



**Department
of Health**

Medicaid
Redesign Team

Regulatory Impact Subcommittee

Meeting #4

October 5, 2015

Today's Agenda

Agenda Item	Time
Welcome and Introduction	1:00 pm
Recap: Final Recommendations from Meeting #3: Self-Referral and AKS	1:15 pm
Proposed Recommendations: Prompt Pay and Civil Monetary Penalties	1:30 pm
Discussion of Model Contract and Provider Contract Suggested Revisions	1:45 pm
Introduction to: a) HIPAA & State Privacy; b) Fraud, Waste & Abuse; and c) Business Laws & Corporate Practice of Medicine	2:30 pm
Closing	3:45 pm

Update: Provider Contract Review Process

- Work continues on the development of the details and guidelines for risk assessment review of Medicaid Provider Contracts (using the 3 Tier Approach).
- Proposed guidelines and additional review details will be presented at the next Subcommittee Meeting on November 10, 2015.
- Additional comments and suggestions are welcome from this group throughout the development process.

Recap of Meeting #3: Final Recommendations*

Recommendation #5 – Stark Law – Revise New York state laws and related regulations to align with federal Stark law.

- Relevant New York Laws:
 - *Public Health Law §§ 238 to 238-e; § 4501*
 - *Education Law § 6530*
- Relevant New York Regulations:
 - *10 NYCRR Part 34*

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

Recap of Meeting #3: Final Recommendations*

Recommendation #6 – Anti-kickback Law – Revise New York state laws and related regulations to align with federal Anti-kickback laws, including safe harbors.

- Relevant New York Laws:
 - Education Law §§ 6530(18), 6530(19)*
 - Social Services Law § 366-d*
- Relevant New York Regulations:
 - 18 NYCRR 515.2*

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

Recap of Meeting #3: Proposed Recommendations

Recommendation #7 – Prompt Payment – No change to New York state laws or regulations is recommended. The SC 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.

Recap of Meeting #3: Proposed Recommendations

Recommendation #8 – 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.

Suggested Revisions to the Model Contract and Provider Contract Guidelines

- The Subcommittee received several proposed revisions to the Model Contract as well as the Provider Contract Guidelines.
- Following today's meeting, the proposed revisions will be sent to the DOH for review and consideration.
- The Subcommittee's recommendation is that the DOH consider these proposed revisions as the DOH amends the Model Contract and Provider Contract Guidelines to accommodate VBP.

Introducing the New 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

FRAUD, WASTE, AND ABUSE (FWA)

What additional program integrity requirements should be enhanced for MCOs and providers to combat potential VBP FWA?

Policy Question #12

CORPORATE PRACTICE OF MEDICINE

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

Policy Question #10: HIPAA and State Privacy

Background

- The federal **Health Insurance Portability and Accountability Act** of 1996 (HIPAA) governs the use and disclosure of Protected Health Information (PHI).
- The primary goal of HIPAA is to protect the confidentiality and security of healthcare information. Both federal HIPAA law and New York state laws and regulations contain restrictions on the sharing of PHI.

Issue

- New York laws and regulations are often more restrictive and certain provisions may have an adverse impact in a VBP environment when sharing of patient data is critical to achieving better patient outcomes and costs savings.

Policy Question #10: HIPAA and State Privacy

SC Action Item

- This Subcommittee must decide whether to align New York law with federal HIPAA protocol, or create exceptions to the NYS laws in an effort to accommodate the shift from a fee-for-service system to VBP.

Examples and Considerations

- Some processes are already in place, such as the DSRIP Opt Out process, but these are limited in scope. The following slides offer five scenarios where New York law presents challenges to VBP:

Policy Question #10: HIPAA and State Privacy

Scenario 1:

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.

Example: PPSs, IPAs, and ACOs may need to compare the quality of different providers to evaluate performance. This may require use of PHI (upstream or provider-to-provider) to determine shared savings and losses. Requiring distinct opt out processes or additional consents would be burdensome and may cause delays in review processes and timing of payments.

Potential solution: Create exceptions to allow for both upstream and provider-to-provider sharing of data for purposes of VBP.

Policy Question #10: HIPAA and State Privacy

Scenario 2:

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.

Example: Care Management organizations and health homes may need access to PHI to gather all necessary information to create a care management plan to better coordinate patient care. Currently, specific patient consent (in addition to current opt-out or treatment consent) may be needed for providers to disclose PHI to each entity or vendor.

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

Policy Question #10: HIPAA and State Privacy

Scenario 3:

RHIO AND SHIN-NY DATA—The RHIO and SHIN-NY data may be incomplete due to NYS patient confidentiality laws which limit 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, mental health, and maternity confidentiality laws which are more restrictive than federal HIPAA.

Example: When a minor provides the consent for treatment, only that minor may provide consent to release the medical records or other PHI related to that visit. The RHIO opt-out and SHIN-NY opt-in do not necessarily include the consent of minor patients. Providers are therefore reluctant to provide access to minor patients’ data through the RHIOs and SHIN-NY.

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

Policy Question #10: HIPAA and State Privacy

Scenario 4:

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 this consent. There is uncertainty among providers regarding the scope of the Medicaid consent which may lead to missing data and delays in data reporting.

Example: There is a lack of guidance on when opt-in/outs are necessary in light of the exception for healthcare operations contained in the Medicaid consent form. Some PPSs fear they need their own opt-out or alternative consent process to receive data from downstream providers.

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

Policy Question #10: HIPAA and State Privacy

Scenario 5:

VITAL STATISTICS (VS) –Vital Statistics have unique restrictions which render them unusable with Medicaid members. New York state regulation 10 NYCRR 400.22 suggests that only state employees may access VS. There are no exceptions or consent processes available to providers, PPSs, and NYS contractors.

Example: When a baby is born, it is not immediately assigned a Medicaid ID, and costs related to the birth are attributed to the mother. Once the baby receives a Medicaid ID, costs are then attributed to the baby. In some cases, the identity of the mother may be unknown (e.g., homelessness) and it is not possible to create this link. Access to VS records (collection of blood records, SSN, etc.) would help to create the mom-baby link and supplement the medical record.

Potential solution: 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.

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 #11: Fraud, Waste & Abuse

Federal and state laws and regulations already require MCOs to have robust programs to identify, investigate, and report Medicaid Fraud, Waste & Abuse (FWA).

MCOs are subject to ongoing monitoring and audits related to:

- Provider Credentialing / Contracting
- Fraudulent Marketing and Enrollment
- Provider Claims and Billings
- Enrollee Fraud
- Quality of Care Issues

On a state level, MCOs and providers are mainly monitored by:

- OHIP BMCCS
- OMIG
- OPMC
- MFCU

Policy Question #11: Fraud, Waste & Abuse

VBP will change both the incentives and methods to commit fraud as parties move from fee-for-service to VBP. Some VBP-specific considerations include:

PATIENT DATA – Manipulation of patient outcomes data may adversely impact whether a provider is owed a bonus payment or is liable for shared losses under VBP Level 1 & 2.

Example – *A provider with 50% of expected Medicaid revenue under VBP Level 2 contracts experiences a spike of patient complications towards the end of a contracting period. There is an incentive to manipulate patient outcomes data to avoid falling below the quality threshold necessary to achieve a shared savings payment.*

CLAIMS QUALITY – Timely and accurate submission of claims is critical to effectively bundling claims under VBP Level 1 & 2. Claims can be manipulated to “push” from a lower to a higher value bundle or to avoid triggering an avoidable complication.

Example – *A provider who specializes in a number of high-volume, low-value, low-risk VBP Level 1 arrangements may be incentivized to misdiagnose and submit claims for a related, higher-value VBP Level 1 bundle.*

Policy Question #11: Fraud, Waste & Abuse

Considerations (cont'd):

MEMBER ELIGIBILITY – The quantum of total losses from capitation payments for ineligible or fictitious members may be higher under VBP Level 3 compared to FFS/VBP Level 1 & 2.

Example – A provider group contracts for over 75% of its Medicaid revenue under a PMPM prepaid capitation arrangement. Because of the revenue shift from FFS to prepaid capitation, there is a higher risk of loss if ineligible members are later identified and payments are clawed back from the provider.

PATIENT CARE QUALITY – Quality of care may decline if providers are unable to perform well under VBP Level 1 & 2 or aggressively seek to reduce utilization under VBP Level 3 to maintain capitation payments.

Example – A provider group contracts for over 75% of its Medicaid revenue under PMPM prepaid capitation arrangements. There is an incentive for the provider to reduce utilization for members, and especially costly members, at the expense of quality of care to maintain as much of the capitation payments as possible.

Policy Question #11: Fraud, Waste & Abuse

Considerations (cont'd):

ACCURACY OF BUNDLE RECONCILIATIONS – MCOs will be responsible for ensuring VBP reconciliations are accurate and timely. Miscalculations may impact provider reimbursement under VBP Level 1 & 2.

Example - Providers may not have the ability to ensure the accuracy and completeness of their own bundle reconciliations. (e.g., providers must rely on the MCO to ensure the correctness of bundle reconciliation gains and losses).

IMPACT ON CONTRACT PRICING– Incomplete and inaccurate claims and patient data may adversely impact individual MCO/provider price negotiations and contracting.

Example – A large provider group routinely underreports a large volume of avoidable complications to achieve a quality benchmark needed to obtain a bonus payment. This type of scheme will muddy claims and outcomes data which may adversely impact contract negotiations between the MCO and other unaffiliated providers.

Policy Question 11: What additional Medicaid program integrity requirements should be enhanced for MCOs and providers to combat potential VBP FWA?

Policy Question #12: Business Laws and Corporate Practice of Medicine

Background

- Current NYS Business and Corporate Practice of Medicine (CPOM) laws require that groups of physicians only practice medicine through a professional corporation (PC) or professional service limited liability company (PLLC) or registered limited partnership, and they cannot provide medical services through a general business corporation (GBC) or limited liability company (LLC).
- NYS Education Law § 6507 authorizes the NYS Education Department to issue Certificates of Authority that certify that the individuals organizing the professional service corporation have met the requirement that they be licensed and currently registered to practice in their respective professions.

Issue

- Current Business and CPOM laws will restrict how health care professionals organize, operate, and manage corporate structures and fee splitting in a VBP environment.

Policy Question #12: Business Laws and Corporate Practice of Medicine

The Office of the Professions (OP) sets forth the requirements with respect to Corporate Entities. Licensed professionals may incorporate a PC, organize a PLLC, or create a registered limited liability partnership. Generally, licensed professionals may not set up a GBC to provide professional services.

Except where specifically authorized by law, a GBC may not:

- provide professional services to the public;
- exercise any judgment over the delivery of professional services;
- have employees who offer professional services to the public;
- hold itself out as offering professional services; or
- share profits or split fees with licensed professionals.

Policy Question #12: Business Laws and Corporate Practice of Medicine

A PC or PLLC may not serve as a management services corporation. A PC or PLLC may only provide services in its field. For example, a hypothetical PC named "Occupational Therapists For Everyone, PC" may only provide occupational therapy services. It cannot offer physical therapy services, speech services or any other professional services. Also, because it is allowed only to provide professional services, it can only manage the services that it provides. That is, it cannot provide management services to other occupational therapists.

There are a number of exceptions to the general rule prohibiting the practice of the professions by an entity that is not specifically established to provide professional services such as a PC. One such exception is a hospital that is authorized to provide health services pursuant to the public health law. Other exceptions include entities established to offer optometry, ophthalmic dispensing, massage therapy, pharmacy, speech-language pathology and audiology services.

Policy Question #12: Business Laws and Corporate Practice of Medicine

A professional service limited liability company may provide professional services in more than one profession provided that the company includes an "owner" (i.e., member, manager, shareholder, partner) licensed in each of the professions in which the company will offer services (*Note that this does not apply in the professions of medicine, dentistry, veterinary medicine, licensed clinical social work, mental health counseling, psychoanalysis, creative arts therapy, or marriage and family therapy*).

For example, the hypothetical LLC, Health Professionals, has seven members: an acupuncturist, an audiologist, a nurse, an occupational therapist, a physical therapist, a psychologist, and a speech-language pathologist. This LLC may provide services in all of these professions. It may not, however, provide respiratory therapy or optometry services, because none of its "owners" are licensed in those two professions. Additionally, a special education teacher may not be a partner in a LLC because its owners must all be professionals licensed in the professions in which the company is authorized to provide services.

Policy Question #12: Business Laws and Corporate Practice of Medicine

Based on the current Business and CPOM laws, the following barriers may arise 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.
- Limitations on which professionals and entities can split fees (e.g., bundled payments for services including physicians and non-physicians).

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

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

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