestone Review phases

General Information:

- (MMIS specific) Depending on approved MMIS development option, state selects the appropriate checklist set.
  - MITA Checklist Set: Ten (10) MITA + Core Checklists (IA Component, TA Access And Delivery, TA Intermediary and Interface, TA Integration and Utility, and Standards and Conditions)
  - MMIS Functional Checklist Set: Ten (10) MMIS Checklists + Core Checklists
  - Custom Set: One workbook to develop custom set of modular checklist(s) + Core checklists. The Custom Set option must be developed in coordination with and receive approval by CMS.
- (E&E specific) State should use 6 Checklists [E&E Checklist + 5 Core Checklists (IA Component, TA Access and Delivery, TA Intermediary and Interface, TA Integration and Utility, and Standards and Co
- The checklists are used for documenting state evidence and IV&V reviewer comments. When completed, checklist data will be imported into a CMS tracking database.
- The first 27 columns are grouped into three sections identified by headers to identify data. The headers are read-only and should not be edited. These are identified as follows:
  - Columns (col) A to C are criteria information labeled as: Ref #, System Review Criteria, and Source respectively.
    Criteria Ref # pattern: MITA Business Area.CSF Code.Unique Number (e.g. CA.CL7.1)
    MITA State Specific Criteria Ref# : MITA Business Architecture.Business Area.Business Process.State Abbr.Unique Number (e.g. BA.CM.FFS.SS.NY.1)
    MITA Architecture (TA, IA, S&C) : MITA Architecture.MITA component.Unique Number (e.g. S&C.BRC.1, TA.SP.33, IA.CDM.1)
  - Entrees in col A are color-coded to indicate status of the criteria (*red italics: state-specific*)
  - Col pairs D and E, J and K, and P and Q are for entering state Evidence data. Each pair is labeled Yes/No/Not Applicable and *X* Evidence Comments where *X* is the Milestone Review
  - Col sets F to I, L to O, and R to U are for entry of IV&V reviewer comments for each of the Milestone Review phases.
  - Each set includes Review Date, Reviewer Name, Reviewer Assessment, and Reviewer Comments
- The column structure (i.e. label names, merged columns, etc.) is used by the database during import of the checklist data and should not be changed
- Criteria in each checklist are grouped into a series of rows. Each group begins with a merged row colored in green to mark the beginning of a group mapping
  - Depending on the package used, each green merged row identifies either a business process, technical service, component, module, or CSF
- Depending on the type of review, CMS may or may not fill out the CMS columns.
- By default, the CMS Assessment columns for R1 and R2 mirror the IV&V contractor assessment column. This is normal. If CMS assesses a criterion differently than the IV&V contractor, it will alter th

State and IV&V Specific Instructions:

- Complete criteria evidence columns prior to each milestone review
- IV&V will work with state to review evidence and annotate review findings and resolutions in the review columns of the checklist
- "Not assessed" is chosen if the IV&V contractor does not assess a criterion. The contractor should indicate in the comments column why it was not assessed.
- "Not Applicable" is chosen if the state does not deem a criterion to apply to its module(s). **The state must indicate in the evidence column why it does not apply.**
  The IV&V contractor must evaluate whether it does or does not apply and indicate whether it concurs or disagrees with the state in the review comments column.
- "Partially meets" is chosen if the module(s) meets some but not all aspects of the criterion. The IV&V contractor should indicate in detail in the comments column why it partially meets.
- "Doesn't meet" is chosen if the module(s) completely fails to meet the criterion.The IV&V contractor should indicate in detail in the comments why it does not meet.
- Evidence columns (D-E for Project Initiation, J-K for Operational, and P-Q for Final) and Review columns (F-I for Project Initiation, L-O for Operational, and R-U for Final):
  - The evidence pair columns have "Yes/No/Not Applicable" to indicate criteria has been met or out-of-scope and "Comments" for entry of supporting evidence text
  - Criteria evidence will be entered in the same row as the criteria under each Milestone Review phase
  - Criteria evidence references to artifacts should be as specific as possible, including section or page numbers, so that the cited evidence can be readily confirmed

Checklist Instructions | InformationArchitecture | MITA Business Processes | Guidanc ...

Figure 36. Instructions Tab

Pharmacy Checklist (MMIS Module)

Select Milestone Review(s) → ☑ Project Initiation ☑ Final ☑ Operational | Check Spelling | Project Initiation Milestone Review

Ref # *(MITA State-specific)*	System Review Criteria	Source	Yes/No/Not Applicable	Project Initiation Milestone Evidence	Review Date	Reviewer Name	Reviewer Assessment	Reviewer Comments	CMS Assessment	CMS Comment
CSF PH1: Point of Sale (POS) systems interfaces are maintained in order to appropriately process, adjudicate and report on claims according to state and federal rules.										
ME.PH1.1	The system provides real-time access to member eligibility. Note: Depends on the timing of the updates maintained in the individual state. See state-specific requirements.	SMM, CFR								
OM.PH1.1	The system ensures that all claims are assigned a unique identification number upon entering the system.	SMM								
PL.PH1.1	The system provides real-time access to the state's drug and formulary file or maintains an up to date copy for POS use. Note: Depends on the timing of the updates maintained in the individual state. See state-specific Requirements.	SMM, CFR								
PL.PH1.2	The system provides real-time access to benefit business rules.	SMM								

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Figure 37. Example Checklist Tab

Note: This sheet shows mapping of MITA Business Area, Business Process, and Criteria to reflect alignment to MITA Goals & Objectives for MMIS Modules

Business Area	Business Process	Criteria Ref #
Care Management	Authorize Treatment Plan	CM.PH3.1
Care Management	Authorize Treatment Plan	CM.PH3.2
Financial Management	Manage Drug Rebate	FM.PH6.1
Financial Management	Manage Drug Rebate	FM.PH6.2
Financial Management	Manage Drug Rebate	FM.PH6.3
Financial Management	Manage TPL Recovery	FM.PH5.1
Financial Management	Manage TPL Recovery	FM.PH5.2
Member Management	Manage Member Information (Under Development)	ME.PH1.1
Operations Management	Generate Remittance Advice	OM.PH2.1
Operations Management	Generate Remittance Advice	TA.CS.2
Operations Management	Process Claims	OM.PH1.1
Operations Management	Process Claims	OM.PH2.10
Operations Management	Process Claims	OM.PH2.11
Operations Management	Process Claims	OM.PH2.13
Operations Management	Process Claims	OM.PH2.14
Operations Management	Process Claims	OM.PH2.15
Operations Management	Process Claims	OM.PH2.16
Operations Management	Process Claims	OM.PH2.17

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Figure 38. Example MITA Business Processes Tab

Information Architecture Checklist

Ref # *(MITA State-specific)*	System Review Criteria	Source	Guidance
IA Component Name: Data Management Strategy (DMS)			
IA.DMS.2	The SMA demonstrates adoption of an intrastate metadata repository where the agency defines the data entities, attributes, data models, and relationships sufficiently to convey the overall meaning and use of Medicaid data and information.	MITA 3.0 IA ML 3	Enterprise: For R1, evidence should include a data management strategy. For R2 and R3, evidence should demonstrate that an interagency data model is being developed and used by multiple state agencies. For R2 (if not a desk review) and R3, states should be prepared to demonstrate and discuss its metadata repository. Modules: If commercial-off-the-shelf, it should include proposed metadata for the module (the state can choose to adopt them or not). If a module is developed by the state, demonstrate that module uses state's metadata standards.
IA.DMS.4	The SMA demonstrates adoption of statewide standard data definitions, data semantics, and harmonization strategies.	MITA 3.0 IA ML 3	For R1, evidence should include a data management strategy. For R2 and R3, evidence could include screenshots or definition documents showing the data definitions, semantics, and harmonization norms. For R2 (if not a desk review) and R3, the state should be prepared to discuss their statewide data management practices as they pertain to Medicaid-related systems' interoperability. Enterprise: Provide evidence that it has created standard data definitions and data semantics and that the strategies are being reviewed/updated as modules are added, if necessary, as rules change, etc. Modules: Demonstrate that the module is using the state's data definitions and semantics.
IA.DMS.5	The system of interest updates all historical claim data, recipient enrollment, provider enrollment, and	MMIS BP	This criterion does not apply to E&E. For R1, evidence could include acquisition documents, requirements, a ConOps that explains how this will be implemented, service level agreements

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Figure 39. Example Guidance Tab

The header across the top of the checklist tab shows the name of the checklist. Below that are the MMIS milestone review checkboxes. When a box is checked in the review selection section, the sheet will automatically display the columns that apply to that period of the certification life cycle and will hide information that does not apply. The state checks the box of the next pending milestone review.

Individual criteria are listed in rows, with a mapping of their sources and criteria number. Appendix G maps the 2007 certification criteria to the current checklists.

The evidence columns are of three types: column for the state to complete, column for the IV&V contractor to complete, and CMS column. The state fills out the Yes/No/Not Applicable column and the evidence column. It is important that states provide answers for each criterion in the checklists, even for those sourced mapped to a higher maturity level (ML) than the state's target ML. Since MITA 3.0 was released, many of the requirements for ML3 have become standard industry practice. The Standards and Conditions for Medicaid IT stipulates that states employ industry best practices. A few examples of ML3 criteria that are now basic IT practices include limiting system access to authorized stakeholders (TA.BI.9), use of single sign-on (TA.SP.63), and use of business rules engine to avoid costly hardcoding changes (TA.DM.1). Failure to address all relevant criteria will result in the state needing to re-submit the checklists, likely causing delays in the review timeline. The IV&V contractor fills in the Review Date, Reviewer Name, Reviewer Assessment, and Reviewer Comments columns. Depending on the type of review, CMS may or may not fill out the CMS comment column. By default for R1 and R2, the CMS

Assessment column mirrors the IV&V contractor assessment column. This is normal. If CMS assesses a criterion differently than the IV&V contractor, it will alter the CMS assessment column entry.

The spreadsheets are imported into the CMS tracking database, so the structure of the checklists must not change (e.g., label names, merged columns), and many cells are locked. Checklist names for the canned checklist sets, tab names, and reference numbers should not be changed; however, column widths and row heights can be adjusted to suit user needs. Numbers are color-coded to indicate the nature of the criteria. The checklist can be filtered by column and by the pre-set filter dropdowns in each column header. The filter function in the data menu bar will not work with the pre-set filters set.

Checklists also contain the factors considered critical to the success of an MMIS. These are called functional critical success factors or CSFs. CSFs are shown as green rows in the checklist tab.

The MITA business area tab is for reference so that the state and IV&V contractor can easily determine which MITA business area maps to which criteria.

5 Certification Milestone Reviews

5.1 Preparing for a Milestone Review

A summary of milestone reviews and an example case is included here. Appendix L_Milestone Review Preparation Guide contains detailed information about the timeline and logistics of milestone reviews.

Before the IV&V contractor prepares an MMIS IV&V Progress Report prior to a milestone review, the state completes the state section of the checklists (including the Information Architecture, Technical Architecture, and Standards and Conditions for Medicaid IT checklists) and stores the checklists and supporting evidence in its repository. The state fills out the Yes/No and evidence column for each criterion and includes a hyperlink that points to evidence in the state's repository.

Only one hyperlink can be added to any one cell. If a state needs to point to more than one artifact for a criterion, the state can point the reviewer to a document that lists all relevant hyperlinks. The state provides a narrative of evidence for the criterion in the checklist. The relationship between the criterion and the evidence provided should be clearly stated. If the state is marking a criterion as not applicable, then the state needs to provide appropriate justification. If a module being evaluated has a criterion that covers functionality being performed by a different module, then the state must demonstrate how data interaction and data flow occur between the two systems.

In all cases, concrete evidence needs to be provided, as appropriate to the milestone review. For example, for a MMIS Certification Final Milestone Review (R3), the evidence for business criteria could include examples of correctly executed use cases and associated operational transactions from the production system(s) as well as database queries or reports showing correct results for each case. If evidence contains PII or PHI, the evidence needs to be protected using appropriate measures.

Clear, simple linkage between the criterion and the evidence is very important. In one early case, a state mapped criteria to a complicated mapping matrix outside the original checklist. The complexity of the mappings within mappings, and the repeated logins that were required every time a document was opened in the evidence repository, resulted in a reviewer having to perform 109,056 operations to complete review of a single checklist. Such complexity is unnecessary and costly. The state should populate the evidence column with one direct link per criterion that leads to a single folder containing all corresponding evidence.

The state should organize evidence by using folders that correspond to each of the checklist criteria. The state must also indicate which evidence contains PHI or PII. For example, the state labels the evidence as "Confidential." The state will also need to ensure that the IV&V contractor and all members of the CMS certification review team have access to the evidence repositories.

The IV&V contractor then submits the reports and checklists simultaneously to the state, to the CMS RO, and to the CMS certification email address (MES@cms.hhs.gov), being sure to include "MMIS" in the subject line. The state should save the IV&V-completed checklists in its repository as a new version of the checklists. (The checklists should continue to be updated as new versions with subsequent progress reports.)

In the checklists, the state must clearly map each checklist criterion directly to the evidence that supports it.

Only one hyperlink can be added to any one checklist cell. So if the state needs to link to more than one artifact for a criterion, it may provide a link to a separate document that lists all the relevant hyperlinks.

5.1.1 An Example

State X is taking a phased approach to its modules, first developing a cohort of three modules—care management, pharmacy, and registries. The IV&V contractor needs to write an MMIS IV&V Progress Report, so the state downloads the zip file for the checklist set from Medicaid.gov and extracts the Care Management, Pharmacy, and Registries, as well as the Technical Architecture, Information Architecture, and the Standards and Conditions for Medicaid IT checklists.

State X sets up a set of folders in the evidence repository. Each checklist criterion has its own folder. State X then starts filling out its first checklist. It first checks the phase box in the upper left-hand corner of the checklist tab. The state then reads through each criterion in the checklist and indicates in the Yes/No/Not Applicable column if each criterion applies to its modules. If a criterion does not apply, State X explains why it does not in the evidence column.

State X then fills out the evidence column for each criterion by putting a short explination in the evidence cell and inserting a hyperlink to that criterion's repository folder. It puts all relevant evidence into that folder. The state indicates which evidence contains PHI/PII by labeling such evidence "Confidential."

For one of the criteria, State X has three artifacts as evidence—two screenshots and a report. The state places the report in that criterion's folder and also uploads a Miscrosoft Word document in which it pastes the two screenshots and gives a short explination for the various pieces of evidence. By placing as much evidence as possible directly into the Word document, the state has reduced the time it will take the CMS reviewers to find evidence. This makes for a quicker review.

The state ensures that the IV&V contractor staff has access to the state's artifact repository and sends the checklists to the IV&V contractor. The IV&V contractor reviews the state entries in the checklists, along with the evidence. The contractor may request interviews or ask for additional information. The IV&V contractor fills out the reviewer comment columns, uses the Progress Report template to complete its report, and appends the completed checklists to the MMIS IV&V Progress Report before sending copies to the state and to CMS simultaneously. The state stores these IV&V-generated versions in its state repository.

In the MMIS IV&V Progress Report prior to the next milestone review for these modules, State X uses the latest version of the checklists from the last milestone review, updates the evidence columns, sends the updated checklists to the IV&V contractor, and then the process repeats.

When State X starts developing its next set of modules, third party liability and member enrollment, it downloads the checklist set zip file and extracts the Third Party Liability and Member Enrollment checklists. The state can either update its previous Technical Architecture, Information Architecture, and Standards and Conditions for Medicaid IT checklists or it can download blank copies of those checklists and fill them out for the two modules about to go through milestone review. The state will use these technical and business checklists to shepherd the next cohort of modules through certification.

5.2 Artifacts Required for Each Review

Toolkit Appendix B lists the artifacts required for each of the milestone reviews. Minimum requirements for each document are given. The requirements are not an exhaustive list of what typically is included in each artifact, and states are encouraged to add elements as appropriate.

Document names used in agile methodologies often differ from those used in traditional waterfall methods, so, wherever possible, the corresponding agile term is used alongside the traditional name. Because of agile methods' lighter approach to documentation, a couple of artifacts are not required for agile implementations until the final milestone review. In general, CMS expects designs created during the Initiation and Planning phase to be at a high level. As part of its periodic MMIS IV&V Progress Reports, the IV&V contractor will review detailed designs as they are developed during the Requirements, Design, and Development phase of the certification life cycle. For the purpose of certification reviews, CMS does not expect detailed designs until the Operational Milestone Review. The state must retain all certification artifacts in preparation for, during, and for two years after the certification review.

6 Reference Material

6.1 Standards and Conditions for Medicaid IT

CMS is a principal stakeholder in the development of state Medicaid IT systems, and has established a core set of binding requirements for states regarding processes, standards, and architecture. 42 CFR Part 433.122(b)(10-22) establishes specific requirements for Medicaid funding. States should incorporate these requirements into their baseline set of project requirements.

The key components of the Standards and Conditions for Medicaid IT are the following (Note: Numbers 10 – 22 are particularly relevant for development tracking purposes):

1. CMS determines the system is likely to provide more efficient, economical, and effective administration of the State plan.
2. The system meets the system requirements, standards and conditions, and performance standards in Part 11 of the State Medicaid Manual, as periodically amended.
3. The system is compatible with the claims processing and information retrieval systems used in the administration of Medicare for prompt eligibility verification and for processing claims for persons eligible for both programs.
4. The system supports the data requirements of quality improvement organizations established under Part B of title XI of the Act.
5. The State owns any software that is designed, developed, installed or improved with 90 percent FFP.
6. The Department has a royalty free, non-exclusive, and irrevocable license to reproduce, publish, or otherwise use and authorize others to use, for Federal Government purposes, software, modifications to software, and documentation that is designed, developed, installed or enhanced with 90 percent FFP.
7. The costs of the system are determined in accordance with 45 CFR 74.27(a).
8. The Medicaid agency agrees in writing to use the system for the period of time specified in the advance planning document approved by CMS or for any shorter period of time that CMS determines justifies the Federal funds invested.
9. The agency agrees in writing that the information in the system will be safeguarded in accordance with subpart F, part 431 of this subchapter.
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. 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.
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. 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 state personnel by name, type and time commitment assigned to each project.
20. Systems and 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 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 for compliance with existing statutory and regulatory requirements, issued through formal guidance procedures, determined by the Secretary to be necessary to update and ensure proper implementation of those existing requirements.

The Secretary of the Department of Health and Human Services may also establish additional conditions in the future, subject to certain limitations. This flexibility will allow CMS to evaluate states' progress as well as evolving business processes on an ongoing basis and add more conditions as necessary. Importantly, any new conditions established under this provision will be limited to ensuring that states properly develop their systems in accordance with the existing statutory and regulatory framework.

6.2 Acronyms

Table 3. Acronyms

APD	Advance Planning Document	**PHI**	Protected Health Information
CHIP	Children's Health Insurance Program	**PII**	Personally Identifiable Information
CMCS	Center for Medicaid and CHIP Services	**PM**	Project Manager
CO	Central Office	**PMP**	Project Management Plan
ConOps	Concept of Operations	**PPU**	Project Partnership Understanding
CSF	Critical Success Factor	**Q&A**	Question and Answer
DDI	Design, Development, and Implementation	**R1**	Project Initiation Milestone Review
DR	Disaster Recovery	**R2**	Operational Milestone Review
DRA	Deficit Reduction Act	**R3**	Certification Final Milestone Review
DSG	Data and Systems Group	**RFI**	Request for Information
DSS	Decision Support System	**RFP**	Request for Proposal
DW	Data Warehouse	**RO**	Regional Office
FAQ	Frequently Asked Questions	**RTM**	Requirements Traceability Matrix
FFP	Federal Financial Participation	**SDD**	System Design Document
HCBS	Home and Community-Based Services	**SDLC**	System Development Life Cycle
HIPAA	Health Insurance Portability and Accountability Act of 1996	**SI**	System Integrator
IAPD	Implementation Advance Planning Document	**SMDL**	State Medicaid Directors Letter
IBP	Industry Best Practice	**SME**	Subject Matter Expert
ICD	International Classification of Diseases	**SPoTT**	State Portfolio Tracking Tool
IT	Information Technology	**SS-A**	State Self-Assessment
IV&V	Independent Verification and Validation		
MECT	Medicaid MMIS System Review Process		
MES	Medicaid Enterprise System		
MITA	Medicaid Information Technology Architecture		
MMIS	Medicaid Management Information Systems		
M&O	Maintenance and Operations		