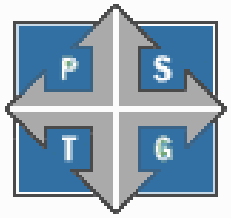

Private Sector
Technology Group

Regulatory and Policy Subcommittee

Considerations for Regulatory and Policy Revisions Affecting Medicaid Procurements White Paper

v2.0, January 9, 2015

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1. Overview

This paper analyzes the regulations that govern the systems which support state Medicaid programs in light of several federal initiatives aimed at streamlining the Medicaid technology procurement processes. The PSTG Regulatory and Policy Subcommittee's purpose was to review the existing regulations, suggest issues that adversely impact state Medicaid technology procurements and suggest changes of those regulations going forward.

It is important to first acknowledge that existing regulations regarding "Mechanized Claims Processing" systems (Medicaid Management Information Systems, MMIS) and particularly the related funding are incompatible with current CMS direction for Medicaid Enterprise Systems. In fact, regulations provided financial incentives to the States to make decisions and follow system design and build processes that are in conflict with published guidance, including the Seven Conditions and Standards, inclusive of the MITA Framework and tenets, components within 42 CFR Part 433, and CMS guidance. It is quite likely that those incentives have in the past and may continue to lead States to expend State and Federal dollars that could be better used to provide additional services for members or to expand and cover additional members. With this in mind, PSTG recommends changes to regulation to re-align financial incentives.

The over-arching precepts that informed the crafting of this paper were to:

- Develop suggestions that would modify regulation so that it is consistent with the Seven Conditions and Standards, inclusive of the MITA 3.0 Framework.
- Promote the greatest degree of flexibility for State needs as well as vendor solutions in support of those needs.
- Identify modifications that in their aggregate would be at least 'budget-neutral' for CMS and the States when compared to the existing enhanced funding regulations.

We have divided the paper into six sections (Issues), each addressing a different aspect of concern, and offered our suggestions within each 'Issue'. Those six issues are:

Issue 1: Enhanced Funding
Issue 2: Costs Ineligible for Enhanced Funding
Issue 3: Ownership
Issue 4: OBM Circular A-87 Exception and Eligibility and Enrollment Regulation
Issue 5: Modular Solutions and Certification
Issue 6: Current Regulatory Capabilities

2. Issue 1: Enhanced Funding

Summary of Current Funding and Impact

The following from www.Medicaid.gov is a summary of the legislation and regulation effecting MMIS funding:

> *The MMIS is an integrated group of procedures and computer processing operations (subsystems) developed at the general design level to meet principal objectives. For Title XIX purposes, "systems mechanization" and "mechanized claims processing and information retrieval systems" is identified in section 1903(a)(3) of the Act and defined in regulation at 42 CFR 433.111. The objectives of this system and its enhancements include the Title XIX program control and administrative costs; service to recipients, providers and inquiries; operations of claims control and computer capabilities; and management reporting for planning and control.*
>
> *In October 1972, Public Law 92-603 was enacted in which Section 235 provided for 90-percent federal financial participation (FFP) for design, development, or installation, and 75-percent FFP for operation of state mechanized claims processing and information retrieval systems approved by the secretary. For Medicaid purposes, the mechanized claims processing and information retrieval system which states are required to have, unless this requirement is waived by the secretary, is the Medicaid Management Information System (MMIS). An implementing regulation, 45 CFR 250.90 was published May 20, 1974, and subsequent reorganization and clarification of this regulation have been made with the current regulation contained in 42 CFR 433, subpart C.*

Challenge 1.1 – Enhanced Funding

Enhanced funding for Medicaid IT projects provides 90% Federal match for custom-developed systems and 75% enhanced match for non-customized software, such as COTS, or licensed software. However, some components of a COTS or licensed software development process, such as custom interface development and the data conversion process, could be funded at 90%.

This federal funding model has established, from most states' financial perspective, incentives to procure, or develop themselves, a customized, one-off, MMIS solution, even if transferred from another state.

Consider the following three simplified solutions where a state has an appropriation of $5M in State dollars to spend on an MMIS.

At 90% funding, the total funds available to the state would be $50M as shown in the following diagram:

As FFP Diminishes, Total Spend Available Decreases At An Accelerated Rate

FFP = 90%

State Share $5mil. CMS Share $45mil.

Total Spend $50 mil.

At 75% funding, the total funds available to the state would be $20M:

FFP = 75%

State Share $5mil. CMS Share $15mil.

Total Spend $20 mil.

Finally, at a 50% rate, the total funds available to the state would be $10M.

FFP = 50%

State Share $5mil. CMS Share $5mil.

Total Spend $10 mil.

Clearly, all financial incentives for the state are aligned with a customized solution, not one that is aligned with the Seven Conditions and Standards, inclusive of MITA. Although the Seven Conditions and Standards', "Leverage Condition" promotes the use of commercial off-the-shelf (COTS) software (and other non-customized software) to reduce overall project implementation costs, the enhanced match does not align with this directive.

Previously the PSTG had presented the example which follows in its White Paper entitled Modernizing Medicaid: Technology Considerations for Moving from Fee for Service to a Managed Care Payment Model. That document contained a funding model example of a historical, customized MMIS implementation and compared it to a revised approach with a full COTS solution. Those examples follow:

- *Project 1:* State A procures a large integrated system that requires customization for claims processing and reporting solution costs include:

Total DDI Budget - Project 1

	Total	Fed Share	State Share
Contractor DDI Cost (90%)	$60,000,000	$54,000,000	$6,000,000
IV&V Contractor (90%)	$5,000,000	$4,500,000	$500,000
PMO Contractor (90%)	$11,000,000	$9,900,000	$1,100,000
Staff Training (75%)	$90,000	$67,500	$22,500
Equipment for Project Staff (90%)	$50,000	$45,000	$5,000
State Staff Time for MES (90%)	$11,000,000	$9,900,000	$1,100,000
DDI Cost for Replacement	**$87,140,000**	**$78,412,500**	**$8,727,500**

* Estimated costs in this example are for illustrative purposes only.

- *Project 2:* State A procures a COTS solution, with the following costs:

Total DDI Budget - Project 2

	Total	Fed Share	State Share
Contractor DDI Cost (90%) - Config./Labor	$20,000,000	$18,000,000	$2,000,000
Contractor DDI Cost (75%) - Sftwre.	$20,000,000	$15,000,000	$5,000,000
IV&V Contractor (90%)	$5,000,000	$4,500,000	$500,000
PMO Contractor (90%)	$11,000,000	$9,900,000	$1,100,000
Staff Training (75%)	$90,000	$67,500	$22,500
Equipment for Project Staff (90%)	$50,000	$45,000	$5,000
State Staff Time for MES (90%)	$11,000,000	$9,900,000	$1,100,000
DDI Cost for Replacement	**$67,140,000**	**$57,412,500**	**$9,727,500**

* Estimated costs in this example are for illustrative purposes only.

In this scenario, by implementing commercial software, although CMS will experience substantial savings, the state must provide additional state dollars. This 'incentive' in funding towards customized, one-off MMIS solutions is at the heart of the issue this Subcommittee is addressing.

At times the issue of higher software lifetime costs has been raised with regard to licensed software. There has been some pushback that, on its face, the operational cost to Federal and State governments for COTS-based solutions appear to be higher, as ongoing licensing costs are

incurred throughout the maintenance and operation period of an MMIS contract. However, this appearance is deceiving for a number of reasons.

First, custom solutions incur significant costs over time for maintaining technical currency and on a modern technology path. Software maintenance is a very broad activity that includes both enhancements to the software as well as bug removal, and improvements to the system and its performance. Just as licensing costs are recurring throughout the operational phase of an MMIS solution, so the ongoing maintenance cost of that software is likewise recurring to both the Federal and State governments. Historically, this effort has been largely ignored in legacy MMIS solutions, and is partly responsible for the massive 'refresh' of MMIS technology required over the last few years to all MMIS solutions to take advantage of modern software capabilities.

States benefit from COTS based solutions in that maintenance costs, including product upgrades, are shared among all users rather than borne solely by the individual state. In addition, states benefit from the ongoing product testing performed on COTS products, not only by the vendor, but by the various customers utilizing the product. Other factors such as the degree to which COTS solutions support an individual State's policy and programs, both currently and as they evolve, must also be considered.

Finally, any software which supports the rapid implementation of program and policy changes has the additional benefit of saving significant program dollars. Within a Medicaid program which generally averages just over 5% administrative costs nationally, the systems costs are less than 50% of that amount. Most program dollars are spent on direct delivery of care. If a policy change can be implemented sooner using a modern solution, savings associated with that change can accrue sooner. These savings are often in the many millions of dollars per month and significantly higher than the amount of the licensing costs associated with the software that enabled the change.

Considering all of the issues above States are financially incented to embrace customized, built from the ground up MMIS solutions by the financial incentives present in current regulation concerning MMIS development.

Recommendation

Consistent with the overarching precepts noted in *Section 1 – Overview*, the following recommendations offer a high degree of parity for solutions, whether they were custom, shared, Cloud Based, Software as a Service (SaaS), Proprietary COTS, ASO, etc. To provide some additional clarity we provide the following definitions of the various types of solutions envisioned:

- **Custom** – is software that is specially developed for a State Medicaid agency. As such, it can be contrasted with the use of software packages developed for the mass market, such as commercial off-the-shelf (COTS) software.
- **Shared Services** –refers to a solution that is structured as a centralized point of service and is focused on defined business functions. In the State Medicaid environment this can be thought of as IT services designed to support multiple State organizations. Shared services may involve single or numerous business functions and IT processes. Execution and long-term delivery would likely be provided by service providers; although a State operated solution could be shared with another state(s). Once a MMIS shared solution is put in place, those who 'share' that service do not have to become involved in the custom development of a solution. Likely there will be conversion, configuration, and interface issues to address, but the effort of implementing new functionality would be significantly reduced.

- **Cloud Based Computing** –is the delivery of computing as a service rather than a product, whereby shared resources, software, and/or information are provided to computers and other devices as a utility over a network.
- **SaaS** – is a software licensing and delivery model in which software is licensed on a subscription basis and is centrally hosted. SaaS is typically accessed by users using a thin client via a web browser.
- **Proprietary COTS** – COTS purchases are alternatives to custom developments or one-off government-funded developments. COTS typically requires configuration that is tailored for specific uses and the key characteristic that differentiates COTS from Custom software is that the user configurations are within the defined parameters of the commercial item and not the result of customizations to the commercial item itself.
- **ASO (Administrative Services Only)** – An arrangement in which an entity hires a third party to deliver administrative services such as claims processing and billing, in this case to a State. The State continues to bear the risk for the cost of services. This can be viewed as "outsourcing" the administration of the claims processing, without detailed instruction by the State of 'how' the processing should be performed as with a custom solution.

The following are 'draft' alternatives for revising Enhanced Funding Policy:

1) **Develop a Parity Rate of Enhanced Funding for DDI. This rate, for example, could be 80% for all covered DDI processes.**

Pros - Likely this would provide an incentive for leveraged solutions (such as shared, SaaS, Cloud based, ASO, etc.) and dis-incentives for custom, build from scratch solutions. Shared solutions, or services, would likely be available at the same or lower cost than custom solutions. Since the funding rate is the same for non-custom solutions, as for custom

solutions, this would provide a lower cost to the States (who don't select custom built solutions). If the rate was set appropriately, CMS would achieve budget neutrality. Generally, it is envisioned that a 'service' based purchase would have development cost related to conversion, configuration, and interfaces, as well as possibly some custom solution development that may be required; however, most of the cost of the solution would be for 'operation' of the solution.

This methodology would be easy for States, CMS, Vendors, and consultants to understand and would simplify the FFP claiming process.

This change to funding supports MITA and the Seven Conditions and Standards and promotes modularity, leverage, and interoperability as there would no longer be an incentive placed solely on 'custom developed' solutions.

Cons – States who still seek a custom solution would face higher state share of the cost and likely would not support parity of the funding rate.

2) Reverse the 90%, and 75% rates and what is funded by each.

Pros – This rate reversal would no longer provide today's financial incentive for custom build solutions. Shared solutions, or services, would likely be available at the same or lower cost than custom solution. Since the funding rate is higher for non-custom solutions, this would provide a lower cost to the States (who don't select custom built solutions). Since CMS would now be funding what should be lower cost solutions at the higher rate than the higher cost solutions, CMS costs should be lowered.

This change to funding supports MITA and the Seven Conditions and Standards and promotes modularity, leverage, and interoperability, as there would no longer be an incentive placed on 'custom developed' solutions.

Cons – States who still seek a custom solution would face higher state share of the cost and likely would not support the change of the funding rates.

3) End the 90% funding; have all enhanced funding at 75%.

Pros - Likely this would provide an incentive for leveraged solutions (such as shared, SaaS, Cloud based, etc.) and dis-incentives for custom, build from scratch solutions. The reason for this is that shared solutions, or services, would likely be available at the same or lower

cost than custom solutions. Since the funding rate is the same as for custom solutions, this would provide a lower cost to CMS and could provide a lower cost to the State for a shared vs custom solution where the rate of funding is equal.

This change to funding would support the Seven Conditions and Standards, including MITA, and promote modularity, leverage, and interoperability as there would no longer be an incentive placed on 'custom developed' solutions.

The potential for negative financial impact on States could be lessened by continuing 90% funding for certain, narrowly defined, functions/processes, such as:

- New interfaces
- Data conversion
- Unique state program functionality

Cons – States who still seek a custom solution would receive a lower federal share, thereby raising the state share of the cost and likely States would not support the lowering of the funding rate.

Note: Regarding Scenarios 1 & 3 above – for each of these there would remain 90% funding under a limited set of circumstances. These circumstances would be:

- State specific interface design, development, implementation
- State specific custom coding required to support program functionality and policy as long as approved in a State Plan Amendment, Waiver, or State Medicaid Manual
- State data conversion

3. Issue 2: Costs Ineligible for Enhanced Funding

The current designation of specific costs that are eligible for enhanced funding was established over 30 years ago, with only minor modifications in the interim. There are a number of items that are excluded that, in today's environment, appear to be counter-productive to successful MMIS implementations and operations and may provide dis-incentives to states.

Challenge 2.1: Training Costs (DDI)

In today's IT environment, solutions are simplified, making increasingly powerful functionality available to the 'End User'. Functionality related to such applications as rules creation, workflow, and analytics can provide tremendous flexibility, rapid deployment, and in-depth understanding of information contained within or accessed by IT solutions. At the same time, they provided tremendous risk to accurate program operation, unintended consequences, and/or misunderstanding if they are misused or misinterpreted. It is extremely important that any staff using these systems have the proper training in how to do so in a manner that will yield the planned-for outcomes and understanding.

Recommendation

It is our recommendation that all training related to the use of the MMIS be reimbursed at the same rate as any other activity related to the development or operation of the MMIS. This change will align the funding of training with the MITA Condition, Business Results, and Reporting Condition. PSTG recommends the matching rate for training be eligible for the DDI enhanced match rate.

Challenge 2.2: Provider Manuals/ Outreach and Educational Materials (DDI)

In years past, provider manuals focused on the proper way to complete a claim form, mailing instructions, and descriptions of claim policy (filing limits, benefit limitations, etc.). As Medicaid Enterprise Solutions have matured, the focus on provider training and instruction is greatly expanded. With emphasis on self-service solutions and paperless environments, provider manuals are critical for full provider utilization of the electronic capabilities of the systems.

Recommendation

Provider Manuals/Outreach and Education have become a key component in a successful implementation, and the development costs should receive the same enhanced funding as other

components of DDI. In addition, increased emphasis on member outreach and training, including member on-line accessibility to information and educational materials, have greatly expanded the activities and processes to support them. Again, the emphasis on self-service solutions and accessibility are considered key components of a successful implementation.
Currently no enhanced funding is available for provider manuals or member outreach or educational materials. PSTG recommends matching these at the DDI enhanced match rate.

Challenge 2.3: DSS for use with other than an MMIS (DDI & Operations)

Today data and analytics are more important than ever to effectively manage State health care programs. Managing the program includes usually managing/overseeing many managed care contractors, various waiver programs, experiments in delivery such as ACOs, Health Homes, or Medical Homes, new payment methods (episodic or bundled payments for example), etc. States also need holistic views of its members, especially as they churn in and out of Exchange programs, Medicaid, and other commercial plans and as state Medicaid programs case manage and coordinate care across settings, programs, and plans.
To do the above, and more, States need access to not only the Medicaid administrative claims data, they need access to clinical data from HIEs, claims data from other plans, data from Human Services programs, public health data, etc. States may be best served by systems which are connected to All Claims Databases, have direct feeds from managed care contractors, or some other source.

Recommendation

PSTG recommends an allocated DDI enhanced match rate for Medicaid/CHIP data portions of a DSS, even if fed directly by MCOs, as part of an APCD, or other mechanism. All applicable OMB Cost Allocation principles would apply to Operations and Maintenance costs.

Challenge 2.4: DSS – User-generated Reporting Costs (Operations)

Today's Decision Support Systems are flexible and adaptable, providing powerful tools to access data , and perform data analysis from which decisions can be made regarding operations, program delivery, and policy. Examples of the usage of a DSS are to monitor program effectiveness, health outcomes, and to detect fraud, waste, and abuse of program assets.
In today's Medicaid programs, easy access to data analytics is essential to achieving the Triple Aim goals of increase access to services, decrease costs, and improve health outcomes. One of the added benefits of DSS is its easy access by a wide range of users; one does not need to be an

ADP professional to create/key-in the necessary parameters which cause the DSS to generate user-requested reports. DSS, when utilized to its full potential, can be used by all trained personnel; including IT specialists, statisticians, other professionals, as well as any trained personnel. Time, money, and resources are saved when the User self-generates reports and/or creates new DSS reports to support program management resulting in more efficient operations.
In a DSS system, the personnel who have been trained to enter/key-in parameters to generate and create reports are performing at a level and in pursuit of critical information. By being able to enter/key-in, they are enabling themselves (on behalf of themselves as well as anyone who has requested a report) to write, revise and refine reports, look at the data produced, search for health outcome trends, and data mine for useful statistics including fraud and abuse trends.

Recommendation

It is PSTG's recommendation that all Users who have been trained to enter/key-in the parameters necessary to generate their own reports and/or to generate user-requested reports from the DSS be reimbursed at the same rate as an ADP professional. All applicable OMB Cost Allocation principles will still apply, as in the case where the above activities make up less than 100% of an individual's time.

Challenge 2.5: Audit functions / Governance and Oversight (Operations)

Audit functions are specifically excluded from enhanced federal match. This appears directly contradictory to the best interest of both State and Federal governments. With the size and complexity of modern Medicaid Enterprise Systems (MES) and all of the various components comprising these systems, it seems that emphasis on accountability of these systems should be of paramount importance. Also, with increased interest in carving out components into separate procurements, often with separate vendors, the need for active audit functions to assure the various components work together to achieve overall success assumes even greater importance.
The importance of accountability of these complex and diverse systems doesn't end with "go live". With the rapidly changing Medicaid landscape at both the federal and state level, coupled with the ever-increasing complexity of the systems that support enterprise-wide programs, ongoing audit of the key solutions and performance standards through operational verification and validation is essential to assure the accuracy and compliance of the solution during its entire lifecycle.

Recommendation

While IV&V costs during DDI are eligible for enhanced match, currently no enhanced funding is available for ongoing Audit functions. To encourage states to maintain an environment of accountability and accuracy, CMS should consider supporting audit functions related to MES ongoing operations through enhanced funding. Likewise, existing regulations are silent on the costs of system integrators, governance and contract oversight. With the increased emphasis on a modular approach to MMIS procurements, increased complexity is added to management of these procurements by involving multiple vendor sources with differing platforms, including data warehouses. The complexity of integration and governance must be considered and built into the implementation and ongoing maintenance coordination costs for all parties. PSTG proposes that these costs should also be eligible for enhanced funding for DDI and Operations phases.

4. Issue 3: Ownership

Challenge 3.1 – System/Software Ownership

Current regulation states the following about ownership with regards to a MMIS (quoted regulatory language appears in italics in Issue 3):

> *"§95.617 Software and ownership rights.*
>
> *(a) General. The State or local government must include a clause in all procurement instruments that provides that the State or local government will have all ownership rights in software or modifications thereof and associated documentation designed, developed or installed with Federal financial participation under this subpart.*
>
> *(b) Federal license. The Department reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use and to authorize others to use for Federal Government purposes, such software, modifications, and documentation.*
>
> *(c) Proprietary software. Proprietary operating/vendor software packages which are provided at established catalog or market prices and sold or leased to the general public shall not be subject to the ownership provisions in paragraphs (a) and (b) of this section. FFP is not available for proprietary applications software developed specifically for the public assistance programs covered under this subpart.*
>
> *[51 FR 45326, Dec. 18, 1986, as amended at 75 FR 66340, Oct. 28, 2010; effective November 1, 2011]"*

PSTG's position is that the above language regarding software and ownership rights is not in concert with modern thoughts or practice with regards to ownership of software. When someone uses software today, they generally do so through a web application, or through licensed software. Ownership of the software doesn't pass to the user of the software or to the licensee of the software.

Recommendation

We recommend that the language regarding 'ownership' as well as the funding associated with software 'ownership' be amended so that it does not penalize States that don't want to own the software solution. Funding rates should be tied to the utility states derive from the solution, not from ownership.

Further, the exemption of FFP for proprietary application software developed specifically for public assistance programs should be stricken. States can derive great benefit for their programs by having access to federal funding for these types of solutions and should not be monetarily penalized for utilizing such solutions where they represent a State's best alternative.

We do concede that custom solutions, or portions thereof, that are developed exclusively with State and Federal funds should be 'owned' (in the current spirit of the existing regulation) by the State and Federal government for use in Government healthcare programs. However proprietary solutions that were not developed in this way (be they Cloud, SaaS, COTS, licensed, ASO, or other model) should be funded at the same or higher rates of FFP than custom solutions. The net effect of this will be to incent States to utilize solutions that are aligned with MITA, which can be implemented more rapidly, and are less costly.

States can and have successfully protected themselves against the event of non-support from a current solution provider who no longer supports the State for whatever reason, by placing software in Escrow with the ability to utilize/modify that software under specific situations for specified reasons, as long as the State needs to do so.

Challenge 3.2 – Termination Requirements

Current regulation states the following about termination requirements with regards to a MMIS:

> ***§ 434.10 Contracts with fiscal agents.***
> *Contracts with fiscal agents must—*
> *(a) Meet the requirements of § 434.6;*
> *(b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—*
> *(1) Computer programs;*
> *(2) Data files;*
> *(3) User and operation manuals, and other documentation;*
> *(4) System and program documentation; and*
> *(5) Training programs for Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;*
> *(c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent's subcontractor has a proprietary right to material specified in paragraph (b) of this section:*
> *(1) Purchasing the material; or*

(2) Purchasing the use of the material through leasing or other means; and

(d) State that payment to providers will be made in accordance with part 47 of this chapter.

PSTG asserts that the above language regarding termination requirements is not in harmony with modern thoughts or practice with regards to software available for use in government healthcare programs today.

Recommendation

As with Challenge 3.1, Ownership, ownership of software should not be required to be passed to the user or licensee of the software; purchasing and passing the right to use is sufficient. One method states have used to successfully protect themselves against the event of non-support from a current solution provider, who no longer supports the State for whatever reason, is to place software in Escrow with the ability to utilize/modify that software under specific situations for specified reasons, as long as the State needs to do so.

We recommend that the termination requirements be amended to allow states to continue to use the software solution without owning it.

Current regulation at 45 CFR 95.617(c) and CMS guidance through Medicaid Director Letter (SMDL #02-005) provides guidance to States on when enhanced FFP is available, including the following statement about a perpetual right to use license:

HCFA will approve the use of such proprietary software….

(b) where the vendor of the proprietary software agrees, in writing, to grant the State a perpetual license for continued use of the software should the State award a contract for a subsequent take-over of the MMIS operations by another fiscal agent/contractor.

In summary, issues of ownership should not impede States from pursuing modern solutions. These solutions can allow States to implement changes to their programs rapidly, providing them with the ability to serve their members, add new programs, and put in place cost saving measures as well as revised delivery methods which improve access or outcomes.

5. Issue 4: OMB A-87 Circular Exception and Eligibility and Enrollment Regulation

(21950 Federal Register / Vol. 76, No. 75 / Tuesday, April 19, 2011 / Rules and Regulations, 42 CFR Part 433, [CMS-2346-F], RIN 0938-AQ53, Medicaid; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities)

PSTG applauds the Administration's leadership in promoting horizontal integration of health and human services through the utilization of the cost allocation exception to OMB's A-87 Circular announced in the Tri-Agency Letters of August 2011 and January 2012. We further applaud the October 2014 announcement of the extension of the exception through 2018 as well as CMS intend to issue new regulations that will codify the availability of the 90/10 federal matching funds for Medicaid eligibility and enrollment systems on a permanent basis. The extension and permanent enhanced eligibility funding will allow many more states to leverage their infrastructure investments to bring their Medicaid eligibility and enrollment systems into compliance with the vision outlined in the Affordable Care Act and further modernize those systems going forward. They will also be able to support their health and human services program integration and the holistic treatment of members needs across programs through the leveraged funding authorized by this time-limited exception.

6. Issue 5: Modular Solutions and Certification

The first of the Seven Conditions and Standards prescribed by CMS is that of modularity. This standard defines modularity as "breaking down systems requirements into component parts." However, the current certification process does not recognize the complexity that such an approach presents to the certification process. Specifically, the following concerns need to be considered when addressing certification of a modular approach to MMIS replacement:

1. **Can individual modules be certified independently of the complete MMIS?** There is precedence for individual certification to be found in the recently promulgated regulations addressing EHR technology. In these regulations, either the Complete EHR or EHR Modules can be certified. This would appear to support a similar approach for certification of the MMIS or individual modules of the MMIS. If independent certification of modules is acceptable, consideration should be given to the responsibility of each entity when changes to interfaces/APIs are required. Validation and testing should also be built into this coordinated effort.

2. **If individual modules are certified separately, how will the timing of the certification process be affected?** As modular components may be implemented by separate vendors, the complexity of the certification process is increased. Implementation timeframes for various modules could be significantly different. As most states tie some level of reimbursement to successful certification, requiring all components to be certified simultaneously could result in significant delays in payment for modules implemented early. The impact of this cash flow constraint could have a significant adverse effect on smaller, niche vendors whose financial depth may not support such delays.

3. **If individual modules are certified as they are implemented, separate from the entire MMIS, how will interdependencies between multiple vendors be addressed?** In a modular environment, interdependencies between vendors are greatly increased and one vendor's solution could be greatly dependent upon timely and accurate performance of another vendor. How will the certification process address this complexity?

4. **If individual modules are certified separately, how will CMS consider future applications using the same modules?** Will that module no longer require certification if it's selected and implemented by another state? The aforementioned regulations related to EHRs addresses this issue somewhat by the introduction of "Gap Certifications", to address recertification of previously certified solutions when the certification criteria has changed from that of the original certification. In addition, the regulations recognize that certified solutions may not require new certifications when "adaptations" to the originally certified solution have been implemented without affecting the "exact same capability or capabilities included in the certified Complete EHR or certified EHR Module." In contemplating this question, consideration should include whether new processes incorporated into the "adapted" module that impact existing processes require re-certification or federal approval?

With states encouraged to move to a modular approach in their MMIS procurements, the implications to the certification process and the impact of multiple modules and vendors contributing to the solution must be thoughtfully addressed, well-timed and defined in advance with all affected parties. While we are making no specific recommendations here to change existing regulation, the PSTG stands ready to work with CMS and/or the States to develop thoughtful processes that would address the outlined issues.

Modularity and Funding

Enhanced funding can and should be applied to modular builds. CMS has indicated movement to simpler and smaller RFPs for modules of the MMIS, and CMS supports the extension of enhanced funding. If an MMIS module build is certified, then the included module(s) is/are entitled to enhanced funding for those module(s). There should not be any difference in the enhanced funding of MMIS modules and a complete MMIS system. A complete system build using numerous modules would have the same rate of enhanced funding as a single large build.

7. Issue 6: Current Regulatory Capabilities

Challenge 6.1: Existing Regulations Seldom Used By States

This section addresses current regulatory capabilities which are seldom utilized. These capabilities allow for flexibility in States' ability to put in place information technology solutions which, although they may not conform to other regulatory language or MITA business process definitions, would provide great value to the State Medicaid agency and to the providers and/or members they serve.

Following is a listing and short discussion of little used regulatory capabilities (Federal Regulation is indicated by the use of italics):

1. *45 CFR 95.610 - Submission of Advanced Planning Documents*
    a. *Advance Planning Document (APD) refers to an Initial advance automated data processing planning document or Initial APD, providing a recorded plan of action to request funding approval for a project which will require the use of ADP services or equipment, including the use of **shared** or purchased services in lieu of State acquired stand-alone resources. Requirements are detailed in paragraph (a), (b) and (c) of this section.* (emphasis added)

This language contained within 45 CFR, provides for the utilization of shared services, and since the language is included in the explanation of the APD process, it appears to give tacit approval to the notion that 'shared' services are eligible for enhanced funding.

2. *45 CFR Part 95.627 Waiver process*

    ***(a) Application for a waiver.** A State may apply for a waiver of any requirement in Subpart F by presenting an alternative approach. Waiver requests must be submitted and approved as part of the State's APD or APD Update.*

    ***(b) Waiver approvals.** The Secretary, or his or her designee, may grant a State a waiver if the State demonstrates that it has an alternative approach to a requirement in this chapter that will safeguard the State and Federal Governments' interest and that enables the State to be in substantial compliance with the other requirements of this chapter.*

    ***(c) Contents of waiver request.** The State's request for approval of an alternative approach or waiver of a requirement in this chapter must demonstrate why meeting the condition is unnecessary, diminishes the State's ability to meet program requirements, or that the alternative approach leads to a more efficient, economical, and effective administration of the programs for which federal financial participation is provided, benefiting both the State and Federal Governments.*

    ***(d) Review of waiver requests.** The Secretary, or his or her designee, will review waiver requests to assure that all necessary information is provided, that all processes provide for*

effective economical and effective program operation, and that the conditions for waiver in this section are met.

(e) Agency's response to a waiver request. *When a waiver is approved by an agency, it becomes part of the State's approved APD and is applicable to the approving agency. A waiver is subject to the APD suspension provisions in § 95.611(c)(3). When a waiver is disapproved, the entire APD will be disapproved. The APD disapproval is a final administrative decision and is not subject to administrative appeal.*

This language implicitly allows a State to apply for a waiver in order to use an 'alternative' approach to the requirements in the regulations. Conditions may include alternate approaches to system solutions that don't readily fit into existing definitions of a mechanized claims processing solution or that don't conform to specified delivery models.

3. *SMM Part 11 Demonstrable Conceptual Equivalent*

"Demonstrable Conceptual Equivalence" per SMM 11.225 – "The concept of demonstrable conceptual equivalence to MMIS requirements has been recognized since the inception of both MMIS and the SPR. This provision permits States to depart significantly from the GSD model so long as those changes satisfy the objectives and functions of the system requirements articulated in Part 11 of the SMM. This provides States sufficient flexibility to allow for the differing administrative needs of their various programs."

Under CMS' current policies:

"…states may maintain multiple claims processing and data retrieval systems provided: (a) they do not appreciably increase the cost or detract from the benefits CMS is seeking from the MMIS; (b) each module or sub-system meets CMS-established criteria; and (c) all sub-systems feed into a single comprehensive utilization and management reporting system that meets CMS' criteria. CMS policies refer to this notion as "demonstrable conceptual equivalence" – i.e., "a concept which permits States to illustrate that the system is technically different from the MMIS but still satisfies the objectives and functions of the MMIS, and is, therefore, its conceptual equivalent."

E. Demonstrable Conceptual Equivalence.--A concept which permits States to illustrate that a system is technically different from the MMIS but still satisfies the objectives and functions of the MMIS, and is, therefore, its conceptual equivalent. (Note: A manual process does not meet this definition.)

11.225 CONSIDERATIONS AND OPTIONS
When you have determined the desirability of designing an MMIS or effecting system improvements which may lead to increased FFP, consider "demonstrable conceptual equivalence" and other options. The following are among options that may be considered:
o To claim the higher FFP under §1903(a)(3) of the Act, you need not have a single comprehensive claims processing and information retrieval system through which all claims for all types of service are processed. You may have multiple claims processing systems provided:
- They do not appreciably increase cost or detract from the primary benefits expressed in this part;

- Each system meets the established criteria in this part; and

- All systems feed into a single comprehensive utilization and management reporting system that meets the criteria established in this part. Under this approach, all of these components (subsystems) comprise the MMIS.

o Other mechanized information retrieval systems under title XIX, such as EPSDT, TPL, and Long Term Care, are eligible for the higher FFP allowed by §1903(a)(3) of the Act provided:

- You have an approved APD for the design, development, and installation of a mechanized claims processing and information retrieval system;

- The systems are used to store, retrieve, and produce utilization and management information about medical care and services which are required by the Medicaid agency and Federal Government for program administration and audit purposes;

- None of the design and operational aspects of such information retrieval system violate other statutory criteria, such as compatibility with information retrieval systems used by Medicare;

- HCFA determines that such systems are likely to provide more efficient, economical, and effective administration of the plan; and

- All procedures that are established in 42 CFR 433, subpart C are followed (i.e., the submission of an APD, prior HCFA approval is obtained before the expenditure of any funds for MMIS to qualify for enhanced matching in these expenditures, etc.)

These additional systems are not part of the required MMIS but qualify for enhanced FFP as optional integral components of the approved system.

These existing regulations allow states to pursue processes (such as modular builds) which don't quite conform to existing MMIS regulatory guidance. Although the use of 'demonstrable conceptual equivalents' was used in the past, it seldom is invoked currently.

Recommendation

PSTG recommends that these capabilities (outlined above), which exist in current regulation, be allowed to continue and be promoted with states to provide flexibility in procurements. We believe that it is CMS's responsibility to ensure that States are aware of these capabilities. This may be done through State Medicaid Director letters, education through webinars or other channels. Further, as CMS promulgates new regulation concerning MMIS and funding, they ought to consider referencing these components of existing regulation or redrafting them using language that clarifies their purpose, allowing states to implement alternative solutions that benefit state programs, their members and providers, and their federal partner.

8. Conclusion

PSTG proposes that the changes to regulations and or policies recommended above will have a profound, positive impact on the State Medicaid community, resulting in a much tighter alignment of State financial incentives with the Seven Conditions and Standards, inclusive of the MITA Framework, and current CMS guidance.

Appendix 1: Glossary of Acronyms

ACA	Patient Protection and Affordable Care Act
ACO	Accountable Care Organization
APD	Advanced Planning Document
APHSA	American Public Human Services Association
CMS	Centers for Medicare and Medicaid Services
COTS	Commercial-off-the-Shelf
DSS	Decision Support System
EHR	Electronic Health Record
FFP	Federal Financial Participation
HHS	U.S. Department of Health and Human Services
IAPD	Implementation Advanced Planning Document
MCO	Managed Care Organization
MES	Medicaid Enterprise Solution
MITA	Medicaid Information Technology Architecture
MMIS	Medicaid Management Information System
OMB	Office of Management and Budget
PSTG	Private Sector Technology Group
RFP	Request for Proposal
SaaS	Software-as-a-Service

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