

Regulatory Impact Subcommittee

Meeting #5

Today's Agenda

Agenda Item	Time
Welcome and Introduction	1:00 pm
Recap: Final Recommendations from Meeting #4: Prompt Pay; Civil Monetary Penalties; Medicaid Managed Care Model Contract; Provider Contract Guidelines	1:10 pm
Presentation of Provider Contract Risk Review Process	1:20 pm
Discussion of Business Laws and Corporate Practice of Medicine	2:20 pm
Discussion of Program Integrity and Compliance	2:40 pm
Discussion of HIPAA and State Privacy Laws	2:50 pm
Introduction to De-regulation	3:10 pm
Closing	3:45 pm



<u>Recommendation</u> – Prompt Payment – No change to New York state laws or regulations is recommended. The Subcommittee recommends considering the application of Prompt Payment rules in certain VBP contractual arrangements (e.g., via the Model Contract, and/or Provider Contracting Guidelines).

While this issue may need to be revisited as the VBP process unfolds, the Subcommittee proposes that the present laws regarding Prompt Payment remain in place. The timing of shared savings bonuses, reimbursements of withholds, and related VBP payment structures should be handled contractually between the relevant parties. The DOH should consider whether additional guardrails or safeguards should be included in the Model Contract and/or Provider Contracting Guidelines to ensure timeliness of payments.



^{*}Subcommittee members were emailed the full written recommendations ahead of this meeting.

<u>Recommendation</u> – Civil Monetary Penalties – No change to New York state laws or regulations is recommended.

Based on the comprehensive coverage of federal CMPs and NYS equivalents, the Subcommittee proposes no new changes at this time.



Recommendation – Medicaid Managed Care Model Contract:

The Subcommittee recommends that the DOH review and consider the Subcommittee members' comments and proposed revisions as the DOH amends the Model Contract to accommodate VBP. DOH will then take these comments into account when negotiating the Medicaid Managed Care contract with the health plan contractors and in discussions with CMS.



<u>Recommendation</u> – Provider Contract Guidelines for MCOs, IPAs:

The Subcommittee recommends that the DOH review and consider the Subcommittee members' comments and proposed revisions as the DOH amends the Provider Contract Guidelines to accommodate VBP. The Subcommittee refrains from providing recommendations on a one-by-one basis as this process should be conducted in a holistic manner taking into account the collection of input.



Multi-Agency Review

DOH Review

Future Financial Review for All Contracts: Bucketing into Tiers



Does the contract involve prepaid capitation and trigger Regulation 164?



of Health





Does the contract involve prepaid capitation and trigger Regulation 164?

Yes

Multi-Agency Review

DOH Review







Does the contract involve prepaid capitation and trigger Regulation 164?

Multi-Agency Review

Yes

- Review Tier 3 Multi-Agency Review contract approval will require:
 - DFS financial review
 - DOH programmatic review
 - The option for DOH to conduct its own financial review







Does the contract involve prepaid capitation and trigger Regulation 164?



More than \$1,000,000 of **annual** payments to provider at risk (shared losses, withhold)?

Program Review will be completed in addition to Financial Review for all contracts

Multi-Agency Review

DOH Review





Does the contract involve prepaid capitation and trigger Regulation 164?



More than \$1,000,000 of **annual** payments to provider at risk (shared losses, withhold)?

- This \$1,000,000 annual payment threshold is applied to:
 - Only the individual contract that is coming in for review
 - Medicaid Managed Care components of the contracts only

Multi-Agency Review

DOH Review

File and Use







Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

Yes

More than 25% of annual payments to provider at risk?

Multi-Agency Review

DOH Review

File and Use

Department of Health





Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

Yes

- This 25% payment threshold is applied to:
 - Only the individual contract that is coming in for review
 - Medicaid Managed Care components of the contracts only
- The ratio is expressed as:

Annual Medicaid Payments at Risk for this Contract

Total Value of All Medicaid Contracts between this MCO and Provider

More than 25% of annual payments to provider at risk?

DOH Review

File and Use

Department of Health





Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

Yes

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Multi-Agency Review

DOH Review

File and Use

Department of Health





Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

Yes

- This 15% revenue threshold is applied to:
 - All MCOs that contract with the provider
 - All Medicaid (inclusive of Medicaid Managed Care and Medicaid FFS) contracts
- The ratio is expressed as:

Value of This Contract's Projected Medicaid Revenue

Total Projected Annual Medicaid Revenue for Provider

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

DOH Review

File and Use

Department of Health





Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

Yes

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Off Menu VBP Arrangement?

Multi-Agency Review

DOH Review







Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

Yes

- Off Menu VBP arrangements are defined as:
 - Arrangements with modifications to services for defined bundles
 - Arrangements with modifications to time period for defined bundles
 - Bundles not included in menu

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Off Menu VBP Arrangement?

DOH Review

File and Use







Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Yes to Any

Off Menu VBP Arrangement?

Multi-Agency Review

DOH Review

File and Use

Department of Health



Multi-Agency Review

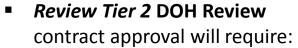


Does the contract involve prepaid capitation and trigger Regulation 164? More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Off Menu VBP Arrangement?



DOH financial review

Yes to Any

DOH programmatic review

DOH Review

File and Use







Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Off Menu VBP Arrangement?

No to All

Multi-Agency Review

DOH Review

File and Use





Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of annual payments to provider at risk (shared losses, withhold)?

No

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Off Menu VBP Arrangement?

No to All

Multi-Agency Review

DOH Review

File and Use





Tier 1



Individual Contract Comes in for Review

- Review Tier 1 File and Use contract approval will require:
 - DOH programmatic review
- This tier will **NOT** require:
 - DFS financial review
 - DOH financial review

Does the contract involve prepaid capitation and trigger Regulation 164?

More than \$1,000,000 of **annual** payments to provider at risk (shared losses, withhold)?

More than 25% of annual payments to provider at risk?

More than 15% provider's Medicaid Revenue?

Off Menu VBP Arrangement?

No

Multi-Agency Review

DOH Review

File and Use



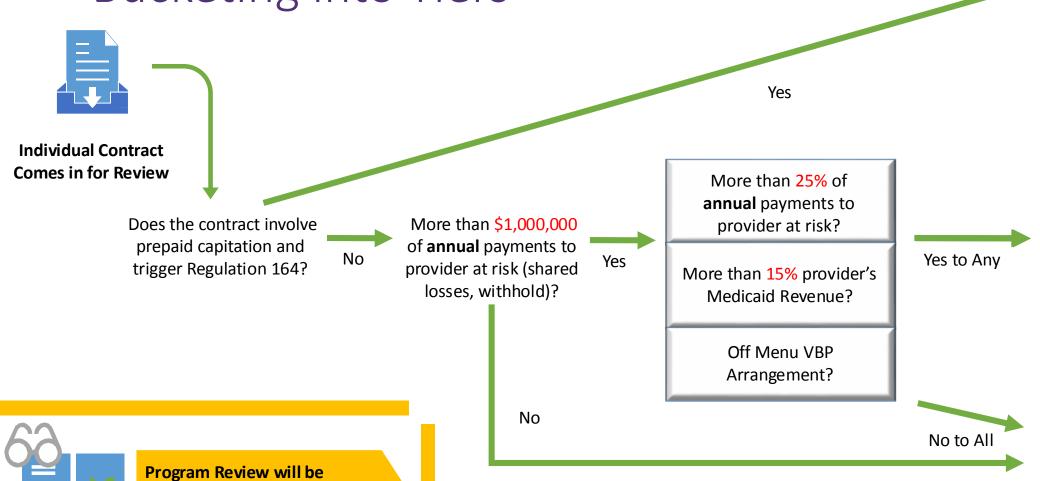
VYORK Department of Health

N

Future Financial Review: Bucketing into Tiers

completed in addition to

Financial Review for all contracts



Multi-Agency Review

DOH Review



Continued Discussion of Meeting #4 Policy Questions:

Policy Question #10

HIPAA AND STATE PRIVACY

Should NYS privacy laws be amended to more fully align (harmonize) with federal HIPAA and the goals of VBP?

Policy Question #11

PROGRAM INTEGRITY (PI)

What changes to Program
Integrity are necessary to
ensure Medicaid PI
compliance for new VBP
needs?

Policy Question #12

BUSINESS LAWS & CORPORATE PRACTICE OF MEDICINE

How should laws surrounding Professional Service Corporations be modified to align with VBP?



Policy Question 12: How should laws surrounding Professional Service Corporations be modified to align with VBP?

CPOM Barriers in a VBP Setting

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



Management and Organizational Restrictions

- Physicians can only practice through professional corporations (PC), a professional service limited liability company (PLLC), or a registered limited partnership.
- Physicians are not permitted to use general business corporation (GBC) or limited liability company (LLC).
- PCs and PLLCs may only manage the specific services that its members are licensed to provide.
- Management companies cannot manage a PC or PLLC.
- The broad NYS laws and regulations regarding organization and management of professional corporations may prove problematic in a VBP setting because various practitioners would inherently need to work together to coordinate patient care. The example depicts a barrier of the integration of primary care and behavioral health.



Corporate Entity Constraints

- Many corporations are beginning to offer professional services since licensed professions' client base have proven to be profitable.
- Services of a managed care company blur the distinction between professional judgment and utilization review.
- A GBC may provide services used by professional if a clear distinction between is established between who is providing professional services and who is providing the management services.



Fee Splitting

- NYS Education Law (§ 6509-a) prohibits providers splitting a fee with a non-physician.
 (This prohibition extends to business corporations and individuals who do not possess a license to provide the relevant health care services).
- The accompanying regulation expressly prohibits compensation arrangements involving fees paid as a percentage of, or even dependent upon revenue earned by healthcare professionals (8 NYCRR 29.1(b)(4)).
- NYS law consists of a prohibition on fee splitting between medical facilities and individuals or entities which have not been approved as a health care establishment by the Department of Health (10 NYCRR 600.9(c)).
 - Set to ensure professionals and/or unlicensed persons do not influence licensed professionals while providing services to the public.



Other Considerations

- In addition to the scenarios and issues presented above, the Subcommittee should also consider:
 - (1) Other potential scenarios and options regarding VBP and the need for collaborative care among various providers; and
 - (2) Whether it would be prudent for the DOH to establish a work group comprised of specific NYS departments and stakeholders to address the pertinent business and CPOM laws to make recommendations one case by case basis.
 - (3) Whether the Subcommittee supports the pending Bill which addresses many of the Business Law and CPOM issues addressed in this Policy Question.



Policy Question #11: Program Integrity

VISION STATEMENT

At Meeting #4 on October 5, 2015, the Subcommittee requested that DOH prepare a "Vision Statement" addressing the long-term future for Medicaid Program Integrity (MPI). VBP will introduce a number of complexities requiring MPI to adapt. The Vision Statement is in progress and will address at a high-level:

- ✓ How do the goals of VBP line up with the current MPI goals and capabilities?
- ✓ What new compliance challenges does VBP bring to the table?
- ✓ Does VBP change the MPI responsibilities for the parties (i.e., the State, MCOs, and providers)?
- ✓ What gaps and improvement opportunities exist in the current MPI framework?
- ✓ How and who will tackle refreshing MPI to ensure VBP success?



Policy Question #10: HIPAA and State Privacy

Compliance with NYS Law

New York's version of the federal law and its related privacy laws are broader in scope and contain fewer exceptions. Therefore, New York law is more restrictive and affords less flexibility for providers compared to federal law. The success of VBP may be hindered due to these current state laws

Policy Question 10: Should New York State privacy laws be amended to more fully align (harmonize) with federal HIPAA and the goals of VBP?



Policy Question #10: Options for Privacy Law Alignment

Option 1 – Full Alignment

- Complete alignment of NYS law with federal HIPAA protocol.
 - o *Pro*: Less restrictive and more updated alterative to many potential data privacy issues.
 - Con: Broad alignment may not take into account NYS specific policies regarding patient confidentiality.



Policy Question #10: Options for Privacy Law Alignment

Option 2 - Edit and Revise

- Specific exceptions made to the NYS laws in order to accommodate the shift from FFS to VBP.
 - o Pro: Would help form NYS law to accommodate VBP
 - Con: The layering of exceptions may become cumbersome to address all relevant privacy and confidentiality laws.



Policy Question #10: Options for Privacy Law Alignment

Option 3 – Complete Replacement

- Completely replace and/or rewrite existing NYS privacy laws and regulations in an effort to accommodate the shift from FFS to VBP.
 - Pro: Perhaps the most comprehensive solution that maintains NYS policy concerns because it takes into consideration the existing federal law while accommodating VBP.
 - Con: Requires the greatest degree of legal work and would require statutory and regulatory changes.



Policy Question #10: HIPAA and State Privacy

<u>Scenario 1</u>: **DSRIP OPT OUT AND DEAA PROCESS** – The DSRIP Opt Out and DEAA process is limited to State provided data. The process only applies to downstream transactions and does not apply to non-state provided data. There is no state guidance on upstream sharing of data or data sharing from provider-to-provider for purposes of VBP. Options below:

	Potential Solution	Notes
1. Align NYS Law	Clarify that the data sharing for purposes of VBP	This may eliminate the need for additional opt outs and
With HIPAA	constitutes health care operations consistent	consents specific to data sharing for purposes of DSRIP and
	with HIPAA and NYS law.	related VBP transactions.
2. Create Exceptions	Create specific exceptions/state interpretation	Relatively efficient solution, but would not necessarily
to NYS Law	to allow for both upstream and provider-to-	eliminate the need for all DEAAs and opt outs for purposes of
	provider sharing of data for purposes of VBP.	DSRIP and VBP.
3. Replace existing	Replace/rewrite existing law to allow for both	Would require a great amount of legal work to rewrite NYS
NYS law	upstream and provider-to-provider sharing of	law, but would allow for an updated law taking into account
	data for purposes of VBP.	VBP with relevant policy considerations built into the law.

<u>Potential solution</u>: Create exceptions to allow for upstream sharing of data and provider-to-provider for purposes of VBP.



Policy Question #10: HIPAA and State Privacy

<u>Scenario 2</u>: CARE MANAGEMENT – There is lack of clarity in the application of state confidentiality laws related to the disclosure of PHI for the purposes of care management organizations. Care management organizations may be neither covered entities nor providers, but may require access to PHI. Options below:

	Potential Solution	Notes
1. Align NYS Law With	Align the application of state confidentiality laws	Also add more resources to support training, tools, development
HIPAA	related to disclosure of PHI for purposes of care	of standardized consents and clearer guidelines for care
	management organizations to the goals of VBP	management agencies and providers.
	(health care operations).	
2. Create Exceptions	Draft exceptions to the relevant Public Health Law,	This would require consideration and cross reference of multiple
to NYS Law	Mental Hygiene, and related laws on a case by case	laws and regulations.
	basis.	
3. Replace existing	Draft specific laws or regulations to govern the	Would require a new NYS law or regulation, but would allow for
NYS law	access and security of PHI for care management	an updated law taking into account VBP with relevant policy
	organizations.	considerations built into the law.

<u>Potential solution</u>: Align the application of state confidentiality laws related to disclosure of PHI for purposes of care management organizations to the goals of VBP.



<u>Scenario 3</u>: RHIO AND SHIN-NY DATA — The RHIO and SHIN-NY data may be incomplete due to NYS patient confidentiality laws which limit alternative provider-to-provider data access. If for non-treatment purposes, it is not clear what would constitute "minimally necessary" standard for health care operations. Other issues include minor consent laws, which may create a gap for 12-17 year old patient info, HIV, and maternity confidentiality laws which are more restrictive than federal HIPAA.

	Potential Solution	Notes	
1. Align NYS Law With	Allow data sharing consistent	Does not fully solve the issue. Certain state restrictions (e.g., minor consent laws)	
HIPAA	with HIPAA (e.g., health care	are important to the State's policy interests. HIPAA does not account for minor	
	operations).	confidentiality, maternity, HIV/AIDS, and related NYS policy considerations.	
2. Create Exceptions	Create exceptions to allow for	Exceptions can be made to all or some of the following restrictions to: minor	
to NYS Law	providers to disclose and access	consent, HIV, mental health, and maternity confidentiality laws. This requires	
	PHI through the RHIOs and SHIN-	analysis and evaluation including an update on how the RHIOs are functioning and	
	NY to accommodate VBP.	what protections are currently in place. This requires further discussion and deeper	
		understanding of the RHIO and SHIN-NY networks and scope of data access.	
3. Replace existing	Replace existing NYS law to allow	This approach will require a great deal of legal work and time. However, replacing	
NYS law	for providers to disclose and	existing, pre-HIPAA law would provide the State with an opportunity to customize	
	access PHI through the RHIOs and	laws and regulations to accommodate VBP while maintaining critical policy	
	SHIN-NY to accommodate VBP.	interests.	

<u>Potential solution</u>: Create exceptions to allow for providers to disclose and access PHI through the RHIOs and SHIN-NY to accommodate VBP.

<u>Scenario 4</u>: SCOPE OF MEDICAID CONSENT – The Medicaid consent form seems to allow disclosure for health care operations, but the DOH legal takes a strict view of the form. There is uncertainty among providers regarding the scope of the Medicaid consent which may lead to missing data and delays in data reporting. Options below:

	Potential Solution	Notes	
1. Align NYS Law With	Clarify that the exception for health care operations	Does not solve issue if the more restrictive NYS laws and	
HIPAA	is consistent with definition and scope contained in	regulations remain in place.	
	HIPAA.		
2. Create Exceptions	Clarify the scope of the Medicaid consent form	Would require case by case analysis of each use of Medicaid	
to NYS Law	and create legal exceptions, as needed, to allow	member PHI to determine whether the Medicaid consent is	
	alternative means of data sharing for purposes of	sufficient in scope and what exceptions to specific NYS law and	
	VBP.	regulations is required.	
3. Replace existing	Replace/amend existing law to add law or	Could require a great amount of legal work as option 2 above,	
NYS law	regulation that addresses the scope of the	but would allow for an opportunity to customize the laws and	
	Medicaid consent form to allow alternative means	regulations to accommodate VBP while maintaining critical	
	of data sharing for purposes of VBP.	policy interests.	

<u>Potential solution</u>: Clarify the scope of the Medicaid consent form and create exceptions, as needed, to allow alternative means of data sharing for purposes of VBP.

<u>Scenario 5</u>: VITAL STATISTICS (VS) — Vital Statistics have unique restrictions which render them unusable with Medicaid patients. New York state regulation 10 NYCRR 400.22 suggests that only state employees may access vital statistics. There are no exceptions or consent processes available to providers, PPSs, and NYS contractors. Options below:

	Potential Solution	Notes
1. Align NYS Law With HIPAA	N/A. There is no HIPAA equivalent.	This is a NYS specific regulation that is analyzed separately from other data privacy categories.
2. Create Exceptions to NYS Law	Create an exception to allow for access to mombaby VS data with a DEAA or related consent process (similar to HIV, and other PHI) for limited purposes.	This may be the easiest solution, but would require additional analysis on the policy reasons behind the Medicaid restriction in the current regulation.
3. Replace existing NYS law	Replace/rewrite the existing regulation.	VS data is state collected information; this option would require coordination of multiple departments to determine the policy considerations and may be beyond what is necessary to effectuate purpose of this scenario.

<u>Potential solution</u>: Create an exception to allow for access to mom-baby VS data with a DEAA or related consent process (similar to HIV, and other PHI) for limited purposes.



Other Considerations

- In addition to the scenarios and options presented above, the Subcommittee should also consider:
 - (1) Other potential scenarios and options regarding patient data privacy and security; and
 - (2) Whether it would be prudent for the DOH to establish a data privacy and security work group comprised of various NYS departments and stakeholders to follow these issues and implement recommendations throughout the development of VBP.



Introducing the New Policy Question:

Policy Question #13

DE-REGULATION

What specific regulations could be eliminated or relaxed to reduce administrative burden while still protecting patient safety?



As part of the DSRIP project, PPSs submitted regulatory waiver requests to assist in the forming and administration of PPSs and contracting. The DOH has processed **536 individual regulatory waiver** requests as of March 2015 with:

- 243 approved
- 95 denied
- 89 do not need waivers
- 109 pending

The most commonly approved waivers relate to:

- Revenue Sharing by PPS leads
- Public Need and Financial Feasibility
- Other Operational Needs
- Credentialing



Revenue Sharing - Regulation: 10 NYCRR 600.9(c)

Nature of Requirement: An individual, partnership or corporation which has not received establishment approval may not participate in the total gross income or net revenue of a medical facility.

Determination: 15 waiver requests were approved to the extent that the regulation otherwise would prohibit providers from receiving DSRIP incentive payments distributed by the PPS Lead.

Public Need and Financial Feasibility - 10 NYCRR 670.1, 709 and 710.2

Nature of Requirements: Used to determine the methodologies for public need, financial feasibility, and the components of the Certificate of Need (CON) process.

Determination: 40 waivers regarding feasibility were waived. Waivers cannot be granted for establishment applications because of statutory limitations. Projects involving construction, regardless of other waivers, must file a construction application through NYSE-CON due to the potential for patient safety implications.



Operational Needs: Off-Site Services and Observation Beds,: 10 NYCRR 401.2(b), 10 NYCRR §405.19(g)(2)(i), (ii) and (v), 14 NYCRR 822-3.1(b)

Nature of Requirements: An operator may use an operating certificate only for the designated site of operation; except where the Commissioner authorizes temporary operation at an alternate site due to an emergency.

The total number of dedicated observation unit beds in a hospital shall be limited to 5% of the hospital's certified bed capacity, and shall not exceed 40.

Determination: 47 waiver requests will be approved contingent upon notification by the PPS of the specific providers, practitioners and services. However, reimbursement for the provision of such services would require approval of a State Plan Amendment (SPA) to the State Medicaid Plan and associated state regulations. **11** waiver requests were approved to allow observation unit stays up to 48 hours.



Credentialing - 10 NYCRR 405.2(e)(3) and 405.4(c)(5)

Nature of Requirements: The governing staff shall ensure the implementation of written criteria for selection, appointment and reappointment of medical staff members and their privileges. Each hospital is to have an organized medical staff that operates under approved bylaws that the medical staff utilizes to carry out its responsibilities.

Determination: 10 waiver requests were approved to allow the PPS to gather and store credentialing information in a central repository and share such information with PPS providers as appropriate. There must be a process in place for each provider in the PPS. Each individual practitioner must be privileged by each facility.



A second round of waiver requests are expected to be processed sometime in November 2015.

DSRIP waiver requests are generally approved if the answer is 'yes' to:

- ✓ Is the DSRIP project's success inhibited by the regulation?
- ✓ Can the regulation be waived without a risk to patient safety?

Other regulations that may impact VBP that have not already addressed by the Regulatory Subcommittee may be considered for future modification.

Policy Question #13: What specific regulations could be eliminated or relaxed to reduce administrative burden while still protecting patient safety?



Next Meeting

Meeting	Date	Time	Location
Meeting 1	7/20/15	10:30 am	Albany
Meeting 2	8/27/15	1:00 pm	NYC
Meeting 3	9/21/15	1:00 pm	Albany
Meeting 4	10/5/15	1:00 pm	NYC
Meeting 5	11/10/15	1:00 pm	Albany
Meeting 6	12/07/15	10:30 am	Albany



Contact Us

Jeffrey Gold

Co-Chair

jgold@hanys.org

Harold Iselin

Co-Chair

iselinh@gtlaw.com

Zamira Akchurina

KPMG Lead

zakchurina@kpmg.com

