

### Meeting #3

Date: September 21, 2015 1:00 PM

Location: School of Public Health, 1 University Place, Rensselaer NY 12144

#### Attendees:



Regulatory Meeting  
3 Attendance Septer

#### Overview

This was the third meeting of the Regulatory Impact Subcommittee (SC). The purpose of meeting #3 was to finalize recommendations for the policy questions related to Provider Risk Sharing (PRS), Default Risk Reserves (DRR), and Contracting Entities, and seek feedback on the proposed recommendation for the tiered DOH/DFS provider contract review process. The SC also had a discussion on modification of the Medicaid Managed Care Model Contract (Model Contract) and Provider Guidelines. The co-chairs introduced the next set of policy questions that the SC will address on Self-Referral (Stark Law), Anti-Kickback, Prompt Payment and Civil Monetary Penalties.

The Agenda for this meeting included:

1. Welcome and Overview
2. Recap: Final Recommendations from Meeting #2 (Provider Risk Sharing, Default Risk Reserves, and Contracting Entities)
3. Detailed Recommendation Discussion: DOH/DFS Provider Contract Review Process
4. Policy Questions and Options: Model Contract and Provider Guidelines
5. Introduction to Self-Referral (Stark Law), Anti-Kickback, Prompt Payment and Civil Monetary Penalties

**Key Discussion Points** (reference the slide deck “Regulatory Impact Subcommittee Meeting 3”)

#### 1) Recap: Final Recommendations from Meeting #2 including the Provider Contract Review Process

The SC confirmed their policy recommendations for Provider Risk Sharing, Default Risk Reserves, and Contracting Entities. The SC also delved into a deeper discussion of their recommendation around a provider contract review process. In meeting #2, the SC requested a more detailed approach to the review process, including the development of specific criteria and triggers for when the Department of Health (DOH) or Department of Financial Services (DFS) would review a provider contract based on the VBP arrangement and level of risk. Three tiers of regulatory review were developed in response to this request, and the tiers were discussed in depth in meeting #3. Please see the review tiers below:



Tier	Owner	Description
<b>3 - Highest</b>	DFS DOH	<b>The existing DFS contract review process under Regulation 164 would apply.</b>  This tier would generally apply to <b>higher risk VBP Level 3</b> arrangements.
<b>2 - Middle</b>	DOH	<b>The existing DOH contract review process would apply.</b> DOH will develop revised guiderails similar to the current DOH Level 3 & 4 review where no cash deposit would be required unless providers are not in a sustainable financial position at the time of entering into the contract.  This tier would generally apply to <b>higher risk VBP Level 2 and lower risk Level 3 arrangements.</b>
<b>1 - Lowest</b>	DOH	<b>No explicit approval from DOH is required</b> for either financial or contractual aspects of the arrangements. In lieu of a full DOH contract review, the MCO would submit a certification document summarizing the key provisions, financial protections, and expected financial outcomes.  This tier would generally apply to <b>VBP Level 1 and lower risk Level 2/3 arrangements.</b>

A document had also been distributed to the SC members, highlighting how the three-tiered review process might apply to numerous VBP payment methods (see corresponding document “12 Examples of VBP Methods”), which helped to inform the discussion. After assessing the proposed review methodology, the SC requested that DOH provide additional clarity for Tier 2. Specifically, the SC requested that DOH define when a DOH review is triggered, and when safeguards would be required for providers entering into contracts that fall under Tier 2. DOH agreed to develop more detailed criteria and provide further guidance on the Tier 2 process at a later SC meeting.

It was noted that, while all VBP contracts will have to be submitted to DOH for tracking purposes (towards the statewide goal), the Department’s intent is to align its incentives with those of providers so that providers are taking on risk only when they are ready to do so. Setting up a tiered review process will enable provider autonomy while also reducing the burden on DOH to need to review a large volume of contracts. Overall, it was recognized that the recommended process may require adjustment over time as lessons are learned and incorporated.

A discussion took place about the development of an MOU between DOH and DFS to clarify the responsibilities of the two agencies regarding the review process. It was noted that an MOU may not be necessary should the current regulations (including Regulation 164) be amended to clearly reflect the new review process and/or a clear set of guidelines be developed and agreed to.

## 2) Recap and Options Review: Model Contract and Provider Guidelines

The deadline for SC comments proposing modifications to the Model Contract and Provider Guidelines was previously extended to September 25th. As of meeting #3 (September 21<sup>st</sup>), no comments had been received. The SC requested that any changes to the Model Contract or Provider Guidelines that do occur as a result of the SC's recommendations be clearly communicated to all stakeholders.

## 3) Introduction to Self-Referral (Stark Law), Anti-Kickback, Prompt Payment and Civil Monetary Penalties

### *Self-Referral (Stark Law)*

The SC reached consensus on recommending the alignment of state rules governing Self-Referral (Stark law) with the federal statute and regulations. Current state laws lack several federal exceptions that allow for additional flexibility when entering into certain value-based contractual arrangements. The SC will prepare a draft recommendation for the next meeting.

### *Anti-Kickback*

The SC reached consensus on recommending the alignment of state rules governing Anti-Kickback (AKS) with the federal statute and regulations. Current state laws lack several federal safe harbor provisions that allow for additional flexibility when entering into contractual arrangements. The SC will prepare a draft recommendation for the next meeting.

### *Prompt Payment*

The SC did not develop a final recommendation defining guidelines or standards governing the payment of VBP shared-savings reconciliation payments from MCOs to providers. SC members discussed whether the timing of these payments should be left to the MCO and provider to negotiate, or if it would be more appropriate for the state to develop a maximum allowable period.




The SC members requested more time to consider the options and will submit feedback by September 28. Feedback submitted by SC members will be used to develop a final recommendation to be discussed at meeting #4.

### *Civil Monetary Penalties (CMP)*

The SC did not develop a final recommendation on the need for changes to state CMP laws and regulations.

The SC members requested more time to consider the options and will submit feedback by September 28. Feedback submitted by SC members will be used to develop a final recommendation to be discussed at meeting #4.

**Materials distributed during the meeting:**

Document	Description
<p>NYS VBP Regulatory Impact Meeting #3</p>  <p>NYS VBP Regulatory Impact Meeting 3_05</p>	<p>A presentation deck of policy questions and options for Provider Risk Sharing/Default Risk Reserves and introduction to Contracting Entities, the Medicaid Managed Care Model Contract, and Provider Contracting Guidelines. Introduced: Self-Referral (Stark Law), Anti-Kickback, Prompt Payment and Civil Monetary Penalties.</p>
 <p>NYS VBP_RI SC_Recommendatio</p>	<p>This document details the draft recommendations for Provider Risk Sharing, Default Risk Reserves, Contracting Entities and Provider Contract Review.</p>
<p>12 Examples VBP Methods</p>  <p>Classification of Review Tiers and 12</p>	<p>Details the Classification of Review Tiers and 12 Examples of VBP Methods.</p>

**Key Decisions**

The SC made decisions on the following key points during meeting #3:

- ✓ The SC confirmed the recommendations for PRS, DRR, and Contracting Entities and asked for additional details from DOH on contract review thresholds and safeguards.
- ✓ The SC agreed that Self-Referral (Stark Law) and Anti-Kickback state laws should be aligned to federal laws and regulations and asked that draft recommendations be developed for these two policy questions.
- ✓ The SC deferred discussion and development of final recommendations for Prompt Payment and Civil Monetary Penalties rules to meeting #4. The SC members are to submit comments by Monday, September 28, 2015.

**Action Items:**

- Comments and suggested alterations to the Model Contract and Provider Guidelines are due September 25th.
- Draft recommendations for the Policy Questions related to Self-referral and Anti-Kickback Statute will be circulated prior to meeting #4.
- DOH will develop additional details regarding Tier 2 Contract review for Provider Risk Sharing arrangements for *meeting #5 on November 10th*. This will include the threshold for review by DOH and guidelines for when the state will require safeguards.



## **Conclusion**

The next SC meeting will be held in NYC on October 5, 2015 and will include:

- 1) A discussion of the SC members' comments on the Model Contract and Provider Guidelines;
- 2) A discussion of the SC members' comments on Prompt Payment and Civil Monetary Penalties;
- 3) Discussion of the Draft Recommendations for Self-Referral and Anti-Kickback Statute; and
- 4) An introduction to the new SC topics including:
  - a. Fraud, Waste & Abuse
  - b. HIPAA and State Patient Privacy
  - c. Corporate Practice of Medicine