

Meeting #6

Date: December 7, 2015 10:30 AM

Location: One Empire Drive, Rensselaer, NY 12144

Attendees:



RI Meeting 6
Attendance.pdf

Overview

This was the sixth final meeting of the Regulatory Impact Subcommittee (SC). The meeting included the review of final draft recommendations for the following policy issues: Business Laws and Corporate Practice of Medicine; Program Integrity; HIPAA and State Privacy Laws; and De-Regulation (Regulatory Reform). There was also a discussion regarding the Provider Contract Review Process and details surrounding the DOH Review Tier and financial security deposit requirements.

The full agenda for Meeting #6 included:

1. Welcome and Introduction
2. Recap: Recommendations from Meeting #4: Business Laws and Corporate Practice of Medicine, Program Integrity, HIPAA and State Privacy Laws, and De-Regulation
3. Discussion of Provider Contract Review Process
4. Discussion of Other Issues and Next Steps

Key Discussion Points (reference the slide deck “Regulatory Impact Subcommittee Meeting 6”)

1) Recap: Recommendations for Business Laws and Corporate Practice of Medicine; Program Integrity; HIPAA and State Privacy Laws; and De-Regulation

A brief summary of primary concepts behind Business Laws and Corporate Practice of Medicine; Program Integrity; HIPAA and State Privacy Laws; and De-Regulation were provided along with a recap of SC Meeting #5. The SC members were asked to develop finalized recommendations for the State’s consideration. The SC agreed on the recommendations for Program Integrity, HIPAA and State Privacy Laws, and De-Regulation. There was some additional discussion surrounding the proposed recommendation for Business Laws and Corporate Practice of Medicine which is further detailed below.

It was reiterated that if details of a solution are not agreed upon within the SC meetings for any specific issue, it does not necessarily mean that work on the issue has concluded. The SC will be willing to accept comments within a reasonable timeframe after the meetings conclude.

Business Laws and Corporate Practice of Medicine



The SC reviewed the recommendations which called for alignment with New York State Senate and Assembly Bills S.5862/A.8153. The topic of physicians' autonomy and decision-making abilities alongside non-physicians was debated in detail in the meeting. In order to protect the physicians' autonomy and control over clinical and non-clinical decision, it was decided that bill language may need to be amended to address this issue. The draft recommendation for Business Laws will be amended to reflect differing views on the scope of changes to current law to allow for the implementation of VBP, but maintain physicians' autonomy and decision-making abilities. It was decided that the DOH should continue discussions, as needed, to address how changes should be made to CPOM laws and regulations.

Program Integrity

The SC identified that the alignment of Program Integrity and VBP is critical to address the structure of future audits and to implement a cost-effective review process. The SC recommended the creation of a Program Integrity workgroup made up of stakeholders including the State, payers, and providers. The new workgroup will be tasked with making recommendations to improve program integrity at all levels of healthcare delivery. The workgroup's focus would need to shift from over-utilization to also include review of potential under-utilization and quality measures. Specifically, the workgroup should focus on developing actionable recommendations addressing compliance in a VBP environment. Recommended changes may include changes to State laws and regulations, contracting requirements between the State and MCOs or providers, and other contracts.

The co-chairs asked that SC members who wish to volunteer should reach out and let the co-chairs know. The list of volunteers will be then provided to the Department of Health.

HIPAA and State Privacy Laws

Due to the broad scope of HIPAA and State Privacy, the SC recommended that it will be reasonable to create a workgroup dedicated to addressing privacy law issues on a scenario-by-scenario basis. Example scenarios discussed included: DSRIP Opt-Out and DEAA Process; Care Management; RHIO and SHIN-NY Data; Scope of Medicaid Consent; and access to Vital Statistics Data. The scope of the workgroup would focus on alignment of laws because the scenarios mentioned are not perfectly defined at this point in time. It was mentioned that, because state laws primarily have stricter and older standards, agencies (such as OMIG, OASAS, OMH) should speak as one to refine the laws to reflect both electronic data sharing as well as other issues, in a VBP setting. The workgroup will be made up of State departments who would work with the above scenarios to implement recommendations throughout the development of VBP as well as other plan/provider representatives.

De-Regulation (Regulatory Reform)

Similar to the previous two recommendations, the SC suggested the creation of a new VBP regulatory relief workgroup that is to be overseen by the DOH. Stakeholders will be able to submit to this workgroup a written request for regulatory relief specific to VBP. Requests for regulatory relief under this new process will focus on regulations that stakeholders see as a significant hindrance to effective VBP implementation. It was decided that the name of this workgroup will be "Regulatory Reform Workgroup."

Recommendations submitted to the workgroup should contain a rationale for any requested waivers to state laws or regulations. Except for patient safety matters, the DOH will consider instituting a waiver

process pending any changes to identified state laws and regulations. Further, it was indicated that the DOH would consider advocating certain federal issues to CMS if those requests were actionable.

2) Discussion of Provider Contract Review Process

Interagency review remains a top issue when considering the provider contract review process. Due to the scale of the program, the State currently reviews only a small percentage of non-Regulation 164 contracts as it is not feasible to review each contract from a financial perspective. The SC recapped the triggers for each of the three Tiers along with the corresponding formulas for the 25% risk threshold as well as the 15% Medicaid revenue threshold.

The SC then described a high level summary of the financial review process and requirements for the DOH Review Tier. There was a suggestion that when a financial security deposit is required for the DOH Review Tier, that the amount be reduced from the 12.5% to 7.25% - to match the requirements for managed care plans and lessen the burden on providers for risk arrangements that do not implicate the business of insurance.

The SC reiterated the need for an MOU between the DFS and DOH to detail when the business of insurance is implicated (implicating the Multi-Agency Review Tier) versus the DOH Review Tier. It is important that contracting parties understand at the beginning of the contracting period whether any risk arrangement constitutes the business or insurance or not. It was agreed that such MOU be drafted and reviewed by both agencies in the near future.

3) Discussion of Other Issues and Next Steps

Other Issues

The concern is that, in a VBP environment, health plans may have an incentive to keep high performing providers in a VBP Level 1 arrangement to limit the amount of shared cost savings. This is an issue that the DOH will need to consider when revising the Medicaid Model Contracts as well as the Provider Contract Guidelines. There is also the need for education so that all parties understand the implications of the newer contracts and risk involved; however, the parties will be expected to take responsibility for negotiating the business and financial terms of the arrangement. It was mentioned that the DOH is planning to educate the providers and the plans in the upcoming year using various education tools.

- *Pharmacist and Physician Collaboration*




The SC discussed several amendments to current policy regarding agreements between physicians and pharmacists proposed by Kinney Drugs. They suggested that pharmacies should implement protocols for pharmacists to write prescriptions to patients at times when patients are unable to visit doctors or a doctors are unavailable. Although community pharmacists should not be managing more complex therapies, the argument is that community pharmacists (with physician agreement) should be able to conduct rapid tests for flu, strep, etc. and could then prescribe the appropriate medications. The basic goal is to replicate care in a community setting that is currently available in hospitals. Medical Society of the State of New York (MSSNY) has already declined to support some aspects of the proposal but indicated a willingness to review the issue of testing. A follow up discussion will need to occur between MSSNY and key pharmaceutical groups. The SC declined to issue a formal recommendation on this topic.

Next Steps

During SC Meeting #6, the SC reached consensus on many issues. In the coming months, smaller workgroups will be established to address many of the SC agenda items. The workgroups identified so far include Data Privacy; Program Integrity; and Regulatory Reform. Appropriate edits will be made to the Business Laws and Contract Review recommendations.

The SC will submit all recommendations created to the VBP Workgroup. The Workgroup together with DOH will issue final decisions on each recommendation. In addition, updates will be made to the VBP Roadmap to reflect many of the changes discussed during the SC meetings to this point.

Materials distributed during the meeting:

Document	Description
NYS VBP Regulatory Impact Meeting #6	A presentation deck of policy questions and options for Business Laws and Corporate Practice of Medicine; Program Integrity; HIPAA and State Privacy Laws; and De-Regulation. Provider Contract Review Process and next steps that need to be taken by the SC are also included.
Recommendations	These documents contain recommendations on each policy question reviewed in the SC meeting.
<p>Supporting Materials:</p> <p>Limited Liability Company Law; Title VIII Memo in Support of PLLC Bill; and Memo in Opposition</p> <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">  Limited Liability Company Law.pdf </div> <div style="text-align: center;">  Title VIII Memo in Support of PLLC bill.doc </div> <div style="text-align: center;">  Memo in Opposition S.5862 L </div> </div>	Included are: a bill that authorizes certain licensed healthcare professionals to form limited liability companies, a memo in support of the bill, and a memo in opposition to the bill.
Meeting #5 Summary	This document is a summary of the topics covered during SC Meeting #5.

Key Decisions



- The SC made finalized recommendations on the following:
 - ✓ Business Laws and Corporate Practice of Medicine
 - ✓ Program Integrity,
 - ✓ HIPAA and State Privacy Laws
 - ✓ De-Regulation
 - ✓ Contract Review Process
- DOH reserves the right to convene this SC in the future should there be a need to deliberate on other regulatory hurdles related to the implementation of VBP.