DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

SMD # 16-010

RE: CMS-2392-F Mechanized Claims Processing and Information Retrieval Systems – Modularity

August 16, 2016

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) is issuing this third in a series of State Medicaid Director letters to provide sub-regulatory guidance to supplement CMS-2392-F, "Mechanized Claims Processing and Information Retrieval Systems (90/10)," which became effective January 1, 2016. This regulation further supports the modular systems development requirement detailed in 42 CFR Part 433, Subpart C - Mechanized Claims Processing and Information Retrieval Systems.

In reviewing the responses to our Request for Comments in our Notice of Proposed Rulemaking (NPRM) (CMS-2392-P) published on April 16, 2015 (80 FR 20455), we determined that there is a need for the development of supporting policy and sub-regulatory guidance. In developing sub-regulatory guidance, CMS is engaging our partners and stakeholders in recognition of their valuable experience and unique perspectives on this final rule.

Each of the letters in this series addresses discrete subject areas impacted by the final rule.[1] This letter addresses modular certification of Medicaid Management Information Systems (MMIS).

Background

On December 4, 2015, CMS published a final rule at 80 FR 75817, "Federal Funding for Medicaid Eligibility Determination and Enrollment Activities." This final rule provided for a temporary enhancement to the federal financial participation (FFP) rate to support the design, development, and installation (DDI) and maintenance and operations (M&O) of Medicaid Eligibility and Enrollment (E&E) systems that are streamlined and interoperable with other systems and that provide a consumer-friendly experience. To further integrated systems, the final rule modified the definition of Claims Processing and Information Retrieval Systems at 42 CFR 433.111(b) to permanently include E&E systems. The broadened definition was also refined to support an enterprise approach where individual processes, modules, sub-systems, and systems are interoperable and work together seamlessly to support a unified Medicaid enterprise.

[1] Previous letters in this series include State Medicaid Director Letter (SMDL) #16-004 and SMDL #16-009 which can be found at https://www.medicaid.gov/federal-policy-guidance/federal-policy-guidance.html.

The Medicaid enterprise includes: (1) An E&E system used to process Medicaid enrollment applications, as well as change in circumstance updates and renewals. The E&E system might be implemented as the core of an integrated eligibility system that also supports eligibility for other human services programs; and (2) An MMIS used to process claims for Medicaid payment from providers of medical care and services furnished to beneficiaries under the medical assistance program, including review of managed care encounter data, and to perform other functions necessary for economic and efficient operations, management, monitoring, and administration of the Medicaid program. To receive enhanced federal matching funding for development, maintenance and operations, the Medicaid E&E systems and the MMIS must meet all applicable standards and conditions, including modularity, along with associated provisions such as the role of independent verification and validation (IV&V).

A module is a packaged, functional business process or set of processes implemented through software, data, and interoperable interfaces that are enabled through design principles in which functions of a complex system are partitioned into discrete, scalable, reusable components. An MMIS module is a discrete piece (component) of software that can be used to implement an MMIS business area as defined in the Medicaid Enterprise Certification Toolkit (MECT). The updated MECT can be found at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/mect.html.

Modules can be added to a system or replaced, as needed, to implement a required functionality. To meet re-use requirements, modules should be made available to be shared and reused by another state or territory, or have been obtained as a result of sharing and reusing software from another state or territory. Modular projects may leverage the use of commercial off-the-shelf (COTS) products or Software-as-a-Service (SaaS) solutions as well as other modular approaches. In the case of proprietary products and SaaS, the same effective module is potentially available to other states subject to a state's contractual arrangement with the vendor.

Under the revised rule, CMS requires states to follow a modular approach that supports timely, cost-effective projects. We believe that a modular approach to the Medicaid Information Technology (IT) enterprise provides the most efficient and cost-effective long-term solution for meeting states' business needs. States will be able to leverage the modular approach to optimize project design for agility, interoperability and other desirable attributes as well as associated acquisition approaches to avoid prolonged development efforts and vendor lock-in. The modular approach is capable of supporting all Medicaid service delivery models, including managed care, fee-for-service, and use of an administrative services organization.

CMS will support projects that address rational, discrete subsets of Medicaid enterprise functionality (modules) that are interoperable with other parts of the Medicaid enterprise and meet all other Standards and Conditions for Medicaid IT. States are required to follow the modularity principles in their development of new or replacement MMIS and E&E modules. The requirement for modular approaches applies to all systems that are eligible for enhanced match within the Medicaid IT enterprise.

Modular Certification of MMIS Modules

Under previous rules, determination that an MMIS meets all applicable requirements (i.e. "certification"), was completed only after implementation of an entire system and an initial period of operational use. States were able to access the enhanced federal match for maintenance and operations only after this determination. Such an approach resulted in replacement or enhancement projects that were often large, lengthy, expensive and high risk, and delayed states' access to the enhanced match. For these reasons CMS discourages replacement of an entire MMIS as a monolithic activity.

Modular certification will be applied to MMIS systems as new modules are introduced and as existing modules are replaced. CMS may require modular certification of portions of a system when proposed changes or enhancements have been determined to be high risk. Modular certification will result in several benefits to states. With smaller, more incremental projects risk and costs should be reduced for all aspects of the project. Modular MMIS certification will allow the states to access the 75 percent enhanced FFP for M&O of the certified module(s) prior to having completed their total MMIS system replacement, improving the state's cash flow.

Modular certification is supported by the updated MECT, which supersedes the prior MMIS Certification Toolkit. Modular certification will leverage the MECT as a dynamic methodology that can be applied to projects variously aligned along business process lines and functionality. The MECT has multiple options for certifying modular projects that should suit the variety of approaches being taken by different states, including a custom certification approach suggested by a state, subject to CMS's review and approval. Project risk will be a major consideration in deciding whether or not to approve enhanced FFP for a modular project.

Although the addition of a new module or changes or enhancements to an existing module or set of modules would call for modular certification, it would not require the recertification of the entire MMIS. Review of a modular implementation would focus on that module's functions within the MMIS, how it interfaces with other MMIS modules, and how effectively and efficiently it serves its purpose within the MMIS. Successful completion of regression testing must also be verified to ensure that the integration of the new module will not have a negative impact on other parts of the system. CMS requires that the state has accepted the modular solution from their vendor and that there has been at least a six-month period of live operations before it will consider a module for certification. Approval is subject to the conditions in the State Medicaid Manual Chapter 2, Approval of MMIS Systems, sections 11210, 11241, and related sections, found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending, as well as the standards and conditions documented in the MECT.

CMS has organized the requirements in the MECT into checklist sets to be used in certifying MMIS modules. States can use MECT checklists based on 1) the MITA 3.0 business areas, 2) MMIS modules, or 3) a tailored checklist set prepared by the state which the state then submits to CMS for acceptance. Appendix A lists the MITA 3.0 and MMIS business area checklists. Whichever checklist set is used, the MITA 3.0 requirements still apply. In support of a more outcome-based approach, the new MECT also incorporates the concept of critical success factors, further unifying the approaches available to the states for managing MMIS projects.

Recommended Modules

CMS expects that states will take different approaches to identifying the best solutions to meet the needs of the Medicaid IT enterprise. CMS will work with states during the planning stage and provide guidance on the appropriate modules to be incorporated into each project based on the state's concept of operations. The need for modular certification will be identified during the planning stages of a project, including advance planning document (APD) review. Appendix A lists modules that could be constructed based on the two standard checklist sets.

Modular Acquisition

A modular approach to acquisition increases the opportunity to select progressive technology from different vendors, along with the flexibility to swap solutions in and out over time as needed. As the market for modular solutions evolves, states should take advantage of acquisition approaches that will avoid vendor lock-in and other risks of a single, massive solutions. States also should be able to replace individual modules to take advantage of specific innovations without significant integration cost and additional risks.

The modular approach supports states in achieving an optimal balance in the use of open source and proprietary COTS software solutions over the use of custom solutions, thereby reducing the need for custom development, promoting reuse, expanding the availability of open source solutions, and encouraging the use of shared services. Open source projects offer the potential to introduce additional efficiency and innovation. Multiple independent developers contribute best practices and new ideas, reacting to each other's work in a collaborative, open environment. Such projects have been highly successful in other subject domains, in terms of both richness of functionality and economy, and could have similar potential in the Medicaid domain as well. A modular approach to acquisition will lower the barriers to entry for smaller vendors, thereby increasing the availability of modules and shared services in the marketplace.

Conditions for modularity and interoperability require acquisition of loosely coupled modules with open, documented interfaces, including COTS solutions, in order to qualify for enhanced federal funding. A key component of this approach is a well-documented set of open interfaces that allow for vendor-independent integration of modules into an overall business solution. These interfaces may take a number of forms including, but not limited to, application programming interfaces (APIs), open services under a service oriented architecture (SOA), and shared standards-based data stores.

States should carefully craft Requests for Proposals (RFPs) to specify these conditions, and may find it efficient to include excerpts from the certification checklists, particularly the critical success factors. CMS expects that states' RFPs and contracts will contain language requiring publication of open APIs.

System Integrator Role

CMS envisions a discrete role for the system integrator (SI) in each state, with specific focus on ensuring the integrity and interoperability of the Medicaid IT architecture and cohesiveness of the various modules incorporated into the Medicaid enterprise. The target outcome for the SI should be to foster ever evolving solutions for Medicaid business requirements, with the SI responsible for the successful integration of the chosen solutions and infrastructure into a seamless functional system. The scope of the SI role shall include the interoperable integration of the Health Information Exchange activities as described in State Medicaid Directors letter #16-003 into the Medicaid enterprise. More information on the SI role can be found in the MECT, Medicaid Enterprise Certification Life Cycle, part 01 Section 1.7.

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. As described above, the goal is to avoid lock-in to a single vendor or an otherwise closed set of solutions.

Independent Verification and Validation

Under regulation at 45 CFR 95.626, Independent Verification and Validation (IV&V) may be required for any major Medicaid IT project. The IV&V contractor represents state and CMS interests throughout each project and, as such, provides an independent and unbiased perspective on the progress of MMIS or E&E system development and the integrity and functionality of the system. The scope of IV&V responsibilities are detailed in the MECT and include evaluation of project management and performance, project development and testing processes, and technical reviews of the modules. The IV&V contractor must also verify that adequate regression testing has been performed to confirm that the replaced or enhanced module does not adversely impact the functionality and operation of the MMIS, E&E systems or other related components of the state's Medicaid Enterprise.

In order to allow time for states to align existing contracts and projects to the new IV&V guidelines, CMS will allow states an 18-month period from the date of this letter to comply with new IV&V requirements. This 18-month period is applicable only to contracts in place as of the date of this letter. Contracts entered into after the date of this letter must comply with all IV&V requirements. To aid in adoption of these new requirements the MECT contains model language for states to include in their IV&V contracts.

MITA 3.0 Compliance

Regulation at 42 CFR 433.112(b)(11) requires alignment with MITA for DDI of MMIS and E&E systems that are funded with enhanced federal matching funds. MITA 3.0 compliance requires that systems be designed, developed, and maintained with up-to-date industry best practices, so that the resulting MMIS and E&E systems are modular and technically suitable for sharing and reuse with other states. See https://www.medicaid.gov/Medicaid-CHIP-Program-

Information/By-Topics/Data-and-Systems/Medicaid-Information-Technology-Architecture-MITA.html.

Module Pre-Certification

CMS will implement a module pre-certification program that will allow vendors to present their Medicaid IT modular solutions to CMS for review, regardless of whether the software has been implemented in a state system or not. Information about the pre-certification criteria and process is available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/modules.html.
This SMDL supersedes previous guidance in the State Medicaid Manual (SMM) Chapter 11 (https://www.cms.gov/Regulations-and-Guidance/guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.html). Supplemental information is available in the MECT and in a series of responses to frequently asked questions (FAQs) maintained at https://questions.medicaid.gov.

If you have additional questions, please contact Martin Rice at Martin.Rice1@cms.hhs.gov. We look forward to working with states to facilitate state system builds, to ensure compliance with this regulation, and to provide assistance implementing these requirements.

Sincerely,

/s/

Vikki Wachino
Director

cc:
Jessica Kahn, Director of the Data and Systems Group, CMS
National Association of Medicaid Directors
National Academy for State Health Policy
National Governors Association
American Public Human Services Association
Association of State Territorial Health Officials
Council of State Governments
National Conference of State Legislatures
Academy Health

Appendix A: List of Modules

Medicaid Management Information System (MMIS) Modules
Below are lists of modules that could be constructed based on the two standard checklist sets available within the Medicaid Enterprise Certification Toolkit (MECT).

I. Medicaid Information Technology Architecture (MITA) Business-Aligned Modules

The following correspond to the set of MITA business-aligned certification checklists of the same names:

- Business Relationship Management
- Care Management
- Contractor Management
- Eligibility & Enrollment
- Financial Management
- Member Management
- Operations Management
- Performance Management
- Plan Management
- Provider Management

II. MMIS System Modules

The following are aligned with MMIS system models:

- Member Enrollment
- FFS Claims & Adjudication
- Pharmacy
- Third Party Liability
- Care Management
- Program Integrity
- Decision Support System
- Reference Data Management
- Provider Management
- Registries