Overview

This was the fourth meeting of the Regulatory Impact Subcommittee (SC). The purpose of the meeting was to discuss and finalize draft recommendations from the previous meeting (see agenda below), continue with key discussions, introduce new topics, and raise any questions or concerns.

The agenda for this meeting included:

1. Recap: Final Recommendations from Meeting #3
   a. Self-Referral Law
   b. Anti-Kickback Law
2. Proposed Recommendations: Prompt Pay and Civil Monetary Penalties
3. Discussion of Model Contract and Provider Contract Suggested Revisions
4. Introduction to New Topics:
   a. HIPAA & State Privacy
   b. Fraud, Waste & Abuse
   c. Business Laws & Corporate Practice of Medicine

Key Discussion Points (reference the slide deck “Regulatory Impact Subcommittee Meeting 4”)

1) Recap: Final Recommendations from Meeting #3 including the Self-Referral and Anti-Kickback Law

   The SC confirmed their policy recommendations for Self-Referral and Anti-Kickback Law, which is to align state law with federal law. The Office of the Medicaid Inspector General (OMIG) requested time to further review these recommendations, and provide comment prior to the next SC meeting.

2) Proposed Recommendations: Prompt Pay and Civil Monetary Penalties

   The SC recommended no legislative change to the current Prompt Pay and Civil Monetary Penalties rules. The SC does, however, suggest the State consider the application of Prompt Payment rules in certain VBP contractual arrangements (e.g. via the Model Contract and/or Provider Contracting Guidelines).
3) **Discussion of Model Contract and Provider Contract Suggested Revisions**

The SC discussed the process of making revisions to the Model Contract and Provider Guidelines to accommodate VBP. The SC has received several proposed revisions, which have been sent to the DOH for review. Following the DOH’s analysis of these revisions, the accepted proposed changes to the Model Contract will be distributed for public comment within a defined timeline.

4) **Introduction to HIPAA & State Privacy; Fraud, Waste & Abuse; and Business Laws & Corporate Practice of Medicine**

**HIPAA & State Privacy**

The SC has been asked to address whether New York State privacy laws should be amended to more fully align with federal HIPAA laws and the goals of VBP. It was acknowledged that the NYS privacy laws are restrictive and provide less flexibility than federal HIPAA regulations, which eventually may hinder the implementation of VBP. The discussion included reviewing five scenarios depicting various VBP challenges, each describing examples of the significant data privacy issues that may arise in a VBP setting. The primary goal of the discussion was to consider the various situations in which providers may need additional data in order to be more proactive and successful in VBP, while continuing to acknowledge members’ individual privacy needs. The SC members identified ways in which member behavior may change should their patient confidentiality appear threatened, particularly in the realms of mental and sexual health.

The next meeting will feature a detailed discussion of each of these scenarios in an issue brief, which will be distributed prior to the meeting. The SC will develop a recommendation in the next meeting on whether to align the state law with federal law, and if so, to what extent.

**Fraud, Waste & Abuse**

The SC considered whether sufficient program integrity safeguards are currently in place or if there are new opportunities for fraud, waste and abuse and non-compliance that need to be considered in a new VBP environment. The main issue when considering fraud, waste and abuse is often errant compliance, with errors occurring in reporting. Since there are a several State departments involved and many different issues to consider, the SC proposed that a first step should be to draft a vision statement of how oversight and compliance may differ in a VBP environment as the payment paradigm will need to change from services provided to outcomes achieved. An issue brief will be prepared and distributed to facilitate further discussion on this topic for the next meeting, as well as a continued review of program integrity framework requirements.

**Business Laws & Corporate Practice of Medicine (CPOM)**

NYS law states that a professional corporation (PC) or professional service limited liability company (PLLC) may only provide services in its field. Historically, a limitation was put in place to avoid non-licensed professionals, who are not medical professionals, from making decisions with respect to a patient’s health.
treatments. The SC indicated an interest in greater clarification around this issue, including its application in both current and future states. Since the goal of the VBP concept is to emphasize a team approach to care, the current Business and CPOM laws present the following barriers in a VBP setting:

- Constraints on how medical professionals structure their corporate entities to optimize VBP implementation;
- Restrictions regarding which professionals can own and manage professional entities; and
- Limitations on which professionals and entities can split fees (e.g., bundled payments for services including physicians and non-physicians).

SC members questioned whether new laws need to be created or current laws amended to address the limitations. The action item was for the SC to further consider these issues and how a team approach in the context of VBP could be implemented. This topic will continue to be discussed in the next meeting, and following the discussion, the SC will prepare its recommendation regarding what changes, if any, need to be made to existing Business Laws and Corporate Practice of Medicine laws. Prior to the meeting, an issue brief will be prepared and distributed on this topic.

Materials distributed during the meeting:

<table>
<thead>
<tr>
<th>Document</th>
<th>Description</th>
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<tbody>
<tr>
<td>NYS VBP Regulatory Impact Meeting #4</td>
<td>A presentation deck of policy questions and options for Self-Referral and AKS, Prompt Pay and Civil Monetary Penalties, Model Contract and Provider Contract, and an introduction to HIPAA &amp; State Privacy, Fraud, Waste &amp; Abuse, and Business Laws &amp; Corporate Practice of Medicine.</td>
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<tr>
<td>NYS VBP RI SC_Recommendation</td>
<td>This document details the final recommendations for Self-Referral and Anti-Kickback.</td>
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Key Decisions
The SC made decisions on the following key points during meeting #4:

- The SC confirmed the recommendations for Self-Referral (Stark Law) and Anti-Kickback state laws.
- The SC did not recommend any changes to NYS laws or regulations for Prompt Pay or Civil Monetary Penalties.

Action Items:
- Draft final recommendations for the Prompt Pay and Civil Monetary Penalties will be circulated prior to meeting #5.
• DOH to receive and review the SC proposed revisions to the Model Contract and Provider Contract guidelines.
• SC members may continue to submit comments on the Provider Contract Risk Review Tiers and review process prior to meeting #5.

Conclusion
The next SC meeting will be held in Albany on November 10, 2015 and will include:

1) A discussion of the SC members’ comments on the Model Contract and Provider Guidelines;
2) Detailed discussion for HIPAA & State Privacy; Fraud, Waste & Abuse; and Business Laws & Corporate Practice of Medicine; and
3) An introduction to the new topics.